GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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HEALTHCARE FACILITY REGULATION DIVISION

HOSPITAL INITIAL MEDICARE CERTIFICATION

This letter will provide information about the requirements and procedures through which a hospital in Georgia may be approved to participate as a Medicare provider of hospital Services. The two independent and important steps in becoming a Hospital Medicare provider are the Application Process and the Medicare Certification process.

1. APPLICATION PROCESS:

As part of your request to participate in Medicare, you must enroll with the Medicare fiscal intermediary (FI). Provider enrollment applications (855A forms) are available for downloading at http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf along with a user's guide providing instructions for completing the forms. The provider enrollment application must be submitted directly to the FI assigned to Georgia hospital providers, Cahaba GBA, Provider Enrollment - Part A, P.O. Box 1537, Birmingham, AL 35201. The FI can also be reached at http://www.cahabagba.com or by calling Provider Enrollment at 1-877-567-3095. If you require help or assistance in completing the CMS 855A form, contact the FI, not the Healthcare Facility Regulation Division (HFRD). The FI will notify HFRD of its recommendation for approval or denial of enrollment for your hospital. The initial certification survey may not be conducted until the FI approves your enrollment application (855A).

Additional CMS forms noted below must be completed and returned to the Health Care Section, Healthcare Facility Regulation Division, Georgia Department of Community Health, 2 Peachtree St., NW, Suite 31-447, Atlanta, GA 30303-3142.

Two (2) Health Insurance Benefit Agreement (CMS-1561) forms must be completed. The Health Insurance Benefits Agreement is your contract with CMS and requires original signatures on both agreement forms. On the first line of the Health Insurance Benefits Agreement, after the term THE SECRETARY OF HEALTH AND HUMAN SERVICES, enter the entrepreneurial name of the hospital, followed by the trade name (if different from the entrepreneurial name) on the second line after (D/B/A). On the third line of the form, after the term Social Security Act, enter the entrepreneurial name of the hospital again, followed by the trade name (if different from the entrepreneurial name) after the term D/B/A. Ordinarily, the entrepreneurial name is the same as the business name used on all official IRS correspondence concerning payroll withholding taxes, such as the W-3 or 941 forms. For example, the ABC Corporation, owner of the Community Hospital, would enter on the agreement, "ABC Corporation d/b/a Community Hospital." A partnership of several persons might complete the agreement to read: "Robert Johnson, Louis Miller and Paul Allen, ptr. d/b/a Community Hospital". A sole proprietorship would complete the agreement to read: "John Smith d/b/a Community Hospital." The person signing the Health Insurance Benefits Agreement must be someone who has the authorization of the owners of the hospital to enter into this provider agreement with CMS.

CMS is also required to obtain information from new providers related to their compliance with Civil Rights requirements. Two (2) HHS 690 forms, entitled Assurance of Compliance, must be completed, have original signatures on each, and be returned along with the Medicare Certification Civil Rights

Information Request Form and the requested documentation. HFRD will forward the completed forms to CMS who will send the forms to the Regional Office of Civil Rights (OCR) for review. In practice, CMS Regional Offices will approve a provider's initial certification pending clearance from OCR. On rare occasions, OCR informs CMS that clearance has been denied or that the required assurances have not been submitted. Failure to provide the needed information or failure to receive clearance from OCR may negatively impact your participation in the Medicare program.

Laboratory Services:
If you anticipate that your facility will be performing any clinical laboratory testing or specimen collection, you need to contact the laboratory section of the **HFRD Diagnostic Services Unit at 404-657-5450**. This unit will assist you in determining whether there are additional Federal and State laboratory requirements that your facility will have to meet.

Radiology Services:
If you anticipate that your facility will be performing any radiology services, you need to contact the x-ray section of the **HFRD Diagnostic Services Unit at 404-657-5400**. This unit will assist you in determining whether there are additional Federal and State radiology requirements that your facility will have to meet.

2. MEDICARE SURVEY PROCESS:

HFRD has contracted with the Centers for Medicare/Medicaid Services (CMS) to perform initial and periodic surveys and to certify whether providers of services meet the hospital Medicare Conditions of Participation. Compliance with the hospital Conditions of Participation is a requirement to participate in Medicare. Such Medicare approval, when required, is a prerequisite to qualifying to participate in the State Medicaid program as well.

Please be aware that due to very substantial federal resource limitations, HFRD must currently adhere to a careful priority schedule as we respond to requests from new hospital providers that seek to participate in Medicare. CMS now requires HFRD to place a higher priority on recertification of existing Medicare certified facilities, on complaint investigations, and on similar work for existing facilities than for initial surveys of facilities newly seeking Medicare participation. The outcome of the required prioritization of our federal workload means that if you wish the HFRD to conduct your initial Medicare survey, you will have to wait a longer period of time for the survey unless you are able to utilize one of the following options:

a. Accreditation:
New hospitals have the option to be accredited by a CMS-approved accrediting organization (AO) and such accreditation is "deemed" to be equivalent to a recommendation by HFRD for CMS certification. There is a fee associated with accreditation, the AO must have evidence that your CMS 855A enrollment application has been approved, and your hospital must have obtained a state license. If you wish to pursue this option, you will need to contact the AO and obtain information on how to proceed in scheduling a survey. Be sure to inform the AO that you are requesting the Medicare "deeming" survey. The following is a list of accreditation organizations currently approved by CMS for Medicare deeming purposes:

Joint Commission (JC) One Renaissance Blvd. Oakbrook Terrace, IL 60081 630-792-5000 Contacts: Steve Misenko smisenko@jointcommission.org Darlene Christiansen dchristiansen@jointcommission.org	American Osteopathic Association (AOA) 142 East Ontario St. Chicago, IL 60611-2864 Contact: George Reuther 312-202-8060 (w) 312-202-8360 (fax) greuther@hfap.org	Det Norske Veritas Healthcare (DNV Healthcare) 463 Ohio Pike, Suite 203 Cincinnati, OH 45255 Contacts: Patrick Horine 513-388-4888 patrick.horine@dnv.com Darrel Scott 513-388-4862 darrel.scott@dnv.com

When you receive your accreditation survey report, send a copy of the report and a copy of the cover letter to HFRD. If your facility receives initial "deeming" accreditation, HFRD will complete the administrative paper work portion of your Medicare approval process, and forward the paperwork to CMS. CMS will issue a Medicare provider number.

b. Underserved Areas:
If your hospital is in an area of the state that lacks hospital providers and beneficiaries are experiencing significant access-to-care problems, you may apply by letter to HFRD for CMS consideration to grant an exception to the priority assignment of the initial survey. HFRD will evaluate the situation and forward the request to CMS with a recommendation. There is no special form required to make a priority exception request. However, the burden is on you to provide data and other evidence that effectively establishes the probability of adverse beneficiary health care access consequences if your hospital is not enrolled to participate in Medicare. CMS has informed us that they will not endorse any request that fails to provide such evidence and fails to establish the special circumstances surrounding the request.

If CMS approves HFRD surveyors to conduct your initial Medicare survey to determine whether Medicare Conditions of Participation are met, you must have obtained a *state license* (see separate packet for licensing instructions), submitted all required *CMS forms to HFRD, obtained approval from the FI of your Medicare enrollment application (CMS-855A), and be fully operational.*

Your hospital must have accepted and provided care to two or more patients (who are not required to be Medicare patients), provided all services needed by the patients, demonstrated the operational capability of all facets of the hospital's operations, and be able to demonstrate compliance with each of the hospital Conditions of Participation.

If HFRD has been approved by CMS to conduct your initial Medicare survey, your hospital must be fully operational and ready for the survey, a request for an initial Medicare survey is required to be made in writing to HFRD. In accordance with CMS policy, all certification surveys will be **UNANNOUNCED.**

At the time of the Medicare survey, it will be determined whether or not your hospital meets the Conditions of Participation for the Medicare program. If you are found to be in full compliance with the Medicare Conditions of Participation, HFRD will recommend to CMS that you be certified in the Medicare program, effective the last day of the survey.

If deficiencies below the condition level are identified during the course of the survey, you will be given an opportunity to submit an **acceptable plan of correction.** Upon receipt of the acceptable plan of correction, HFRD will *recommend* to CMS that your hospital be certified effective the date you submitted your acceptable plan of correction.

If condition level deficiencies are identified during the course of the survey, HFRD will *recommend* to CMS that your application to participate in the Medicare program be **denied**. If CMS accepts this recommendation, CMS will send a notice giving the reasons for denial and informing you of your right to appeal the denial.

Issuance of Provider Number:
After a determination is made that all requirements for participation in the Medicare program are met, you will be assigned a Medicare provider number. CMS will notify you, HFRD, and your FI of your assigned provider number. The FI will subsequently contact you with information about submitting reimbursement claims for Medicare services. Your hospital **cannot claim provider reimbursement for services rendered to Medicare patients prior to the effective date of your Medicare provider number.**

The two (2) Health Benefit Agreements will be countersigned by CMS and HFRD will forward one signed agreement to you for your files and will keep one signed agreement in your HFRD facility file.

Change in Ownership:
If operation of the hospital is later transferred to another owner, ownership group, or a lessee, the Medicare agreement will usually be automatically assigned to the successor. (If the new owner does not wish to accept assignment of the Medicare number, the new owner must make a specific request for a new provider number to CMS in writing). You are required to notify CMS through the HFRD at the time you plan such a change of ownership. Please note that under state law and regulations, you must notify HFRD at least 30 days in advance of any changes in ownership.

We hope this letter is helpful to you in understanding the steps and options available to you in becoming certified to participate in Medicare as a hospital provider of services and we regret that the resource limitations under which we operate may complicate the process of enrolling in Medicare as a certified provider of hospital services.

Please do not hesitate to call this office at 404-657-5449 if you have questions about the application and certification process other than completion of the CMS 855A form. Questions about completing the CMS 855A form should be addressed to the FI.

Additional Required Forms:
1. Hospital/CAH Database Worksheet
2. CMS 1561 Health Insurance Benefit Agreement (two signed originals)
3. HHS 690 – Assurance of Compliance/Civil Rights (two signed originals)
4. Medicare Certification Civil Rights Information Request Form

SURVEY MATERIAL

1. Governing Body Bylaws
2. Minutes of the governing body and its committees, if any.
3. Copy of the hospital's organizational chart.
4. Current contracts or plans for building modifications.
5. Most recent fire inspection reports.
6. Record of fire and disaster drills.
7. Current fire, evacuation and disaster plans.
8. Copy of the hospital's floor plan indicating locations of patient care areas and departments.
9. Diet manual.
10. If food service is contracted, the current contract governing such arrangements.
11. Employee list with job titles.
12. Infection control plan.
13. CLIA Certificate.
14. Medical staff bylaws, rules, and regulations.
15. Minutes of meetings of the medical staff and its committees, if any.
16. Minutes of recent departmental meetings, if any.
17. Current list of medical staff and specialty.
18. Current policy and procedural manuals.
19. List of all contracted services and copies of the contracts.
20. List of all off-site locations that will provide services under hospital permit with their addresses and names of department head.
21. List of all locations that will provide any form of surgery/anesthesia.
22. List of all locations for pharmacies and satellite pharmacies.

23. List of all locations where radiologic services will be performed.

24. List of all locations for satellite dietary kitchens.

25. List of all locations for satellite rehabilitation services.

26. List of all locations for satellite respiratory care services.

27. List of all locations where any procedures will be performed, i.e., nursery, GI Lab, Interventional Radiology, cath lab, etc.

28. Designated contact person for each area, with phone/pager number.

Regulations and Interpretive Guidelines

A-0001

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if--

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by non-participating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

Interpretive Guidelines §482.2

The statutory requirements that a hospital must meet are:

- The hospital is primarily engaged in providing, by or under the supervision of MD/DOs, to inpatients, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the injured, disabled, or sick persons;

- The hospital maintains clinical records on all patients;

- The hospital has medical staff bylaws;

- The hospital has a requirement that every Medicare patient must be under the care of a MD/DO;

- The hospital provides 24-hour nursing services rendered or supervised by a registered professional nurse and has a licensed, practical or registered professional nurse on duty at all times; and

- The hospital is licensed or is approved as meeting the standards for licensing as a hospital as defined by the State.

A-0002

§482.11 Condition of Participation: Compliance With Federal, State and Local Laws

A-0003

§482.11(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

Survey Procedures §482.11(a)

Interview the CEO, or appropriate individual designated by the hospital, to determine whether the hospital is in compliance with Federal laws related to patient health and safety. (e.g., if the hospital has been convicted of violating section 504 of the Rehabilitation Act of 1973 by denying people with disabilities access to care. If so, verify that satisfactory corrections have been made to bring the hospital into compliance with that law.) Refer or report noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood borne pathogens, universal precautions, TB control to OSHA; hazardous chemical/waste issues to EPA; etc.)

A-0004

§482.11(b) The hospital must be--

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

Survey Procedures §482.11(b)

Prior to the survey, determine whether the hospital is subject to licensure requirements and verify that the licensing agency has approved the hospital as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing hospitals.

A-0005

§482.11(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.
Interpretive Guidelines §482.11(c)

All staff that are required by the State to be licensed must possess a current license. The hospital must assure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory therapists and hospital administrators.

All staff must meet all applicable standards required by State or local law for hospital personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications;
- Training/education requirements; and
- Permits (such as food handlers permits).

When telemedicine is used and the practitioner and patient are located in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.

Survey Procedures §482.11(c)

- Verify for those personnel required to be licensed, certified, and/or permitted by the State, that the hospital has established, and follows procedures for determining that personnel are properly licensed, certified, and/or permitted.
- Verify that staff and personnel are licensed, certified, and/or permitted in accordance with State and local requirements.
- Verify that staff and personnel meet all standards (such as continuing education, basic qualifications, etc.) required by State and local laws or regulations. Verify that the hospital has a mechanism established and enforced to ensure compliance.
- Review a sample of personnel files to verify that licensure and/or other required credentials information is up to date. Verify State licensure compliance of the direct care personnel as well as administrators and supervisory personnel.

A-0006

§482.12 Condition of Participation: Governing Body

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

Interpretive Guidelines §482.12

The hospital must have only one governing body and this governing body is responsible for the conduct of the hospital as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.

Survey Procedures §482.12

Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.

A-0007

§482.12(a) Standard: Medical Staff

The governing body must:

A-0008

§482.12(a)(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

Interpretive Guidelines §482.12(a)(1)

The governing body must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

Survey Procedures §482.12(a)(1)

Review documentation and verify that the governing body has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.

A-0009

§482.12(a)(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

Interpretive Guidelines §482.12(a)(2)

It is the responsibility of the governing body to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering existing medical staff members recommendations, and in accordance with established hospital medical staff criteria and State and Federal laws and regulations, the governing body appoints new members or reappoints current members to the medical staff.

Survey Procedures §482.12(a)(2)

- Review records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members.

- Confirm that the governing body appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

A-0010

§482.12(a)(3) Assure that the medical staff has bylaws;

Interpretive Guidelines §482.12(a)(3)

The governing body must assure that the medical staff has bylaws and that those bylaws comply with State and Federal law and the requirements of the Medicare hospital Conditions of Participation.

Survey Procedures §482.12(a)(3)

Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

A-0011

§482.12(a)(4) Approve medical staff bylaws and other medical staff rules and regulations;

Interpretive Guidelines §482.12(a)(4)

The governing body decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body before they are considered effective.

Survey Procedures and §482.12(a)(4)

- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body.

- Verify that any revisions or modifications in the medical staff bylaws, rules and policies have been approved by the medical staff and the governing body, e.g., bylaws are annotated with date of last review and initialed by person(s) responsible.

A-0012

§482.12(a)(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

Interpretive Guidelines §482.12(a)(5)

The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. The governing body is responsible for the conduct of the hospital and this conduct includes the quality of care provided to patients.

All hospital patients must be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Survey Procedures §482.12(a)(5)

- Verify that the governing body is periodically apprised of the medical staff evaluation of patient care services provided hospital wide, at every patient care location of the hospital.

- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.

A-0013

§482.12(a)(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

Interpretive Guidelines §482.12(a)(6)

The governing body ensures that the criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment.

Survey Procedures §482.12(a)(6)

- Verify that there are written criteria for staff appointments to the medical staff.
- Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.
- Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

A-0014

§482.12(a)(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

Interpretive Guidelines §482.12(a)(7)

The governing body must ensure that the hospital's rules and criteria for medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.

A hospital is not prohibited from requiring board certification when considering a MD/DO for medical staff membership. Rather, the regulation provides that a hospital may not rely solely on the fact that a MD/DO is or is not board certified in making a judgment on medical staff membership. In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence and judgment. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff.

Survey Procedures §482.12(a)(7)

Verify that there are written criteria for staff appointments, and that these criteria are based on individual character, competence, training, experience, and judgment, and are not dependent solely upon certification, fellowship, or membership in a specialty body or society.

A-0015

§482.12(b) Standard: Chief Executive Officer

The governing body must appoint a chief executive officer who is responsible for managing the hospital.

Interpretive Guidelines §482.12(b)

The Governing Body must appoint one chief executive officer who is responsible for managing the entire hospital.

Survey Procedures §482.12(b)

- Verify that the hospital has only one chief executive officer for the entire hospital.
- Verify that the governing body has appointed the chief executive officer.
- Verify that the chief executive officer is responsible for managing the entire hospital.

A-0016

§482.12(c) Standard: Care of Patients

In accordance with hospital policy, the governing body must ensure that the following requirements are met:

A-0017

§482.12(c)(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in §410.71 of this chapter, but only with respect to clinical psychologist services as defined in §410.71 of this chapter and only to the extent permitted by State law.

Interpretive Guidelines §482.12(c)(1)

Practitioners other than doctors of medicine or osteopathy may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with State law.

Every Medicare or Medicaid patient must be under the care of a licensed practitioner as defined in this requirement.

Survey Procedures §482.12(c)(1)

Verify that Medicare patients are under the care of a licensed practitioner as defined by (c)(1).

A-0018

§482.12(c)(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.

Survey Procedures §482.12(c)(2)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.

- Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body in accordance with State laws and medical staff bylaws.

A-0019

§482.12(c)(2) continued
If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

Interpretive Guidelines §482.12(c)(2)

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, midwives, etc), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a MD/DO. However, CMS regulations do require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD/DO. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.

Survey Procedures §482.12(c)(2)

If the hospital grants admitting privileges to these practitioners, select patients that are admitted to the hospital by these practitioners. Determine if the patient is/was under the care of an MD/DO.

A-0020

§482.12(c)(3) A doctor of medicine or osteopathy is on duty or on call at all times.

Survey Procedures §482.12(c)(3)

- Verify the governing body has established and monitors the enforcement of policies that ensure a doctor of medicine or osteopathy is on duty or on call at all times to provide medical care and onsite supervision when necessary.

- Review the "call" register and documents that assure that a doctor of medicine or osteopathy is on duty or on call at all times.

- Interview nursing staff. How do they know who is on call? Are they able to call the on-call MD/DO and speak with him/her at all times? When appropriate, do on-call MD/DOs come to the hospital to provide needed care.

A-0021

§482.12(c)(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that--

(i) Is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is--

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

Interpretive Guidelines §482.12(c)(4)

CMS hospital regulations do permit licensed practitioners (i.e., doctors of dental surgery, dental medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital. However, CMS does require that Medicare and Medicaid patients who are admitted by a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist be under the care of a MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the

scope of practice of the admitting practitioner. If a hospital allows a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff must establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §482.12(c)(4)

- Verify that an assigned doctor of medicine or osteopathy is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization.

- If non-MD/DOs admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical or psychiatric problem outside the scope of practice of the admitting practitioners.

A-0022

§482.12(d) Standard: Institutional Plan and Budget

The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

Survey Procedures §482.12(d)

Verify that an institutional plan and budget exist, includes items 1-4, and complies with all items in this standard. Do not review the specifics or format in the institutional plan or the budget.

A-0023

§482.12(d)(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.)

Survey Procedures §482.12(d)(5)

Determine that the hospital's plan for capital expenditures has been submitted to the planning agency designated to review capital expenditures. In certain cases facilities used by HMO and CMP patients are exempt from the review process.

A-0024

§482.12(d)(5) continued
A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because--

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

A-0025

§482.12(d)(6) The plan must be reviewed and updated annually

Survey Procedures §482.12(d)(6)

Verify that the plan and budget are reviewed and updated annually.

A-0026

§482.12(d)(7) The plan must be prepared--

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

Survey Procedures §482.12(d)(7)

Verify that the governing body, administrative staff, and medical staff have participated in the development of the institutional plan and budget.

A-0027

§482.12(e) Standard: Contracted Services

The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guidelines §482.12(e)

The governing body has the responsibility for assuring that hospital services are provided in compliance with the Medicare Conditions of participation and according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by contract. The governing body must take actions through the hospital's QAPI program to: assess the services furnished directly by hospital staff and those services provided under contract, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities. See §482.21 QAPI.

Survey Procedures §482.12(e)

Ascertain that all contractor services provided in the hospital are in compliance with the Conditions of Participation for hospitals.

A-0028

§482.12(e)(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

Interpretive Guidelines §482.12(e)(1)

Indirect arrangements may take into consideration services provided through formal contracts, joint ventures, informal agreements, shared services, or lease arrangements. The patient care services, and all other services, provided under contract are subject to the same hospital-wide quality assessment and performance improvement (QAPI) evaluation as other services provided directly by the hospital.

Survey Procedures §482.12(e)(1)

- Determine if the hospital has a mechanism to evaluate the quality of each contracted service and ensures that each contracted service is provided in a safe and effective manner.

- Review the QAPI plan to ensure that every contracted service is evaluated.

A-0029

§482.12(e)(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

Survey Procedures §482.12(e)(2)

Review the list of contracted services and verify that there is a delineation of contractor responsibility.

A-0030

§482.12(f) Standard: Emergency Services

A-0031

§482.12(f)(1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.

A-0032

§482.12(f)(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

Interpretive Guidelines §482.12(f)(2)

This requirement applies hospital-wide (all on-campus and off-campus locations) to hospitals that do not provide emergency services.

The hospital must have and implement medical staff policies and procedures for the appraisal of emergencies, initial treatment, and referral when appropriate.

The hospital must have appropriate policies and procedures in place for dealing with emergency care situations at the hospital. This includes emergencies that occur to hospital patients, staff, visitors, and others at any hospital location and to individuals who come to the hospital or any of its off-campus locations seeking/needing emergency care. Hospital staff at all on-campus and off-campus locations must know what to do when a patient or other individual seeks/needs emergency care. Staff must know the hospital's policies and procedures and, as appropriate, be capable of appraising, providing initial care, and referring individuals who are seeking or needing emergency care.

Survey Procedures §482.12(f)(2)

- Verify that the medical staff has adopted written policies and procedures for the management of medical or psychiatric emergencies.

- Review emergency care policies and procedures. Do they address emergency procedures for all on-campus and off-campus locations?

- Interview hospital staff at various locations. Can they state their duties and what they are to do if an individual seeks or needs emergency care at their location?

A-0033

§482.12(f)(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

Interpretive Guidelines §482.12(f)(3)

This requirement applies to off-campus non-emergency departments/locations of hospitals that provide emergency services.

Hospital off-campus non-emergency departments/locations must have and implement medical staff policies and procedures for the appraisal of emergencies and referral when appropriate.

The hospital must have appropriate policies and procedures in place for dealing with emergency care situations at off-campus non-emergency departments and locations. This includes emergencies that occur to patients, staff, visitors or others at those locations or to individuals who come to those locations seeking/needing emergency care. Hospital staff at those locations must know what to do when any individual seeks/needs emergency care. Staff must know and be able to implement the hospital's policies and procedures for appraisal and referral of emergencies when appropriate.

Initial treatment and stabilization of patients needing emergency care must be provided in accordance with the complexity of services provided at that location, the type and qualifications of healthcare staff at that location and the other resources at that location. For example an off-campus cardiac rehabilitation clinic would be expected to have the appropriate qualified staff, equipment (such as a crash cart), and policies and procedures in place to appropriately provide appraisal, initial interventions, and referral of a patient who experiences a cardiac emergency.

The hospital's medical staff are responsible for the quality of the medical care provided to patients (See Governing Body and Medical Staff Conditions of Participation (CoP)). The Outpatient Services CoP requires that hospital outpatient services meet the needs of the patients in accordance with acceptable standards of practice, outpatient services must be appropriately organized and integrated with inpatient services, and outpatient services must have appropriate professional and nonprofessional personnel available. The Emergency Services CoP requires the hospital to meet the emergency needs of patients in accordance with accepted standards of practice. The Surgical Services CoP requires that outpatient surgical services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

See the hospital emergency services CoP (§482.55) for the emergency requirements for hospital locations with emergency services.

Survey Procedures §482.12(f)(3)

- Review emergency care policies and procedures. Determine if they address emergency procedures for all off-campus locations?

- Interview off-campus hospital department staff. Can they state their duties and what they are to do if an individual seeks emergency care?

A-0038

§482.13 Condition of Participation: Patients' Rights

A hospital must protect and promote each patient's rights.

Interpretive Guidelines §482.13

These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, childrens' and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e)).

These requirements, as well as the other Conditions of Participation in 42 CFR §482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital.

Survey Procedures §482.13

Survey of the Patients' Rights Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.

A-0039

§482.13(a) Standard: Notice of Rights

A-0040

§482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

Interpretive Guidelines §482.13(a)(1)

This regulation requires that whenever possible, the hospital informs each patient of his or her rights in a language or method of communication that the patient understands. The hospital must notify all patients, both inpatients and outpatients of their rights. The hospital has the responsibility to establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights under the Act. This responsibility includes, and is not limited to, providing all notices required by statute and regulation regarding patients' rights. For example, the patient **must be given notice** of the rights afforded to him/her

by the provider agreement, including the **right to formulate an advance directive, notice of beneficiary discharge rights, and notice of non-coverage rights** (See 42 CFR part 489), must be given notice of the beneficiary **right to appeal premature discharge**, as well as the other **rights discussed in this CoP**. Depending on other factors, the hospital may have existing mechanisms for notifying patients of their rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

In providing this information, the hospital must be sensitive to the communication needs of its patients. As part of its provider agreement, the hospital agrees to comply with Civil Rights laws that assure that it will provide interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient. These civil rights laws and regulations also apply to the provision of this information.

The hospital's obligation to inform requires that the hospital presents information in a manner and form that can be understood, e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.

This regulation does not require nor preclude documentation in the patient's record that this information has been provided. For example, as part of its admission procedure, the hospital may routinely provide this information with each admission packet. The method for achieving notification of patients' rights is determined by the hospital.

Survey Procedures §482.13(a)(1)

- Determine the hospital's policy for notifying all patients of their rights, both inpatient and outpatient.

- Review patient information that is provided to patients by the hospital. Determine if the provided information completely notifies the patient of their patient rights.

- Review records and interview staff to examine how the hospital meets the needs of diverse patients.

- Individuals who need assistive devices (e.g., magnifying glass, Braille, sign language), or have a communications challenge, such as deafness, low vision, blindness, or not being proficient in English, are at risk of not being informed of their rights. Include in the patient sample current patients who use assistive devices. Interview these patients, and/or their representatives to determine how the hospital assures that patients with these needs have been informed of their rights in a language and manner they understand.

- Ask patients to tell you what the hospital has told them about their rights.

- Does the hospital have alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary?

- Do staff know what steps to take to inform a patient, if a patient has special communication needs?

A-0041

§482.13(a)(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

Interpretive guidelines §482.13(a)(2)

A "**patient grievance**" is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient's representative, when a patient issue cannot be resolved promptly by staff present. If a complaint cannot be resolved promptly by staff present or is referred to a complaint coordinator, patient advocate, or hospital management, it is to be considered a grievance.

A patient issue is not a grievance if the patient issue can be resolved promptly, on the spot by staff present.

A patient issue could be a grievance if the patient (currently in the hospital) calls the Patient Representative first and has not tried to resolve the issue with the involved unit/department. If the Patient Representative can immediately call the patient's unit and if the patient care staff present are able to resolve the issue at that moment, then it is not a grievance. Issues that are not resolved on the spot by staff present are grievances.

If other staff must be called in (e.g., the Patient Representative) to resolve an issue that patient care staff cannot (or do not) resolve immediately, then it would be considered a grievance in most cases.

Billing issues are not considered grievances unless the complaint also contains elements addressing patient service or care issues.

Patient grievances would also include situations where patients or the patient's representative call or write to the hospital about concerns related to care or services, who were not able to resolve their concern during their stay or who did not wish to address their issue during their stay.

Additionally, whenever the patient or the patient's representative requests their complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, then the complaint is a grievance and all the requirements apply.

The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although §482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverages may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response.

The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process. The hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency.

Survey Procedures §482.13(a)(2)

- Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. Does the hospital adhere to its policy/procedure established for referrals?

- Interview patients or the patient's legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance).

- Is the hospital following its grievance policies and procedures?

- Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner?

- Does the patient or the patient's representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?

- Has the hospital provided the telephone number for the State agency to all patients/patient representatives?

- Are beneficiaries aware of their right to seek review by the QIO for quality of care issues, coverage decisions, and to appeal a premature discharge?

A-0042

§482.13(a)(2) continued
The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

Survey Procedures §482.13(a)(2)

- Determine if the hospital's governing body approved the grievance process?

- Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee?

- Determine how effectively the grievance process works. Are patient or the patient representative's concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities?

- Is the grievance process reviewed and analyzed through the hospital's QAPI process or some other mechanisms that provides oversight of the grievance process?

A-0043

§482.13(a)(2) continued
The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization. At a minimum:

Interpretive Guidelines §482.13(a)(2)

Quality Improvement Organizations (QIO) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request. The regulations mention the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a **complaint regarding quality of care**, disagree with a **coverage decision**, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so

that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Survey Procedures §482.13(a)(2)

- Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27?

- Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? What time frames are established?

- Interview Medicare patients. Are they aware of their right to appeal premature discharge?

A-0044

§482.13(a)(2)(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

Interpretive Guidelines §482.13(a)(2)(i)

The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.

Survey Procedures §482.13(a)(2)(i)

- Review the information provided to patients explaining the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance?

- Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance?

A-0045

§482.13(a)(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

Interpretive Guidelines §482.13(a)(2)(ii)

The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

Most complaints are not complicated and should not require extensive investigation. Occasionally a complaint is complicated and may require an extensive investigation. A timeframe of 7 days for the provision of the response would be considered appropriate. We do not require that the grievance be resolved during the hospital's specified timeframe for the response, although most should be resolved. The Code of Federal Regulations at 42 CFR §482.13(a)(2)(iii) specifies information the hospital must include in their response. In most cases, the hospital includes the resolution of the grievance in their response. If the grievance is not resolved, if the investigation is not complete, or if the corrective action is still being evaluated, the hospital's response should address that the hospital is still working to resolve the complaint and states that the hospital will follow-up with another written response within so many days (depending on what actions the hospital may have to take). The hospital should attempt to resolve all grievances as soon as possible.

Survey Procedures §482.13(a)(2)(ii)

What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the hospital's grievance process?

A-0046

§482.13(a)(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §482.13(a)(2)(iii)

The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative, when necessary, understands.

The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family, or other methods it finds effective. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). The written response must contain the elements listed in this requirement.

Survey Procedures §482.13(a)(2)(iii)

Review the hospital's copies of written notices (responses) to patients. Are all patients provided a written notice? Do the notices comply with the requirements?

A-0047

§482.13(b) Standard: Exercise of Rights

A-0048

§482.13(b)(1) **The patient has the right to participate in the development and implementation of his or her plan of care.**

Interpretive Guidelines §482.13(b)(1)

This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient's care, with patient participation, to meet the patient's psychological and medical needs.

The patient's (or patient's representatives, as allowed by State law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to: participate in the **development and implementation** of his/her **inpatient treatment/care plan**, **outpatient treatment/care plan**, participate in the development and implementation of his/her **discharge plan**, and participate in the development and implementation of his/her **pain management plan**.

Survey Procedures §482.13(b)(1)

- Determine the extent to which the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care. If the patient refused to participate, interview the patient to verify his/her refusal.

- What do you observe about the interactions between staff and patients?

- Is there evidence that the patient or the patient's legal representative was included or proactively involved in the development and implementation of the patient's plan of care?

- Were revisions in the plan of care explained to the patient?

- Have patients been notified of their right to be involved in their plan of care to include the development and implementation of their inpatient treatment/care plan, outpatient treatment/care plan, discharge plan, and pain management plan?

A-0049

§482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

Interpretive Guidelines §482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information, explanations, consequences, and options needed in order to make "informed" decisions regarding his/her care. For example, the hospital needs to explain the options the patient has when post-hospital care is needed. For patients needing post-hospital hospice, home health or nursing home care, the patient must be given the choices of available Medicare participating post-hospital care providers such as Hospice Agencies, Home Health Agencies or Nursing Homes.

A patient may wish to delegate decision-making to specific persons, or the patient and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital must consult the patient's advance directives. In the advance directive, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, relevant information should be provided to him/her so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient.

The right to make informed decisions regarding care includes the right to make informed decisions about their care including the development of their plan of care, medical and surgical interventions (e.g., deciding whether to sign a surgical consent), pain management, patient care issues and discharge planning.

Section 1802 of the Social Security Act guarantees free choice by Medicare patients. It provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate under Medicare law if the institution, agency, or person undertakes to provide him or her those services.

Survey Procedures §482.13(b)(2)

Is there evidence that patients/patient representatives are provided information and then allowed to make informed decisions about their care to include: inpatient treatment/care, clinical procedures and interventions, pain management, and discharge planning, and as appropriate, their selection of post-hospital extended care providers (hospice, HHA, and nursing homes)?

A-0050

§482.13(b)(2) continued
The patient's rights include being informed of his or her health status,

Interpretive Guidelines§482.13(b)(2)

The patient has the right to be informed of his/her health status. This would include being informed of his/her diagnosis and prognosis.

Survey Procedures §482.13(b)(2)

- Have patients been notified of their right to:
    - Be informed of his/her health status;
    - Be informed of his/her diagnosis;
    - Be informed of his/her prognosis.
- Have patients been informed in a language or method of communication that they understand?
- Have patients been informed of their health status, diagnosis and prognosis?

A-0051

§482.13(b)(2) continued
being involved in care planning and treatment,

Interpretive Guidelines §482.13(b)(2)

The patient's rights include being involved in care planning and treatment. The hospital must include the patient or the patient's representative in the development and any revisions to the patient's care plan and patient treatment decisions.

Survey Procedures §482.13(b)(2)

Conduct record reviews and interviews with staff and patients to determine what happens when staff and a patient disagree regarding the patient's plan of care. Is there evidence that patients or their representative are involved with care planning and treatment decisions?

A-0052

§482.13(b)(2) continued
and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Interpretive Guidelines §482.13(b)(2)

The patient (or the patient's representative) has the right to request or refuse treatment. This regulation stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary.

Survey Procedures §482.13(b)(2)

- Does evidence indicate the hospital respected a patient's request for or refusal of certain treatments?

- Does evidence indicate that a patient's request for treatment was denied? If so what was the reason for that denial?

A-0053

§482.13(b)(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these

directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).

Interpretive Guidelines §482.13(b)(3)

The patient (inpatient or outpatient)has the right to formulate advance directives (as defined in §489.100), and to have hospital staff implement and comply with their advance directive. The regulation at 42 CFR part 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions (e.g., pain management) and to formulate an advance directive and requires the hospital to:

- Disseminate its policies regarding the implementation of advance directives, including a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

- Clarify any differences between institution-wide conscience objections and those that may be raised by individual MD/DOs;

- Identify the State legal authority permitting such an objection; and

- Describe the range of medical conditions or procedures affected by the conscience objection.

The hospital must:

- Provide written information to patients at the time of admission concerning their rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care including their right to accept or refuse medical care and their right to formulate an advance directive. (Both inpatients and outpatients have the same rights under this requirement. However, the hospital is not required to provide written information concerning these rights to outpatients.);

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and

- Provide community education regarding advance directives and the hospital must document its efforts.

An advance directive refers to instructions about the patient's medical care in the event that he/she becomes unable to communicate for himself/herself. An advance directive may take the form of a living will or a medical power of attorney. A **psychiatric advance directive** is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the hospital, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. Hospitals should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them inasmuch as this regulation also supports the patient's right to participate in the development and implementation of his or her plan of care. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the MD/DOs, nurses, and other staff as they develop a plan of care and treatment for the patient.

Survey Procedures §482.13(b)(3)

- Review the records of a sample of patients for evidence of hospital compliance with advance directive notice requirements. Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has the patient's advance directive been placed in the medical record? Is there evidence that the hospital provides written notice to inpatients or their representative of the patient's right to formulate an advance directive and to have hospital staff comply with the advance directive (in accordance with State law and stated conscientious objection)?

- What mechanism does the hospital have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the hospital is promoting and protecting each patient's right to formulate an advance directive?

- Determine to what extent the hospital educates its staff regarding advance directives.

- Interview staff to determine their knowledge of the advance directives of the patients in their care.

- Determine to what extent the hospital provides education for the patient population (inpatient and outpatient) regarding one's rights under State law to formulate advance directives.

A-0054

§482.13(b)(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

Survey Procedures §482.13(b)(4)

Is there evidence that the hospital has a system in place to assure that a patient's family and MD/DO are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done)?

A-0055

§482.13(c) Standard: Privacy and Safety

A-0056

§482.13(c)(1) The patient has the right to personal privacy.

Interpretive Guidelines §482.13(c)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate. The right to personal privacy would also include limiting the release or disclosure of patient information such as the patient's presence in the facility or location in the hospital, or

personal information such as name, age, address, income, health information without prior consent from the patient, as required by the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule). However, patients that are admitted due to emergency circumstances may not wish that family members or significant others be uninformed as to their presence or status. The hospital should have procedures in place, in accordance with State law, to provide appropriate information to patient families or significant others in those situations where the patient is unable to make their wishes known.

People not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. Privacy should be afforded when the MD/DO or other staff visits the patient to discuss clinical care issues or conduct any examination.

Additionally, audio/video monitoring (does not include recording) patients in medical-surgical intensive-care type units would not be considered violating the patient's privacy as long as patients/patient representatives are aware of the monitoring and the monitors or speakers are located so that the monitor screens are not visible or where speakers are not audible to visitors or the public. Staff must take appropriate precautions to provide patient privacy while patients are toileting, bathing, or being examined.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm self (such as when the patient is under suicide precautions or special observation status) or others exists. In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc., are not generally affected by this requirements.

Survey Procedures §482.13(c)(1)

- Conduct observations to determine if patients are provided privacy during examinations, procedures, treatments, surgery, personal hygiene activities and discussions about their health status/care and other appropriate situations?

- Are patient names posted in public view?

- Is patient information posted in public view? Is the hospital promoting and protecting each patient's right to privacy?

A-0057

§482.13(c)(2) The patient has the right to receive care in a safe setting.

Interpretive Guidelines §482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. The hospital must protect vulnerable patients, including newborns and children. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment.

Survey Procedures §482.13(c)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospitals.

- Review QAPI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment.

- Observe the environment where care and treatment are provided.

- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?

- Review policy and procedures on what the facility does to curtail unwanted visitors or contaminated materials.

- Access the hospital's security efforts to protect vulnerable patients including newborns and children. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients?

A-0058

§482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment.

Interpretive Guidelines §482.13(c)(3)

The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors. The hospital must ensure that patients are free from all forms of abuse, neglect, or harassment. The hospital must have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

The following components are suggested as necessary for effective abuse protection:

- **Prevent**. A critical part of this system is that there are adequate staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (See information regarding meaning of adequate at those requirements that require the hospital to have adequate staff. Adequate staff would include that the hospital ensures that there are the number and types of qualified, trained, and experienced staff at the hospital and available to meet the care needs of every patient.)

- **Screen**. Persons with a record of abuse or neglect should not be hired or retained as employees.

- **Identify**. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.

- **Train**. The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection.

- **Protect**. The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment.

- **Investigate**. The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment.

- **Report/Respond**. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or Federal law.

As a result of the implementation of this system, changes to the hospital's policies and procedures should be made accordingly.

Survey Procedures §482.13(c)(3)

- Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. In particular, determine the extent to which the hospital addresses the following issues.

- Are staffing levels across all shifts sufficient to care for individual patient's needs?

- Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations?

- How does the hospital substantiate allegations of abuse and neglect?

- Do incidents of substantiated abuse and neglect result in appropriate action?

- Has the hospital implemented an abuse protection program? Does it comply with Federal, State and local laws and regulations? Is it effective?

- Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect?

- Can staff identify various forms of abuse or neglect?

- Do staff members know what to do if they witness abuse and neglect?

- What evidence is there that allegations of abuse and neglect are thoroughly investigated?

- Does the hospital conduct criminal background checks as allowed by State law for all potential new hires?

- Is there evidence the hospital employs people with a history of abuse, neglect or harassment?

A-0059

§482.13(d) Standard: Confidentiality of Patient Records

A-0060

§482.13(d)(1) The patient has the right to the confidentiality of his or her clinical records.

Interpretive Guidelines §482.13(d)(1)

The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the hospital, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

Survey Procedures §482.13(d)(1)

Observe care units. Is patient information posted where it can be viewed by visitors or other non-hospital staff? Are medical records accessible to people not involved with the patient's care? Is it likely that unauthorized persons could read or remove the clinical record? Are patient clinical information/records available and accessible at the bedside or in the patient's room where people not involved in the patient's care could likely read the information.

A-0061

§482.13(d)(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and

must actively seek to meet these requests as quickly as its record keeping system permits.

Interpretive Guidelines §482.13(d)(2)

The requirements of the Department of Health and Human Services with regard to the confidentiality rights of individuals are set forth in the Privacy Rule at 42 CFR §164.500 et seq., pursuant to §264 of the Health Insurance Portability and Accountability Act of 1996." The regulation at 42 CFR §164.524 specifies that patients should be allowed to inspect and obtain a copy of health information about them that is held by providers; and that providers may not withhold information except under limited circumstances. These circumstances include:

- Psychotherapy notes;
- A correctional institution or a health care provider acting at the direction of a correctional institution may deny an inmate's request for access, if providing such access would jeopardize the health or security of the individual, other inmates, or officers or employees of the correctional institution;
- The information is about another person (other than a health care provider) and the hospital determines that the patient inspection is reasonably likely to cause sufficient harm to that person to warrant withholding;
- A licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
- The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source;
- The information is collected in the course of research that includes treatment and the research is in progress, provided that the individual has agreed to the denial of access and the provider informs the individual that his or her right of access will be reinstated when the research is completed;
- The protected health information is subject to the Clinical Laboratory Improvements Amendments of 1988, 42 CFR §263a, to the extent that providing the requested access would be prohibited by law;
- The protected health information is exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR §493.3(a)(2);

- The information is compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding; and

- The request is made by an individual's personal representative (as allowed under state law) and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to the individual or another person.

In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified above. In these cases, the record holder may decide to withhold portions of the record; however, to the extent possible, the patient should be given as much information as possible.

If the patient is incompetent, the patient record should be made available to his or her representative (as allowed under State law). Upon the patient's request, other designated individuals may access the patient's records.

The patient has the right to easily access his/her medical records. Reasonable cost-based fees may be imposed only to cover the cost of copying, postage, and/or preparing an explanation or summary of patient health information, as outlined in 42 CFR §164.524(c). The cost of duplicating a patient's record must not create a barrier to the individual's receiving his or her medical record.

Survey Procedures §482.13(d)(2)

- Does the hospital promote and protect the patient's right to access information contained in his/her clinical record?

- Does the hospital have a procedure for providing records to patients within a reasonable time frame?

- Does the hospital's system frustrate the legitimate efforts of individuals to gain access to their own medical record?

- Does the procedure include the method to identify what documents were not provided and the reason?

A-0062

§482.13(e) Standard: Restraint for Acute Medical and Surgical Care

Interpretive Guidelines §482.13(e)

Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f),

emergency use of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion.

The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects can cause confusion, agitation, and combative behaviors. Addressing these medical issues can often eliminate or minimize the need for the use of restraints.

For the purposes of this CoP, the phrase "seclusion and restraint for behavior management" applies to emergencies where the patient's behavior is violent or aggressive. The use of a restraint for a non-combative, otherwise cooperative individual is governed by standard (e) of the regulation. For example, a patient is displaying symptoms of Sundowner's Syndrome, is not acting out or behaving destructively or dangerously; however, the patient has an unsteady gait and continues to get out of bed even after staff have tried alternatives to keep him/her from getting out of bed. In the scenario described, the patient's behavior is not violent or aggressive.

We stress, however, that there is nothing inherently dangerous about a patient being able to walk or wander, even at night. The rationale that the patient should be restrained because he "might" fall is an inadequate basis for using a restraint for the purposes of this regulation. When assessing and care planning for the patient, the hospital should consider whether he/she has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed. A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients.

In the case described in this question, assessment is critical. An assessment should minimally address the following questions: Are there safety interventions or precautions that can be taken to reduce the risk of the patient slipping, tripping, or falling if the patient gets out of bed? Is there a way to enable the patient to safely ambulate? Is there some assistive device that will improve his or her ability to self ambulate? Is a medication or a reversible condition causing this unsteady gait? Would the patient be content to walk with a staff person? Could the patient be brought closer to the nurse's station where he or she could be supervised?

If an assessment reveals a medical symptom or condition that indicates an intervention to protect the patient from harm, the regulation at §482.13(e)(3) requires that the hospital determine that less restrictive interventions are ineffective in protecting the patient from harm. Upon making this determination, the hospital may consider the use of a restraint;

however, that consideration should weigh the risks of using a restraint (which are widely documented in research) against the risks presented by the patient's behavior. If the hospital chooses to use the restraint, it must meet the requirements of standard (e).

In the case of a patient with cognitive impairment, such as Alzheimer's Disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification.

- Example 1: A patient with Alzheimer's Disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior presents a danger to himself, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard (§482.13(f)).

- Example 2: A patient diagnosed with Alzheimer's Disease has surgery for a fractured hip. Staff determines that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives has been evaluated or was unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)).

If a patient has a diagnosed chronic medical or psychiatric condition such as those associated with Lesch-Nyhan Syndrome, and he/she engages in repetitive self-mutilating behavior, the use of restraint would need to meet the requirements of standard (e) for acute medical and surgical care rather than standard (f) for behavioral management. In these situations where the patient exhibits chronic self-injurious behavior, a PRN order that is applied in accordance with the specific parameters established in the treatment plan would be permitted (note than PRN application is not otherwise permitted with uses of restraint under standard (e)). Again, this use of restraint would need to be integrated into the plan for the patient's care and treatment. As always, the use of alternative interventions should be pursued when feasible, and use of restraint should be discontinued as quickly as possible. Since the use of restraints to prevent self-injury for these types of rare, severe medical and psychiatric conditions is considered a standard (e) use of restraint for acute medical and surgical care, the requirement for face-to-face assessment within one hour and the limitation of length of orders (4, 2, or 1 hour(s) depending on the patient's age are not applicable).

Restraint must not be used unless it is to meet the patient's individual clinical needs. When used, restraints must be the least restrictive intervention that protects the patient's safety and alternatives have failed. Restraint use must end as soon as possible.

Patient care staff must be able to demonstrate that the restraints are the least restrictive intervention that protects the patient's safety. Patient care staff must demonstrate through their documentation that the use of restraint is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint. Documentation by the

physician or other staff once a day may not be adequate to support that the restraint intervention needs to continue and may not comply with the requirement to end the restraint as soon as possible. A patient's clinical needs often change as time passes or at differing times of the day.

The use of a protocol does not substitute for compliance with all the requirements nor does the use of a protocol necessarily demonstrate compliance with the requirements. All restraint interventions must be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Questions staff should ask (and surveyors will evaluate to determine compliance):

- Is the restraint intervention the least restrictive intervention that meets the patient's clinical needs/protects the patient's safety?

- Did the staff demonstrate that alternatives will not meet the patient's clinical needs/protects the patient's safety?

- Do ongoing documented assessments demonstrate that the restraint intervention is needed at this time (or at a time in the past) and that the restraint intervention remains the least restrictive way to protect the patient's safety?

CMS does not consider **the use of weapons** in the application of restraint as safe appropriate health care interventions. We consider the term "weapons" to include pepper spray, mace, nightsticks, Tazers, cattle prods, stun guns, pistols and other such devices. Security staff may carry weapons as allowed by hospital policy and State and Federal law. The use of weapons by security staff is considered as a law enforcement use and not a health care intervention. CMS does not approve the use of weapons by any hospital staff as a means of subduing a patient to place that patient in restraint/seclusion.

If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be turned over to local law enforcement.

Again, CMS does not consider the use of weapons as safe appropriate "health care" interventions and their use is not appropriate in the application of patient restraint or initiation of seclusion.

Handcuffs, manacles, shackles, and other chain-type restraint devices are considered law enforcement restraint devices and would not be considered safe appropriate health care restraint interventions for use by hospital staff to restrain patients.

The use of such devices by non-hospital employed or contracted law enforcement officers is governed by Federal and State law and regulations. If non-hospital employed

or contracted law enforcement officers bring a prisoner wearing handcuffs or other restraints, into the hospital for care, the officers are responsible for monitoring and maintaining the custody of their prisoner (the hospital's patient) and the officers will determine when their prisoner's restraint device can be removed in accordance with Federal and State law and regulations. This does not diminish the hospital's responsibility for appropriate assessment and provision of care for their patient (the officer's prisoner).

A-0063

§482.13(e)(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.

The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.

A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition.

Interpretive Guidelines §482.13(e)(1)

The regulation states that patients have the right to be free from restraint/seclusion that is not medically necessary. Hospitals must ensure that this right is implemented. The hospital must take actions to comply with the requirements through its QAPI activities. Its hospital leadership should assess and monitor their use of restraint/seclusion, implement actions to ensure that only medically necessary restraints are used, and that when used the hospital complies with the requirements. One suggested method to assess and monitor restraint and seclusion use may be the use of a log to record restraint/seclusion use. Components of this log could include:

- Shift;
- Date, time of order;
- Staff who initiated the process;
- The length of each episode;

- Date and time each episode was initiated;
- Day of the week each episode was initiated;
- Type of restraint used;
- Whether injuries were sustained by the individual or staff;
- Age of individual;
- Gender of individual.

In acute medical and post-surgical care, a restraint may be necessary to ensure that (for example) an intravenous (IV) or feeding tube will not be removed, or that a patient who is temporarily or permanently incapacitated with a broken hip will not attempt to walk before it is medically appropriate. That is, medical restraint may be used to limit mobility or, temporarily immobilize a patient related to a medical, post-surgical or dental procedure.

If the intervention is undertaken because of an unanticipated outburst of severely aggressive, violent or destructive behavior that poses an imminent danger to the patient or others, standard (f) applies. Other uses of restraint for acute medical and post-surgical care should be considered under standard (e).

Risks associated with any intervention must be considered in the context of an ongoing process of assessment, intervention, evaluation, and re-intervention. A corollary principle is that the greater the risks associated with an intervention, the more careful and thorough the assessment must be.

The rationale that the patient should be restrained because he/she "might" fall is an inadequate basis for using a restraint. When assessing and care planning for the patient, the hospital should consider whether he/she has a history of falling or a medical condition or symptom that indicates a need for a protective intervention. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients.

The use of a restraint intervention must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

Exceptions:

The **use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital** is for custody, detention, and public safety reasons, and is not involved in the provision of health care.

Therefore, the use of restrictive devices applied by and monitored by law enforcement officers who are not employed or contracted by the hospital, and who maintain custody and direct supervision of their prisoner, are not governed by §§482.13(e)(1)-482.13(e)(3) of the regulation. The individual may be the law enforcement officer's prisoner but he/she is also the hospital's patient. The hospital is still responsible for providing safe and appropriate care to their patient. The condition of the patient must be continually assessed, monitored, and re-evaluated.

A **voluntary mechanical support** used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint, (some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces).

A medically necessary and voluntary **positioning or securing device** used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Physically holding a patient during a **forced psychotropic medication procedure** is considered physical restraint and is not included in this exception. **Recovery from anesthesia** that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of the regulation. However, if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of standard (e) must be followed.

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation. The use of these safety interventions needs to be addressed in the hospital's policies or procedures.

Devices That Serve Multiple Purposes

Devices that serve multiple purposes such as a Geri chair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint. Use of these restraints are not typically used to address violence or aggression, therefore their use would be governed by standard (e). Standard (f) would apply if used to address violent behavior.

The hospital should base its assessment for device use on what constitutes the least risk for the patient: the risk of what might happen if the device is not used versus the risk it poses as a restraint.

Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Side rails

If a patient is in a hospital bed with side rails raised, and the side rails restrict the patient's freedom to exit the bed, and the patient cannot easily remove or release the side rail, the side rail is a restraint and must meet the requirements of standard (e). Additionally, bed design varies. On some hospital beds, patients may be able to lower the side rail. If the patient is able to easily lower the side rail independently, it is not a restraint. Other types of hospital beds have divided side rails. One section may be raised or lowered independently. For example, the side rails are in sections and all but one section are raised and if the patient is able to easily get out of bed if he/she wishes then, for this patient, the side rail is not acting as a restraint.

Even when assessment indicates the presence of a clinical symptom that may warrant the use of a side rail, side rails present an inherent safety risk, particularly if the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised side rails.

If the patient is on a **stretcher** (a narrow, elevated and highly mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width and high mobility. Additionally, since stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers in emergency departments and when transporting patients are not considered restraint, but a prudent safety intervention. Such use would not require a MD/DO or LIP's order.

If the patient is being transported by stretcher or wheelchair to another area for a diagnostic or surgical procedure and must wait briefly, an order would not be required for raised side rails or a seatbelt. In the case of a patient who is awaiting a treatment or a procedure, we expect that even though an order is not required, as a matter of standard practice staff will assure that the patient is continuously monitored and not abandoned while he/she awaits treatment or care, and that his or her basic care needs are met.

Drugs Used as a Restraint

The regulation states, "A drug used as a restraint is a medication used to control behavior or to restrict the patient's movement, and is not a standard treatment for the patient's medical or psychiatric condition." The regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of psychotropic medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious...hence the notation that medications that are a standard treatment for a patient's medical or psychiatric conditions are NOT subject to the requirements of the regulation.

Of course, as with any use of restraint, staff must engage in active patient assessment to determine whether there is some root cause or issue for the targeted problem that can be alleviated through other types of clinical or non-clinical interventions before using the drug intervention. A patient may be agitated because of pain, an adverse reaction to an existing medication, or an unmet care need or concern.

A "**standard treatment**" for a medication used to address a patient's medical or psychiatric condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved for it by the Food and Drug Administration and the manufacturer, for the indications it is manufactured and labeled to address, listed dosage parameters, etc; and

- The use of the medication follows national practice standards established or recognized by the appropriate medical community and/or professional medical association or organization; and

- The use of the medication to treat a specific patient's clinical condition is based on that patient's target symptoms, overall clinical situation, and on the MD/DO's or other LIP's knowledge of that patient's expected and actual response to the medication.

- An additional component of "standard treatment" for a medication is the expectation that the standard use of a psychotherapeutic medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him or her than would be possible without the use of the medication. Psychotherapeutic medications are to enable, not disable. If a psychotherapeutic medication reduces the patient's ability to effectively or appropriately interact with the world around him or her, then the psychotherapeutic medication is not being used as a "standard treatment" for the patient's condition.

If a medication is used as a standard treatment (as described above) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is NOT subject to the requirements of this regulation. The patient would still need to receive assessments, monitoring, interventions and care that are appropriate for that patient's needs.

A medication that is not being used as a standard treatment (as described above) for the patient's medical or psychiatric condition and that results in controlling the patient's behavior and/or in restricting his or her freedom of movement would be a drug used as a restraint.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical non-surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by staff, including drugs that are used as restraints. Two examples serve to clarify drugs as restraint in standards (e) and (f).

- **Example 1:** A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff find the patient's behavior bothersome, and ask the MD/DO to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint.

- **Example 2**: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administer a PRN medication ordered by the patient's MD/DO or LIP to address this outburst of specific behaviors. The use of the medication enables the patient to better interact/function. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, or aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is "a standard treatment for his medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e) or (f).

Physical Restraint

The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or

equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement (this would include **therapeutic holds**) constitutes restraint for that patient. Many deaths have involved these practices and they may be just as restrictive and potentially dangerous as restraining methods that involve devices.

Placing **hand mitts on infants** would not be considered restraint but pinning or otherwise attaching those same mitts to bedding would meet the definition of physical restraint and the requirements would apply.

For the purposes of this regulation a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child is not considered restraint. Interventions that include the use of a **helmet** to protect a patient's head, and the patient is unable to easily remove the helmet, would meet the definition of physical restraint and the requirements would apply.

An object may be a restraint by functional definition; that is when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as:

- Tucking a patient's sheets in so tightly that he or she cannot move; or

- Using a side rail to prevent a patient from voluntarily getting out of bed.

The following questions need to be considered when defining an intervention as a physical restraint..

- Does the patient have the ability/skill to easily remove the intervention? **AND**

- Is the patient's freedom to move (or get out of bed) when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention?

A restraint such as a soft wrist restraint, an arm restraint, wrapping or bundling, or some similar type of intervention to prevent an infant or toddler from removing invasive lines or reopening a surgical site, meets the definition of physical restraint and the requirements apply.

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Survey Procedures §482.13(e)(1)

- Obtain a sample of patients who are currently in restraints or who have been in restraints during their hospital stay. Are inordinate numbers of patients restrained given the hospital's patient composition at that time?

- What evidence is there that hospital staff identified the reason for the restraint, and eliminated other less invasive measures before applying the restraint?

- Determine if there is a pattern of increased restraint use related to staff coverage.

- Are there patterns of applying the same type of restraint regardless of the medical condition of patients?

- Review patient incident/accident reports to determine the frequency (percent) of injured patients who were also restrained at the time of their injury. If record review indicates that restrained patients sustained injuries, determine what the hospital did to prevent additional injury while it investigated possible changes to its restraint protocol.

- Were the reasons for the use of a restraint in relation to the medical condition explained to the patient in understandable terms? Could the patient articulate his/her understanding?

A-0064

§482.13(e)(2) A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective.

Interpretive Guidelines §482.13(e)(2)

Restraint is only to be used when clinically necessary to improve the patient's well being and when other less restrictive measures have been found to be ineffective to protect the patient from harm. It is a last resort. Accordingly, when deciding whether a patient's condition is such that restraint is the only viable option, there needs to be a connection between the patient's condition and the necessity for restraint.

In restraint use, it is important to ask what is the patient doing that is a hazard. Hospital staff should be specific on this point.

Hospital staff should use concrete, objective observations in describing the behavior, encourage good assessment to determine the cause of the behavior (if determination is possible), and make the connection with why the patient's behavior is so hazardous for that patient that restraint is necessary.

Documentation in the patient's medical record should include:

- The patient's behavior and the intervention used;
- The rationale for the use of the restraint; and
- The patient's response to the use of restraint.

Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted or determined to be ineffective prior to the introduction of more restrictive measures.

Survey Procedures §482.13(e)(2)

- Review hospital procedures for use of restraints.
- Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training.
- Does the number of patients who are restrained increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units?
- Do MD/DO or other LIP orders specify the reason for restraint, the type of restraint and the duration?

A-0065

§482.13(e)(3) The use of a restraint must be--

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm.

Interpretive Guidelines §482.13(e)(3)(i)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but prior to the use of a restraint, alternative interventions must be found to be ineffective to protect the patient or others from harm.

Survey Procedures §482.13(e)(3)(i)

- Is there documentation in the medical record to explain the rationale for the use of restraints, including alternatives attempted?

- Were less intrusive measures considered first?

A-0066

§482.13(e)(3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital or order a restraint. This order must--

Interpretive Guidelines §482.13(e)(3)(ii)

A protocol cannot serve as a substitute for obtaining a MD/DO or other LIP's order before initiating each episode of restraint use, and the requirements of the regulation must still be met. The philosophy that serves as a foundation for the regulation is that restraint use is an exceptional event, not a routine response to a certain condition or behavior. Each patient must be thoroughly assessed and interventions should be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint is a last resort when less restrictive measures have been determined ineffective, not a standard response to a behavior or patient need.

The hospital should have a written policy, conforming to state law, indicating which LIP are permitted to order restraints in that facility.

The regulation requires an MD/DO or LIP to order restraint prior to the application of restraint. In some situations, the need for a restraint intervention may occur so quickly that an order cannot be obtained prior to the application of restraints. In these **emergency application situations** the order must be obtained either during the emergency application of the restraint or immediately (without time interval) after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. This procedure should specify who can initiate the emergency application of restraint prior to obtaining an MD/DO's or LIP's order. The use of verbal orders should be addressed.

Licensed Independent Practitioner (LIP)

For the purpose of ordering restraint, a LIP is any practitioner permitted by State legislated law and hospital policy as having the authority to independently order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a MD/DO can carry out functions reserved for a MD/DO or LIP by the regulation. A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending MD/DO; therefore, he or she is not licensed or independent. A medical school student is not an LIP.

Survey Procedures §482.13(e)(3)(ii)

- Review hospital policy and medical by-laws to ascertain clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged in this area.

- Know what categories of practitioners the State recognizes as a LIP or as having the right to order restraints or seclusion.

A-0067

§482.13(e)(3)(ii)(A) Never be written as a standing or on an as needed basis (that is, PRN); and

Interpretive Guidelines §482.13(e)(3)(ii)(A)

This regulation prohibits the use of PRN orders for restraint use. If a patient was recently released from restraint and exhibits behavior that can only be handled by the reapplication of restraint, a new order would be required. Staff cannot discontinue an order and then re-start it under the same order because that would constitute a PRN order. Each episode of restraint use must be initiated in accordance with the order of a MD/DO or other LIP. However, a temporary release that occurs for the purpose of caring for a patient's needs--for example toileting, feeding, and range of motion--is not considered a discontinuation of the invention.

Survey Procedures §482.13(e)(3)(ii)(A)

- Verify in the patient's medical record, and/or the MD/DO's order, that the intent of the order is for the specific reason, and for the specified time period.

- Review the medical record including the progress notes, flow charts and nursing notes to evaluate any patterns of use and if orders were obtained.

- Is there evidence of restraints being implemented on a PRN basis?

A-0068

§482.13(e)(3)(ii)(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

Interpretive Guidelines §482.13(e)(3)(ii)(B)

The "treating" physician is the MD/DO who is responsible for the management and care of the patient. It is important to consult with the treating physician, as soon as possible, because information regarding the patient's history may have a significant impact on selection of restraint intervention.

Survey Procedures §482.13(e)(3)(ii)(B)

Check the patient's medical record for documentation of contact with the treating physician if he/she did not order the restraint.

A-0069

§482.13(e)(3)(iii) In accordance with a written modification to the patient's plan of care;

Interpretive Guidelines §482.13(e)(3)(iii)

The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan.

Survey Procedures §482.13(e)(3)(iii)

- Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a loop of assessment, intervention, evaluation, and re-intervention?
- Is there evidence of assessment of the identified problem or of individual patient assessment?
- Does the patient's plan of care reflect that assessment?
- What was the goal? Was it outcome oriented?
- What was the described intervention?
- Who is responsible for implementation?
- Did the MD/DO or other LIP write orders that included a time-limit? Were these orders incorporated into the plan of care?
- After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?

A-0070

§482.13(e)(3)(iv) Implemented in the least restrictive manner possible.

Interpretive Guidelines §482.13(e)(3)(iv)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Survey Procedures §482.13(e)(3)(iv)

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? That is, what documentation is in the medical record to explain the rationale for the use of restraint?
- Were less restrictive measures tried or considered first?
- Are those measures documented?
- Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

A-0071

§482.13(e)(3)(v) In accordance with safe and appropriate restraining techniques, and

Interpretive guidelines §482.13(e)(3)(v)

Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining technique in that environment. Restraint use should not cause harm or pain to the patient.

Survey Procedures §482.13(e)(3)(v)

- Examine medical records of patients for whom restraints are used in the sample.
- After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safely applied?

- Was nursing procedure and policy followed?

- What was the patient's response? If negative, were timely changes made?

- Was there any evidence of injury to the patient?

A-0072

§482.13(e)(3)(vi) Ended at the earliest possible time.

Interpretive Guidelines §482.13(e)(3)(vi)

The use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition.

Staff should continually assess the patient to ascertain his/her condition and to determine whether restraint can be discontinued. The regulation requires that these interventions be ended as quickly as possible. However, the decision to discontinue the intervention should be based on the determination that the medical need for restraint is no longer present or the patient's needs can be met with less restrictive methods. When the physician continues the restraint, there must be documentation in the patient's medical record describing the patient's clinical needs and supporting the continued use of restraint.

Who is Authorized to Remove a Restraint?

The hospital should address in its policies and procedures, at a minimum:

- Who has the authority to discontinue restraints (based on a state law and hospital policies); and

- Under what circumstances restraints are to be discontinued.

Survey Procedures §482.13(e)(3)(vi)

- If the time of restraint use is lengthy, look for evidence that the symptoms necessitating the restraint use have persisted. Is there evidence to indicate that the staff have evaluated if the restraint can be safely removed?

- What are the hospital's policies and procedures for ending restraint use for medical and post surgical care?

A-0073

§482.13(e)(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

Interpretive Guidelines §482.13(e)(4)

The determination of frequency of monitoring should be made on an individual basis that includes a rationale that reflects consideration of the individual patient's medical needs and health status. Hospital policies and/or nursing policies should address: frequencies of assessment, assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity), and provide for nutritional needs, range of motion, and elimination needs.

Standard (e) does not require one-to-one observation (a staff member constantly in the presence of the patient). We expect that the hospital will establish a policy and procedure (or guidelines for staff) to guide staff in how to determine an appropriate interval for assessment, monitoring, and re-evaluation based on the individual needs of the patient, his or her condition, and the type of restraint used. For example, placing staff at the bedside of a patient with an IV arm board may be unnecessary. However, for a more restrictive or risky intervention, staff may determine that constant one-to-one monitoring is needed.

Continuous face-to-face monitoring may be appropriate when the intervention leaves a patient vulnerable. Restraint limits an individual's ability to move or escape harm. Patients are vulnerable to assault or other abuse when they are immobilized in this manner. The hospital is responsible for providing monitoring and reassessment that will protect the patient's safety.

Survey Procedures §482.13(e)(4)

- Was there a valid rationale for the decision regarding the frequency of assessment/monitoring documented in the medical record?
- Was documentation consistent, relevant, and reflective of the patient's condition?
- If the patient's mental status, coordination, or gait improved, what actions did the staff take?
- What evidence do you find the hospital's/nursing assessment/monitoring policies are put into practice on all restrained patients?
- Do the patient's care needs dictate how frequently the reassessment is made, and is there documented evidence of the reassessment?

A-0074

§482.13(e)(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

Interpretive Guidelines §482.13(e)(5)

Ongoing restraint education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing in-service training for all staff who have direct patient care responsibilities, responsibilities for application of restraint, or the monitoring or assessment of patients in restraint.

Survey Procedures §482.13(e)(5)

- Does the facility have a documented educational, instructional training program for the use of all restraint techniques used?
- Are all levels of staff that have direct patient care responsibilities or restraint application, monitoring, and/or assessment responsibilities, trained in the proper and safe application and use of restraints? Is this documented?
- Does the training require staff to demonstrate knowledge of the assessment loop and the safe application of restraints before they are allowed to apply restraints?
- Does the training review alternatives to the use of restraints?
- Do all contract/agency personnel with direct patient care responsibilities have documented training in the hospital's restraint/seclusion policies?

A-0075

§482.13(f) Standard: Seclusion and Restraint for Behavior Management

Interpretive Guidelines §482.13(f)

Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f), **emergency use** of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that

for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion.

In the case of a patient with cognitive impairment, such as Alzheimer's disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification.

- **Example 1**: A patient with Alzheimer's disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior presents a danger to him, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard at §482.13(f).

- **Example 2**: A patient diagnosed with Alzheimer's disease has surgery for a fractured hip. Staff determines that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives has been evaluated or was unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)).

The behavior management standard for restraints and seclusion should be followed in emergency or crisis situations if a patient's behavior becomes aggressive or violent, presenting an immediate, serious danger to his/her safety or that of others and the least restrictive measure that will assure the patient's or other's safety is restraint or seclusion. The behavior management standard governs the use of a restraint or seclusion in this type of a crisis situation whether it occurs on acute medical and surgical units, psychiatric units, Alzheimer's units, or in general, psychiatric, alcohol-drug, children's, rehabilitation, short-term, or long-term care hospitals. A restraint or seclusion for behavior management is used only as an emergency measure and is reserved for those occasions when severely aggressive, combative, or destructive behavior places the patient or others in imminent danger. While different factors may precipitate this type of psychiatric, behavioral, and physical outburst for an individual patient, the need for rapid assessment and continuous monitoring is applicable in each case.

The behavior management standard (Standard (f)) does not apply to situations where the hospital wishes to restrain a patient to address behavior where a confused patient is pulling at their central arterial lines, pulling at their intubation tube while on a ventilator, or attempting to get out of bed with an unstable fractured leg. The use of restraint for a non-violent or non-aggressive, otherwise cooperative patient may be governed by the Restraint for acute medical and surgical care (standard (e)). It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain or seclude a patient nor can restraint or seclusion use serve as a substitute for adequate staffing to monitor a patient.

The use of restraint or seclusion interventions must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

CMS does not consider the **use of weapons** in the application of restraint as safe appropriate health care interventions. We consider the term "weapons" to include pepper spray, mace, nightsticks, Tazers, cattle prods, stun guns, pistols and other such devices. Security staff may carry weapons as allowed by hospital policy and State law. The use of weapons by security staff is considered as a law enforcement use and not a health care intervention. CMS does not approve the use of weapons by any hospital staff as a means of subduing a patient to place that patient in patient restraint/seclusion.

If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be turned over to local law enforcement.

Again, CMS does not consider the use of weapons as safe appropriate "health care" interventions and their use is not appropriate in the application of patient restraint or initiation of seclusion.

Handcuffs, manacles, shackles, and other chain-type restraint devices are considered **law enforcement restraint devices** and would not be considered safe appropriate health care restraint interventions for use by hospital staff to restraint patients in hospitals.

The use of such devices by non-hospital employed or contracted law enforcement officers is governed by Federal and State law and regulations. If non-hospital employed or contracted law enforcement officers bring a prisoner wearing handcuffs or other restraints, into the hospital for care, the officers are responsible for monitoring and maintaining the custody of their prisoner (the hospital's patient) and the officers will determine when their prisoner's restraint device can be removed in accordance with Federal and State law and regulations. This does not diminish the hospital's responsibility for appropriate assessment and provision of care for their patient (the officer's prisoner).

Restraint/seclusion must not be used unless it is to meet the patient's individual clinical needs. When used, restraints/seclusion must be the least restrictive intervention that protects the patient's safety and alternatives have failed. Restraint/seclusion use must end as soon as possible.

Patient care staff must be able to demonstrate that the restraint/seclusion is the least restrictive intervention that protects the patient's safety. Patient care must demonstrate through documentation that the use of restraint/seclusion is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint/seclusion. Documentation by the physician or other staff once a day is not adequate to support that

the restraint/seclusion intervention needs to continue and would not comply with the requirement to end the restraint/seclusion as soon as possible. A patient's clinical needs often change as time passes or at differing times of the day.

The use of a protocol does not substitute for compliance with all the requirements nor does the use of a protocol necessarily demonstrate compliance with the requirements. All restraint/seclusion interventions are to be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Questions staff should ask (and surveyors will evaluate to determine compliance):

- Is the restraint/seclusion intervention the least restrictive intervention that meets the patient's clinical needs/protects the patient's safety or the safety of others?

- Did the staff demonstrate that alternatives will not meet the patient's clinical needs/protect the patient's safety?

- Do ongoing documented assessments demonstrate that the restraint intervention is needed at this time (or at a time in the past) and that the restraint/seclusion intervention remains the least restrictive way to protect the patient's safety?

A-0076

§482.13(f)(1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.

A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

A drug used as a restraint is a medication used to control the behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

Interpretive Guidelines §482.13(f)(1)

This regulation requires that patients have the right to be free from restraint or seclusion that is not clinically necessary. Hospitals must ensure that this right is implemented. The hospital must take actions to comply with the requirements through its QAPI activities. Its hospital leadership should assess and monitor their use of restraint/seclusion, implement actions to ensure that only clinically necessary restraints are used, and that when used the hospital complies with the requirements. One suggested method to assess and monitor restraint and seclusion use may be the use of a log to record restraint/seclusion use. Components of this log could include:

- Shift;
- Date and time of the order;
- Staff who initiated the process;
- The length of each episode;
- Date and time each episode was initiated;
- Day of the week each episode was initiated;
- Type of restraint/seclusion used;
- Whether injuries were sustained by the individual or staff;
- Age of individual;
- Gender of individual.

Seclusion

"Seclusion" does not include confinement on a locked unit or ward where the patient is with others. Seclusion is not just confining an individual to an area but involuntarily confining him/her alone in a room or area where he/she is physically prevented from leaving. A situation where a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room, is considered seclusion.

Seclusion is different from timeout. **Timeout** means the restriction of a patient for any period of time to a designated area from which the patient is not physically prevented from leaving and for the purpose of providing the patient an opportunity to regain self-control.

Physical Restraint

The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement (this would include **therapeutic holds**) constitutes restraint for that patient.

An object may be a restraint by functional definition; that is when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as:

- Tucking a patient's sheets in so tightly that he or she cannot move; or
- Using a side rail to prevent a patient from voluntarily getting out of bed.

Interventions that include the use of a **helmet** to protect a patient's head and the patient is unable to easily remove the helmet would meet the definition of physical restraint and the requirements would apply.

The following questions need to be considered when defining an intervention as a physical restraint:

- Does the patient have the ability/skill to easily remove the intervention? AND
- Is the patient's freedom to move when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention?

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Drugs Used as a Restraint

Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical or post-surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right that appears in both standards (e) and (f) is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or

retaliation by staff, including drugs that are used as restraints. Two examples serve to clarify drugs as restraint in standards (e) and (f):

- **Example 1**: A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff finds the patient's behavior bothersome, and asks the MD/DO to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint.

- **Example 2**: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administers a PRN medication ordered by the patient's MD/DO or LIP to address this outburst of specific behaviors. The use of the medication enables the patient to better interact/function. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, or aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is "a standard treatment for his medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e) or (f).

The regulation states, "A drug used as a restraint is a medication used to control behavior or to restrict the patient's movement, and is not a standard treatment for the patient's medical or psychiatric condition." The regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of psychotropic medication to improve their functioning state so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious...hence the notation that medications that are a standard treatment for a patient's medical or psychiatric conditions are NOT subject to the requirements of the regulation.

Of course, as with any use of restraint, staff must engage in active patient assessment to determine whether there is some root cause or issue for the targeted problem that can be alleviated through other types of clinical or non-clinical interventions before using the drug intervention. A patient may be agitated because of pain, an adverse reaction to an existing medication, or an unmet care need or concern.

A "**standard treatment**" for a medication used to address a patient's medical or psychiatric condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved for it by the Food and Drug Administration and the manufacturer, for the indications it is manufactured and labeled to address, listed dosage parameters, etc.;

- The use of the medication follows national practice standards established or recognized by the appropriate medical community and/or professional medical association or organization; and

- The use of the medication to treat a specific patient's clinical condition is based on that patient's target symptoms, overall clinical situation, and on the MD/DO's or other LIP's knowledge of that patient's expected and actual response to the medication.

An additional component of "standard treatment" for a medication is the expectation that the standard use of a psychotherapeutic medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him/her than would be possible without the use of the medication. Psychotherapeutic medications are to enable, not disable. If a psychotherapeutic medication reduces the patient's ability to effectively or appropriately interact with the world around him/her, then the psychotherapeutic medication is not being used as a "standard treatment" for the patient's condition.

If a medication is used as a standard treatment (as described above) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is NOT subject to the requirements of this regulation. The patient would still need to receive assessments, monitoring, interventions and care that are appropriate for that patient's needs.

A medication that is not being used as a standard treatment (as described above) for the patient's medical or psychiatric condition and that results in controlling the patient's behavior and/or in restricting his or her freedom of movement would be a drug used as a restraint.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Exceptions:

The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital is for custody, detention, and public safety reasons, and is not involved in the provision of health care. Therefore, the use of restrictive devices applied by and monitored by law enforcement officers who are not employed or contracted by the hospital, and who maintain custody and direct supervision of their prisoner, are not governed by §482.13(f)(1-3). The individual may be the law enforcement officer's prisoner but he/she is also the hospital's patient. The hospital is still responsible for providing safe and appropriate care to their patient. The condition of the patient must be continually assessed, monitored, and re-evaluated.

A **voluntary mechanical support** used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint, (some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces).

A medically-necessary and voluntary **positioning or securing device** used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Physically holding a patient during a **forced psychotropic medication procedure** is considered physical restraint and not included in this exception.

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation. The use of these safety interventions needs to be addressed in the hospital's policies or procedures. For the purposes of this regulation a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child is not considered restraint.

A-0077

§482.13(f)(2) Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

Interpretive Guidelines §482.13(f)(2)

Emergency is defined as a situation where the patient's behavior is violent or aggressive and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others.

Restraint/seclusion is only to be used when clinically necessary to improve the patient's well-being and when other less restrictive measures have been found to be ineffective to protect the patient or others from harm. It is a last resort. Accordingly, when deciding whether a patient's condition is such that restraint or seclusion is the only viable option, there needs to be a connection between the patient's condition and the necessity for restraint or seclusion.

In restraint/seclusion use, it is important to ask what is the patient doing that is a hazard. Hospital staff should be specific on this point.

Hospital staff should use concrete, objective observations in describing the behavior, encourage good assessment to determine the cause of the behavior (if determination is possible), and make the connection with why the patient's behavior is so hazardous for that patient that restraint is necessary.

Documentation in the patient's medical record should include:

- The patient's behavior and the intervention used;
- The rationale for the use of the restraint or seclusion; and
- The patient's response to the use of restraint or seclusion.

Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted (or considered prior to the introduction of more restrictive measures).

Survey Procedures §482.13(f)(2)

- Review hospital procedures for emergency use of restraints and seclusion.
- Look at incident and accident reports to determine if incidents and accidents are greater with restrained or secluded patients.
- Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training.
- Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units?
- Do MD/DO or other LIP orders specify the reason for seclusion/restraint, the type of restraint and the duration?
- Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others?
- Is there evidence that the hospital considers factors other than the individual patient in determining causes for the need for restraints or seclusion (i.e., environmental factors)?
- Does the clinical record reflect assessment and/or a revision of the plan of care?

A-0078

§482.13(f)(3) The use of a restraint or seclusion must be--

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.

Interpretive Guidelines §482.13(f)(3)(i)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but prior to the use of a restraint or seclusion, must be found to be ineffective to protect the patient or others from harm. Alternatives attempted or the rationale for not using alternatives must be documented.

Survey Procedures §482.13(f)(3)(i)

- Does the clinical record reflect changes in behavior and staff concerns regarding potential danger on the unit/ward prompting use of seclusion or restraints?
- Did the patient's behavior place others/self at risk of harm?
- Were other behavior interventions tried and documented?

A-0079

§482.13(f)(3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint.

The following requirements will be superseded by existing State laws that are more restrictive:

Interpretive Guidelines §482.13(f)(3)(ii)

The regulation requires a MD/DO or LIP to order restraint prior to the application of the restraint. Hospitals should have policies and procedures for the initiation of restraint or seclusion to manage violent, aggressive behavior that places the patient or others in danger.

In some emergency situations, the need for a restraint intervention may occur so quickly that an appropriate order cannot be obtained prior to the application of restraints. In these emergency situations the order must be obtained either during the **emergency application** of the restraint or immediately (without time interval) after the restraint has

been applied. The hospital should address this process in its restraint policies and procedures. This procedure should specify who can initiate restraints or seclusion in an emergency prior to obtaining a MD/DO's or LIP's order. The use of verbal orders should be addressed.

A protocol cannot serve as a substitute for obtaining a MD/DO or other LIP's order before initiating each episode of restraint or seclusion use, and the requirements of the regulation must still be met. Restraint use is an exceptional event, not a routine response to a certain condition or behavior. Each patient must be thoroughly assessed. Interventions must be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint is a last resort when less restrictive measures have been determined ineffective, not a standard response to a behavior or patient need.

Licensed Independent Practitioner (LIP)

For the purpose of ordering restraint or seclusion under Standard (f), a LIP is any practitioner permitted by State legislated law and hospital policy as having the authority to independently order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a MD/DO can carry out functions reserved for a MD/DO or LIP by the regulation. A medical school student holds no license, and his or her work is reviewed and must e countersigned by the attending MD/DO; there, he/she is not licensed or independent. A medical school student is not an LIP.

Survey Procedures §482.13(f)(3)(ii)

- Does the hospital have written policy indicating which practitioners are permitted to order seclusion or restraints in the facility?

- Do the hospital's written policies conform to State law?

- Does the hospital have written policies on the use of verbal orders?

- Does the hospital have established policies for who can initiate restraint and seclusion?

A-0080

§482.13(f)(3)(ii)(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

Interpretive Guidelines §482.13(f)(3)(ii)(A)

Ongoing authorization of restrictive techniques is not permitted. If a patient was recently released from restraint or seclusion and suddenly exhibits behavior that can only be handled by the reapplication of restraint or seclusion, a new order would be required. Staff cannot discontinue an order and then re-start it under the same order because that would constitute a PRN order. Restraints/seclusion instituted based on a contingent situation are considered PRN. PRN orders for restraint and seclusion are not permitted by the regulation. Accordingly, the same order cannot be used to reapply restraints or reinstitute seclusion if the patient's behavior escalates again after he or she has been released. Each episode of restraint or seclusion use must be initiated in accordance with the order of a MD/DO or other LIP. However, a temporary release that occurs for the purpose of caring for a patient's needs--for example, toileting, feeding, and range of motion--is not considered a discontinuation of the intervention.

In the case mentioned above, a new order is required, but another face-to-face assessment of the patient by a MD/DO or other LIP is not. In this situation, an RN can perform a thorough patient assessment and communicate his or her findings to the appropriate LIP when he or she obtains the new order. The LIP should conduct a face-to-face assessment if requested by the RN, or if in his or her judgment, the patient's condition warrants another in-person visit.

Survey Procedures §482.13(f)(3)(ii)(A)

Is there evidence of restraints or seclusion being implemented on a PRN basis?

A-0081

§482.13(f)(3)(ii)(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

Survey Procedures §482.13(f)(3)(ii)(B)

- Determine the hospital's policies and procedures for prompt notification of treating physician when seclusion or restraint is ordered by someone other than the treating physician.

- Determine if medical records reflect hospital policies and procedures.

A-0082

§482.13(f)(3)(ii)(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

Interpretive Guidelines §482.13(f)(3)(ii)(C)

A MD/DO or LIP evaluation of a patient must be face-to-face. A telephone call or telemedicine methodology is not adequate. This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate the face-to-face assessment to a Nurse Practitioner or Physician's Assistant to the extent recognized under State law or a State's regulatory mechanism. The face-to-face assessment includes both a physical and psychological assessment of the patient. The MD/DO, other LIP, or delegated nurse practitioner or physician assistant who conducts the face-to-face assessment must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice and hospital policy.

If a patient who is restrained for combative, assaultive or violent behavior quickly recovers and is released before the MD/DO or LIP arrives to perform the assessment, the MD/DO or LIP must still see the patient face-to-face to perform the assessment within 1 hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt assessment of the incident/situation that led to the intervention, as well as the physiological and psychological condition of the patient at the time of the assessment. We expect that the assessment would also determine whether there is a continued need for the intervention, the cause of the incident, and whether the intervention was appropriate to address the behavior.

If a medication is being used as a restraint to address violent or aggressive patient behavior, the patient would need to be seen within one hour of the administration of the drug.

A-0083

§482.13(f)(3)(ii)(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

The use of physical restraint or seclusion must be limited to the duration of the emergency safety situation regardless of the length of the order. The time frames specified in these requirements are maximums. The MD/DO or LIP has the discretion to

decide that the order should be written for a shorter period of time; and in the meantime, staff should be assessing, monitoring, and re-evaluating the patient so that he or she is released from the restraint or seclusion at the earliest possible time.

If restraints or seclusion are discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating seclusion or reapplying the restraint and the requirements restart.

The MD/DO is not required to perform another face-to-face assessment of the adult patient after 4 hours (or 2 hours or 1 hour for younger patients). While we encourage MD/DO or LIP participation in the delivery of care and treatment, when the original order is about to expire, a qualified RN can telephone the MD/DO or LIP, report the results of his/her most recent assessment and request that the original order be renewed for another period of time (not to exceed the time limits established in the regulation).

A-0084

§482.13(f)(3)(ii)(D) continued
The original order may only be renewed in accordance with these limits for up to a total of 24 hours.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

Orders for restraints must be renewed on a daily basis.

Survey Procedures §482.13(f)(3)(ii)(D)

Does the renewal for seclusion/restraint provide a rationale that is based on an individual assessment of the patient?

A-0085

§482.13(f)(3)(ii)(D) continued
After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

At a minimum, if the patient has been in a restraint or in seclusion for 24 hours, the MD/DO or LIP (if allowed by State law) will at that point return to complete a face-to-face reevaluation. Twenty-four hours of restraint or seclusion is an extreme measure with the potential for serious harm to the patient.

Survey Procedures §482.13(f)(3)(ii)(D)

If patients are in seclusion or restraints for longer than 24 hours, is there evidence of a new written order and assessment documentation in the medical record that provides a reasonable rationale supporting the decision to continue with that intervention?

A-0086

§482.13(f)(3)(iii) In accordance with a written modification to the patient's plan of care;

Interpretive Guidelines §482.13(f)(3)(iii)

The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan.

Survey Procedures §482.13(f)(3)(iii)

- Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a process of assessment, intervention, evaluation, and re-intervention?
- Is there evidence of assessment of the identified problem or of individual patient assessment?
- Does the patient's plan of care reflect that assessment?
- What was the goal? Was it outcome oriented?
- What was the described intervention?
- Who is responsible for implementation?
- Did the MD/DO or other LIP write orders that included a time-limit? Did these orders get incorporated into the plan of care?
- After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?

A-0087

§482.13(f)(3)(iv) Implemented in the least restrictive manner possible;

Interpretive Guidelines §482.13(f)(3)(iv)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Survey Procedures §482.13(f)(3)(iv)

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? What documentation is in the medical record to explain the rationale for the use of restraint?
- Were less restrictive measures tried or considered first?
- Are those measures documented?
- Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

A-0088

§482.13(f)(3)(v) In accordance with safe appropriate restraining techniques; and

Interpretive Guidelines §482.13(f)(3)(v)

Restraint/seclusion use should not cause harm or pain to patient.

Survey Procedures §482.13(f)(3)(v)

- Examine and include patients for whom restraint is used in the sample.
- Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining techniques.
- Is there a clear description of the physical intervention utilized?
- Did staff do an immediate assessment of the patient to ensure that the restraints were safely and correctly applied?
- Was nursing procedure and policy followed?
- What was the patient's response? If negative, were changes made?

- Was there any evidence of injury to the patient?

A-0089

§482.13(f)(3)(vi) Ended at the earliest possible time.

Interpretive Guidelines §482.13(f)(3)(vi)

The use of restraints/seclusion should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Staff should continually assess the patient to ascertain his or her condition and to determine whether restraint or seclusion can be discontinued. The regulation requires that these interventions be ended as quickly as possible. However, the decision to discontinue the intervention should be based on the determination that the patient's behavior is no longer a threat to himself or herself. When the physician or LIP continues restraint or seclusion, there must be documentation in the medical record describing the patient's clinical needs and supporting the continued use of restraint or seclusion.

Who is Authorized to Remove a Restraint?

The hospital should address in its policies and procedures, at a minimum:

- Who has the authority to discontinue restraints (based on state law and hospital policies; and

- Under what circumstances restraints are to be discontinued.

Survey Procedures §482.13(f)(3)(vi)

- If the time of restraint use is lengthy, is there evidence that the symptoms necessitating the restraint use have persisted?

- What are the hospital policies and procedures for ending restraint use for behavior management?

- Does the evidence indicate that the staff have evaluated the patient's behavior so that the restraint can safely be removed?

A-0090

§482.13(f)(4) A restraint and seclusion may not be used simultaneously unless the patient is--

(i) Continually monitored face-to-face by an assigned staff member; or

Interpretive Guidelines §482.13(f)(4)(i)

When using both seclusion and restraints at the same time, continual monitoring is defined as uninterrupted monitoring. The monitoring must be face-to-face or by using both audio and video monitoring equipment.

An individual who is physically restrained alone in his or her room is not necessarily being simultaneously secluded. A key point to consider is that the individual's privacy and dignity should be protected to the greatest extent possible during any intervention. The purpose in restraining the individual alone in his or her room may be to promote privacy and dignity instead of simultaneously using seclusion and restraint. While this distinction may be difficult to make, it is helpful to consider whether the individual would, in the absence of the physical restraint, be able to voluntarily leave the room. If so, then he/she is not also being secluded. However, if the physical restraint was removed and yet the individual was still unable to leave the room because staff physically prevented him or her from doing so, then he or she is also being secluded.

Staff must take extra care to protect the safety of the patient when interventions that are more restrictive are used. Monitoring must be appropriate to the intervention chosen, so that the patient is protected from possible abuse, assault, or self injury during the intervention.

Survey Procedures §482.13(f)(4)(i)

- Conduct document review and staff interviews to determine if the hospital provides uninterrupted monitoring.

- Does the clinical record reflect uninterrupted monitoring?

A-0091

§482.13(f)(4)(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Interpretive Guidelines §482.13(f)(4)(ii)

Continually monitored is defined as uninterrupted monitoring. The monitoring must be face-to-face monitoring or by using both video and audio monitoring equipment. The person monitoring the patient using the audio and video equipment must be in close proximity to the patient and their monitoring must be uninterrupted.

The use of video and audio equipment does not eliminate the need for frequent assessment of the patient's needs and status. The hospital should ensure that staff that are assigned monitoring duties are competent to assess physical and psychological signs of distress. The basis for the requirement that the monitoring be in close proximity to the patient is to ensure that there are staff immediately available to intervene and render appropriate interventions to meet patient needs.

Survey Procedures §482.13(f)(4)(ii)

- Is the staff person monitoring the patient in close proximity to the patient so as to allow emergency intervention if a problem arises?

- Does the video equipment cover all areas of the room or location where the patient is restrained or secluded?

A-0092

§482.13(f)(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

Interpretive Guidelines §482.13(f)(5)

The frequency of monitoring will vary according to the type and design of the restraint device/intervention or seclusion; the patient's emotional, psychological and medical condition; and the patient's physical needs, clinical symptoms, and safety needs. We expect that the hospital will establish a policy and procedure (or guidelines for staff) to guide staff in how to determine an appropriate interval of assessment, monitoring, and re-evaluation based on the individual needs of the patient, his/her condition and the type of intervention used. When a more restrictive or higher risk intervention is required and/or a patient is suicidal, self injurious, or combative, staff may determine that one-to-one monitoring is needed.

Continuous face-to-face monitoring may be appropriate when the intervention leaves a patient vulnerable. For example, restraint limits an individual's ability to move or escape harm. Patients are vulnerable to rape or other abuse when they are immobilized in this manner. The hospital is responsible for providing monitoring and reassessment that will protect the patients' safety.

Survey Procedures §482.13(f)(5)

- Review the hospital's policy on restraints and seclusion to determine how the facility is assessing and monitoring patient medical and behavioral status. Obtain a sample of the patient population in restraints.

- Look for a cycle of removing restraints, then reapplying them without evaluating the patient.

- Does hospital policy describe which staff members are responsible for assessing and monitoring the patient?

- Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks?

- Is there documentation of ongoing patient assessment (e.g., skin integrity, circulation, respiration, intake and output, weight, hygiene, injury, etc)?

- Is the patient's mental status assessed? Is this documented in the medical record?

- Does the policy include frequent opportunities for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the record?

- Is the patient assessed regarding continued need for use of seclusion or restraint? Is there adequate justification for continued use and is this documented?

- Did the patients understand the reasons for the use of restraints or seclusion?

A-0093

§482.13(f)(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and

Interpretive Guidelines §482.13(f)(6)

Ongoing restraint and seclusion education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing in-service training for all staff who have direct patient care responsibilities, responsibilities for the application of restraint, or the monitoring or assessment of patients in restraint or seclusion.

Hospitals are required to have appropriately trained staff for the proper and safe use of seclusion and restraint interventions. Appropriately trained staff would include both that

the hospital has adequate numbers and types of trained staff, as well as, that those staff have been trained in the safe use and application of all the restraint and seclusion interventions used by the hospital. It would not be appropriate for a hospital to routinely or consistently call upon a law enforcement agency or agencies as a means of applying restraint or initiating seclusion on its patients.

Survey Procedures §482.13(f)(6)

Does the hospital have evidence that all staff that have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards, EMTs on the premises) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?

A-0094

§482.13(f)(6) continued
[All staff who have direct patient contact must have ongoing education and training in] alternative methods for handling behavior, symptoms and situations that traditionally have been treated through the use of restraints or seclusion.

Interpretative Guidelines §482.13(f)(6)

Staff must not simply respond to the behavior but must work to understand what the behavior means. Direct care staff must be trained to intervene early in the escalation cycle with verbal and non-verbal de-escalation techniques. Restraint should only be used when alternatives have been tried and failed.

Trying less restrictive alternatives does not mean attempting a complex series of interventions or a lengthy checklist of steps to initiate before laying hands on the individual. Rather, a whole toolbox of possible interventions are implemented during the course of the interaction and modified based upon the assessment of the individual's response. Hospital staff must utilize least restrictive measures during the course of an interaction and modify them based upon the assessment of the individual's response.

Survey Procedures §482.13(f)(6)

- Are the staff members who are able to initiate restraint and seclusion trained in the safe use and application of restraint and seclusion and able to demonstrate competency?

- Is there evidence that staff are updated and trained on alternative interventions other than restraint/seclusion techniques?

- Determine if the hospital has experienced negative outcomes when handling these situations (through review of complaints, incident reports, and other available

data). If there have been negative outcomes when handling these situations, has the hospital incorporated this problem into its QAPI program (See §482.21)? Has the hospital incorporated any needed changes into revisions of its policies/ procedures, training programs, and staff competency evaluations?

A-0095

§482.13(f)(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

Interpretive Guidelines §482.13(f)(7)

In patient restraint/seclusion-associated deaths, when the patient was in seclusion or had been in seclusion, or when the restraint was applied or had been applied, to address violent, aggressive, assaultive, etc. behavior toward self or others, the death reporting requirements of the behavior management standard apply. In these restraint or seclusion situations (behavior management) the death of **any patient that dies, for any reason,** while in restraint or seclusion **must** be reported to the CMS Regional Office (RO). Also **any patient's death** that occurs after seclusion or restraint (that had been applied/used for the management of violent behavior) has been discontinued **and** where the patient's death could be **reasonably related** to that patient having been in restraint or seclusion **must** be reported to the RO. The hospital must report all patient deaths associated with the use of seclusion or restraint, by telephone, to their CMS-RO prior to the close of business the next business day after the patient's death.

CMS requires the hospital to report patient restraint or seclusion deaths to the hospital's RO for the circumstances and in the methods and times stated in the previous paragraphs. The hospital is **not** to postpone reporting the patient's death until after the hospital's investigation. The hospital is reporting to CMS that a patient died while in behavior management restraint or seclusion, or that the death could reasonably be related to the patient having been in seclusion or restraint; not the cause of the patient's death.

Survey Procedures §482.13(f)(7)

- Review the written hospital policy on reporting deaths that occur while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

- Interview patient care staff to determine their knowledge of the hospital's policy or protocol regarding the determination whether a death reasonably may have resulted from seclusion or restraint, and their knowledge of CMS reporting requirements.

- Is there evidence of deaths, associated with restraints or seclusion, not reported to CMS?

- If there have been deaths associated with seclusion or restraints, were they reported to CMS in a timely manner? Was this documented in the medical record?

- Does the hospital have a written policy on reporting deaths associated with seclusion or restraints to CMS in a timely manner?

- Do patient care staff know the CMS death reporting requirements?

A-0141

§482.21 Condition of Participation: Quality Assessment and Performance Improvement

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

A-0142

§482.21(a) Standard: Program Scope

A-0143

§482.21(a)(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and

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A-0144

§482.21(a)(1) continued
[The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will]

identify and reduce medical errors.

A-0145

§482.21(a)(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

A-0146

§482.21(b) Standard: Program Data

A-0147

§482.21(b)(1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

A-0148

§482.21(b)(2) The hospital must use the data collected to--

(i) Monitor the effectiveness and safety of services and quality of care; and

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A-0149

§482.21(b)(2)(ii) [The hospital must use the data collected to--] Identify opportunities for improvement and changes that will lead to improvement.

A-0150

§482.21(b)(3) The frequency and detail of data collection must be specified by the hospital's governing body.

A-0151

§482.21(c) Standard: Program Activities

A-0152

§482.21(c)(1) The hospital must set priorities for its performance improvement activities that--

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes and quality of care.

A-0153

§482.21(c)(1) continued
[The hospital must set priorities for its performance improvement activities that--

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and]

(iv) Affect patient safety.

A-0154

§482.21(c)(2) Performance improvement activities must track medical errors and adverse patient events,

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A-0155

§482.21(c)(2) continued
[Performance improvement activities must track medical errors and adverse patient events,] analyze their causes, and

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A-0156

§482.21(c)(2) continued
[**Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and] implement preventive actions and mechanisms that include feedback and learning throughout the hospital.**

A-0157

§482.21(c) (3) The hospital must take actions aimed at performance improvement and,

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A-0158

§482.21(c) (3) continued
after implementing those actions, the hospital must measure its success, and

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A-0159

§482.21(c) (3) continued
track performance to ensure that improvements are sustained.

A-0160

§482.21(d) Standard: Performance Improvement Projects

As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

A-0161

§482.21(d)(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

A-0162

§482.21(d)(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

A-0163

§482.21(d)(3) The hospital must document what quality improvement projects are being conducted.

A-0164

§482.21(d)(3) continued
[The hospital must document] the reasons for conducting these projects, and

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A-0165

§482.21(d)(3) continued
[The hospital must document] the measurable progress achieved on these projects.

A-0166

§482.21(d)(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

A-0167

§482.21(e) Standard: Executive Responsibilities

The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

A-0168

§482.21(e)(1) That an ongoing program for quality improvement [is defined, implemented, and maintained.]

A-0169

§482.21(e)(1) continued
[That an ongoing program for] patient safety, including the reduction of medical errors, [is defined, implemented, and maintained.]

A-0170

§482.21(e)(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care, and that all improvement actions are evaluated.

A-0171

§482.21(e)(2) continued
[That the hospital-wide quality assessment and performance improvement efforts address priorities for improved] patient safety [and that all improvement actions are evaluated.]

A-0172

§482.21(e)(3) That clear expectations for safety are established.

A-0173

§482.21(e)(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and

A-0173

§482.21(e)(4) continued
[That adequate resources are allocated for] reducing risk to patients.

A-0174

§482.21(e)(5) That the determination of the number of distinct improvement projects is conducted annually.

A-0181

§482.22 Condition of Participation: Medical staff

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

Interpretive Guidelines §482.22

The hospital may have only one medical staff for the entire hospital (including all campuses, provider -based locations, satellites, remote locations, etc.). The medical staff must be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws must apply equally to all practitioners within each category of practitioners at all locations of the hospital and to the care provided at all locations of the hospital. The single medical staff is responsible for the quality of medical care provided to patients by the hospital.

A-0182

§482.22(a) Standard: Composition of the Medical Staff

The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

A-0183

§482.22(a)(1) The medical staff must periodically conduct appraisals of its members.

Interpretive Guidelines §482.22(a)(1)

The purpose of the appraisal is for the medical staff to determine the suitability of individual members for continued membership on the medical staff and to determine if that individual practitioner's clinical privileges should be continued, discontinued, revised, or otherwise changed.

The medical staff appraisal procedures must evaluate each individual member's training, experience, and demonstrated competence as established by the hospital QAPI program, credentialing process, and the member's adherence to medical staff bylaws and rules and regulations.

The medical staff bylaws must establish the frequency and other factors that determine when appraisals of medical staff members will be conducted.

After the medical staff conducts its appraisal of individual members, the medical staff makes recommendations to the governing body for continued medical staff membership that are specific to the type of appointment and extent of clinical privileges, and the governing body takes final appropriate action. A separate credentials file must be maintained for each medical staff member.

Survey Procedures §482.22(a)(1)

- Determine that the medical staff has a system in place that is used to periodically appraise its current members and their qualifications in accordance with approved medical staff bylaws and State law requirements.

- Determine that the medical staff bylaws specify the timeframes for the periodic appraisal.

- Verify that an outcome-oriented appraisal system is conducted for all individual members of the medical staff.

- Determine how the medical staff conducts the periodic appraisals of any current member of the medical staff who has not provided patient care at the hospital or who has not provided care for which he/she is privileged to patients at the hospital during the appropriate evaluation time frames. Is this method in accordance with State law and the hospital's written criteria for medical staff membership and for granting privileges?

A-0184

§482.22(a)(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

Interpretive Guidelines §482.22(a)(2)

There must be a mechanism established to examine credentials of individual prospective members(new appointments or reappointments) by the medical staff. The credentials examined include at least:

- A request for clinical privileges;

- Current licensure;

- Training and professional education;

- Documented experience; and

- Supporting references of competence.

The medical staff makes recommendations to the governing body for each new member and for reappointment of members that are specific to type of appointment and extent of the individual practitioner's specific rather than general clinical privileges, and then the

governing body takes final appropriate action. A separate credentials file must be maintained for each individual medical staff member or applicant.

A-0185

§482.22(b) Standard: Medical Staff Organization and Accountability

The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3)The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

Interpretive Guidelines §482.22(b)

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients. The organization of the medical staff must comply with these requirements.

Survey Procedures §482.22(b)

- Verify that the medical staff has a formalized organizational structure, that lines of function and responsibility are delineated between the governing body and other parts of the organization, and that the governing body has sanctioned its approval on the organizational structure and relationships.

- If there is an active executive committee, verify that a majority of the members are doctors of medicine or osteopathy.

- Verify that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff through review of the organizational structure and interviews with members of the medical staff.

A-0186

§482.22(c) Standard: Medical Staff Bylaws

The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

Interpretive Guidelines §482.22(c)

The medical staff must develop and adopt bylaws, and after the hospital's governing body approves the bylaws, the medical staff must enforce its bylaws.

Survey Procedures §482.22(c)

- Verify that the medical staff have bylaws.
- Verify that the bylaws describe a mechanism for ensuring enforcement of its provisions along with rules and regulations of the hospital.
- Verify that the medical staff enforce the bylaws.

A-0187

§482.22(c)(1) Be approved by the governing body.

Interpretive Guidelines §482.22(c)(1)

The medical staff must regulate itself by bylaws, rules and regulations that are consistent with acceptable medical staff practices. The bylaws must be enforced and revised as necessary. Medical staff bylaws and any revisions of those bylaws must be submitted to the governing body for approval. The governing body has the authority to approve or disapprove bylaws suggested by the medical staff. The bylaws and any revisions must be approved by the governing body before they are considered effective.

Survey Procedures §482.22(c)(1)

Verify the medical staff is operating under current medical staff bylaws, rules, and policies that are in accordance with Federal and State laws and regulations and accepted standards of practice and have been approved by the medical staff and the governing body.

A-0188

§482.22(c)(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

Interpretive Guidelines §482.22(c)(2)

The medical staff bylaws must include a statement of the duties, responsibilities, and privileges of each category of medical staff.

Survey Procedures §482.22(c)(2)

Verify that the bylaws specify the roles and responsibilities of each category of practitioner on medical staff.

A-0189

§482.22(c)(3) Describe the organization of the medical staff.

Interpretive Guidelines §482.22(c)(3)

The medical staff bylaws must describe the organizational structure of the medical staff, and lay out the rules and regulations of the medical staff to make clear what are acceptable standards of patient care for all diagnostic, medical, surgical, and rehabilitative services.

Survey Procedures §482.22(c)(3)

- Verify that the bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body.

- Verify that the bylaws describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff and describe the formation of medical staff leadership.

A-0190

§482.22(c)(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

Interpretive Guidelines §482.22(c)(4)

The medical staff bylaws must describe the qualifications to be met by a candidate for membership on the medical staff. The medical staff then recommends individual

candidates that meet those requirements to the governing body for appointment to the medical staff.

Survey Procedures §482.22(c)(4)

Verify that the medical staff bylaws describe the qualifications such as licensure, specific training, experience, current competence, judgment, character, and health status to be met by an individual candidate for the medical staff to recommend appointment or reappointment.

A-0191

§482.22(c)(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

Interpretive Guidelines §482.22(c)(5)

The Medical Staff bylaws must include a requirement that a physical examination and medical history (H & P) must be performed on each patient by a MD, DO or for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon. The practitioner who performs the H & P must have been granted such privileges by the medical staff in accordance with State law.

The H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND

- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48 hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the

patient's condition, and any co-morbidities, in relation to the reason the patient was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND

- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P, and /or the update assessment and note. (Update assessments and update notes are considered part of the H & P.)

Survey Procedures §482.22(c)(5)

Determine that the medical staff bylaws require a physical examination and medical history be done for each patient by an MD or DO or where appropriate, an oromaxillofacial surgeon, no more than 7 days before admission/outpatient surgery or 48 hours after admission but prior to surgery/outpatient surgery. (However, the medical staff bylaws may allow the currency methodology and/or the delegation of this responsibility as discussed in the above interpretation.)

A-0192

§482.22(c)(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

Interpretive Guidelines §482.22(c)(6)

All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff's review of that individual practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body.

Survey Procedures §482.22(c)(6)

- Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying these criteria.

- Verify that practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.

A-0193

§482.22(d) Standard: Autopsies

The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

Survey Procedures §482.22(d)

Verify that the medical staff has policies requiring the practitioners to attempt to secure permission to perform autopsies, that the mechanism for documenting permission to perform an autopsy is defined, and that there is a system for notifying the medical staff, specifically the attending practitioner, when an autopsy is performed.

A-0199

§482.23 Condition of Participation: Nursing Services

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

Interpretive Guidelines §482.23

The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least 1 registered nurse (RN) furnishing or supervising the service 24 hours a day, 7 days a week (Exception: small rural hospitals operating under a waiver as discussed in §482.23(b)(1)).

The Social Security Act (SSA) at §1861(b) states that nursing services must be furnished to inpatients and **furnished by the hospital**. The SSA at §1861(e) further requires that the hospital have a **RN on duty at all times** (except small rural hospitals operating under a nursing waiver).

The nursing service must be a well-organized service of the hospital and under the direction of a registered nurse.

The nursing service must be integrated into the hospital-wide QAPI program.

Survey Procedures §482.23

- Determine if the nursing service is integrated into the hospital-wide QAPI program.

- Interview the director of the service. Request the following items:

    - Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;

    - Job or position descriptions for all nursing personnel including the director's position description.

- Select at least one patient from every inpatient care unit. Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, patients, family members, accident and investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities and reports. Interview patients for information relative to the delivery of nursing services.

A-0200

§482.23(a) Standard: Organization

The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

Interpretive Guidelines §482.23(a)

The hospital may have only one nursing service hospital-wide and the single nursing service must be under the direction of one RN.

The director of the nursing service must be a currently licensed RN and he/she is responsible for the operation of the nursing service. The operation of the nursing service would include the quality of the patient care provided by the nursing service.

The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the hospital.

The organization will include various configurations of the following hospital personnel as determined necessary by the hospital and the Director of Nursing:

- Assistant/Associate Director(s);
- Supervisors/Coordinators;
- Head Nurses/Nurse Managers;
- Staff Nurses;
- Unit Secretaries/Clerks;
- Nurses Aide/Orderlies.

Survey Procedures §482.23(a)

- Review the organizational chart or plan for nursing services. Determine that the organizational chart(s) displays lines of authority that delegates responsibility within the department.
- Read the position description for the director of nursing (DON) to determine that it delegates to the DON specific duties and responsibilities for operation of the service.
- Verify that the director is currently licensed in accordance with state licensure requirements.
- Verify that the DON is involved with or approved the development of the nursing service staffing policies and procedures.
- Verify that the DON approves the nursing service patient care policies and procedures.

A-0201

§482.23(b) Standard: Staffing and Delivery of Care

The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

Interpretive Guidelines §482.23(b)

The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

There must be a RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient.

A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

Survey Procedures §482.23(b)

- Determine that there are written staffing schedules which correlate to the number and acuity of patients. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration:

    - Physical layout and size of the hospital;
    - Number of patients;
    - Intensity of illness and nursing needs;

- Availability of nurses' aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.;

- Training and experience of personnel;

- Do not count personnel assigned to areas other than bedside patient care.

- Review medical records to determine if patient care that is to be provided by nurses is being provided as ordered.

A-0202

§482.23(b)(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54 of this chapter.

Interpretive Guidelines §482.23(b)(1)

The hospital must provide nursing services 24 hours a day, 7 days a week. A LPN can provide nursing services if a RN, who is immediately available for the bedside care of those patients, supervises that care.

Exception: §488.54 set forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24 hour registered nurse requirement by the regional office.

Rural is defined as all areas not delineated as "urbanized" areas by the Census Bureau, in the most recent census. Temporary is defined as a one year period or less and the waiver cannot be renewed.

Survey Procedures §482.23(b)(1)

- Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage. Document daily RN coverage for every unit of the hospital. Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage.

- **Exception:** If the hospital has a temporary waiver of the 24-hour RN requirement in effect, verify and document the following:

    - 50 or fewer inpatient beds;

- The character and seriousness of the deficiencies do not adversely affect the health and safety of patients

- The hospital meets all the other statutory requirements in section 1861(e)(1-8).

- The hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement. Determine the recruitment efforts and methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies. Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.

- The hospital's failure to comply fully with the 24 hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

- A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week.

- On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.

A-0203

§482.23(b)(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

Interpretive Guidelines §482.23(b)(2)

The hospital's procedure must ensure that all nursing personnel have valid and current licensure that complies with State licensure laws. Furthermore, the Condition of Participation (CoP) Compliance with Federal, State and local laws (42 CFR §482.11) requires the hospital to assure that personnel meet applicable standards (such as continuing education, certification or training) required by State or local law.

Survey Procedures §482.23(b)(2)

- Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses.

- Review the nursing service licensure verification policies and procedures. Is licensure verified for each individual nursing services staff person for whom licensure is required?

A-0204

§482.23(b)(3) A registered nurse must supervise and evaluate the nursing care for each patient.

Interpretive Guidelines §482.23(b)(3)

A RN must supervise the nursing care for each patient. A RN must evaluate the care for each patient upon admission and when appropriate on an ongoing basis in accordance with accepted standards of nursing practice and hospital policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Survey Procedures §482.23(b)(3)

- Review staffing schedules and assignments.

- Determine that a RN is assigned to supervise and evaluate the nursing care furnished to each patient.

A-0205

§482.23(b)(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

Interpretive Guidelines §482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the requirements for patient records and other patient information.

Survey Procedures §482.23(b)(4)

- Select a sample of nursing care plans. Approximately 6-12 plans should be reviewed.
    - Are they initiated as soon as possible after admission for each patient?
    - Do they describe patient goals and as appropriate physiological and psychosocial factors and patient discharge planning?
    - Is each plan consistent with the attending MD/DO's plan for medical care?
    - Are they revised as the needs of the patient changes?
    - Are nursing care plans implemented in a timely manner?

A-0206

§482.23(b)(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

Interpretive Guidelines §482.23(b)(5)

A RN must make all patient care assignments. The director of the nursing service and the hospital are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Survey Procedures §482.23(b)(5)

- Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient's care needs and the competence and specialized qualifications of the nursing staff.
- Ask a charge nurse what considerations are necessary when making staff assignments. Answers should include:
    - Patient needs;
    - Complexity of patients;
    - Any special needs of individual patients;

- Competence of nursing personnel;
- Qualifications of nursing personnel;
- Education of nursing personnel;
- Experience of nursing personnel.

A-0207

§482.23(b)(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing services.

Interpretive Guidelines §482.23(b)(6)

The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients nursing care needs. In order to meet their patient's needs the hospital may supplement their hospital employed licensed nurses with volunteer and or contract non-employee licensed nurses.

The hospital and the director of the nursing service are responsible for the clinical activities of all nursing personnel. This would include the clinical activities of all non-employee nursing personnel (contract or volunteer).

Non-employee licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital. The hospital and the director of the nursing service are responsible for ensuring that non-employee nursing personnel know the hospital's policies and procedures in order to adhere to those policies and procedures.

The hospital and the director of the nursing service ensure that each non-employee nursing care staff person is adequately supervised and that their clinical activities are evaluated. This supervision and evaluation of the clinical activities of each non-employee nursing staff person must be conducted by an appropriately qualified hospital-employed RN.

Survey Procedures §482.23(b)(6)

- Review the method for orienting non-employee licensed nurses to hospital policies and procedures. The orientation should include at least the following:
  - The hospital and the unit;

- Emergency procedures;
- Nursing services policies and procedures; and
- Safety policies and procedures.

- Determine if non-employee nursing personnel are appropriately oriented prior to providing care.
- If the hospital uses non-employee licensed nurses, are they supervised by a RN who is a regular employee of the hospital?
- Observe the care provided by non-employee nursing personnel.
  - Do they know and adhere to hospital policies?
  - Do they know appropriate emergency procedures?
  - Are they adequately supervised by an appropriately experienced hospital employed RN?
  - Are their clinical activities being evaluated adequately?
  - Are they licensed in accordance with State law?
- Confirm with the director of nurses that a non-employee nurse's performance is evaluated by the hospital at least once a year. If the performance evaluation is not considered confidential, review two evaluations.

A-0208

§482.23(c) Standard: Preparation and Administration of Drugs

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

Interpretive Guidelines §482.23(c)

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c).

Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.

Accepted standards of practice include maintaining compliance with applicable Federal and State laws, regulations (including all the hospital Conditions of Participation (CoP) such as Pharmacy, Medical Records, Patients' Rights, QAPI), and guidelines governing drug and biological use in hospitals, as well as, any standards and recommendations promoted by nationally recognized professional organizations.

Survey Procedures §482.23(c)

- Select patients from the patient sample. Review their medication orders, medication administration records, and appropriate medication documentation in the medical record. Observe the preparation and administration of medications to those patients.

- Are medications prepared and administered in accordance with Federal and State laws, other hospital CoP, accepted national standards of practice, manufacturer's directions, and hospital policy?

A-0209

§482.23(c)(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Survey Procedures §482.23(c)(1)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.

- Review a sample of medication administration records to see that they conform with the practitioner's order, that the order is current, and that drug and dosage are correct and administered as ordered.

- Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Are patients addressed by name and/or identiband checked? Does the nurse remain with the patient until medication is taken? Are drugs administered within 30 minutes of the scheduled time for administration?

- Verify that nursing or other personnel authorized by medical staff policy to administer drugs have completed appropriate training courses or are licensed or authorized to do so by State law and function under supervision as necessary.

- Check the QAPI activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors, their nature, frequency and the corrective action taken.

- Interview supervisory nursing personnel to determine how supervision is provided. Also interview personnel who administer medication to verify that the supervision is, in fact, provided.

    - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations. Use the above procedures to determine compliance.

A-0210

§482.23(c)(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be--

Interpretive Guidelines §482.23(c)(2)

All entries in the medical record must be legible, timed, dated and authenticated. All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient.

Verbal orders are orders for medications, treatments, interventions or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone.

Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible.

Hospitals should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal orders;
- Provide a mechanism to ensure validity/authenticity of the prescriber;
- List the elements required for inclusion in a complete verbal order;
- Describe situations in which verbal orders may be used;
- List and define the individuals who may send and receive verbal orders; and
- Provide guidelines for clear and effective communication of verbal orders.

Hospitals should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication.

Elements that should be included in any verbal medication order include:

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants);
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Purpose or indication;
- Specific instructions for use; and
- Name of prescriber.

The content of verbal orders must be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be reduced immediately to writing and signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible.

We recognize that in some instances, the ordering physician may not be able to authenticate his or her verbal order (e.g., the ordering physician gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering physician to co-sign the verbal order of the ordering physician. The signature indicates that the covering physician assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the hospital's policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a physician's verbal order or otherwise authenticate a medical record entry for the physician who gave the verbal order.

As noted above, CMS further requires that verbal orders, when used, be used infrequently (§482.23(c)(2)(iii)). Therefore, it is not acceptable to allow covering physicians to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the hospital.

Survey Procedures §482.23(c)(2)

- Determine that all drug orders, including verbal orders, are written in the patient charts and signed by the practitioner caring for the patient.

- Read the hospital's policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?

- Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

A-0211

§482.23(c)(2)(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

Interpretive Guidelines §482.23(c)(2)(i)

A telephone or verbal order must be written in the medical record by a nurse or other professional who is permitted by State law and hospital policy to accept verbal orders. The written verbal order must be legible and include the date, time, order, name of the

ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time that he or she signs the order.

Survey Procedures §482.23(c)(2)(i)

- Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized hospital personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so.

A-0212

§482.23(c)(2)(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

Interpretive Guidelines §482.23(c)(2)(ii)

As soon as possible would be the **earlier** of the following:

- The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record,

- The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and hospital policy, or

- Within 48 hours of when the order was given.

Survey Procedures §482.23(c)(2)(ii)

Review verbal order entries in the medical record. Have verbal orders been signed or initialed by the prescribing practitioner as soon as possible as defined above?

A-0213

§482.23(c)(2)(iii) Used infrequently.

Interpretive Guidelines §482.23(c)(2)(iii)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders is not a common practice. Verbal orders pose an increased risk of miscommunication that could result in a patient adverse event (which includes medication errors). Verbal orders should be used only to meet the care needs of the patient when the ordering practitioner is unable to write the order himself/herself. Verbal orders are not to be used for the convenience of the ordering practitioner.

Survey Procedures §482.23(c)(2)(iii)

- Review patient medical records for the use of verbal orders.
    - Are verbal orders used infrequently?
    - Is there a pattern to the use of verbal orders?
    - Are verbal orders used frequently for certain situations?
    - Do certain practitioners use verbal orders frequently?

A-0214

§482.23(c)(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

Survey Procedures §482.23(c)(3)

- Review the transfusions and intravenous medications practices:
    - Does the hospital have special training for administering blood transfusions and intravenous medications?
    - Are blood transfusions and IVs administered in accordance with State law and approved hospital policies and procedures?
    - Are blood transfusions and IVs administered by personnel who are trained and working within their scope of practice in accordance with State law and hospital policies?
    - Review transfusion records. Determine the identity of practitioners who administered the blood. Do they have documented special training.
    - Review a sample of medical records to determine that only doctors of medicine or osteopathy or specially trained personnel perform this duty. If the nursing service trains personnel for IV administration, look at the content of the in-service course. It should include:
        - Fluid and electrolyte balance;
        - Blood components; and

- Venipuncture techniques, demonstrations and supervised practice.

A-0215

§482.23(c)(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Survey Procedures §482.23(c)(4)

Request the hospital procedure for reporting adverse drug reactions and errors and transfusion reactions. Review the incident reports or other documentation that the procedure is being implemented and regularly monitored through hospital's QAPI program.

A-0221

§482.24 Condition of Participation: Medical Record Services

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

Interpretive Guidelines §482.24

The term "hospital" includes all locations of the hospital.

The hospital must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and out patient records. The hospital must create and maintain a medical record for every individual, both inpatient and out patient evaluated or treated in the hospital.

The term "**medical records**" includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

Survey Procedures §482.24

- Review the organizational structure and policy statements and interview the person responsible for the medical records service to ascertain that the service is structured appropriately to meet the needs of the hospital and the patients.

- Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and hospital

policy. The sample should be 10 percent of the average daily census and be no less than 30 records. Additionally, select a sample of outpatient records in order to determine compliance in outpatient departments, services, and locations.

A-0222

§482.24(a) Standard: Organization and Staffing

The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

Interpretive Guidelines §482.24(a)

The medical records service must be organized, equipped, and staffed in accordance with the scope and complexity of the hospital's services and in such a manner as to comply with the requirements of this regulation and other Federal and State laws and regulations.

There must be an established medical record system that is organized and employs adequate personnel to ensure prompt:

- Completion of medical records;
- Filing of medical records; and
- Retrieval of medical records.

The term "employs adequate personnel" includes:

- That medical record personnel are employees of the hospital;
- That the hospital employs an adequate number of medical record personnel, employs adequate types of medical record personnel, and employs personnel who possess adequate education, skills, qualifications and experience to ensure the hospital complies with requirements of this regulation and other Federal and State laws and regulations.

Survey Procedures §482.24(a)

- Verify that there is an established system that addresses at least the following activities of the medical records services:
    - Timely processing of records;
    - Coding/indexing of records;

- Retrieval of records;
- Compiling and retrieval of data of quality assurance activities.

- Verify that the system is reviewed and revised as needed.
- Interview staff, if needed, review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.
- Verify that the hospital employs adequate medical record personnel as previously described.
- Are medical records promptly completed in accordance with State law and hospital policy?
- Select a sample of past patients of the hospital (inpatient and/or outpatient). Request those patients' medical records. Can the hospital promptly retrieve those records?

A-0223

§482.24(b) Standard: Form and Retention of Record

The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

Interpretive Guidelines §482.24(b)

The hospital must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital.

All medical records must be **accurately written**. The hospital must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

All medical records must be **promptly completed**. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, care plans, discharge plans, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.

The record must be completed promptly after discharge in accordance with State law and hospital policy but no later than 30 days after discharge.

The medical record must be **properly filed and retained**. The hospital must have a medical record system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the hospital within the past 5 years. [§482.24(b)(1) addresses the 5 year medical record retention requirement]

The medical record must be **accessible**. The hospital must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the hospital within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats.

Medical information such as consultations, orders, practitioner notes, x-ray interpretations, lab test results, diagnostic test results, patient assessments and other patient information must be accurately written, promptly completed and properly filed in the patients' medical record, and accessible to the physicians or other care providers when needed for use in making assessments of the patient's condition, decisions on the provision of care to the patient, and in planning the patient's care. This requirement applies to the medical records of current inpatients and outpatients of the hospital.

The hospital must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of **all** record entries. The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries. The medial record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. Locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. These requirements apply to both manual and electronic medical record systems.

Survey Procedures §482.24(b)

- Determine the location(s) where medical records are maintained.

- Verify that a medical record is maintained for each person treated or receiving care. The hospital may have a separate record for both inpatients and outpatients. However, when two different systems are used they must be appropriately cross referenced and accessible.

- Verify that procedures ensure the integrity of authentication and protect the security of patient records.

- Verify that medical records are stored and maintained in locations where the records are secure, that protects them from damage, flood, fire, etc., and limits access to only authorized individuals.

- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed, in all locations where medical records are maintained.

A-0224

§482.24(b)(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

Interpretive Guidelines §482.24(b)(1)

Medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory, or other electronic storage media. The hospital must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the hospital within the last 5 years.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 5 years (for example: FDA, OSHA, EPA).

Survey Procedures §482.24(b)(1)

- Determine that records are retained for at least 5 years, or more if required by State or local laws.

- Select a sample of patients, both inpatient and outpatient who were patients of the hospital between the previous 48-60 months. Request their medical record. Is it promptly retrieved? Is it complete? Is it in original or in a legally reproduced form?

A-0225

§482.24(b)(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

Survey Procedures §482.24(b)(2)

Verify that the hospital uses a coding and indexing system that permits timely retrieval of patient records by diagnosis and procedures.

A-0226

§482.24(b)(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals,

Interpretive Guidelines §482.24(b)(3)

The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §482.24(b)(3)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.

- Verify that the hospital has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., MD/DO responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.

- Verify that medical records and other confidential patient information are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.

- Verify that copies of medical records and other confidential patient information are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by Federal and State law.

- Verify that precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

A-0227

§482.24(b)(3) continued
and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

Interpretive Guidelines §482.24(b)(3)

The hospital's patient record system must ensure the security of patient records. The hospital must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

Survey Procedures §482.24(b)(3)

- Observe the hospital's security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

- Verify that there is an established system in place that addresses protecting the confidentiality of medical information.

- If the hospital uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

A-0228

§482.24(b)(3) continued
original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

A-0229

§482.24(c) Standard: Content of Record

The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

Interpretive Guidelines §482.24(c)

The medical record must contain information such as notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;
- Justify continued hospitalization;
- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities.

Patient medical record information, such as, laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc. must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to justify continued hospitalization, to support the diagnosis, to describe the patient's progress, and to describe the patient's response to medications, interventions, and services, in planning the patient's care, and in making decisions on the provision of care to the patient`.

A-0230

§482.24(c)(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

Interpretive Guidelines §482.24(c)(1)

Entries in the medical record may be made only by individuals as specified in hospital and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the hospital a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The hospital must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of MD/DO examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be legible. Orders, progress notes, nursing notes or other entries in the medical record that are not legible, that may be misread or misinterpreted could lead to medical errors or other adverse patient events. The hospital must ensure that entries in the medical record are legible.

All entries in the medical record must be complete.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The hospital has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.

- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

- The timing of the entry is noted and correct. Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events.

Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §482.24(c)(1)

- Verify that entries are legible and complete and appropriately authenticated, timed and dated by the person who is responsible for ordering, providing, or evaluating the service provided.

- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

- Verify that the hospital's governing body authorizes computer or other code signatures and that a list of these codes is maintained under adequate safeguards by the hospital administration. Verify that the hospital's policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

- Examine the hospital's policies and procedures for using the system, and determine if documents are being authenticated after transcription.

A-0231

§482.24(c)(1)(i) The author of each entry must be identified and must authenticate his or her entry.

Interpretive Guidelines §482.24(c)(1)(i)

The hospital must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of

the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

A-0232

§482.24(c)(1)(ii) Authentication may include signatures, written initials or computer entry.

Interpretive Guidelines §482.24(c)(1)(ii)

For the purposes of this regulation, electronic signatures comply with the signature requirement for medical record entries that include a requirement for a signature.

A-0233

§482.24(c)(2) All records must document the following, as appropriate:

A-0234

§482.24(c)(2)(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

Interpretive Guidelines §482.24(c)(2)(i)

The medical record must contain a history and physical examination (H & P). The H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND

- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48 hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the reason the patient

was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND

- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P, and /or the update assessment and note. (Update assessments and update notes are considered part of the H & P.)

Survey Procedures §482.24(c)(2)(i)

Determine that the medical records contain a physical examination and medical history completed for each patient by an MD or DO or where appropriate, an oromaxillofacial surgeon, no more than 7 days before admission/outpatient surgery or 48 hours after admission but prior to surgery/outpatient surgery. (Or, the medical staff bylaws may allow the currency methodology and/or the delegation as discussed in the above interpretation.)

A-0235

§482.24(c)(2)(ii) Admitting diagnosis.

Interpretive Guidelines §482.24(c)(2)(ii)

All inpatient medical records must contain the admitting diagnosis.

Survey Procedures §482.24(c)(2)(ii)

Verify in a sample of medical records that the patient's admitting diagnosis is documented in each medical record.

A-0236

§482.24(c)(2)(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

Interpretive Guidelines §482.24(c)(2)(iii)

All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient's medical record in order to be available to the physician or other care providers to use in making assessments of the patient's condition, to justify treatment or continued hospitalization, to support or revise the patient's diagnosis, to support or revise the plan of care, to describe the patient's progress and to describe the patient's response to medications, treatments, and services.

Survey Procedures §482.24(c)(2)(iii)

Review a sample of medical records of patients who have orders for consultative evaluations. Are the results/reports and other clinical findings of those consultative evaluations included in the patient's medical record?

A-0237

§482.24(c)(2)(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

Interpretive Guidelines §482.24(c)(2)(iv)

All patient medical records, both inpatient and outpatient, must document:

- Complication;
- Hospital-acquired infections;
- Unfavorable reactions to drugs; and
- Unfavorable reactions to anesthesia.

Survey Procedures §482.24(c)(2)(iv)

Through observations, interviews, and reviews of hospital reports and documentation, determine if patient complications, hospital-acquired infections, unfavorable reactions to drugs/anesthesia have been documented in the applicable patient's medical record.

A-0238

§482.24(c)(2)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(2)(v)

All inpatient and outpatient medical records must contain a properly executed and completed written informed consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations, consequences, and options needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;
- Name of specific procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedures, as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Risks;

- Alternative procedures, treatments or therapies;
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

Situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of that information, the patient may not have consented to the procedure or made the same decisions would not be considered **informed consent**.

Survey Procedures §482.24(c)(2)(v)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatments are required by hospital policy.
- Verify that consent forms are properly executed and contain at least the information identified above.

A-0239

§482.24(c)(2)(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

Interpretive Guidelines §482.24(c)(2)(vi)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);

- All nursing notes (including nursing care plans);
- All reports of treatment (including complications and hospital-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

Survey Procedures §482.24(c)(2)(vi)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

A-0240

§482.24(c)(2)(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

Interpretive Guidelines §482.24(c)(2)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and hospital policy, who admitted the patient is responsible for the patient during the patient's stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other MD/DOs who work with the patient's MD/DO and who are covering for the patient's MD/DO and who are knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans may write the discharge summary at the responsible MD/DO's request.

In accordance with hospital policy, and 42 CFR part 482.12(c)(1)(i) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State's regulatory mechanism.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content.

The discharge summary requirement would include outpatient records. For example:

- The outcome of the treatment, procedures, or surgery;
- The disposition of the case;
- Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.

Survey Procedures §482.24(c)(2)(vii)

- Verify that a discharge summary is included to assure that proper continuity of care is required.
- For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care.
- Verify that a final diagnosis is included in the discharge summary.

A-0241

§482.24(c)(2)(viii) Final diagnosis with completion of medical records within 30 days following discharge.

Interpretive Guidelines §482.24(c)(2)(viii)

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Survey Procedures §482.24(c)(2)(viii)

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient's final diagnosis?

A-0247

§482.25 Condition of Participation: Pharmaceutical Services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

Interpretive Guidelines §482.25

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used instead of a pharmacy at any location providing pharmacy services, that storage area must be under competent supervision in accordance with State and Federal law.

Pharmaceutical Services would include:

- The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices.

- Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes.

- Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

Functions of Pharmaceutical Care are the:

- Collection and organization of patient-specific information;
- Determination of the presence of medication-therapy problems both potential and actual;
- Summary of the patient's medication related health care needs;
- Identification and specification of pharmacotherapeutic goals;
- Development of a pharmacotherapeutic regimen;
- Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals;
- Monitoring the effects of the pharmacotherapeutic regimen; and
- Redesigning the regimen and monitoring plan as indicated.

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital's medical staff must develop policies and procedures to minimize drug errors, but may delegate this function to the hospital's organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

- High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;
- Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Standardization of prescribing and communication practices to include:
    - Avoidance of dangerous abbreviations;

    - All elements of the order – dose, strength, units (metric), route, frequency, and rate;

    - Alert systems for look-like and sound-alike drug names;

    - Use of facility approved pre-printed order sheets whenever possible.

- That orders to "resume previous orders" are prohibited;

- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);

- The preparation, distribution, administration and proper disposal of hazardous medications;

- Drug recalls;

- That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;

- Identification of when weight-based dosing for pediatric populations is required; and

- Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities.

The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient's clinical records, identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies.

The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include: Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

The hospital's pharmacy services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.25

- Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

- Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.

- Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and medicine develop policies and procedures?

- Are there policies and procedures to minimize drug errors?

- Are policies and procedures reviewed and amended based on:

    - Facility-generated reports of adverse drug events;

    - Facility QAPI activities pertaining to pharmaceutical care;

    - Evaluation of external alerts and/or recommendations from national associations;

    - Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations.

- Is the staff familiar with the medication-related policies and procedures?

- Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?

- Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?

- Are pharmacists an integral component of pharmaceutical care?

- Verify that the hospital's pharmacy services is integrated into its hospital-wide QAPI program.

A-0248

§482.25(a) Standard: Pharmacy Management and Administration

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

Interpretive Guidelines §482.25(a)

The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations. Agencies and organizations could include FDA, NIH, American Society of Health-System Pharmacists, etc.

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate hospital staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a hospital may use to maintain professional principles include:

- Policies and procedures have been developed and are being followed;
- Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;
- Employees provide pharmaceutical services within their scope of license and education;
- Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the hospital through dispensation/administration;
- Maintaining controls over drugs and medications including the floor stock and those of the pharmacy or drug room;
- Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;

- Ensuring that drugs are being dispensed only by a licensed pharmacist;

- Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Survey Procedures §482.25(a)

- Are the policies and procedures consistent with accepted professional principles?

- Determine that professional principles are maintained by verifying that:

    - Policies and procedures have been developed and are being followed;

    - Drugs and biologicals are stored in accordance with manufacturers directions and State and Federal requirements;

    - Records have sufficient detail to follow the flow of control from entry through dispensation; and

    - Employees provide pharmaceutical services within their scope of license and education.

- Does the hospital have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration?

- Are policies developed to promote consistent application of pharmaceutical services and care throughout the hospital?

- Is the pharmacy director periodically monitoring implementation of policies and procedures?

- Are policies and procedures reviewed and revised as warranted?

- Are services provided in a manner consistent with accepted professional principles?

- Is the pharmacy responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?

A-0249

§482.25(a)(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Interpretive Guidelines §482.25(a)(1)

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service and must be responsible for developing, supervising, and coordinating all the activities of the hospital wide pharmacy service.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

A professional, competent, legally qualified pharmacist must manage the pharmacy. The Director of pharmacy service must be thoroughly knowledgeable about hospital pharmacy practice and management.

Pharmacists and pharmacy technicians must perform their duties within scope of their license and education.

The Pharmacy Director should be actively involved in those committees responsible for establishing medication-related policies and procedures.

Survey Procedures §482.25(a)(1)

- Determine whether the pharmacist is a full-time, or part-time employee or employed on a consultative basis.

- Review the implementation of the chief pharmacist's responsibilities by:

    - Reviewing written status reports;

    - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;

    - Reviewing schedules, time logs, etc.;

- Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services;

- Determining whether the Pharmacy Director routinely evaluates the performance and competency of pharmacy personnel? Do performance evaluations include high-risk activities such as the compounding of hazardous medications, pharmacy-based prescriptive activities (e.g. aminoglycoside protocols) and pharmaceutical care for high-risk patients (pediatric, ICU, geriatric etc)?

- Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures?

A-0250

§482.25(a)(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

Interpretive Guidelines §482.25(a)(2)

There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the hospital's pharmaceutical services.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

Survey Procedures §482.25(a)(2)

- Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

- Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

A-0251

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

Interpretive Guidelines §482.25(a)(3)

Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- Records trace the movement of scheduled drugs throughout the service.

- The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?

- Facility policies and procedures should minimize scheduled drug diversion.

Survey Procedures §482.25(a)(3)

- Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

- Review the records to determine that they trace the movement of scheduled drugs throughout the service.

- Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the hospital system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

A-0252

§482.25(b) Standard: Delivery of Services

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

Interpretive Guidelines §482.25(b)

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of

practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical care and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate hospital staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices and biologicals.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to; checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. "**High risk medications**" are those medications involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes. Lists of high-risk or high-alert drugs are available from such organizations as the Institute for Safe Medication Practices (ISMP) and the United States Pharmcopoeia (USP). Examples of high-risk drugs may include investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital.

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.

Review of medication orders should include:

- Therapeutic appropriateness of a patient's medication regimen;
- Therapeutic duplication in the patient's medication regimen;
- Appropriateness of the drug, dose, frequency, route and method of administration;
- Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- Real or potential allergies or sensitivities;
- Variation from organizational criteria for use

- Other contraindications;

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;

- Physical signs and clinical symptoms relevant to the patient's medication therapy;

- Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in hospital decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines? The evaluation and monitoring should include the potential for medication errors.

There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program?

There is a policy that addresses the use of medications brought into the hospital by patients or their families.

There is a process and policy to ensure that investigational medications are safety controlled and administered. Procedures for the use of investigational medications include the following: A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.

Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

The hospital pharmacy must ensure that medication orders are accurate and that medications are administered as ordered. The pharmacy should have a system to reconcile medications that are not administered, that remain in the patient's medication drawer, slot, etc., when the pharmacy inventories patient medications or restocks patient

medications. The pharmacy should determine the reason the medications were not used. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

Survey Procedures §482.25(b)

- Are there limits on the number of possible concentrations for a medication, particularly high-alert drugs like morphine and heparin?

- Is access to concentrated solutions (e.g. potassium chloride, sodium chloride solutions greater than 0.9%) restricted?

- Are questions regarding the order resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order?

- Identify and assess the quality assurance procedures for the preparation of sterile products.

- Is appropriate monitoring of medication therapy being conducted?

- Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.

- Is there a process to report serious adverse drug reactions to the Federal MedWatch program?

- Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

- Are medication storage areas periodically inspected to make sure medications are properly stored?

- Does the hospital retrieve and remove medications available or patient use when the hospital has been informed of a drug recall? Does the recall include notification of patients that have been impacted and those that would order, dispense or administer the medication?

A-0253

§482.25(b)(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

Interpretive Guidelines §482.25(b)(1)

All compounding, packaging, and dispensing of drugs and biologicals must be conducted by a registered pharmacist or under the supervision of a registered pharmacist and performed consistent with State and Federal laws.

Medications must be prepared safely. Safe preparation procedures could include:

- Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).

- Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.

- Wherever medications are prepared, staff uses techniques to assure accuracy in medication preparation.

- Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include but are not limited to the following:

    - Using clean or sterile technique as appropriate;

    - Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;

    - Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and

    - Visually inspecting the integrity of the medications.

Medications should be dispensed in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;

- Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.

- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy;

- The hospital consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and

- All concerns, issues or questions are clarified with the individual prescriber before dispensing.

Survey Procedures §482.25(b)(1)

- Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:

    - Reviewing policies and procedures;

    - Interviewing pharmacy and hospital staff to determine how drugs and biologicals are prepared and dispensed;

    - Observing on site dispensing and compounding operations (if applicable);

    - Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and

    - Inspecting drug storage areas.

- Verify through interviews of pharmacy and hospital staff, observation of on-site dispensing operations, inspection and review of hospital records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws and in a manner to promote patient safety.

A-0254

§482.25(b)(2) Drugs and biologicals must be kept in a locked storage area.

Interpretive Guidelines §482.25(b)(2)

All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals.

All drugs and biologicals must be stored in a manner to prevent access by non-authorized individuals.

Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the hospital is not in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts

When not in use, nursing medication carts, anesthesia carts, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. However, due to the mobility of carts, when not in use, locked carts that contain drugs or biologicals must be stored in a locked room or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and hospital policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Survey Procedures §482.25(b)(2)

- Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.

- Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

- Determine if the facility identifies what personnel may have access to medications.

A-0255

§482.25(b)(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §482.25(b)(3)

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures §482.25(b)(3)

- Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:
    - Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.
    - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date.
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

A-0256

§482.25(b)(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

Interpretive Guidelines §482.25(b)(4)

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night

cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State Law.

If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility.

The hospital must have a process for providing medications to meet patient needs when the pharmacy is closed.

When non-pharmacist health care professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:

- Access is limited to a set of medications that has been approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy.

- Only trained, designated prescribers and nurses are permitted access to medications.

- Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors.

- The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provides medications beyond those accessible to non-pharmacy staff.

- This process is evaluated on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

- Changes are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Survey Procedures §482.25(b)(4)

- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.

- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-

pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.

- Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.

- Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

- Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital.

A-0257

§482.25(b)(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

Interpretive Guidelines §482.25(b)(5)

In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses. The hospital must implement, monitor, and enforce this automatic stop system.

Survey Procedures §482.25(b)(5)

Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients' medical records to determine compliance with stop-order policy.

A-0258

§482.25(b)(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

Interpretive Guidelines §482.25(b)(6)

Drug administration errors, adverse drug reactions, and drug incompatibility must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending

physician not being available, the patient's attending physician must be notified as soon as he/she is available. Additionally in accordance with the regulation and 482.21, the hospital must report drug administrative errors, adverse drug reactions and drug incompatibilities to its hospital wide QAPI program.

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs.

An example is the use of the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error.

> "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

When compared to the traditional definition of a medication error (right patient, right drug, right route, right time, right dose) all errors secondary to any aspect of medication utilization (including purchasing, ordering, dispensing, administrative, preparation, compounding, etc.) would be reported versus only those that occurred in the administration phase of medication utilization.

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

The facility must have a method by which to measure the effectiveness of their reporting system so as to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Survey Procedures §482.25(b)(6)

- Determine that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

- Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

- Is the facility's definition of an adverse drug reaction and medication error based on established benchmarks or studies on report rates published in peer-review journals? Is it identifying as many medication errors and adverse drug reactions as would be expected for the size and scope of services provided by the hospital?

- If upon review of patient's clinical records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or on-call physician, in accordance, with written procedures and that it was promptly recorded in the patient's medical record.

- Review QAPI activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.

- Determine if the number of medication errors and adverse drug reactions reported is consistent with the size and scope of services provided by the hospital.

- Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions

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A-0259

§482.25(b)(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Survey Procedures §482.25(b)(7)

- Interview the pharmacists, or pharmacy employees to determine their understanding of the controlled drug policies.

- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

- Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?

- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

- Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

A-0260

§482.25(b)(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

Interpretive Guidelines §482.25(b)(8)

The facility has immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

Survey Procedures §482.25(b)(8)

- Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.

- Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

A-0261

§482.25(b)(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Interpretive Guidelines §482.25(b)(9)

The medical staff must establish a formulary system. The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

Processes and mechanisms should be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration within the hospital.

Medications designated as available for dispensing or administration are reviewed periodically based on emerging safety and efficacy information.

The hospital should have processes to approve and procure medications that are not on the hospital's medication list.

The hospital should have processes to address medication shortages and outages, including the following:

- Communicating with appropriate prescribers and staff;
- Developing approved substitution protocols;
- Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and
- Obtaining medications in the event of a disaster.

Survey Procedures §482.25(b)(9)

- Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.
- Interview the Pharmacy Director to determine that there is a process for creation and periodic review of a formulary system.
- Determine that the formulary lists drugs that are available.

A-0267

§482.26 Condition of Participation: Radiological Services

The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet the professionally approved standards for safety and personnel qualifications.

Interpretive Guidelines §482.26

The hospital must maintain, or have available, diagnostic radiological services according to the needs of their patients. These services must be maintained or available at all times. All radiological services provided by the hospital, including diagnostic and, if offered, therapeutic, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc).

Radiological services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiology services provided under contract may be provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

The hospital's radiological services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.26

Verify that radiological services are integrated into the hospital-wide QAPI program.

A-0268

§482.26(a) Standard: Radiology Services

The hospital must maintain, or have available, radiology services according to the needs of the patients.

Interpretive Guidelines §482.26(a)

The scope and complexity of radiology services provided must meet the needs of the patients.

Radiological services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiology services provided under contract may be provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

Survey Procedures §482.26(a)

Verify that the hospital maintains, or has available, organized radiology services that meet the needs of the patients, are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.

A-0269

§482.26(b) Standard: Safety for Patients and Personnel

The radiological services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel.

Survey Procedures §482.26(b)

Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?

A-0270

§482.26(b)(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials.

Interpretive Guidelines §482.26(b)(1)

The hospital policies must contain safety standards for at least:

- Adequate shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Proper storage of radiation monitoring badges when not in use;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- Methods of identifying pregnant patients.

The hospital must implement and ensure compliance with its established safety standards.

Survey Procedures §482.26(b)(1)

- Verify that patient shielding (aprons, etc) are properly maintained and routinely inspected by the hospital.
- Verify that hazardous materials are stored properly in a safe manner.
- Observe areas where testing is done for violations in safety precautions.

A-0271

§482.26(b)(2) Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place, qualified employees or contracts, to correct hazards. The hospital must be able to demonstrate current inspection and proper correction of all hazards.

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.

- Determine that any problems identified are properly corrected in a timely manner.

A-0272

§482.26(b)(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiological services personnel, as well as, other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include personnel such as certain nursing and maintenance staff.

Survey Procedures §482.26(b)(3)

- Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.

- Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.

- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

A-0273

§482.26(b)(4) Radiology services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

Survey Procedures §482.26(b)(4)

Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with State law.

A-0274

§482.26(c) Standard: Personnel

A-0275

§482.26(c)(1) A qualified full-time, part-time or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

Interpretive Guidelines §482.26(c)(1)

The medical staff must establish, in accordance with this regulation and other Federal and State laws, regulations and guidelines, the qualifications necessary for radiologist appointment to the medical staff.

There must be written policies developed and approved by the medical staff to designate which radiological tests require interpretation by a radiologist.

When telemedicine is used, and the radiologist who interprets radiological tests and the patient are located in different states, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following:

- Ensuring that radiology reports are signed by the practitioner who interpreted them;
- Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;
- Enforcing infection control standards;
- Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;
- Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and
- Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

Survey Procedures §482.26(c)(1)

- Review the radiologist's credentialing file to verify that he/she meets the qualifications established by the medical staff for appointment.
- Review records to determine that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist.
- Verify that supervision of the radiology services is restricted to a radiologist who is a member of the medical staff.

A-0276

§482.26(c)(2) Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures.

Interpretive Guidelines §482.26(c)(2)

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

Survey Procedures §482.26(c)(2)

Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

A-0277

§482.26(d) Standard: Records

Records of radiology services must be maintained.

Interpretive Guidelines §482.26(d)

The hospital must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The hospital should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. Patient radiology records are considered patient medical records and the hospital must comply with the medical records CoP (§482.24). The medical records CoP requires that medical records, which would include radiology films, image records, scans, reports, and printouts must be secure, properly stored, be accessible and promptly retrievable for any care, procedure, treatment, or test provided or conducted within the past 5 years.

Survey Procedures §482.26(d)

Determine the hospital's procedures for maintaining radiology records.

A-0278

§482.26(d)(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

Survey Procedures §482.26(d)(1)

Review radiological records to determine that reports are signed by the practitioner who reads and evaluates the roentgenogram.

A-0279

§482.26(d)(2) The hospital must maintain the following for at least 5 years:

Copies of reports and printouts
Films, scans, and other image records, as appropriate.

Interpretive Guidelines §482.26(d)(2)

Patient radiology records are a type of patient medical record. The hospital must maintain radiology records in compliance with the medical records CoP and this CoP. Medical records, including radiology records, must be maintained for 5 years.

Survey Procedures §482.26(d)(2)

- Verify that the hospital maintains records for at least 5 years.
- Verify that radiology records are maintained in the manner required by the Medical Records CoP.

A-0284

§482.27 Condition of Participation: Laboratory Services

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.

Interpretive Guidelines §482.27(a)

The hospital must maintain or have available laboratory services whenever its patients need those services. The hospital may maintain laboratory services at the hospital, or for other than emergency lab services, may make laboratory services available through contractual agreements. The scope and complexity of the hospital laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. Every hospital laboratory service must be operating under a current CLIA certificate appropriate to the level of services performed.

The hospital's laboratory services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the hospital must comply with the requirements of the Medical Records CoP.

Survey Procedures §482.27(a)

- Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed.

- Verify that the laboratory service and all laboratory locations are integrated into the hospital-wide QAPI program.

- If laboratory services are contracted, verify that the review of the quality of those services is integrated into the hospital-wide QAPI program.

A-0285

§482.27(b) Standard: Adequacy of Laboratory Services

The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of Part 493 of this chapter.

Interpretive Guidelines §482.27(b)

The CLIA certification may be accomplished by having one certificate for the entire hospital's laboratory services, by having one certificate for each laboratory, or by the hospital having a mixture. Whatever the arrangement, all laboratory services must be provided in accordance with CLIA requirements and under a current CLIA certificate, even when those laboratory services take place outside of a lab.

Survey Procedures §482.27(b)

- Determine which services are provided directly by the facility and which are provided through contractual agreements.

- Determine if the referral laboratory is CLIA certified for the appropriate test specialty.

- If the hospital provides laboratory services in multiple locations, verify that all laboratory services are operating under a current CLIA certificate.

- Examine records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.

A-0286

§482.27(b)(1) Emergency laboratory services must be available 24 hours a day.

Interpretive Guidelines §482.27(b)(1)

The hospital must provide emergency laboratory services 24 hours a day, 7 days a week. The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the hospital or those patients who may arrive at the hospital in an emergency condition. The emergency laboratory services (procedures, tests, personnel) available should reflect the scope and complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

Survey Procedures §482.27(b)(1)

Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24- hour availability of emergency services and that those services are provided when required.

A-0287

§482.27(b)(2) A written description of services provided must be available to the medical staff.

Survey Procedures §482.27(b)(2)

Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). Verify that the description of services is accurate and current.

A-0288

§482.27(b)(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

Interpretive Guidelines §482.27(b)(3)

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Survey Procedures §482.27(b)(3)

Review tissue records (accession records, worksheets, and test reports) to determine whether the laboratory follows the written protocol.

A-0289

§482.27(b)(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

Interpretive Guidelines §482.27(b)(4)

Laboratory written policies, approved by the medical staff and a pathologist, must state which tissue specimens require a macroscopic examination and which tissue specimens require both macroscopic and microscopic examination.

Survey Procedures §482.27(b)(4)

- Verify that the hospital has a written policy for examination requirements.
- Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.
- Verify that the policies are in accordance with these requirements and other Federal and State laws, regulations, and guidelines.

A-0290

§482.27(c) Standard: Potentially Infectious Blood and Blood Products

(1) Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and look back procedures are set forth at 21 CFR §610.45-et seq.)

(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify all patients in accordance with paragraph (c)(4) of this section.

(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless--

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) Content of notification. The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restriction the program may impose.

(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

Interpretive Guidelines §482.27(c)

This regulation requires the hospital to have a system in place to take appropriate action when notified that blood or blood products it received are at increased risk of transmitting HIV.

The "**window period**" is defined as that period early in infection when the antibody to HIV is not detectable by the screening test. (Currently, the average infectious window

period, when a person may be infected with HIV, but the HIV antibody is not detectable by current screening test methods, is approximately 22 to 25 days.)

The term "**repeatedly reactive**" means that the initial HIV antibody screening test is reactive, re-tested in duplicate, and one or both of the duplicate tests are reactive. If repeatedly reactive, a licensed, more specific (confirmatory) test, e.g., Western Blot, is used to confirm the presence of HIV.

"**Look back**" is considered to include: the quarantine of products from a window period donor; notification of consignees (facilities having received such window period products) to quarantine those products; and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient.

Despite the best practices of blood banks, a person may have donated blood during the window period. If the donor attempts to donate blood at a later date, the screening test for the antibody to HIV may, at that time, be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV and a recipient of blood or blood products collected during the window period would not know whether the donor was infected with HIV at the time of the previous donations.

CMS regulations apply only to transfusion services in hospitals that participate in Medicare, where the transfusion service does not include more than the performance of compatibility testing, i.e., the hospital receives blood and blood products from an outside source and only performs compatibility (cross match) testing in preparation for transfusion to patients. Most hospitals that do not draw donors or process donor blood would fall under CMS' regulations.

FDA's regulations apply to facilities collecting, processing, and storing (manufacturing) blood and blood products, e.g., collecting donor blood, washing, or freezing red blood cells, and irradiating blood components. FDA's regulations also apply to facilities that do not participate in Medicare, such as Indian Health Services and Veteran's Administration hospitals. An independent laboratory performing compatibility testing and issuing blood and blood products directly to a non-hospital entity, i.e., home health agency, nursing facility, or ambulatory surgery center, would come under the jurisdiction of the FDA's rule as well, since it is considered a transfusion service that is not subject to the conditions of Medicare participation for hospitals.

FDA's companion regulation to these requirements (21 CFR §§610.45), also published 9/9/96, requires that, within 72 hours, blood banks notify the hospital (the consignee) for which it supplied whole blood, blood components, source plasma, or source leukocytes that are at increased risk for transmitting HIV infection and follow up this notification within 30 days of the results of the more specific (confirmatory) test for HIV.

A blood bank that is part of a hospital and collects, processes, and stores (manufactures) blood products for that hospital is not required to have an agreement with the hospital

administration. It would be required to meet the aforementioned FDA regulations and requirements as well as those of other regulatory and accrediting bodies.

Details of agreements or practice policies are worked out between the hospital and blood bank and are consistent with applicable Federal, State, and local laws, but can be written flexibly so that any changes in FDA or CMS requirements can be incorporated into operating procedures rather than by constructing a new agreement.

Under certain circumstances, such as during blood emergencies. hospitals may receive blood from a source other than the contracted blood bank. FDA regulations require a blood bank to notify the hospital in the event it furnished the hospital with potentially HIV-infected blood.

No release of quarantined blood or blood products is permitted before the results of further testing are available. If a blood bank fails to notify the hospital of the more specific (confirmatory) test results within the 30-day limit, immediate destruction of quarantined units is not required because further testing and notification was not completed within the 30 days. The blood shall not be released until the subsequent, more specific (confirmatory) test result, when reported, is negative.

The hospital's policy should reflect that release (from quarantine) of potentially HIV-infected blood is possible only if the more specific (confirmatory) test is negative, and the blood bank's (the facility that notified the hospital) records show the donor has no other informative test results that show evidence of HIV infection. "Other" informative tests are tests that a blood bank may voluntarily perform, i.e., HIV antigen tests, viral cultures, etc. If these tests are positive, the blood and blood products are disposed of if still available. The blood bank will communicate this information to the hospital. If no other informative test results exist, the hospital may release the blood and blood products from quarantine. If other informative test results exist that indicate possible HIV infection, the hospital must dispose of the blood and blood products.

The reference to 21 CFR §606.40 refers to the requirements for facilities, such as hospitals, that perform blood compatibility testing. Specifically "the facility must provide for the safe and sanitary disposal of blood and blood components not suitable for use or distribution." (21 CFR §606.40(d)(2)).

The hospital retains flexibility to develop its own policies and procedures in order to meet notification requirements. The physician of record is the first choice to notify the patient that he or she received potentially HIV-infectious blood. If the physician declines, then the notification responsibility falls to the hospital. The hospital may designate an appropriate, competent hospital representative to inform the patient. This may be another physician, such as the medical director of the transfusion service, an infection control officer, a nurse, a clinical laboratory scientist, a social worker, or a non-physician with medical expertise.

This requirement also applies when the hospital transfusion service furnishes blood or blood products to another facility, such as an ambulatory surgery center, clinic, nursing facility, or home setting (via a home health agency). The hospital retains responsibility for patient notification.

If the physician who orders the transfusion is not the same as the physician of record, e.g., the physician identified on the admitting form, the hospital may ask either physician to perform the notification. It is recommended that the hospital make 3 attempts within one week to notify the physician.

If the hospital is unable to locate the physician, or the physician does not agree to notify the patient, the hospital should promptly make efforts to locate the patient. In this way, it is reasonable to expect the hospital to locate and notify the patient in the remaining 7 weeks. If after 3 attempts, the hospital is not able to locate the patient within the 8-week notification period, it is not expected to continue its search. However, there is no limit on how much time a hospital may choose to expend on this effort.

Documentation related to notification, e.g., contacting physician, telephone log, return receipt from a certified or registered letter, becomes part of the patient's medical record. Policies and procedures for the notification process must conform to all Federal, State, and local laws regarding confidentiality. There are no Federal penalties imposed on physicians who decline to notify the patient.

When the physician accepts the responsibility for notification, the hospital is not required to follow up with the physician to determine whether notification occurred. It is expected that the physician would inform the hospital if notification did not occur, but this is part of professional relationships and not a requirement.

If the physician accepts responsibility for notification, and later informs the hospital that the patient was not notified, or the hospital otherwise learns that no follow up occurred, it must attempt notification, regardless of the time that elapsed after the hospital first notified the physician. Once a hospital is notified of a potentially HIV-infectious product, there is never a time that patient notification need not be attempted. It is only when, after the hospital has made a good faith effort of at least 3 attempts but is not able to locate the patient within 8 weeks, that the notification process may come to an end.

This regulation does not require the hospital to provide HIV testing or counseling, but merely to refer the patient for testing and counseling. Referral for testing and counseling will be made to a physician or organization that provides high quality HIV testing and has extensive experience in providing HIV counseling. In addition, the patient should be told about any requirements or restrictions the programs may impose, such as, whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. The CDC National AIDS Hotline operates a toll-free number (1-800-342-2437) 24 hours a day that the hospital or physician can give to the patient for more assistance.

A hospital that delegates notification must ensure that the notification, which includes referral for counseling, is performed in accordance with these requirements.

Hospital requirements for confidentiality in record keeping exist at §482.24. Documents related to notification become part of the patient's medical record and are subject to the normal safeguards for access, information release, patient consent, and other precautions for confidential information. Hospitals must retain notification records for 5 years.

Hospitals should contact their State concerning special statutes regarding HIV status, testing, and confidentiality. Messages should not be left on telephone answering machines about the need for HIV testing. Any written correspondence would also need to be conducted with confidentiality in mind.

If the patient in question is competent, but the physician believes the information should not be given to the patient, and State law permits a legal representative or relative to receive information on the patient's behalf, then the physician must notify the patient's representative or relative. Upon learning of the death of the transfused patient, the hospital must pursue the notification process to inform the patient's family. It would not be appropriate for a physician or hospital to determine that neither the patient nor someone acting on his or her behalf need be informed.

Survey Procedures §482.27(c)

- In a hospital, investigation of an incident related to look back or the lack of look back policy will most likely occur in response to an allegation of a hospital patient receiving HIV-infected blood or blood products. However, on a routine certification or validation survey, without a specific case to investigate, the surveyor should inquire about how the hospital plans to meet the requirements of §482.27(c**).** If a specific case is identified, determine if the hospital has developed and effectively implemented its look back plan.

- Review the written agreement for notification expectations and approval by an appropriate hospital representative.

- If the hospital receives notification from the blood bank of receipt of potentially HIV-infected blood, review how and where the follow up confirmatory test results are documented. How does the hospital handle the situation where confirmatory test results are not received from the blood bank within 30 days?

- What is the hospital's policy for quarantining potentially HIV-infected blood and blood products?

- Does it include documentation of the quarantine, follow up testing (required of the blood bank to be communicated to the hospital within 30 days), and disposal of infected blood products, if warranted?

- If the hospital was notified that it had received potentially infectious blood and blood products, what did it do?

- Was the potentially HIV-infectious blood quarantined according to policy? If not, why not?

- Was the potentially HIV-infectious blood disposed of when confirmatory testing showed evidence of HIV infection? How was it disposed?

- How does hospital policy address notification of potentially HIV-infectious blood or blood products?

- Ask the hospital representative to explain what the hospital did (or would do) in the event it received such notification.

- Has the hospital ever been notified that it received potentially HIV-infectious blood or blood products? If so, was follow up according to the hospital's policy? Were there any negative outcomes attributed to a breakdown in the notification process?

- How does the hospital ensure that the notification process is carried out within the 8-week timeframe specified in this requirement?

- If the hospital had a look back incident, is there documentation of notification efforts in the patient's medical record, including any extenuating circumstances that prevented patient notification within the 8-week timeframe?

- If the three attempts at notification extended beyond the 8-week timeframe, what would the hospital do differently should notification be necessary in a future incident?

- What system does the hospital have in place to assist the patient in seeking testing and counseling?

- What role does the patient's physician play in explaining the need for testing and counseling?

- What information does the hospital make available to the patient transfused with potentially HIV-infectious blood or blood products?

- Review the hospital's notification procedures. Was notification performed in such a manner as to ensure that names of patients requiring notification and records relating to the notification were kept confidential?

- Under what circumstances does the hospital determine it necessary to notify someone other than the patient who received potentially HIV infectious blood or blood products?

A-0295

§482.28 Condition of Participation: Food and Dietetic Services

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietician who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

Interpretative Guidelines §482.28

The hospital's food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and acceptable standards of practice.

The hospital should have written policies and procedures that address at least the following:

- Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;
- Frequency of meals served;
- System for diet ordering and patient trays delivery;
- Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc);
- Integration of the food and dietetic service into the hospital-wide QAPI and Infection Control programs;
- Guidelines for acceptable hygiene practices of food service personnel; and
- Guidelines for kitchen sanitation.

The same standards apply whether the food and dietetic services are provided by the hospital directly, through a contractual agreement, or by off-site vendor.

The hospital must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

A-0296

§482.28(a) Standard: Organization

A-0297

§482.28(a)(1) The hospital must have a full-time employee who–

(i) Serves as director of the food and dietetic services;

(ii) Is responsible for daily management of the dietary services; and

(iii) Is qualified by experience or training

Interpretive Guidelines §482.28(a)(1)

The service director must be a full-time employee who has been granted the authority and delegated responsibility by the hospital's governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes, the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following:

- Safety practices for food handling;
- Emergency food supplies;
- Orientation, work assignments, supervision of work and personnel performance;
- Menu planning, purchasing of foods and supplies, and retention of essential records (e.g., cost, menus, personnel, training records, QAPI reports, etc);
- Service QAPI program.

Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operations.

Survey Procedures §482.28(a)(1)

- Verify that the director of the food and dietetic services is a full-time employee.

- Review the service director's job description to verify that it is position-specific and that responsibility and authority for the direction of the food and dietary service has been clearly delineated.

- Review the service director's personnel file to verify that he/she has the necessary education, experience, and training to manage the service, appropriate to the scope and complexity of food service operations.

A-0298

§482.28(a)(2) There must be a qualified dietitian, full-time, part-time or on a consultant basis.

Interpretive Guidelines §482.28(a)(2)

A qualified dietitian must supervise the nutritional aspects of patient care. Responsibilities of a hospital dietitian may include, but are not limited to:

- Approving patient menus and nutritional supplements;

- Patient, family, and caretaker dietary counseling;

- Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;

- Collaborating with other hospital services (e.g., medical staff, nursing services, pharmacy service, social work service, etc) to plan and implement patient care as necessary in meeting the nutritional needs of the patients;

- Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.

Qualification is determined on the basis of education, experience, specialized training, State licensure or registration when applicable, and maintaining professional standards of practice.

If the qualified dietitian does not work full-time, and when the dietitian is not available, the hospital must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.

Survey Procedures §482.28(a)(2)

- Review the dietitian's personnel file to determine that he/she is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.

- If the dietitian is not full-time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the hospital makes adequate provisions for a qualified consultant coverage when the dietitian is not available.

A-0299

§482.28(a)(3) There must be administrative and technical personnel competent in their respective duties.

Interpretive Guidelines §482.28(a)(3)

Administrative and technical personnel must be competent in their assigned duties. This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that the staff member(s) is competent in their respective duties.

Survey Procedures §482.28(a)(3)

Review personnel files for administrative and technical staff to determine they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

A-0300

§482.28(b) Standard: Diets

Menus must meet the needs of the patients.

Interpretive Guidelines §482.28(b)

Menus provided by the hospital must be nutritionally balanced and meet the special needs of the patients. Current menus should be posted in the hospital kitchen. In order to ensure that the hospital is meeting the nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. Once a patient is identified as at altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as

necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);

- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;

- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc);

- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc).

Patients who refuse the food served should be offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs.

A-0301

§482.28(b)(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines §482.28(b)(1)

Therapeutic diets should be:

- Prescribed in writing by a qualified practitioner or a qualified dietitian;

- Documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and

- Evaluated for nutritional adequacy.

Survey Procedures §482.28(b)(1)

Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.

A-0302

§482.28(b)(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines §482.28(b)(2)

Recognized dietary practices include following current national standards for recommended dietary allowances, i.e., the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council.

Survey Procedures §482.28(b)(2)

- Ask the hospital to show you what national standard they are following in their menus to meet the nutritional needs of their patients.

- Review patient records to verify that diet orders are provided as prescribed by the practitioner(s) responsible for the care of the patient.

- From the sample patient records, identify patients with special nutritional needs to determine:

    - If their nutritional needs have been met;

    - If appropriate therapeutic diets have been ordered; and

    - As appropriate, if their dietary intake and nutritional status is being monitored.

A-0304

§482.28(b)(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Interpretive Guidelines §482.28(b)(3)

The therapeutic diet manual must be approved by the dietitian and the medical staff. The publication or revision date of the approved therapeutic diet manual must not be more than 5 years old. The therapeutic diet manual (or copies of it) must be available to all medical, nursing and food service personnel.

Survey Procedures §482.28(b)(3)

- Determine that the therapeutic diet manual is current, and:
    - Has been approved by both the medical staff and a qualified dietitian;
    - Is readily available to MD/DOs, nursing and food service personnel;
    - Is in accordance with the current national standards, such as RDA or DRI;
    - Includes the different types of therapeutic diets routinely ordered at the hospital; and
    - Is consistently used as guidance for ordering and preparing patient diets.

A-0308

§482.30 Condition of Participation: Utilization Review

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

Interpretive Guidelines §482.30

The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities. It should also establish procedures for the review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services.

Survey Procedures §482.30

- Determine that the hospital has a utilization review plan for those services furnished by the hospital and its medical staff to Medicare and Medicaid patients.
- Verify through review of records and reports, and interviews with the UR chairman and/or members that UR activities are being performed as described in the hospital UR plan.
- Review the minutes of the UR committee to verify that they include dates, members in attendance, extended stay reviews with approval or disapproval noted in a status report of any actions taken.

A-0309

§482.30(a) Standard: Applicability

The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.

Interpretive Guidelines §482.30(a)

Under Medicare, a QIO must perform UR functions for a hospital, the hospital must have a contract with their QIO to perform UR functions. Under Medicaid, the State must undertake review of UR activities in participating hospitals either directly or optionally by a QIO or other contractor. If a QIO contract exists, the State Plan must comply with 42 CFR §431.630.

Survey Procedures §482.30(a)

- Do not apply these UR requirements if **any** of the following situations apply:
    - A QIO has assumed binding review for the hospital, or
    - The State has entered into a contract with a QIO that is deemed under section 431.630, or
    - CMS has determined that the UR procedures established by the State under Medicaid are superior to these requirements and has required hospitals in that State to meet them. In these cases, the State requirements are applied to both Medicare and the Medicaid patients. The State requirements will then be used for survey in those States.

A-0310

§482.30(b) Standard: Composition of Utilization Review Committee

A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine

or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1).

(1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution--

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee or group's reviews may not be conducted by any individual who--

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

Survey Procedures §482.30(b)

- Determine the composition of the UR committee;
- Determine that the governing body has delegated to the UR committee the authority and responsibility to carry out the UR function;
- Verify that small hospitals delegate the UR function to an outside group if it is impractical to have a staff committee;
- Ascertain that committee members are not financially involved in the hospital (ownership of 5 percent or greater) nor participants in the development or execution of the patient's treatment plan.

A-0311

§482.30(c) Standard: Scope and Frequency of Review

(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.

Interpretive Guidelines §482.30(c)

Admissions may be reviewed before, during, or after hospital admission as stated in the hospital's UR plan.

Reviews may be conducted on a sample basis, except for reviews of extended stay cases.

In a PPS hospital, to determine outlier review compliance, "reasonably assumes" is a good faith test. The question to ask is whether the hospital is reviewing outlier cases. In instances where there was no other review of outlier cases, the question is whether it was reasonable for the hospital not to have known that the cases were in fact outliers. Some medical judgment might be required to determine whether it is reasonable for the hospital to have assumed that a patient fell into a DRG other than the one eventually assigned by the intermediary. This would be an issue in long stay outlier cases where the hospital did

not review because the hospital erroneously assumed that the patient was in a DRG under which the case would not have been an outlier.

Survey Procedures §482.30(c)

- Examine the UR plan and other documentation to determine that the medical necessity for Medicare and Medicaid patients is reviewed with respect to admission, duration of the stay, and the professional services furnished.

- Determine if the hospital is reimbursed under PPS. This requirement does not apply to PPS excluded hospitals or units.

- Verify that in a PPS hospital the following are being reviewed:

    - Duration of stay in cases reasonably assumed to be outlier cases; and

    - Professional services in cases reasonably assumed to be outlier cases.

A-0312

§482.30(d) Standard: Determination Regarding Admissions or Continued Stays

(1) The determination that an admission or continued stay is not medically necessary-

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of §482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c);

Interpretive Guidelines §482.30(d)

When other than a doctor of medicine or osteopathy makes an initial finding that the written criteria for extended stay are not met, the case must be referred to the committee, or subgroup thereof which contains at least one physician. If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified and allowed an opportunity to present his views and any additional information relating to the patient's needs for admissions or extended stay. When a physician member of the committee performs the initial review instead of a non-physician reviewer, and he finds that admissions or extended stay is not necessary no referral to the committee or subgroup is necessary and he may notify the attending practitioner directly.

If the attending practitioner does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final.

If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient's need for extended stay, at least one additional physician member of the committee must review the case. If the two physician members determine that the patient's stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. Written notification of this decision must be sent to the attending physician, patient (or next of kin), facility administrator, and the single State agency (in the case of Medicaid) no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period.

There are only 5 working days in a given week. Normally these days are Monday through Friday, however, the institution has the option to establish 5 other days as working days. When a holiday falls on a working day, that day is not counted as a working day.

In no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate.

If, after referral of a questioned case to the committee or subgroup thereof, the physician reviewer determines that an admission or extended stay is justified, the attending physician shall be so notified and an appropriate date for subsequent extended stay review will be selected and noted on the patient's record.

Written notification of this final determination must be sent to the attending physician, the patient (or next of kin), the facility administrator and the single State agency (in the case of Medicaid) no later than 2 days after such final determination and in no event later than 3 working days after the end of the assigned extended stay period.

Where possible, the written notification should be received by all involved parties within the stated time period. Where appropriate and desired, verbal notification may precede written notification.

Survey Procedures §482.30(d)

- Review a sample of "medically unnecessary" decisions involving admissions or continued stay that are not medically necessary and determine that these decisions are made by:

    - One member of the UR committee, if the practitioner(s) responsible for the patient's care concurs with the determination or fails to present his/her views. The practitioner must be one of those specified in §482.12(c), or

    - At least two members of the UR committee in all cases not qualified under the above.

- Review a sample of "medically unnecessary" decisions and verify that the physician or practitioners, as specified in §482.12(c), were informed of the committees expected decision and were given an opportunity to comment.

- Review a sample of "medically unnecessary" cases and verify that all involved parties are notified of the decision that care is medically not necessary no later than two days following the decision.

A-0313

§482.30(e) Standard: Extended Stay Review

(1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, or each current inpatient receiving hospital services during a continuous period of extended duration.

The scheduling of the periodic reviews may--

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

Survey Procedures §482.30(e)

- Review the facility's definition of extended stay in the UR plan.
- Verify that the hospital's UR plan requires a periodic review of each current Medicare/Medicaid inpatient receiving hospital services of extended duration and that the review is carried out at the specified time stated in the facility's UR plan.
- The review may be the same for all cases or be different for different classes of care.
- If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor must verify that there is a written list with lengths of stay designated for each diagnosis of functional category.
- Determine if the hospital is under PPS. Hospitals under PPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis.
- Review minutes of the UR committee. Determine that the periodic reviews of extended stay are carried out on or before the expiration of the stated period or no later than 7 days after the day required in the hospital's plan.

A-0314

§482.30(f) Standard: Review of Professional Services

The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

Interpretive Guidelines §482.30(f)

"**Professional**" services includes the aspects of care rendered by laboratory personnel, physical therapists, nurses, and others, as well as services provided by MD/DOs.

The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are:

- Availability and use of necessary services - underused, overuse, appropriate use

- Timeliness of scheduling of services - operating room, diagnostic
- Therapeutic procedures

Survey Procedures §482.30(f)

Determine that the committee performs a review of professional services.

A-0317

§482.41 Condition of Participation: Physical Environment

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

Interpretive Guidelines §482.41

This CoP applies to all locations of the hospital, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The hospital's Facility Maintenance and hospital departments or services responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the hospital's QAPI program and be in compliance with the QAPI requirements.

Survey Procedures §482.41

Survey of the Physical Environment CoP should be conducted by one surveyor. However, each surveyor as he/she conducts his/her survey assignments should assess the hospital's compliance with the Physical Environment CoP. The Life Safety Code survey may be conducted separately by a specialty surveyor.

A-0318

§482.41(a) Standard: Buildings

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well being of patients are assured.

Interpretive Guidelines §482.41(a)

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the hospital's **QAPI** plan.

Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The hospital must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The hospital must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- The differing needs of each location where the certified hospital operates;
- The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the hospital itself;
- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;

- Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans;

- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;

- Provisions if gas, water, electricity supply is shut off to the community;

- Transfer or discharge of patients to home, other healthcare settings, or other hospitals;

- Transfer of patients with hospital equipment to another hospital or healthcare setting; and

- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures §482.41(a)

- Verify that the condition of the hospital is maintained in a manner to assure the safety and well being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

- Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

- Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations.

A-0319

§482.41(a)(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

Interpretive Guidelines §482.41(a)(1)

The hospital must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

Survey Procedures §482.41(a)(1)

Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

A-0320

§482.41(a)(2) There must be facilities for emergency gas and water supply.

Interpretive Guidelines §482.41(a)(2)

The hospital must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the hospital in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The hospital should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The hospital should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures §482.41(a)(2)

- Review the system used by hospital staff to determine the hospital's emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the hospital in need of care during emergencies.

- Determine the source of emergency gas and water, both the quantity of these supplies readily available at the hospital, and that are needed within a short time through additional deliveries.

- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.

A-0321

§482.41(b) Standard: Life Safety From Fire

A-0322

§482.41(b)(1) Except as otherwise provided in this section, the hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, and at the Office of the Federal Register, 800 North Capital Street N.W., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(i) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to hospitals.

Interpretive Guidelines §482.41(b)(1)(i)

Medicare-participating hospitals, regardless of size or number of beds, must comply with the hospital/healthcare Life Safety Code requirements for all inpatient care locations. Hospital departments and locations such as emergency departments, outpatient care locations, etc. must comply with hospital/healthcare Life Safety Code Requirements. Additionally, the hospital must be in compliance with all applicable codes referenced in the Life Safety Code, such as, NFPA-99: Health Care Facilities.

Survey Procedures §482.41(b)(1)(i)

There is a separate survey form, (Form CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code.

A-0323

§482.41(b)(1)(ii) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §482.41(b)(1)(ii)

Life Safety Code waivers may be recommended by the State survey agency but only CMS (at the regional office level) may grant those waivers for Medicare or Medicaid-participating hospitals.

Survey Procedures §482.41(b)(1)(ii)

Consideration, assessment, and recommendation for waivers of specific Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.

A-0324

§482.41(b)(1)(iii) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

A-0325

§482.41(b)(1)(iv) A hospital must be in compliance with the following provisions beginning on March 13, 2006:

(A) Chapter 19.3.6.3.2 exception number 2.

(B) Chapter 19.2.9 Emergency Lighting.

Interpretive Guidelines §482.41(b)(1)(iv)

§482.41(b)(1)(i) states "Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to hospitals." The wording in §482.41 (b)(1)(i) and §482.41 (b)(1)(i)(iv)(A) when used together means that after March 13, 2006 a hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf.

Beginning March 13, 2003, Medicare-participating hospitals must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101. Beginning March 13, 2006, Exception number 2 of chapter 19.3.6.3.2 **will not be allowed** in Medicare-participating hospitals.

Hospitals should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches **prior to** March 13, 2006.

Beginning March 13, 2006, Medicare-participating hospitals **must be in compliance** with Chapter 19.2.9 of the 2000 Edition of NFPA 101.

This section gives hospitals until March 31, 2006, to replace roller latches and to replace 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources. After March 13, 2006 a hospital with doors in service with roller latches or with emergency lighting systems with less than 1 ½ hour batteries will not be in compliance and will be cited at §482.41(b)(1)(i).

A-0326

§482.41(b)(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

Interpretive Guidelines §482.41(b)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Conditions of Participation for Radiology and Nuclear Medicine Services address handling and storage of radioactive materials.

Survey Procedures §482.41(b)(2)

Verify that the hospital has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the hospital has signage, as appropriate.

A-0327

§482.41(b)(1)(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.
Survey Procedures §482.41(b)(3)

- Review the hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.

- Verify that hospital staff reported all fires as required to State officials.

- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

A-0328

§482.41(b)(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

Survey Procedures §482.41(b)(4)

Examine copies of inspection and approval reports from State and local fire control agencies.

A-0329

§482.41(c) Standard: Facilities

The hospital must maintain adequate facilities for its services.

Interpretive Guidelines §482.41(c)

Adequate facilities means the hospital has facilities that are:

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and

- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Survey Procedures §482.41(c)

- Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

- Review the facility's water supply and distribution system to ensure that the water quality is acceptable for its intended use (drinking water, irrigation water, lab water, etc.). Review the facility water quality monitoring and, as appropriate, treatment system.

A-0330

§482.41(c)(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

Interpretive Guidelines §482.41(c)(1)

Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended.

Survey Procedures §482.41(c)(1)

Determine that x-ray, physical therapy, and other specialized services are provided in areas appropriate for the service provided.

A-0331

§482.41(c)(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

Interpretive Guidelines §482.41(c)(2)

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies must be maintained to ensure an acceptable level of safety and quality.

This would include that supplies are stored in such a manner to ensure the safety of the stored supplies (protection against theft or damage, contamination, or deterioration), as well as, that the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.).

Additionally, "supplies must be maintained to ensure an acceptable level of safety" would include that the hospital identifies the supplies it needs to meet its patients' needs for both day-to-day operations and those supplies that are likely to be needed in likely emergency situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc.; and that the hospital makes adequate provisions to ensure the availability of those supplies when needed.

Equipment must be maintained to ensure an acceptable level of safety and quality.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment

(e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services.

"Equipment must be maintained to ensure an acceptable level of safety" would include that the hospital identifies the equipment it needs to meet its patients' needs for both day-to-day operations and equipment that is likely to be needed in likely emergency/disaster situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc.; and that the hospital makes adequate provisions to ensure the availability of that equipment when needed.

Survey Procedures §482.41(c)(2)

- Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.

- Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.

- Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

- Are supplies maintained in such a manner as to ensure that safety?

- Are supplies stored as recommended by the manufacturer?

- Are supplies stored in such a manner as to endanger patient safety?

- Has the hospital identified supplies and equipment that are likely to be needed in emergency situations?

- Has the hospital made adequate provisions to ensure the availability of those supplies and equipment when needed?

A-0332

§482.41(c)(3) The extent and complexity of facilities must be determined by the services offered.

Interpretive Guidelines §482.41(c)(3)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §482.41(c)(3)

Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

A-0333

§482.41(c)(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §482.41(c)(4)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.); and
- Laboratory locations.

There must be adequate lighting in all the patient care areas, and food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote

patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into hospital policy.

The hospital must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §482.41(c)(4)

- Verify that all food and medication preparation areas are well lighted.

- Verify that the hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.

- Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on a nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.

- Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.

- Verify that each operating room has temperature and humidity control mechanisms.

- Review temperature and humidity tracking log(s) to ensure that appropriate temperature and humidity levels are maintained.

A-0338

§482.42 Condition of Participation: Infection Control

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

Interpretive Guidelines §482.42

This regulation requires the hospital to develop, implement and maintain an infection control program for the prevention, control, and investigation of infections (which includes, but is not limited to nosocomial infections) and communicable diseases of patients and personnel (which includes, but is not limited to patient care staff).

The hospital must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of **infections and communicable diseases** in the hospital. There must be a mechanism to evaluate the effectiveness of the program(s) and take corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases (e.g., the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc).

The active infection control program should have policies that address the following:

- Definition of nosocomial infections and communicable diseases;

- Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;

- Measures for identifying, investigations and controlling post-operative infections in outpatient surgery patients and post-operative infections in inpatients who are discharged soon after surgery;

- Measures for assessing and identifying patients and health care workers, including hospital personnel, contract staff (e.g., agency nurses, housekeeping staff) and volunteers, at risk for infections and communicable diseases;

- Methods for obtaining reports of infections and communicable diseases on inpatients, outpatients, and health care workers, including all hospital personnel, contract staff (e.g., agency nurses, housekeeping staff, etc) and volunteers, in a timely manner;

- Measures for the prevention of infections, especially infections caused by organisms that are antibiotic-resistant or in other ways epidemiologically important; device related infections e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc, surgical site infections; and those infections associated with tracheostomy care, respiratory

therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;

- Measures for prevention of communicable disease outbreaks, such as airborne diseases (TB, SARS, etc.), food borne diseases (Hepatitis A, Salmonella, etc.), blood borne diseases (HIV, Hepatitis B, etc.), and others (VRE, MRSA, pseudomonas, etc.).

- Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;

- Isolation procedures and requirements for infected or immunosuppressed patients;

- Use and techniques for standard precautions;

- Education of patients, family members and caregivers about infections and communicable diseases;

- Methods for monitoring and evaluating practices of asepsis;

- Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean items from dirty items, as well as other means for limiting the spread of contagion;

- Authority and indications for obtaining microbiological cultures from patients;

- A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children;

- Orientation of all new hospital personnel to infections, communicable diseases, and to the infection control program;

- Measures for the screening and evaluation of health care workers, including all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;

- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work;

- A procedure for meeting the reporting requirements of the local health authority;

- Procedures for working with local, State, and Federal health authorities in emergency preparedness situations;

- Policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and

- Provision for program evaluation and revision of the program, when indicated.

The hospital infection control program must be hospital-wide, include all locations, all campuses, all departments and services. It must include a program for the prevention, control, and investigation of infections and communicable diseases in patients and staff, including both patient care and non-patient care staff. In many circumstances, non-patient care staff can readily serve as a reservoir or a means of transmission of infections or communicable disease within the hospital environment.

The hospital's infection control program must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.42

- Survey of the Infection Control CoP should be coordinated by one surveyor. However, each surveyor as he/she conducts his/her survey assignments should assess the hospital's compliance with the Infection Control CoP.

- Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel, including contract workers and volunteers.

- Determine that this system is an active program, that it is both hospital-wide and program-specific, and that it is implemented correctly.

- Throughout the hospital, observe the environment of care, noting the cleanliness of horizontal surfaces, bedside equipment, and air inlets, etc, because infectious organisms may spread from these places.

- Verify that the hospital's infection control program is integrated into its hospital-wide QAPI program.

A-0339

§482.42(a) Standard: Organization and Policies

A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

Interpretive Guidelines §482.42(a)

The hospital must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers.

The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases.

Survey Procedures §482.42(a)

- Interview the infection control officer regarding the hospital's infection control program, hospital issues regarding infection control, and to verify and evaluate integration of the hospital infection control program into the hospital's QAPI program.

- Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.

- Review the personnel file of the infection control officer(s) to verify that he/she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

- Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.

A-0340

§482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §482.42(a)(1)

The infection control officer(s) is responsible for:

- Implementing policies governing asepsis, sterilization, and infection control;
- Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and hospital personnel, including contract staff and volunteers;
- Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and hospital personnel, including contract staff and volunteers, especially those occurring in clusters;
- Preventing and controlling the spread of infections and communicable diseases among patients and staff;
- Cooperating with hospital-wide orientation and in-service education programs;
- Cooperating with other departments and services in the performance of quality assurance activities;
- Cooperating with disease control activities of the local health authority; and
- Cooperating with Federal, State and local emergency preparedness and public health officials to develop and implement emergency preparedness programs regarding bioterrorism and communicable disease threats.

Survey Procedures §482.42(a)(1)

- Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.
- Determine if the hospital has an infection control committee. Review committee minutes to evaluate compliance with requirements.

A-0341

§482.42(a)(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

Interpretive Guidelines §482.42(a)(2)

The infection control officer or officers must maintain a **log of all incidents related to infections and communicable diseases**, including those identified through employee

health services. The log is not limited only to nosocomial infections. All incidents of infection and communicable disease must be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non patient care, employees, contract staff and volunteers). This would include incidents of post-operative infections in inpatients who are discharged soon after surgery or outpatients who received outpatient surgery.

Survey Procedures §482.42(a)(2)

Verify that the infection control officer(s) maintains a log of all incidents related to infections and communicable diseases, including those identified through employee health services.

A-0342

§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services

The chief executive officer, the medical staff, and the director of nursing must--

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

Interpretive Guidelines §482.42(b)

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection control program.

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Survey Procedures §482.42(b)

- Determine that the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s).

- Determine that problems identified are reported to the medical staff, nursing and administration, and addressed in the hospital's quality assurance and in-service training programs.

A-0349

§482.43 Condition of Participation: Discharge Planning

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

Interpretive Guidelines §482.43

This CoP applies to all types of hospitals and requires all hospitals to conduct appropriate discharge planning activities for all inpatients. It applies to patients who are admitted to the hospital as inpatients. This CoP does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients.

The written discharge planning process must reveal a thorough, clear, comprehensive process that is understood by the hospital staff.

Adequate discharge planning is essential to the health and safety of all patients. Patients may suffer adverse health consequences upon discharge without benefit of appropriate planning. Such planning is vital to mapping a course of treatment aimed at minimizing the likelihood of having any patient rehospitalized for reasons that could have been prevented.

Survey Procedures §482.43

- Review hospital written policies and procedures to determine the existence of a discharge planning process.

- Review patient care plans for discharge planning interventions.

- Interview a sample of hospital staff that are involved in direct patient care. Ask the following questions:

    - How is discharge planning conducted at this hospital?

    - How are you kept apprised of the hospital's policies and procedures for discharge planning?

    - How is this communicated and integrated into a plan of care?

A-0350

§482.43(a) Standard: Identification of Patients in Need of Discharge Planning

The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

Interpretive Guidelines §482.43(a)

Medicare participating hospitals are afforded great flexibility in setting the criteria for identifying patients who are likely to suffer adverse health consequences upon discharge without adequate discharge planning. Presently there is no nationally accepted tool or criteria for identifying these individuals. However, the following factors have been identified as important: functional status, cognitive ability of the patient, and family support. Patients at high-risk of requiring post-hospital services must be identified through a screening process. The hospital should reevaluate the needs of the patients on an ongoing basis, and prior to discharge, as they may change based on the individual's status.

There is no set time frame for identification of patients requiring a discharge planning evaluation other than it must be done as early as possible. The timing is left up to the hospital, its staff, and attending MD/DO.

Survey Procedures §482.43(a)

- Interview staff. How are the patients who are in need discharge planning identified?
- Review the hospital's high-risk screening procedure.
    - Does it identify patients who need discharge planning evaluations?
    - How does the hospital's high-risk screening procedure work?
    - What staff are involved? Who is ultimately accountable?
    - Who evaluates the procedure to make sure patients are appropriately evaluated and that patients do not suffer adverse consequences due to lack of or insufficient discharge planning?

A-0351

§482.43(b) Standard: Discharge Planning Evaluation

(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

Interpretive Guidelines §482.43(b)(1)

The needs assessment can be formal or informal. A needs assessment generally includes an assessment of factors that impact on a patient's needs for care after discharge from the acute care setting. These may include assessment of biopsychosocial needs, the patient's and caregiver's understanding of discharge needs, and identification of post-hospital care resources.

At the present time, there is no nationally accepted standard for the evaluation. The purpose of a discharge planning evaluation is to determine continuing care needs after the patient leaves the hospital setting. It is not intended to be a care-planning document. The hospital may develop an evaluation tool or protocol.

Survey Procedures §482.43(b)(1)

- Interview a sample of hospital staff and ask: How are patients and caregivers made aware of their rights to request a discharge plan?

- Talk to a sample of patients and family members who are expecting a discharge soon and ask:

    - Did the hospital staff assist them in planning for post-hospital care? Does the patient/family express that they feel prepared for discharge?

    - Are you given the pamphlet, "Important Message from Medicare?"

    - Are you aware that you may request assistance with discharge planning?

A-0352

§482.43(b)(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

Interpretive Guidelines §482.43(b)(2)

The responsibility for discharge planning is often multidisciplinary. It is not restricted to a particular discipline. The hospital has flexibility in designating the responsibilities of the registered nurse, social worker, or other appropriate qualified personnel for discharge planning. The responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge clinical and social needs.

Ideally, discharge planning will be an interdisciplinary process, involving disciplines with specific expertise, as dictated by the needs of the patient. For example, for a patient with emphysema, the discharge planner could coordinate respiratory therapy and nursing care, and financial coverage for home care services and oxygen equipment, and patient/caregiver education utilizing cost effective, available community services in an expedient manner.

Survey Procedures §482.43(b)(2)

- Review the written policy and procedure that designates discharge-planning responsibilities.

- Determine who is responsible for discharge planning. Ask the designated personnel to describe their qualifications for and experience with discharge planning and evaluate whether they are familiar with the community standard of practice. If needed, review the job descriptions of the designated personnel for discharge planning expectations. If licensing is required, current credentials must be on file.

A-0353

§482.43(b)(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.

Interpretive Guidelines §482.43(b)(3)

The hospital is responsible for developing the discharge plan for patients who need a plan and for arranging its initial implementation. The hospital's ability to meet discharge planning requirements is based on the following:

- Implementation of a needs assessment process with identified high risk criteria;

- Evidence of a complete, timely, and accurate assessment;

- Maintenance of a complete and accurate file on community-based services and facilities including long term care, sub acute care, home care or other appropriate levels of care to which patients can be referred; and

- Coordination of the discharge planning evaluation among various disciplines responsible for patient care.

Survey Procedures §482.43(b)(3)

- What is the process the hospital uses to identify patients who need a discharge plan?

- Does the hospital use its QAPI program to determine whether the discharge planning process effectively identifies patients in need of plans, and whether the plans are adequate and appropriately executed?

- Ascertain whether various disciplines are involved with discharge planning, including physical, speech, occupational, and respiratory therapists and dietitians, in addition to MD/DOs, nurses, and social workers.

A-0354

§482.43(b)(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

Interpretive Guidelines §482.43(b)(4)

The capacity for self-care includes the ability and willingness for such care. The choice of a continuing care provider depends on the self-care components, as well as, availability, willingness, and ability of family/caregivers and the availability of resources. The hospital must inform the patient or family as to their freedom to choose among providers of post-hospital care. Patient preferences should also be considered; however, preferences are not necessarily congruent with the capacity for self- care.

Patients should be evaluated for return to the pre-hospital environment, but also should be offered a range of realistic options to consider for post-hospital care. This includes patients admitted to a hospital from a SNF, who should be evaluated to determine an appropriate discharge site.

Hospital staff should incorporate information provided by the patient and/or caregivers to implement the process.

The Social Security Act (SSA) at §1861(ee) requires Medicare participating hospitals, as part of their discharge planning evaluations, share with each patient, as appropriate, a list of Medicare-certified home health agencies (HHA) that serve the geographic area in which the patient resides and that request to be included on the list. In addition the SSA prohibits hospitals from limiting or steering patients to any particular HHA and must identify those HHA to whom the patient is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.

The SSA, section 1861(ee) requires a hospital's discharge plan to include an evaluation of the patient's likely need for hospice care and post-hospital extended care services and to provide a list of the available Medicare certified hospice and SNFs that serve the geographic area requested by the patient. In addition, the discharge plan shall not specify or limit qualified hospice or SNFs and must identify those entities to whom the patient is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.

Therefore, we expect hospitals to provide a list of Hospice, HHAs or SNFs that are available to the patient, that participate in the Medicare program, and that serve the geographic area that the patient requests. The list must be presented only to patients for whom post-hospital Hospice services, HHA services or SNF extended care services are indicated and appropriate as determined by the discharge planning evaluation. It is not expected that patients without a need for post-hospital Hospice services, HHA services, or SNF extended care services would receive the list. The hospital must document in the patient's medical record that a list of Hospices, HHAs or SNFs was presented to the patient or individual acting on the patient's behalf. This serves as documentation that the requirement was met. Finally, the hospital has the flexibility to develop and maintain its own list of Hospices or SNFs; or in the case of SNF, simply print a list from the Nursing Home Compare site on the CMS Web site, http://www.medicare.gov/ based on the geographic area that the patient requests.

Survey Procedures §482.43(b)(4)

- Review a sample of discharge planning evaluations.
    - Gather information about the patient's self-care capacity from the clinical record, direct clinical observation, and information obtained from the patient, caregiver, and staff involved in the care of the patient; judge appropriateness of discharge disposition.
    - Note if appropriate interdisciplinary input is documented.
    - Did the patient and/or caregiver participate in the needs assessment and decision for post-hospital care resources?

- Is a patient who was admitted from a home or another setting given a full-range of realistic options for post-hospital continuation of care?

- Interview patients who the discharge evaluation identified as needing home health services. Was a list of Medicare certified HHA providers that serve the geographic area in which the patient resides presented to the patient or the individual acting on the patient's behalf? Was the patient's choice of HHA respected, when possible? Was the choice of HHA limited? Was the patient inappropriately steered to a particular HHA? Was the patient informed of any HHA in which the hospital has a financial interest?

- Interview patients who the discharge evaluation identified as needing hospice care or post-hospital extended care SNF services. Was a list of Medicare certified Hospice or skilled nursing facilities that serve the geographic area in which the patient resides presented to the patient or individual acting on the patient's behalf? Was the patient's choice of Hospice or SNF respected, when possible? Was the choice of Hospice or SNF limited? Was the patient inappropriately steered to a particular Hospice or SNF? Was the patient informed of any Hospice or SNF in which the hospital has a financial interest?

A-0355

§482.43(b)(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

Interpretive Guidelines §482.43(b)(5)

Patient hospital length of stay varies widely. The timing of the discharge evaluation should be relative to the patient's clinical condition and anticipated length of stay. Assessment should start as soon after admission as possible and be updated periodically during the episode of care.

Information about the patient's age and sex could be collected on admission while functional ability data is best collected closer to discharge, indicating more accurately a patient's continuing care requirements.

Survey Procedures §482.43(b)(5)

- Review several patients' discharge plans for the appropriate coordination of health and social care resources based on the individual patient and caregiver's expected post-hospital needs.

- Is there a pattern of prolonged length of stay for certain patient populations because the evaluation for post-hospital care was delayed? If so, is the delay due to circumstances beyond the hospital's control (e.g., inability to reach the beneficiary's responsible person(s), continuing change in the patient's condition, and/or is the delay due to poor hospital planning for timely post-hospital arrangements)?

A-0356

§482.43(b)(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

Interpretive Guidelines §482.43(b)(6)

The hospital must demonstrate its development of discharge plan evaluation for patients in need and then must discuss the results of the evaluation with the patient or individual acting on his/her behalf. Documentation of these activities is expected.

The discharge plan evaluation is generally found in the clinical notes if there is no dedicated form. The hospital will be expected to document its decision about the need for a plan, document the existence of plans when needed, and indicate what steps were taken to implement the plans initially. Evidence of an ongoing evaluation of the discharge planning needs of the patient is the important factor.

Documented evidence of discussion of the discharge planning evaluation with the patient, if possible, and interested persons should exist in the medical record. Although not mandated by this CoP, it is preferable that the hospital staff seek information from the patient and family to make the discharge planning evaluation as realistic and viable as possible. The Patients' Rights CoP (§482.13) does provide the patient the right to participate in the development of their plan of care. Discharge planning is considered a part of the plan of care.

Survey Procedures §482.43(b)(6)

- Review several clinical records for evidence of a discharge planning evaluation.

- Through review of the clinical record notes and questioning of the patient and/or caregiver and staff, verify discussion of the evaluation with the involved persons.

A-0357

§482.43(c) Standard: Discharge Plan

A-0358

§482.43(c)(1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

Interpretive Guidelines §482.43(c)(1)

It is a management function of the hospital to ensure proper supervision of its employees. Existing training and licensing requirements of a registered nurse and social worker in discharge planning are sufficient. "Other appropriately qualified personnel" may include an MD/DO. The hospital should determine who has the requisite knowledge and skills to do the job regardless of how these were acquired. However, because post-hospital services and, ultimately, the patient's recovery and quality of life can be affected by the discharge plan, the plan should be supervised by qualified personnel to ensure professional accountability.

The hospital CoP at §482.13(b): Patients' Rights states that "The patient has the right to participate in the development and implementation of his or her plan of care." (CMS views discharge planning as part of the patient's plan of care). "The patient or his/her representative (as allowed under State law) has the right to make informed decisions regarding his/her care" and "The patient's rights include...being involved in care planning and treatment."

Survey Procedures §482.43(c)(1)

- Examine patients' clinical records for references to a registered nurse, social worker, or other designated qualified personnel or their signature on a written discharge plan notation.

- Ask staff to describe who oversees the development of a discharge plan.

A-0359

§482.43(c)(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

Interpretive Guidelines §482.43(c)(2)

The physician can make the final decision as to whether a discharge plan is necessary. The hospital will develop a plan if a physician requests one even if the interdisciplinary team had determined one to be unnecessary.

Survey Procedures §482.43(c)(2)

- Review the hospital policy and procedure to determine who may request a discharge plan.

- Is there reference to or existence of a discharge plan in the clinical record when requested by a physician?

- Ask a physician involved with discharge planning about experiences with requesting development of discharge plans when the interdisciplinary team does not recommend a plan.

A-0360

§482.43(c)(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

Interpretive Guidelines §482.43(c)(3)

The hospital is required to arrange for the initial implementation of the discharge plan. This includes arranging for necessary post-hospital services and care, and educating patient/family/caregivers/community providers about post-hospital care plans.

Survey Procedures §482.43(c)(3)

- Review a sample of patient records. Determine if there is documented evidence of implementation of the discharge plan, including contact and transmission of information to the patient (when possible) and the next caregiver. Ask staff responsible for the patient's care to describe the steps taken to implement the plan initially for the patients.

- Interview the patient or caregiver regarding implementation of the plan by facility staff.

A-0361

§482.43(c)(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

Interpretive Guidelines §482.43(c)(4)

The discharge plan should be initiated as soon as possible after admission. As changes in the patient's condition and needs occur, the discharge plan must be reassessed and updated to address those changes.

Survey Procedures §482.43(c)(4)

- Review the hospital's policy on reassessment of discharge plans.
- Review several clinical records for evidence of reassessment of the patient and related changes with regard to the care plan/critical pathway(s) in the discharge plan when warranted.
- Ask staff involved with discharge planning to discuss the reassessment process and/or present a clinical record that documents reassessment.

A-0362

§482.43(c)(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

Interpretive Guidelines §482.43.(c)(5)

Evidence should exist that the patient and/or family and/or caregiver is/are provided information and instructions in preparation for post-hospital care and kept informed of the progress. It is important that the patient and caregivers who are expected to provide the care know, and as appropriate, can demonstrate or verbalize the care needed by the patient.

Use of family caregivers in providing post-hospital care should occur when the family is both willing and able to do so. It is appropriate to use community resources with or without family support whenever necessary.

Survey Procedures §482.43(c)(5)

Where possible, interview patients and their family members to determine whether they have been instructed in post-hospital care. Potential training could include the timing and dosage of medications, the wide effects of medications, treatments, and therapy regimens.
If the patient is being transferred to an alternate care delivery setting, has this information been shared with the patient?

A-0363

§482.43(d) Standard: Transfer or Referral

The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

Interpretive Guidelines §482.43(d)

The hospital must ensure that patients receive proper post-hospital care within the constraints of a hospital's authority under State law and within the limits of a patient's right to refuse discharge-planning services. If a patient exercises the right to refuse discharge planning or to comply with a discharge plan, documentation of the refusal is recommended.

"Medical information" may be released only to authorized individuals according to provision §482.24(b)(3). Examples of necessary information include functional capacity of the patient, requirements for health care services procedures, discharge summary, and referral forms.

"Appropriate facilities" refers to facilities that can meet the patient's assessed needs on a post-discharge basis and that comply with Federal and State health and safety standards.

Survey Procedures §482.43(d)

- Ask staff involved with discharge planning to describe the process of transfer of patient information from the hospital to a post-discharge facility.
- Does the process assure continuity of care?
- Are the patient's rights, such as for confidentiality, refusal, and preference considered?
- If required, is there evidence of written authorization by the patient before release of information?
- Is there documentation that care instruction has been communicated to the post hospital care setting?

A-0364

§483.43(e) Standard: Reassessment

The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

Interpretive Guidelines §483.43(e)

The hospital's discharge planning process must be integrated into its QAPI program.

The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process. Although specific parameters or measures that would be included in a reassessment are not required, the hospital should assure the following factors in the reassessment process:

- Time effectiveness of the criteria to identify patients needing discharge plans;
- The quality and timeliness for discharge planning evaluations and discharge plans;
- The hospital discharge personnel maintain complete and accurate information to advise patients and their representatives of appropriate options; and
- The hospital has a coordinated discharge planning process that integrates discharge planning with other functional departments, including the quality assurance and utilization review activities of the institution and involves various disciplines.

Survey Procedures §482.43(e)

- Review hospital policies and procedures to determine how often the discharge planning process is reassessed.
- Does the hospital's QAPI program determine whether its discharge planning process effectively identifies patients who need discharge planning, whether the plans are adequate and whether the plans are effectively executed?
- Ask hospital staff how often the discharge planning process is reassessed. What data is examined to determine how well the process is working in providing for continued care of the patient?

A-0369

§482.45 Condition of Participation: Organ, Tissue and Eye Procurement

A-0370

§482.45(a) Standard: Organ Procurement Responsibilities

The hospital must have and implement written protocols that:

Interpretive Guidelines §482.45(a)

The hospital must have written policies and procedures to address its organ procurement responsibilities.

A-0371

§482.45(a)(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

Interpretive Guidelines §482.45(a)(1)

The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital;
- Includes a definition of “imminent death”;
- Includes a definition of “timely notification”;
- Addresses the OPO’s responsibility to determine medical suitability for organ donation;

- Specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s);

- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;

- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the hospital;

- Permits the OPO, tissue bank, and eye bank access to the hospital's death record information according to a designated schedule, e.g., monthly or quarterly;

- Includes that the hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and

- The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable.

Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital's medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the hospital's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;

- Is in an intensive care unit (ICU) or emergency department; **AND**

- Exhibits clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**

- MD/DOs are evaluating a diagnosis of brain death; **or**

- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

Hospitals and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glascow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital's OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each hospital.

Hospitals may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital's responsibility to notify the OPO.

"**Timely notification**" means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the hospital does not consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the

option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

Survey Procedures §482.45(a)(1)

- Review the hospital's written agreement with the OPO to verify that it addresses all required information.

- Verify that the hospital's governing body has approved the hospital's organ procurement policies.

- Review a sample of death records to verify that the hospital has implemented its organ procurement policies.

- Interview the staff to verify that they are aware of the hospital's policies and procedures for organ, tissue and eye procurement.

- Verify that the organ, tissue and eye donation program is integrated into the hospital's QAPI program.

A-0372

§482.45(a)(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretative Guidelines §482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §482.45(a)(2)

Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. The agreement should also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

A-0373

§482.45(a)(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate.

Interpretive Guidelines §482.45(a)(3)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.

Survey Procedures §482.45(a)(3)

- Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.

- Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate?

A-0374

§482.45(a)(3) continued
The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §482.45(a)(3)

The individual designated by the hospital to initiate the request to a family must be an organ procurement representative, an **organizational representative of a tissue or eye bank**, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.

The individual designated by the hospital to initiate the request to the family must be an OPO, tissue bank, or eye bank representative or a designated requestor. A "**designated requestor**" is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached. If possible, the OPO representative and a designated requestor should approach the family together.

The hospital must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §482.45(a)(3)

- Review training schedules and personnel files to verify that all designated requestors have completed the required training.

- How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate?

A-0375

§482.45(a)(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

Interpretive Guidelines §482.45(a)(4)

Using discretion does not mean a judgment can be made by the hospital that certain families should not be approached about donation. Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §482.45(a)(4)

- Interview a hospital-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the hospital's complaint file for any relevant complaints.

A-0376

§482.45(a)(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues;

Interpretive Guidelines §482.45(a)(5)

Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;

- Quality improvement activities; and

- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's QAPI program.

Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.

Survey Procedures §482.45(a)(5)

- Review in-service training schedules and attendance sheets.

- How does the hospital ensure that all appropriate staff has attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?

A-0377

§482.45(a)(5) continued
Reviewing death records to improve identification of potential donors; and

Interpretive Guidelines §482.45(a)(5)

Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

Survey Procedures §482.45(a)(5)

- Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.

- Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.

- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.

- Determine how confidentiality is ensured.

A-0378

§482.45(a)(5) continued
Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

Interpretive Guidelines §482.45(a)(5)

The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs. The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §482.45(a)(5)

- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

- Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.

A-0379

§482.45(b) Standard: Organ Transplantation Responsibilities

(1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ transplant related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

Interpretive Guidelines §482.45(b)

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

Survey Procedures §482.45(b)

Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.

A-0384

§482.51 Condition of Participation: Surgical Services

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

Interpretive Guidelines §482.51

The provision of surgical services is an optional hospital service. However, if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

If surgical services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.)

Outpatient surgical services must be in compliance with all hospital CoPs including the surgical services CoP. Outpatient surgical services must be provided in accordance with acceptable standards of practice. Additionally, the hospital's outpatient surgical services must be consistent in quality with the hospital's inpatient surgical services. Post-operative care planning, coordination for the provision of needed post-operative care and appropriate provisions for follow-up care of outpatient surgery patients must be consistent in quality with inpatient care in accordance with the complexity of the services offered and the needs of the patient.

The hospital's inpatient and outpatient surgical services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.51

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:

    - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;

    - The conformance to aseptic and sterile technique by all individuals in the surgical area;

    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

    - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;

    - That equipment is available for rapid and routine sterilization of operating room materials;

    - That equipment is monitored, inspected, tested, and maintained by the hospital's biomedical equipment program and in accordance with Federal and State law, regulations and guidelines and manufacturer's recommendations;

    - That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- That temperature and humidity are monitored and maintained within accepted standards of practice;

- That medical/surgical devices and equipment are checked and maintained routinely by clinical/biomedical engineers.

- Verify that all surgical service activities and locations are integrated into the hospital-wide QAPI program.

A-0385

§482.51(a) Standard: Organization and Staffing

The organization of the surgical services must be appropriate to the scope of the services offered.

Interpretive Guidelines §482.51(a)

When the hospital offers surgical services, the hospital must provide the appropriate equipment and the appropriate types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.

The scope of surgical services provided by the hospital should be defined in writing and approved by the medical staff.

Survey Procedures §482.51(a)

Review the hospital's organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

A-0386

§482.51(a)(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

Interpretive Guidelines §482.51(a)(1)

The operating room (inpatient and outpatient) must be supervised by an experienced RN or MD/DO. The RN or MD/DO supervising the operating room must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The

hospital should address its required qualifications for the supervisor of the hospital's operating rooms in its policies and the supervisor's personnel file should contain information demonstrating compliance with the hospital's established qualifications.

Survey Procedures §482.51(a)(1)

- Verify that an RN or a doctor of medicine or osteopathy is assigned responsibility for supervision of the operating rooms.

- Request a copy of the supervisor's position description to determine that it specifies qualifications, duties and responsibilities of the position. Verify that the supervisor is experienced and competent in the management of surgical services.

A-0387

§482.51(a)(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

Interpretive Guidelines §482.51(a)(2)

If the hospital utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care.

Survey Procedures §482.51(a)(2)

- Determine that an RN is available for supervision in the department or service. Validate the availability by requesting and reviewing a staffing schedule for the OR.

- Review staffing schedules to determine adequacy of staff and RN supervision.

A-0388

§482.51(a)(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

Interpretive Guidelines §482.51(a)(3)

The circulating nurse must be an RN. An LPN or surgical technologist may assist an RN in carrying out circulatory duties (in accordance with applicable State laws and medical-

staff approved hospital policy) but the LPN or surgical technologist must be under the supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist. The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties.

Survey Procedures §482.51(a)(3)

- If LPNs and surgical technologists (STs) are assisting with circulating duties, verify that they do so in accordance with applicable State laws and medical-staff approved policies and procedures.

- Verify in situations where LPNs and STs are permitted to assist with circulating duties that a qualified RN supervisor is immediately available to respond to emergencies.

- Verify that RNs working as circulating nurses are working in accordance with applicable State laws and medical-staff approved policies and procedures.

A-0389

§482.51(a)(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

Interpretive Guidelines §482.51(a)(4)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal

procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised) be delineated in that practitioner's surgical privileges and included on the surgical roster.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges.

Survey Procedures §482.51(a)(4)

- Review the hospital's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

A-0390

§482.51(b) Standard: Delivery of Service

Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

Interpretive Guidelines §482.51(b)

Policies governing surgical care should contain:

- Aseptic and sterile surveillance and practice, including scrub techniques;
- Identification of infected and non-infected cases;
- Housekeeping requirements/procedures;
- Patient care requirements:
    - Preoperative work-up;
    - Patient consents and releases;
    - Clinical procedures;
    - Safety practices;
    - Patient identification procedures;
- Duties of scrub and circulating nurse;
- Safety practices;
- The requirement to conduct surgical counts in accordance with accepted standards of practice;
- Scheduling of patients for surgery;
- Personnel policies unique to the O.R.;
- Resuscitative techniques;
- DNR status;

- Care of surgical specimens;
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment;
- Sterilization and disinfection procedures;
- Acceptable operating room attire;
- Handling infections and biomedical/medical waste; and
- Outpatient surgery post-operative care planning and coordination, and provisions for follow-up care.

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Survey Procedures §482.51(b)

Review policies and procedures, ascertain whether they contain the minimum policies specified in the interpretive guidelines.

A-0391

§482.51(b)(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

Interpretive Guidelines §482.51(b)(1)

There must be a complete history and physical examination (H & P) in the medical record of every patient prior to surgery, except in emergencies.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

An H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND

- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48 hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the reason the patient was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND

- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P (update assessments and update notes are considered part of the H & P). This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P and/or the update assessment and note.

Survey Procedures §482.51(b)(1)

Review a minimum of six medical records of surgical patients to determine if a complete history and physical examination by a doctor of medicine or osteopathy is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

A-0392

§482.51(b)(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

Interpretive Guidelines §482.51(b)(2)

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues);
- Risks;
- Alternative procedures and treatments;
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Consent would not be considered informed consent in situations where the patient consents to a procedure and information was withheld from the patient, where if the

patient had been informed of the withheld information, the patient may not have consented to the procedure or made the same decisions.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Survey Procedures §482.51(b)(2)

Review a minimum of six random medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

A-0393

§482.51(b)(3) The following equipment must be available to the operating room suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

Survey Procedures §482.51(b)(3)

- Check to determine that the operating room suite has available the items listed:
    - On-call system;
    - Cardiac monitor;

- Resuscitator;
- Defibrillator;
- Aspirator (suction equipment);
- Tracheotomy set (a cricothyroidotomy set is not a substitute)

Verify that all equipment is working and, as applicable, in compliance with the hospital's biomedical equipment inspection, testing, and maintenance program.

A-0394

§482.51(b)(4) There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
  - Level of activity;
  - Respirations;
  - Blood pressure;
  - Level of consciousness;
  - Patient color;
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by a qualified RN in the patient's room.

Survey Procedures §482.51(b)(4)

- Verify that the hospital has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room area.

A-0395

§482.51(b)(5) The operating room register must be complete and up to date.

Interpretive Guidelines §482.51(b)(5)

The register includes at least the following information:

- Patient's name;
- Patient's hospital identification number;
- Date of the operation;
- Inclusive or total time of the operation;
- Name of the surgeon and any assistant(s);
- Name of nursing personnel (scrub and circulating);
- Type of anesthesia used and name of person administering it;
- Operation performed;
- Pre and post-op diagnosis;
- Age of patient.

Survey Procedures §482.51(b)(5)

Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

A-0396

§482.51(b)(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

Interpretive Guidelines §482.51(b)(6)

The operative report includes at least:

- Name and hospital identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §482.51(b)(6)

Review a minimum of six random medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

A-0416

§482.52 Condition of Participation: Anesthesia Services

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

Interpretive Guidelines §482.52

The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

The hospital's anesthesia services must be integrated into the hospital-wide QAPI program.

The anesthesia services must be under the direction of a qualified MD/DO. The hospital's medical staff establishes criteria for the qualifications for the director of the anesthesia services in accordance with State laws and acceptable standards of practice. A single anesthesia director must be responsible for the single hospital-wide anesthesia service.

The single anesthesia service is responsible for all anesthesia administered in the hospital. The anesthesia service must be organized and staffed in such a manner as to ensure the health and safety of patients.

Survey Procedures §482.52

- Request a copy of the organizational chart for anesthesia services. Determine that a doctor of medicine or osteopathy has the authority and responsibility for directing the administration of all anesthesia throughout the hospital.

- Request evidence of the director's appointment. Review the position description. Confirm that the director's responsibilities include at least the following:

    - Planning, directing, and supervising all activities of the service

    - Establishing staffing schedules, including written on-call schedule for anesthesia coverage when the department is normally closed

    - Monitoring of the quality and appropriateness of the anesthesia patient care

- Evidence of responsibility for anesthesia services delivered in all areas of the hospital where applicable:
    - Operating room suite(s), both inpatient and outpatient;
    - Obstetrical suite(s);
    - Radiology department;
    - Clinics;
    - Outpatient surgery areas.
- Verify that anesthesia services is integrated into the hospital-wide QAPI program.

A-0417

§482.52(a) Standard: Organization and Staffing

The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by --

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

§482.52(c) Standard: State Exemption

(1) A hospital may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the

best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.]

(5) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

Interpretive Guidelines §482.52(a)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The hospital must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and hospital policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and hospital policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies, education and training of the practitioner and the practitioner's compliance with the hospital's credentialing criteria.

When a hospital permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §482.52(c)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. " Immediately available" to intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit;
- Prepared to immediately conduct hands-on intervention if needed; and
- Not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

Survey Procedures §482.52(a)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

A-0418

§482.52(b) Standard: Delivery of Services

Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

Interpretive Guidelines §482.52(b)

Policies at a minimum address:

- The qualifications, responsibilities and supervision required of all personnel who administer anesthesia;
- Patient consent;
- Infection control measures;
- Safety practices in all anesthetizing areas;
- Protocol for supportive life functions, e.g., cardiac and respiratory emergencies;
- Reporting requirements;
- Documentation requirements;
- Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia equipment in the hospital's biomedical equipment program.

Survey Procedures §482.52(b)

Review the policies developed on anesthesia procedures. Determine that the anesthesia service incorporates the minimum policies identified in interpretive guidelines.

A-0419

§482.52(b)(1) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

Interpretive Guidelines §482.52(b)(1)

The pre-anesthesia evaluation must be performed within 48 hours of inpatient or out-patient surgery. An individual qualified to administer anesthesia in accordance with §482.52(a) must perform the pre-anesthesia evaluation. At a minimum, the pre-operative anesthetic evaluation includes:

- Notation of anesthesia risk;
- Anesthesia, drug and allergy history;
- Any potential anesthesia problems identified;
- Patient's condition prior to induction of anesthesia

Survey Procedures §482.52(b)(1)

Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed within 48 hours prior to surgery.

A-0420

§482.52(b)(2) An intraoperative anesthesia record.

Interpretive Guidelines §482.52(b)(2)

The intraoperative anesthesia record includes at a minimum:

- Name and hospital identification number of the patient;
- Name of practitioner who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;
- Name, dosage, route and time of administration of drugs and anesthesia agents;
- IV fluids;

- Blood or blood products, if applicable;

- Oxygen flow rate;

- Continuous recordings of patient status noting blood pressure, heart and respiration rate; and

- Any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

Survey Procedures §482.52(b)(2)

Review records to determine that each patient has an intraoperative anesthesia record documenting all pertinent events taking place during anesthesia.

A-0421

§482.52(b)(3) With respect to inpatients, a post-anesthesia follow-up report by the individual who administers the anesthesia that is written within 48 hours after surgery.

Interpretive Guidelines §482.52(b)(3)

The post-anesthesia follow-up report must be written within 48 hours after the inpatient surgery. The follow-up report must be written by the individual who administered the anesthesia or in accordance with §482.12(c)(1)(i), an MD/DO may delegate the post-anesthesia assessment and writing the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and hospital policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. At a minimum, the post-anesthesia follow-up report documents the following:

- Cardiopulmonary status;

- Level of consciousness;

- Any follow-up care and/or observations;

- Any complications occurring during post-anesthesia recovery

Survey Procedures §482.52(b)(3)

Review records to determine that a post-anesthesia follow-up report is written for each patient by the individual who administered the anesthesia, or by a delegated practitioner

who is qualified to administer anesthesia, within 48 hours after surgery. Documentation should include those items specified in interpretive guidelines.

A-0422

§482.52(b)(4) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

Interpretive Guidelines §482.52(b)(4)

A post-anesthesia evaluation must be conducted on patients who have had outpatient surgery. The evaluation must be documented in the patient's medical record. The evaluation must be performed in accordance with policies and procedures approved by the medical staff and in accordance with State law and acceptable standards of practice.

At a minimum, the outpatient surgery post-anesthesia evaluation includes and documents:

- Cardiopulmonary status;
- Level of consciousness;
- Any complications occurring during post-anesthesia recovery; and
- Any follow-up care needed or patient instructions given.

Survey Procedures §482.52(b)(4)

Review records to determine that outpatients have a post-anesthesia evaluation for proper anesthesia recovery in accordance with hospital policies and procedures. Depending on the type of anesthesia and length of surgery, the post-operative check should include the items listed in the interpretive guidelines.

A-0428

§482.53 Condition of Participation: Nuclear Medicine Services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretative Guidelines §482.53

This is an optional hospital service. However, if a hospital provides any degree of nuclear medicine services to its patients, the hospital must comply with the requirements of this Condition of Participation.

The hospital's nuclear medicine services must be integrated into its hospital-wide QAPI program.

If nuclear medicine services are provided under arrangement, the governing body must ensure that the services are provided in a safe and effective manner, in accordance with §482.12(e).

Nuclear medicine services must be provided in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing the use of nuclear medicine, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc).

Survey Procedures §482.53

- Determine if the hospital provides nuclear medicine services. If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided.

- Determine if the hospital's nuclear medicine services are integrated into its hospital-wide QAPI program.

A-0429

§482.53(a) Standard: Organization and Staffing

The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

Interpretive Guidelines §482.53(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.

The scope of nuclear medicine services offered by the hospital should be defined in writing, and approved by the Medical staff.

Survey Procedures §482.53(a)

Review the hospital policies & procedures to verify that the scope of the nuclear medicine services offered is defined in writing.

A-0430

§482.53(a)(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

Interpretive Guidelines §482.53(a)(1)

The nuclear medicine service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine, appropriate to the scope and complexity of services offered.

Survey Procedures §482.53(a)(1)

Review the service director's credentialing file to verify that he/she is a M.D. or D.O. and has the necessary education, experience and specialized training in nuclear medicine, appropriate to the scope and complexity of services offered.

A-0431

§482.53(a)(2) The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.

Interpretive Guidelines §482.53(a)(2)

The hospital must have written policies, developed and approved by the nuclear medicine service director and medical staff, that specify the qualifications, training, functions and experience of personnel responsible for performing each type of nuclear medicine procedure. Qualifications include at a minimum, job title, education, experience, specialized training, and licensure/certification, consistent with Federal and State law.

Survey Procedures §482.53(a)(2)

- Review personnel files for nuclear medicine staff to verify that they meet the necessary qualifications, specified by the medical staff, to perform their specified duties and responsibilities.

- Verify that the qualifications, training, functions and responsibilities of nuclear medicine staff are specified by the director and approved by the medical staff.

A-0432

§482.53(b) Standard: Delivery of Service

Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

Interpretive Guidelines §482.53(b)

The hospital must establish, in writing, safety standards for radioactive materials that address, at a minimum:

- Handling of equipment and radioactive materials;
- Protection of patients and personnel from radiation hazards;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

The hospital must implement and ensure compliance with its established safety standard

Survey Procedures §482.53(b)

- Verify that safety precautions are followed in the functioning of the nuclear medicine service and that personnel and patients wear appropriate body shielding (e.g., lead aprons or lead gloves) when appropriate.
- Verify that radioactive materials are prepared, labeled, used, transported, stored and disposed of in accordance with Federal and State laws and regulations and acceptable standards of practice.

A-0433

§482.53(b)(1) In-house preparation of radio pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

Interpretive Guidelines §482.53(b)(1)

In-house preparation of radio pharmaceuticals must be performed by, or directly supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law.

Survey Procedures §482.53(b)(1)

If radio pharmaceuticals are prepared in-house, determine that the preparation is performed by, or directly supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, consistent with Federal and State law.

A-0434

§482.53(b)(2) There is proper storage and disposal of radioactive material.

Survey Procedures §482.53(b)(2)

- Verify through observation and document review that radioactive materials, including radioactive waste, have appropriate storage and disposal.

- Determine how the hospital disposes of unneeded radio nuclides and radio pharmaceuticals.

    - Are these methods in accordance with Federal and State laws, regulations and guidelines?

    - Are the methods described in hospital policy?

A-0435

§482.53(b)(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.

Interpretive Guidelines §482.53(b)(3)

Refer to the guidelines under §482.27 for independent laboratory if laboratory tests are performed in the nuclear medicine service.

All in vitro tests and all in vivo procedures classified under radio bioassay must be performed in accordance with the requirements of §482.27 including quality control calibration and record retention, etc.

A-0436

§482.53(c) Standard: Facilities

Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.

Interpretive Guidelines §482.53(c)

The nuclear medicine service must function in accordance with applicable Federal and State regulations and guidelines governing radiation safety. For more information, see 21 CFR Subpart J, "Radiological Health," and 10 CFR, Chapter 1, Part 20, "U.S. Nuclear Regulatory Commission Standards for Protection Against Ionizing Radiation."

Reagents must be labeled to ensure proper identification, use, storage and safe handling and date of preparation and assay.

A-0437

§482.53(c) The equipment must be--

(1) Maintained in safe operating condition; and

(2) Inspected, tested and calibrated at least annually by qualified personnel.

Interpretive Guidelines §482.53(c)(1-2)

The hospital must develop and implement a preventive maintenance schedule to ensure that nuclear medicine equipment is maintained in safe operating condition to ensure accurate results and patient, staff, and public safety.
Nuclear medicine equipment must be inspected, tested and calibrated at least annually by qualified personnel in accordance with Federal and State laws, regulations and guidelines.

Survey Procedures §482.53(c)(1-2)

Verify that the nuclear medicine service follows its preventive maintenance schedule and that any problems identified are corrected in a timely manner.

Review preventive maintenance records to verify that equipment is inspected, tested and calibrated at least annually by qualified personnel.

A-0438

§482.53(d) Standard: Records

The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

Interpretive Guidelines §482.53(d)

The hospital must maintain records for all nuclear medicine procedures performed. At a minimum, the records must include signed and dated reports of nuclear medicine interpretations, consultations, and procedures. Nuclear medicine patient records, including interpretations, consultations, and procedures are patient medical records and the hospital must comply with the Medical Records CoP (§482.24).

A-0439

§482.53(d)(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

Interpretive Guidelines §482.53(d)(1)

Nuclear medicine patient records, like all patient medical records, must be maintained in accordance with the Medical Records CoP (§482.24).

Survey Procedures §482.53(d)(1)

Verify that copies of nuclear medicine reports are maintained for at least 5 years.

A-0440

§482.53(d)(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

Survey Procedures §482.53(d)(2)

Verify that reports of nuclear medicine interpretations are signed and dated only by practitioners authorized by the medical staff to perform these interpretations.

A-0441

§482.53(d)(3) The hospital must maintain records of the receipt and distribution of radio pharmaceuticals.

Survey Procedures §482.53(d)(3)

Verify that the hospital maintains accurate records of the receipt and distribution of radio pharmaceuticals. Request to see the most recent documentation for the delivery of radio pharmaceuticals.

A-0442

§482.53(d)(4) Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

Survey Procedures §482.53(d)(4)

Verify that nuclear medicine services are ordered only by practitioners authorized to do so by the medical staff, consistent with Federal and State law.

A-0446

§482.54 Condition of Participation: Outpatient Services

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.54

This is an optional hospital service, however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP).

The Medicare Hospital CoP apply to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations.

All outpatient services provided by the hospital, both on campus and at any provider-based clinics, must meet the needs of the patients, in accordance with acceptable standards of practice. The hospital must ensure that services, equipment, staff, and facilities are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

If the hospital offers outpatient surgical services, the Surgical Services CoP (§482.5) requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered.

The hospital's outpatient services must be integrated into its hospital-wide QAPI program.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc).

Survey Procedures §482.54

- Verify that equipment, staff and facilities are adequate to provide the outpatient services offered at each location are in accordance with acceptable standards of practice.

- Verify that outpatient services at all locations are in compliance with the hospital CoP.

- Determine locations and type(s) of outpatient services provided.

- Verify that the hospital's outpatient services are integrated into its hospital-wide QAPI program.

A-0447

482.54(a) Standard: Organization

Outpatient services must be appropriately organized and integrated with inpatient services.

Interpretive Guidelines §482.54(a)

The organization of the hospital's outpatient services must be appropriate to the scope and complexity of services offered.

The hospital's outpatient services, at all locations, must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia (including pain management) services, other diagnostic services, etc), as appropriate to the outpatient services offered. The hospital must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

The hospital must coordinate the care, treatment and services provided to a patient. In order to provide continuity of care, it should have an established method of communication between inpatient services and outpatient care in order to provide continuity of care to its patients.

Survey Procedures §482.53(a)

- Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.

- Verify that the hospital has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care.

- Review medical records of outpatients who were later admitted to the hospital in order to determine that pertinent information from the outpatient record has been included in the inpatient record.

- Determine that each outpatient service location is integrated with the appropriate hospital inpatient services in accordance with the needs of the patient care provided at each of those locations.

A-0448

482.54(b) Standard: Personnel

The Hospital must:

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

Interpretive Guidelines §482.54(b)

The outpatient services department must be accountable to a single individual who directs the overall operation of the hospital's entire outpatient services (all locations, all outpatient services). The hospital should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include

necessary education, experience and specialized training consistent with State law and acceptable standards of practice.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the hospital's outpatient department. The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients.

Survey Procedures 482.54(b)

- Verify that one person is assigned to manage and be responsible for outpatient services.

- Review the organization's policies and procedures to determine the person's responsibility.

- Review the position description and personnel file of the individual responsible for the outpatient services to ensure that he/she meets the qualifications, in accordance with State law, acceptable standards of practice and hospital policy.

- Review personnel files to verify that the staff qualifications including education, experience, certifications, current licensure where appropriate, and competencies are appropriate for assigned responsibilities.

- Compare duty rosters to patient log to verify that sufficient MD/DOs, nurses and other staff are available to provide care to verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care, and the frequency, duration, and complexity of services offered.

- Review policies and contracts, if services provided are under an arrangement.

A-0452

§482.55 Condition of Participation: Emergency Services

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.55

The hospital must meet the emergency needs of its patients in accordance with §482.12(f) even if it chooses not to provide emergency services in a dedicated emergency department. The provision of emergency services is an optional service for Medicare

participation, but may be required by State law or regulation or the State's hospital licensing requirements.

If the hospital provides emergency services, the hospital must comply with all the requirements of this Condition of Participation (CoP) and provide those services in accordance with acceptable standards of practice.

"Acceptable standards of practice" includes maintaining compliance with applicable Federal and State laws, regulations, and guidelines regarding hospital emergency services, as well as any standards or recommendations promoted by or established by nationally recognized professional organizations (e.g., American Medical Association, American Nurses Association, American College of Emergency Medicine, etc.).

The hospital's emergency services must be integrated into the hospital-wide QAPI program.

The medical staff is responsible for the quality of care provided to its patients. Appropriate provisions for follow-up care for emergency patients, who are not admitted to the hospital or transferred to another hospital, must be made.

Survey Procedures §482.55

Verify that the hospital's emergency services is integrated into the hospital-wide QAPI program.

A-0453

§482.55(a) Standard: Organization and Direction

If emergency services are provided at the hospital--

A-0454

§482.55(a)(1) The services must be organized under the direction of a qualified member of the medical staff;

Interpretive Guidelines §482.55(a)(1)

The hospital's emergency services must be under the direction of a qualified member of the hospital's medical staff. The hospital's medical staff establishes criteria for the qualifications for the director of the hospital's emergency services in accordance with State law and acceptable standards of practice. A single emergency services director must be responsible for the hospital's emergency services.

Survey Procedures §482.55(a)(1)

Verify that emergency services are organized under the direction of a qualified member of the medical staff.

A-0455

§482.55(a)(2) The services must be integrated with other departments of the hospital;

Interpretive Guidelines §482.55(a)(2)

The hospital's emergency service/department must be integrated with the other departments of the hospital such as surgical services, lab, ICU, diagnostic services, etc. The hospital must demonstrate that its emergency services are truly integrated into its other departments. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and render appropriate care for an emergency patient.

Emergency Services integration would include at a minimum:

- Coordination and communication between the Emergency Department and other hospital services/departments;

- Physical access for emergency department patients to the services, equipment, personnel, and resources of other hospital departments/services;

- The immediate availability of services, equipment, personnel, and resources of other hospital departments/services to emergency patients; and

- That the provision of services, equipment, personnel and resources of other hospital departments/services to emergency department patients is within timeframes that protect the health and safety of patients and is within acceptable standards of practice, including:

    - The length of time it takes to transport the emergency patient from the ED to another hospital department where needed interventions or diagnostic services will be rendered.

    - The length of time it takes to deliver equipment or supplies, or for the staff from other departments to travel from their location to the emergency department in order to provide needed interventions, tests, care, or services.

Time is critical in the provision of emergency care. The hospital must be able to demonstrate how the hospital's other departments provide emergency patients the care and services needed within safe and appropriate times.

In emergency care situations, the time needed to provide the patient with appropriate diagnostic and care interventions can have a significant effect on the patient. Delays in diagnosis and the provision of needed interventions is likely to adversely affect the health and safety of patients who require emergency care. Therefore, a hospital that cannot demonstrate integration of its emergency services with its other departments (including radiological services, OR, intensive care, laboratory, etc) would not be in compliance with the Emergency Services CoP.

Many hospitals offer urgent care services on the hospital campus or in provider-based clinics in the communities they serve. Those clinics must be in compliance with the hospital CoP. Hospitals may organize their **urgent care clinics** as part of their outpatient department or emergency services department. An urgent care clinic that:

- The hospital holds out to the public as providing only urgent care services and possibly other services;

- Clearly advises the public that the urgent care clinic is not an emergency services department; and

- Does not meet the EMTALA definition of dedicated emergency department;

would be evaluated for compliance with the integration requirement in the Outpatient Services CoP (§482.54(a)) rather than the integration requirement in the Emergency Services CoP. In most urgent care situations, the time, qualified personnel, equipment, and other resources needed to provide the patient with appropriate diagnostic and care interventions are less than needed in emergency situations.

Survey Procedures §482.55(a)(2)

Verify that there are established procedures to assure integration with either hospital services including laboratory, radiology, and operating services to provide continuity of care.

A-0456

§482.55(a)(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

Interpretive Guidelines §482.55(a)(3)

The hospital's medical staff must establish policies and procedures governing the medical care provided in the emergency service or emergency department. The medical staff must have had ongoing/continuing assessment of the medical care provided in the emergency service or department. Emergency service or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QAPI activities.

Survey Procedures §482.55(a)(3)

Verify that procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis.

A-0457

§482.55(b) Standard: Personnel

A-0458

§482.55(b)(1) The emergency services must be supervised by a qualified member of the medical staff.

Interpretive Guidelines §482.55(b)(1)

A qualified member of the medical staff must be on premises and available to supervise the provision of emergency services at all times the hospital offers emergency services. A qualified member of the medical staff must be physically present in the emergency department and available to directly supervise the provision of emergency care to a patient.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the supervision of the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

Survey Procedures §482.55(b)(1)

Verify that a qualified member of the medical staff is designated to supervise emergency services.

A-0459

§482.55(b)(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

Interpretive Guidelines §482.55(b)(2)

The hospital must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility.

The hospital must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the hospital needs to met its anticipated emergency needs.

The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

As a suggested prudent practice the hospital should conduct periodic assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Additionally, the hospital should work cooperatively with Federal, State and local emergency preparedness agencies and officials in order to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.), to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs.

Survey Procedures §482.55(b)(2)

- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care personnel and a clear chain of command.

- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:

    - Parenteral administration of electrolytes, fluids, blood and blood components;

- Care and management of injuries to extremities and central nervous system;

- Prevention of contamination and cross infection.

A-0463

§482.56 Condition of Participation: Rehabilitation Services

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

Interpretive Guidelines §482.56

This is an optional hospital service. However, if a hospital provides any degree of rehabilitative services to its patients, the hospital must comply with the requirements of the Condition of Participation.

If rehabilitative services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice. Acceptable standards of practice include compliance with any applicable Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, American Medical Association, etc.).

The hospital's rehabilitation services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.56

- Determine if the hospital provides any degree of rehabilitation services.

- Determine if the hospital's rehabilitation services are integrated into its hospital-wide QAPI program.

A-0464

§482.56(a) Standard: Organization and Staffing

The organization of the service must be appropriate to the scope of the services offered.

Interpretive Guidelines §482.56(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the hospital in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the hospital should be defined in written policies and procedures, and approved by the Medical staff.

Each service, whether provided through a single discipline department or within a multi-discipline department, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.

Survey Procedures §482.56(a)

- Review the hospital's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing.
- If services are provided under an arrangement, review policies and contracts.
- For each service, determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment.
- Review medical records to verify that a qualified professional evaluates the patient and initiates each treatment episode.
- Review a sample of personnel files to verify current licensure, certifications and ongoing training, consistent with applicable State laws.

A-0465

§482.56(a)(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

Interpretive Guidelines §482.56(a)(1)

Each service must be accountable to an individual that directs the overall hospital-wide operation of that service. An individual may serve as the director of a multi-service department or as director of single service departments.

The service director must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service(s).

The director may be part-time or full time. In all situations the director retains professional and administrative responsibility for personnel providing the service. If the director is part-time, the time spent directing the service should be appropriate to the scope of the services provided.

Survey Procedures §482.56(a)(1)

- Verify that each service is accountable to an individual who directs the overall operation of that service.

- Review the service director's position description to verify that he/she has been granted the authority and responsibility for operation of the service, consistent with hospital policies, State law, and accepted standards of practice.

- If the director does not work full-time, determine that the number of hours (review timesheets) spent working is appropriate to the scope of services provided.

- Review the director's personnel file to determine that he/she has the necessary education, experience and specialized training to properly supervise and administer the service. This includes maintaining current licensure and certifications as required by State law.

- Interview the director to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

A-0466

§482.56(a)(2) Physical therapy, occupational therapy, or speech therapy or audiology services, if provided, must be provided by staff that meets the qualifications specified by the medical staff, consistent with State law.

Interpretive Guidelines §482.56(a)(2)

The Medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered, (e.g., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, and audiologists, etc). Qualifications should include the necessary education, experience, specialized training, and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law.

A qualified professional, of the applicable discipline, must:

- Perform an initial evaluation of each patient for whom rehabilitative services were ordered;
- Perform periodical evaluations as applicable and in accordance with accepted standards of practice and State laws;
- Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and
- Supervise supportive personnel when they furnish services as appropriate and consistent with State law.

For the purposes of this requirement, "qualified professional" means a physical therapist, an occupational therapist, or a speech language pathologist, who is licensed in accordance with State law and credentialed in accordance with the hospital medical staff criteria.

Survey Procedures §482.56(a)(2)

- Review medical staff documentation to determine that specific qualifications have been established for all rehabilitation staff.
- Review documentation indicating the services provided and the various levels of personnel permitted to provide the services.

- Verify the hospital has a procedure for periodically reviewing the qualifications of staff and for keeping informed of changes in State law regarding personnel qualifications/requirements.

- Review personnel files to determine that staff meets the qualifications specified by the Medical staff as demonstrated through education, experience, current licensure, certifications, and competency as appropriate for their assigned responsibilities.

A-0467

§482.56(b) Standard: Delivery of Services

Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

Interpretive Guidelines §482.56(b)

Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must:

- Be established by the practitioner ordering the service in collaboration with individuals qualified to provide the service(s);

- Be based on the patient's individualized assessment;

- Include the type, amount, frequency and duration of services;

- Include measurable short-term and long-term goals; incorporate patient, family and caregiver goals; and

- Be reviewed and revised, as necessary, to reflect changes in the patient's response to therapeutic intervention. Updated treatment goals should reflect the changes the patient's status.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders.

The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.

Verbal orders for the provision of treatment may be accepted and must be authenticated in accordance with the requirements in §482.23 and with Federal and State Laws.

Survey procedures §482.56(b)

- Review patient records to verify that rehabilitation services are provided only in accordance with practitioner orders and that those orders are incorporated into the medical record.

- Verify that each patient has a plan of treatment established in writing prior to the beginning of treatment.

- Verify that the plan is established by the practitioner ordering the service in collaboration with individual(s) qualified to provide the service(s).

- Verify that changes in the treatment plan are documented in writing, supported by clinical record information such as evaluation, test results, or orders, and that changes have been approved by the practitioner.

A-0471

§482.57 Condition of Participation: Respiratory Services

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care services.

Interpretive Guidelines §482.57

If a hospital provides care to patients who require respiratory care services, the hospital must meet the needs of those patients, in accordance with acceptable standards of practice. This is an optional hospital service. However, if a hospital provides any degree of respiratory care to its patients, the hospital must comply with the requirements of this Condition of Participation.

Acceptable standards of practice include compliance with applicable standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Medical Association, American Association for Respiratory Care, American Thoracic Association, etc).

The hospital's respiratory services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.57

- Determine if the hospital provides any degree of respiratory care services.

- Determine that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.
- Determine if the hospital's respiratory services are integrated into its hospital-wide QAPI program.

A-0472

§482.57(a) Standard: Organization and Staffing

The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

Interpretive Guidelines §482.57(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.

The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing, and approved by the Medical staff.

Survey Procedures §482.57(a)

- Review the hospital's organizational chart to determine the relationship of respiratory care services to other services provided by the hospital.

- Review the hospital policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing.

A-0473

§482.57(a)(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

Interpretive Guidelines §482.57(a)(1)

The service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she has the qualifications necessary to supervise and administer the service properly, appropriate to the scope and complexity of services offered.

If the director serves on a part-time basis, the time spent directing the department should be appropriate to the scope and complexity of services provided.

Survey Procedures §482.57(a)(1)

- Verify that a director has been appointed and that he/she has fixed lines of authority and delegated responsibility for operation of the service.

- Interview staff regarding the role and oversight activities conducted by the director.

- Review the service director's credentialing file to determine that he/she is a M.D. or D.O. and has the necessary education, experience and specialized training to supervise and administer the service properly.

A-0474

§482.57(a)(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

Interpretive Guidelines §482.57(a)(2)

There must be sufficient personnel available to respond to the respiratory care needs of the patient population being served.

Survey Procedures §482.57(a)(2)

- Interview respiratory care staff regarding: services provided, schedules, and availability of respiratory care staff throughout the day and week to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing and on-call schedules.

- Review a sample of personnel files for respiratory care staff to determine that the personnel meet the qualifications specified by the medical staff, consistent with State law.

A-0475

§482.57(b) Standard: Delivery of Services

Services must be delivered in accordance with medical staff directives.

Interpretive Guidelines §482.57(b)

There should be written policies for the delivery of respiratory care services that are developed and approved by the medical staff. Appropriate to the scope of services provided, the written policies should address at least the following:

- Equipment assembly, operation, and preventive maintenance;
- Safety practices, including infection control measures for equipment, sterile supplies, biohazardous waste, posting of signs, and gas line identification;
- Handling, storage, and dispensing of therapeutic gases to both inpatients and outpatients;
- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Storage, access, control, administration of medications and medication errors; and
- Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases).

A-0476

§482.57(b)(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

Interpretive Guidelines §482.57(b)(1)

The hospital must have written policies to address, at a minimum:

- Each type of respiratory care service provided by the hospital;
- The qualifications, including job title, licensure consistent with State law, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision; and
- The type of personnel qualified to provide the direct supervision.

Survey Procedures §482.57(b)(1)

- Review treatment logs, job descriptions of respiratory care staff, and policies and procedures to determine the following:
    - Duties and responsibilities of staff;
    - Qualifications and education required, including licensure, consistent with State law;
    - Specialized training or experience needed to perform specific duties.

A-0477

§482.57(b)(2) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.

Interpretive Guidelines §482.57(b)(2)

Refer to the guidelines under §482.27 for independent laboratory if blood gases and laboratory tests are performed in the respiratory care unit.

A-0478

§482.57(b)(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

Survey Procedures §482.57(b)(3)

Review the medical records of patients receiving respiratory services to verify that those services are provided only upon the orders of a doctor of medicine or osteopathy, and that the services are provided in accordance with those orders.

HOSPITAL/CAH MEDICARE DATABASE WORKSHEET

CMS Certification Number (CCN):_____ Date of Worksheet Update: _____

Medicaid Provider Number:_____ (MMDDYYYY) (M1)

National Provider Identification Number (NPI):_____

Fiscal Year Ending Date (MMDD): _____

Name and Address of Facility (Include City, State):

_____

_____

_____Zip Code:_____

Telephone Number (M2):_____ Fax Number (M3):_____

Email Address:_____

Accreditation Status:_____

0 Not Accredited

1 JC Accredited

2 AOA Accredited

4 Both

Effective Date of Accreditation: _____

(MMDDYYYY) (M4)

Renewal Date of Accreditation:_____

(MMDDYYYY) (M5)

State/County Code (M6):_____

State Region Code (M7):_____

Type of Program Participation (M8):_____

1 Medicare

2 Medicaid

3 Both

CLIA ID Numbers (M9):

_____

_____

_____

_____

Type of Hospital or a Critical Access Hospital (CAH) (select 1) (M10):_____

01 Short-term
02 Long-term
03 Religious Non-medical Health Care Institution
04 Psychiatric
05 Rehabilitation
06 Childrens
07 Distinct Part Psychiatric Hospital
08 Cancer Hospital
11 Critical Access Hospital (CAH)

Affiliation with a Medical School (M11):_____

01 Major **03 Graduate School**

02 Limited **04 No Affiliation**

Resident Programs (M12):_____

(select all that apply)

01 AMA **02 ADA** **03 AOA**

04 Other **05 No Program** **06 Podiatric**

Ownership Type (select 1) (M13):_____

01 Church

02 Private (Not for Profit)

03 Other (specify)_____

04 Proprietary (For Profit)

05 Federal

06 State

07 Local

08 Hospital District or Authority

09 Physician Ownership

10 Tribal

Average Daily Census (M14):_____

Number of Staffed Beds (M15):_____

Type of Chain/Health System Involvement (M16):_____

01 None

02 System Ownership

03 System Management

04 Both System Owned and Managed

Name of System (M17):_____

Corporate Headquarters City (M18):_____ State (M19):_____

Number of Employees Salaried by Hospital/CAH (Use Full Time Equivalents FTE)					
M20	Physicians (Salaried only)		M30	Medical Technologists (Lab)	
M21	Physicians - Residents		M31	Nuclear Medicine Technicians	
M22	Physician Assistants (PA)		M32	Occupational Therapists	
M23	Nurses - CRNA		M33	Pharmacists (Registered)	
M24	Nurses - Practitioners		M34	Physical Therapists	
M25	Nurses - Registered		M35	Psychologists	
M26	Nurses - LPN		M36	Radiology Technicians (Diagnostic)	
M27	Dieticians		M37	Respiratory Therapists	
M28	Medical Social Workers		M38	Speech Therapists	
M29	Medical Laboratory Technicians		M39	All Others	

Type of Reimbursement or Status Categories of a Hospital or a CAH (select all that apply) (M40):_____

01	CAH Psychiatric DPU		07	Hospital PPS Excluded Psych Unit	
02	CAH Rehabilitation DPU		08	Hospital PPS Excluded Rehab Unit	
03	CAH Swing Beds		09	Hospital Swing Beds	
04	Specialty Hospital		10	Medicare Dependent Hospital	
05	Hospital in a Hospital - Host		11	Regional Referral Center	
06	Hospital in a Hospital - Tenant		12	Sole Community Hospital	

Services Provided by the Facility (M41):_____

0 Service not provided

1 Services provided by facility staff only

2 Services provided by arrangement or agreement

3 Services provided through a combination of facility staff and through agreement

01	Ambulance Services (Owned)		34	Operating Rooms	
02	Alcohol and/or Drug Services		35	Opthalmic Surgery	
03	Anesthesia		36	Optometric Services	
04	Audiology		37	Organ Bank	
05	Blood Bank – FDA Approved		38	Organ Transplant Services	
06	Burn Care Unit		39	Orthopedic Surgery	
07	Cardiac Catheterization Laboratory		40	Outpatient Services	
08	Cardiac-Thoracic Surgery		41	Pediatric Services	
09	Chemotherapy Service		42	Pharmacy	
10	Chiropractic Service		43	Physical Therapy Services	
11	CT Scanner		44	Positron Emission Tomography Scan	
12	Dental Service		45	Post-Operative Recovery Rooms	
13	Dietetic Service		46	Psychiatric Services - Emergency	
14	Emergency Department (Dedicated)		47	Psychiatric - Child/Adolescent	
15	Emergency Services		48	Psychiatric - Forensic	
16	Extracorporeal Shock Wave Lithotripter		49	Psychiatric - Geriatric	
17	Gerontological Specialty Services		50	Psychiatric - Inpatient	
18	Home Health Services		51	Psychiatric - Outpatient	
19	Hospice		52	Radiology Services - Diagnostic	
20	ICU - Cardiac (non-surgical)		53	Radiology Services - Therapeutic	
21	ICU - Medical/Surgical		54	Reconstructive Surgery	
22	ICU - Neonatal		55	Respiratory Care Services	
23	ICU - Pediatric		56	Rehab -Inpatient (CARF Acc)	
24	ICU - Surgical		57	Rehab -Inpatient (Not CARF Acc)	
25	Laboratory - Anatomical		58	Rehab -Outpatient	
26	Laboratory - Clinical		59	Renal Dialysis (Acute Inpatient)	
27	Long Term Care (swing-beds)		60	Social Services	
28	Magnetic Resonance Imagining (MRI)		61	Speech Pathology Services	
29	Neonatal Nursery		62	Surgical Services - Inpatient	
30	Neurosurgical Services		63	Surgical Services - Outpatient	
31	Nuclear Medicine Services		64	Tissue Bank Services	
32	Obstetric Service		65	Trauma Center (Certified)	
33	Occupational Therapy Services		66	Urgent Care Center Services	

Sprinkler Status, Primary Location (select 1) (M42):_____

01 Totally sprinklered: All required areas are sprinklered

02 Partially sprinklered: Some but not all required areas are sprinklered

03 Sprinklers: None

Total number of off-site locations under the same CCN (M43):_____

01	**Inpatient Remote Locations**		**07**	**Satellites of a PPS Excluded Psych Unit**	
02	**Offsite Freestanding Outpatient Surgery**		**08**	**Satellites of a Long Term Care Hospital**	
03	**Urgent Care Center (Freestanding)**		**09**	**Satellites of a cancer hospital**	
04	**Satellites of a Rehabilitation Hospital**		**10**	**Satellites of a Childrens' Hospital**	
05	**Satellites of a Psychiatric Hospital**		**11**	**Other Provider-Based Location**	
06	**Satellites of a PPS Excluded Rehab Unit**		**12**	**Off-campus Emergency Department**	

Identification Number Assigned to the Specific Off-site Location (from table)

(M44):_____

Name of Off-site Location (M45):_____

Off-site Street Address (M46):_____

County (M47)_____

City (M48):_____State (M49):_____ Zip Code (M50):_____

Sprinkler Status of Off-site Location (select 1) (M51)_____

01 Totally sprinklered: All required areas are sprinklered

02 Partially sprinklered: Some but not all required areas sprinklered

03 Sprinklers: None

04 Sprinklers are not required but the location is sprinklered

If there is more than one off-site location, complete and attach the Provider-Based Off-Site Locations

Continuation Worksheet until all locations are accounted for.

Number of related or affiliated providers or suppliers (M52):_____

01	**Ambulatory Surgery Center (ASC)**		**06**	**Home Health Agency**	
02	**Co-located Hospitals**		**07**	**Hospice**	
03	**Co-located Satellites of Another Hospital**		**08**	**Psychiatric Residential Treatment Facility**	
04	**End Stage Renal Disease (ESRD Center**		**09**	**Rural Health Clinic (RHC)**	
05	**Federally Qualified Health Center (FQHC)**		**10**	**Skilled Nursing Facility (SNF)**	

Identification Number of related or affiliated provider numbers (M53):_____

Provider Number (M54):_____

If there is more than one related or affiliated provider or supplier, attach the Related or Affiliated Provider Numbers Continuation Worksheet until all are accounted for.:

Signature of Authorized Individual:_____

Print Name of Authorized Individual:_____ Date:_____

PROVIDER-BASED OFF-SITE LOCATION CONTINUATION WORKSHEET PAGE 1 OF _____

Type of off-site location and total number of each type of off-site location

- **Identify every location (that bills for services using the provider's Medicare CCN) of the provider that is located off the provider's primary campus/location.**
- **In the block "Number of off-site locations with the same provider number (M43)", write the total number of off-campus location.**
- **Place the total number of each type of off-site location in the space beside that type of location. Example: If a hospital has two additional campuses, enter the number "2" in the block beside "01 Inpatient Remote Location".**

Total Number of off-site locations with the same CCN (M43):_____

TYPES OF OFF-SITE LOCATIONS					
01	Inpatient Remote Locations		07	Satellites of a PPS Excluded Psych Unit	
02	Off-site Freestanding Outpatient Surgery		08	Satellites of a Long Term Care Hospital	
03	Urgent Care Center (Freestanding)		09	Satellites of a Cancer Hospital	
04	Satellites of a Rehabilitation Hospital		10	Satellites of a Children's Hospital	
05	Satellites of a Psychiatric Hospital		11	Other Provider-Based Locations	
06	Satellites of a PPS Excluded Rehab Unit		12	Off-campus Emergency Department	

- **Complete an identification entry for each off-site location that bills for services under the provider's CCN. Example: If a hospital has seven off-site locations that bill for services under the hospital's CCN, complete seven separate entries.**
- **Complete all the blocks for each off-site location.**
- **From the table above, enter the identification number for the type of off-site location. Example: enter "02" for an off-site freestanding outpatient surgery location.**
- **Using the Code number provided, enter the sprinkler status of each location.**

ENTRY_____
Identification Number Assigned to the Specific Off-site Location (from table) (M44):_____
Name of Off-site Location (M45):_____
Off-Site Street Address (M46):_____
County (M47):_____
City (M48):_____State (M49):_____Zip Code (M50):_____
Sprinklered Status of Off-site Location (select 1) M51):_____

01 Totally sprinklered: All required areas are sprinklered
02 Partially sprinklered: Some but not all required areas sprinklered
03 Sprinklers: None
04 Sprinklers are not required but the location is sprinklered

ENTRY_____
Identification Number Assigned to the Specific Off-site Location (from table) (M44):_____
Name of Off-site Location (M45):_____
Off-Site Street Address (M46):_____
County (M47):_____
City (M48):_____State (M49):_____Zip Code (M50):_____
Sprinklered Status of Off-site Location (select 1) M51):_____

01 Totally sprinklered: All required areas are sprinklered
02 Partially sprinklered: Some but not all required areas sprinklered
03 Sprinklers: None
04 Sprinklers are not required but the location is sprinklered

Make additional copies as needed for additional off-site locations.

RELATED OR AFFILIATED CCN CONTINUATION WORKSHEET PAGE 1 OF _____

Identify all related or alliliated Medicare or Medicaid providers/suppliers that are:

---Owner and/or operated by the hospital or CAH, or
---Located on a campus or location of the hospital or CAH, and
---Do not bill for services under the hospital or CAH CCN.

- **In the block "Number of related or affiliated provider/suppliers (M52)", write the total number of all related or affiliated providers/suppliers. Example: If a hospital has 1 collocated hospital, 1 hospice, and 1 SNF to which it is related or affiliated, the number "3" would be entered.**

- **In the block beside the identified provider/suppliers, write the total number of that particular provider/supplier type that is related or affiliated to the hospital/CAH. Example: If a CAH has one provider based RHC, enter the number "1" in the block beside "09 RHC"; if a hospital has two affiliated Medicare certified ASC which have their own CCN, enter the number "2" in the block beside "01 ASC"**

TYPES OF AFFILIATED PROVIDER/SUPPLIERS					
01	**Ambulatory Surgery Center (ASC)**		**06**	**Home Health Agency**	
02	**Co-located Hospitals**		**07**	**Hospice**	
03	**Co-located Satellites of Another Hospital**		**08**	**Psychiatric Residential Treatment Facility**	
04	**End Stage Renal Disease (ESRD Center**		**09**	**Rural Health Clinic (RHC)**	
05	**Federally Qualified Health Center (FQHC)**		**10**	**Skilled Nursing Facility (SNF)**	

- **In the block "Type of provider (M53)", enter the number from the above table that identifies the particular type of related or affiliated provider/supplier. Example: Enter the number "10" for a distinct part SNF or a collocated SNF related or affiliated.**

- **In the block "Provider number (54)", enter the related or affiliated provider's Medicare provider number. In the case of PRTF, write the Medicaid provider number.**

Type of Provider (M53):_____ CCN (M54):_____

Type of Provider (M53):_____ CCN (M54):_____

Type of Provider (M53):_____ CCN (M54):_____

Type of Provider (M53):_____ CCN (M54):_____

Type of Provider (M53):_____ CCN (M54):_____

Type of Provider (M53):_____ CCN (M54):_____

Make additional copies as needed for additional related or affiliated provider numbers.

Part II - Interpretive Guidelines - Psychiatric Hospitals

B98

§482.60 Condition of Participation: Special Provisions Applying to Psychiatric Hospitals

Psychiatric hospitals must--

B99

§482.60(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.

Guidance §482.60(a)

The hospital will be deemed to meet standard (a) if it meets standards (c) and (d).

B100

§482.60(b) Meet the Conditions of Participation specified in§§482.1 through 482.23 and §§482.25 through 482.57;

Guidance §482.60(b)

The hospital is either accredited by JCAHO or AOA; or meets the Condition of Participation for Hospitals, §§482.1 through 482.23 and §§482.25 through 482.57.

B101

§482.60(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries as specified in §482.61; and

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B102

§482.60(d) Meet the staffing requirements specified in §482.62.

B103

§482.61 Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

Guidance §482.61

The clinical record should provides information that indicates need for admission and treatment, treatment goals, changes in status of treatment and discharge planning, and follow-up and the outcomes experienced by patients.

The structure and content of the individual patient's record must be an accurate functional representation of the actual experience of the individual in the facility. It must contain enough information to indicate that the facility knows the status of the patient, has adequate plans to intervene, and provides sufficient evidence of the effects of the intervention, and how their interventions served as a function of the outcomes experienced. You must be able to identify this through interviews with staff, and when possible with individuals being served, as well as through observations.

§482.61(a) Standard: Development of Assessment/Diagnostic Data

B104

§482.61(a) Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

B105

§482.61(a)(1) The identification data must include the patient's legal status.

Guidance §482.61(a)(1)

Definition: Legal Status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated - i.e., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements.

Determine through interview with hospital staff the terminology they use in defining "legal status." If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Changes in legal status should also be recorded with the date of change.

B106

§482.61(a)(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis.

Guidance §482.61(a)(2)

There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. This diagnosis is made and entered into the chart of each patient at the time of the admission examination. The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change.

If a diagnosis is absent, there must be justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others.

Intercurrent (other than psychiatric) diagnoses must be documented when they are made. Attention should be paid to physical examination notes, including known medical conditions, even allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis.

These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the "admission work up " or the physician's progress notes. Diagnostic categories should include physical illness when present.

Probes §482.61(a)(2)

Are abnormal physical examination findings and/or laboratory findings justified by further diagnostic testing and/or development of an intercurrent diagnosis, and, if so, was such done?

If an identified physical illness requires immediate treatment, is the treatment being given?

How will an identified physical illness be likely to impact on the patient's eventual outcome? To what extent has this potential impact been addressed by the team?

B107

§482.61(a)(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

Guidance §482.61(a)(3)

The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient's response to admission.

The hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers.

Records should not contain vague, ill-defined reports from unknown sources. Records should record "who," "what," "where," "when," and "why."

Probes §482.61(a)(3)

Can the patient describe problems, stresses, situations experienced prior to hospitalization or do they still exist?

Who is the informant?

Did the informant witness the patient's behavior? If not, on what basis has the informant come to know the patient's behavior?

Has staff elicited whether the patient has exhibited similar behavior previously? If so, what was different this time to make hospitalization necessary?

Were there other changes/events in the patient's environment (death, separations of significant others) which contributed to the need for hospitalization? If so, has staff explored how these will impact in the patient's treatment? Has this been addressed by the treatment team?

Has there been an interruption or change in the patient's medication which may have been a factor in the patient's hospitalization?

B108

§482.61(a)(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

Guidance §482.61(a)(4)

The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.

Patient length of stay is a key factor influencing hospital documentation policy, i.e., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record.

A psychosocial history/assessment must be completed on all patients. Three key components to be addressed:

A. Factual and Historical Information

1. Specific reasons for the patient's admission or readmission;

2. A description of the patient's past and present biopsychosocial functioning;

3. Family and marital history, dynamics, and patient's relationships with family and significant others;

4. Pertinent religious and cultural factors;

5. History of physical, sexual and emotional abuse;

6. Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others;

7. Educational, vocational, employment, and military service history;

8. Identification of community resources including previously used treatment sources;

9. Identification of present environmental and financial needs.

B. Social Evaluation

1. Patient strength and deficits;

2. High risk psychosocial issues requiring early treatment planning and intervention - i.e., unattended child(ren) in home; prior noncompliance to specific treatment and/ or discharge interventions; and potential obstacles to present treatment and discharge planning.

C. Conclusions and Recommendations

Assessment of Sections A and B shall result in the development of (C) recommendations related to the following areas:

1. Anticipated necessary steps for discharge to occur;

2. High risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay;

3. Specific community resources/ support systems for utilization in discharge planning - i.e., housing, living arrangements, financial aid, and aftercare treatment sources;

4. Anticipated social work role(s) in treatment and discharge planning.

Probes §482.61(a)(4)

Does the psychosocial history/assessment indicate:

1. Clear identification of the informants(s) and sources of information?

2. Whether information is considered reliable?

3. Patient participation to the extent possible in provision of data relative to treatment and discharge planning?

4. Integration of significant data including identified high risk psychosocial issues (problems) into the treatment plan?

5. How does the hospital insure the information is reliable?

B109

§482.61(a)(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

Guidance §482.61(a)(5)

Upon admission the patient should receive a thorough history and physical examination with all indicated laboratory examinations. These investigations must be sufficient to discover all structural, functional, systemic and metabolic disorders. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible *sequelae* any of which may turn out to be significant and pertinent to the present mental illness. Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder.

The screening neurological examination

As part of the physical examination, the physician will perform a "screening" neurological examination. While there is no precise definition of a screening neurological examination in medical practice such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detailed, fine testing of each division. Gross testing of Cranial Nerves II through XII should be included. Statements such as "Cranial Nerves II to XII intact" are not acceptable. These areas may be found in various parts of the physical examination and not just grouped specifically under the neurological.

In any case where a system review indicate positive neurological symptomatology, a more detailed examination would be necessary, with neurological work-up or consultation ordered as appropriate after the screening neurological examination was completed.

Complete neurological examination.

A complete, comprehensive neurological examination includes a review of the patient's history, physical examination and for psychiatric patients, a review of the psychiatric evaluation. The neurologist/psychiatrist himself/herself also takes a history to obtain the necessary information not already available in the medical record or referral form. The neurological examination is a detailed, orderly survey of the various sections of the nervous system. As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient's sight (cranial nerve II) in a complete neurological examination, the neurologist may test visual acuity with a snellen chart, perform a

fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient's visual fields. In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even individual muscles are tested. In a complete neurological examinations all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested.

Probes §482.61(a)(5)

Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of an intercurrent diagnosis? If the finding justified further follow-up in either situation, was such follow-up done?

Is there evidence that a screening neurological examination was done and recorded at the time of the physical examination?

Was the screening neurological or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma?

If indicated, was a complete, comprehensive neurological exam ordered, completed and recorded in the medical record in a timely manner?

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§482.61(b) Standard: Psychiatric Evaluation

B110

Each patient must receive a psychiatric evaluation that must--

Guidance §482.61(b)

The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment.

The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness. Through the psychiatric evaluation the physician seeks to secure a biographical-historical perspective of the patient's personality, with a clear psychological picture of the patient as a specific human being with his or her individual problems. While performing the psychiatric evaluation, the physician reaches an understanding of the patient's basic personality structure, of the patient's developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her

supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness. In the psychiatric evaluation the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity.

The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment. A physician's signature is necessary. In those cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is credentialed by the hospital, legally authorized by the State to perform that function, and a physician review and countersignature is present, where required by hospital policy or State law.

In order to satisfy the requirements §482.61(b) (1-7) of this standard, and to meet the standards of medical practice, the psychiatric evaluation should include the following component parts:

Probes §482.61(b)

1. The patient's chief complaints and/or reaction to hospitalization, recorded in patient's own words where possible.

   Why is the patient in the hospital?

   Was it his/her idea? (Does he/she feel ill/disturbed/frightened?)

   Is the patient in the hospital against his/her will? Who decided to hospitalize/why?

2. Past history of any psychiatric problems and treatment, including prior precipitating factors, diagnosis, course and treatment.

   Has the patient been chronically ill? Continuously/repeatedly?

   How severely has the past illness/treatment interfered with the patient's development and/or adjustment?

   Are there persistent symptoms/signs/behaviors that must be addressed and treated in order to favorably impact on the future psychiatric course?

   What medications or supports helped him/her improve in the past? Are the same resources available to impact on the patient's treatment during this episode?

3. Past family, educational, vocational, occupational and social history.

   To what extent, if any, is there a presence or absence of familial predisposition?

   What is the patient's educational level? Was he/she a good student? Is he/she still interested in learning?

What jobs has the patient held? For how long? Is he/she now employed/unemployed? For how long? Has he/she ever worked?

How does the patient get along with people? As a child, did he/she have friends? Does he/she have friends now?

Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors, that justify the diagnosis?

B111

§482.61(b)(1) Be completed within 60 hours of admission;

B112

§482.61(b)(2) Include a medical history;

Guidance §482.61(b)(2)

The psychiatric evaluation must include the non-psychiatric medical history including physical disabilities, mental retardation and treatment.

Probes §482.61(b)(2)

Does the evaluation include:

Relevant past surgery? Past medical conditions and disabilities especially those of a chronic nature?

Have these contributed to the patient's psychiatric condition? How?

Are any of these conditions still present to any significant degree? Are they likely to impact on the patient's recovery/remission? Should they be addressed immediately? Does the facility have the capability to intervene? If not, how is the need to be met?

B113

§482.61(b)(3) Contain a record of mental status;

Guidance §482.61(b)(3)

The mental status must describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and

observed by the examiner at the time of the examination. This description is appropriate to the patient's condition.

Explore the mental status for descriptions of the patient's presentation during the examination that are relevant to the diagnosis and treatment of the patient. An example of a portion of the patient interview: The patient periodically states the examiner's name correctly during this examination after hearing it once, accurately describes his past history in great detail, precisely characterizes his present situation, can list events in logical sequence that have led to his present illness, but believes that his pre-admission insomnia, anorexia, and 35 pound weight loss over the past four months are totally the result of his sexual promiscuity of ten years ago and have nothing to do with his concurrent use of 50 to 60 mg. of Amphetamine daily." From this information one can conclude that the patient is oriented, his memory is intact, but that he has poor judgment and no insight. It is not acceptable just to write "oriented, memory intact, judgment poor, and insight nil," without any supportive information.

B114

§482.61(b)(4) Note the onset of illness and the circumstances leading to admission;

Guidance §482.61(b)(4)

In a hospitalized patient, the identified problem should be related to the patient's need for hospital admission. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received.

Probes §482.61(b)(4)

How long has the patient been ill? Was it a gradual or sudden onset?

Is this a recurrence?

What were the precipitating factors? What happened?

What symptoms, signs, behaviors made this hospitalization necessary?

What treatment has the patient already received before coming to the hospital?

Is any medication he received listed?

B115

§482.61(b)(5) Describe attitudes and behavior;

Guidance §482.61(b)(5)

The problem statement should describe behavior(s) which require change in order for the patient to function in a less restrictive setting. The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.

B116

§482.61(b)(6) Estimate intellectual functioning, memory functioning and orientation; and

Guidance §482.61(b)(6)

Refer to §482.61(b)(3)

B117

(7) Include an inventory of the patient's assets in descriptive, not interpretive fashion.

Guidance §482.61(b)(7):

Although the term strength is often used interchangeably with assets, only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan. For purposes of the regulation, words such as "youth," "pretty," "Social Security income," and "has a car" do not represent assets. (See also §482.61(c)(1).)

§482.61(c) Standard: Treatment Plan

B118

§482.61 (c)(1) Each patient must have an individual comprehensive treatment plan

Guidance §482.61 (c)(1)

The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan is the outline of what the hospital has committed itself to do for the patient, based on an assessment of the patient's needs. The facility selects its format for treatment plans and treatment plan updates.

Survey Procedure §482.61(c)(1)

Determination of compliance regarding treatment plans is accomplished by the surveyor using the following methods, and to the extent possible, the following order:

1. Observation of the patient and staff at planned therapies/meetings, in various settings both on and off the patient units, in formal and informal staff-patient interactions and in a variety of daily settings;

2. Interviews with patients, families, treatment staff and others involved directly or indirectly with active treatment;

3. Reviews of scheduled treatment programs (individual, group, family meetings, therapeutic activities, therapeutic procedures);

4. Attendance at multidisciplinary treatment planning meetings, if time permits; and

5. Medical record review.

Probe §482.61(c)(1)

Has the information gained from assessing/evaluating the patient been utilized to create an individualized treatment plan?

B119

§482.61(c)(1) The plan must be based on an inventory of the patient's strengths and disabilities.

Guidance §482.61(c)(1)

A disability is any psychiatric, biopsychosocial problem requiring treatment/intervention. The term disability and problem are used interchangeably. The treatment plan is derived from the information contained in the psychiatric evaluation and in the assessments/diagnostic data collected by the total treatment team. Based on the assessment summaries formulated by team members of various disciplines, the treatment team identifies which patient disabilities will be treated during hospitalization. Patient strengths that can be utilized in treatment must be identified. (See also §482.61(b)(7).)

Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the hospital stay, the fewer disciplines may be involved in the patient's treatment.

There must be evidence of periodic review of the patient's response and progress toward meeting planned goals. If the patient has made progress toward meeting goals, or if there is a lack of progress, the review must justify: (1) continuing with the current goals and approaches; or (2) revising the treatment plan to increase the possibility of a successful treatment outcome.

Consideration must be given to the type of psychiatric program(s) under review to determine the timeframe for treatment plan review. The interval within which treatment plan reviews are conducted is determined by the hospital, however, the hospital's review system must be sufficiently responsive to ensure the treatment plan is reviewed: whenever a goal(s) has been accomplished; when a patient is regressing; when a patient is failing to progress; or when a patient requires a new treatment goal. The facility is expected to pursue aggressively the attendance of all relevant participants at the team meetings. Question any routine and regular absences of individuals who would be expected to attend.

Probes §482.61(c)(1)

Is the treatment plan individualized, i.e., patient-specific, or is there a predictable sameness from plan to plan?

When packaged plans or programs are used, do staff include needed individual adaptations in the plan?

Are the patient's observed behaviors consistent with the problems and strengths identified in the plan or update?

Have the views which the patient communicated to the surveyor regarding problems which require treatment during hospitalization and plans for discharge, been incorporated in the plan or update?

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§482.61(c)(1) The written plan must include—

B120

§482.61(c)(1)(i) A substantiated diagnosis;

Guidance §482.61(c)(1)(i)

The substantiated diagnosis serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.

At the time of admission, the patient may have been given an initial diagnosis or a rule-out diagnosis. At the time of treatment planning, a substantiated diagnosis must be recorded. It may be the same as the initial diagnosis, or, based on new information and assessment, it may differ.

Rule-out diagnoses, by themselves are not acceptable as a substantiated diagnosis.

Data to substantiate the diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others.

Probes §482.61(c)(1)(i)

What specific problems will be treated during the patient's hospitalization?

Does the treatment plan identify and precisely describe problem behaviors rather than generalized statements i.e., "paranoid," "aggressive," "depressed?" or generic terminology i.e., "alteration in thought process," "ineffective coping," "alteration in mood?"

Are physical problems identified and included in the treatment plan if they require treatment, or interfere with treatment, during the patient's hospitalization?

B121

§482.61(c)(1)(ii) Short-term and long range goals;

Guidance §482.61(c)(1)(ii)

Based on the problems identified for treatment, short-term and long-range goals are developed. Whether the use of short-term or a combination of short-term and long-range goals is appropriate is dependent on the length of hospital stay.

Short-term and long-range goals include specific dates for expected achievement. As goals are achieved, the treatment plan should be revised. When a goal is modified, changed or discontinued without achievement, the plan should be reviewed for relevancy, and updated as needed.

In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of hospital stay increases (often because of the long-term chronic nature of the patient's illness), both long-range and short-term goals are needed.

The long-range goal is achieved through the development of a series of short-term goals, i.e., smaller, logical sequential steps which will result in reaching the long-range goal. Both the short-term and long-range goals must be stated as expected behavioral outcomes for the patient. Goals must be related to the problems identified for treatment. Goals must be written as observable, measurable patient behaviors to be achieved. Discharge criteria may be included as long-range goals.

Probes §482.61(c)(1)(ii)

How do treatment plan goals relate to the problems being treated?

Do goals indicate the outcomes to be achieved by the patient?

Are the goals written in a way that allow changes in the patient's behavior to be measured?

If not apparent, what criteria do staff use to measure success?

How relevant are the treatment plan goals to the patient's condition?

B122

§482.61(c)(1)(iii) The specific treatment modalities utilized;

Guidance §482.61(c)(1)(iii)

This requirement refers to all of the planned treatment modalities used to treat the patient during hospitalization. Having identified the problems requiring treatment, and defining outcome goals to be achieved, appropriate treatment approaches must be identified.

Modalities include all of the active treatment measures provided to the patient. It describes the treatment that will be provided to the patient. It describes the treatment that will be provided by various staff.

A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient attends various treatment modalities/activities, it is a part of individualized planning with a specific purpose and focus for that patient.

Simply "naming" modalities (i.e., individual therapy, group therapy, occupational therapy, medication education) is not acceptable. The focus of the treatment must be included.

Simply "stating" modality approaches (i.e., "set limits," "encourage socialization," "discharge planning as needed") is not acceptable. Modality approaches must be specifically described in order to assure consistency of approach.

Observation of staff implementing treatment, both in structured and non-structured settings, is a major criterion to determine whether active treatment is being provided in accordance with planned treatment.

It must be clear to you that the active treatment received by the patient is internally consistent and not simply a series of disconnected specific modalities delivered within certain scheduled intervals.

Probes §482.61(c)(1)(iii)

Are qualified staff observed following the methods, approaches and staff intervention as stated?

Can staff explain the focus of the modality they have provided?

Are observed treatment methods, approaches and interventions from all disciplines included in the plan?

Do the pieces of the treatment plan work together to achieve the greatest possible gain for the patient?

Does the hospital integrate its activities, therapies, treatments, and patient routines to work for the patient's therapeutic interest first, and its own convenience second?

Do the disciplines present at observed treatment planning meetings represent all of the patient's needs?

If the patient attends treatment planning, how do the staff prepare the patient to participate?

If the patient does not attend, what reasons do staff give to explain the absence?

Is there a process to enable staff to reach a consensus regarding how treatment will be carried out?

Is the patient included in the decision-making, whenever possible?

Are the final decisions regarding treatment approaches defined clearly by the end of the discussion?

How does the patient get to know his/her treatment regime?

How does the treatment team encourage the patient to accept responsibility for engaging in the treatment regime, rather than accepting it passively?

B123

§482.61(c)(1)(iv) The responsibilities of each member of the treatment team; and

Guidance §482.61(c)(1)(iv)

There are no "correct" number of staff who comprise the treatment team. The disciplines involved in the patient's treatment depend upon the problems to be treated, the short-term and long-range goals and the treatment approaches and modalities used to achieve the goals.

The intent of the regulation is to insure that each individual on the treatment team who is primarily responsible for ensuring compliance with particular aspects of the patient's individualized treatment program is identified. Identification of the staff should be recorded in a manner that includes the name and discipline of the individual. If other professionals or paraprofessionals provide care, the facility has the latitude to decide the manner with which it will identify them on the treatment plan.

The patient, as well as family/significant others, should be aware of the staff responsible for various aspects of treatment.

Probes §482.61(c)(1)(iv)

Are staff who are designated in the treatment plan observed carrying out treatment activities and therapies? Is the information in the plan consistent with surveyor observations?

Are the patients able to name the staff responsible for implementing their treatment? Is this information consistent with the treatment plan?

B124

§482.61(c)(1)(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

Guidance §482.61(c)(1)(v)

When the progress and treatment notes are reviewed, the content of the notes must relate to the treatment plan. The notes must indicate what the hospital staff is doing to carry out the treatment plan and the patient's response to the interventions.

Probes §482.61(c)(1)(v)

Are the treatment notes relative to the identified problems?

Are the treatment notes indicative of the patient's response to treatment?

Do the progress notes relate to specific patient problems or progress?

B125

§482.61(c)(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

Guidance §482.61(c)(2)

Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist. The patient is in the hospital because it has been determined that the patient requires intensive, 24 hour, specialized psychiatric intervention that cannot be provided outside the psychiatric hospital. The medical record must indicate

that the hospital adheres to the patient's right to be counseled about medication, its intended effects, and the potential side effects. If the patient requires, because of danger to self or others, a more restrictive environment, the hospital must indicate that the staff attempted to care for the patient in the least restrictive setting before progressing to a more restrictive setting.

Through observation, look for evidence that each patient is receiving all the aspects of treatment to which the hospital has committed itself based upon his/her assessment, evaluation and plan of care. It is the hospital's responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning.

Through observation and interviews, look for evidence that each patient's rights are being addressed and protected. There should be policies and procedures in place to address the following areas: informed consent, confidentiality, privacy, and security. Expect to see detailed policies and procedures regarding the therapeutic use of restrictions, such as visitors, mail, and phone calls. Seclusion and restraint policies and procedures must address patient protection and safety while in a restricted setting.

Clarification of the types of notes found in the medical record.

Treatment notes are recordings in the medical record that indicate provision of, and a patient's response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician or anyone credentialed by the facility, in accordance with the State law, to write orders in the medical record.

A combined treatment and progress note may be written.

Progress notes are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan. These are frequently shift notes, weekly notes, or monthly notes.

Probes §482.61(c)(2)

Does the patient know his/her diagnosis?

What did the patient contribute to the formulation of the treatment plan? Goals of treatment?

If the patient receives medication, does the patient understand the reason for the medication? The name of the medication? The dose prescribed? The time of administration? The desired effects? The potential side effects?

If medication is changed, is there a rationale for the change?

Are staff members recording their observations relative to the patient's response to the treatment modalities, including medication?

Is there evidence that the patient was afforded the opportunity to participate in his/her plan of care?

What progress has the patient made? Has the patient achieved his/her optimal level of functioning? If not, why? Are these reasons/barriers reflected in the current treatment plan? Do treatment and progress notes support these insights?

Does the observed status of the patient in the various treatment modalities correspond to the progress note reports of status?

Do all treatment team members document their observations and interventions so that the information is available to the entire team?

If a restrictive procedure is used (e.g., restraint and/or seclusion), is there evidence that attempts were made systematically to treat the patient in the least restrictive manner?

Is there evidence that the rights of the patient were protected while in the restrictive setting in accordance with Federal and State law and accepted standards of practice?

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§482.61(d) Standard: Recording Progress

B126

§482.61(d) Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in §482.12(c),

Guidance §482.61(d)

Refer to §482.61(c)(2) Guidance for clarification between treatment notes and progress notes. The recording of progress is evidence of individual patient performance. Specifically, the progress notes recorded by the professional staff, or others responsible for the patient's treatment, must give a chronological picture of the patient's progress or lack of progress towards attaining short and long-range goals outlined in the individual treatment plan. Progress notes should relate to the goals of the treatment plan. Notes that state, "patient slept well" or "no complaints" constitute observations and do not indicate how the patient is responding to treatment and progressing towards set goals. Frequency alone does not determine the adequacy of progress notes. Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind. Notes should be dated and signed (signature and title or discipline).

Probes §482.61(d)

Are the physicians who are significantly involved in active treatment modalities/interventions actually documenting progress?

Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress?

Is there a correlation between what is observed by the surveyor and what is described in the notes?

Do the notes give a clear picture of the patient's progress or lack thereof, during the course of hospitalization?

In reviewing the patient's progress, are aftercare/discharge plans being evaluated?

B127

§482.61(d) nurse

Probes §482.61(d)

Are the nurses who are significantly involved in active treatment modalities/interventions actually documenting progress?

B128

§482.61(d) social worker

Probes §482.61(d)

Are the social workers that are significantly involved in active treatment modalities/interventions plan actually documenting progress?

B129

§482.61(d) when appropriate, others significantly involved in active treatment modalities.

Probes §482.61(d)

Are staff from other disciplines, i.e., rehabilitative therapy and psychology, which are significantly involved in active treatment modalities/interventions actually documenting progress?

B130

§482.61(d) The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter,

Probes §482.61(d)

What is the frequency of progress notes in relation to the condition of the patient?

§482.61(d) and must contain

B131

§482.61(d) recommendations for revisions in the treatment plan as indicated as well as

Probes §482.61(d)

Do the progress notes contain documentation substantiating changes/revisions in the treatment plan and subsequent assessment of the patient's responses and progress

B132

§482.61(d) a precise assessment of the patient's progress in accordance with the original or revised treatment plan.

Probes §482.61(d)

Do the notes give a clear picture of the patient's progress, or lack thereof, during the course of hospitalization?

Are the progress notes related to the goals of the treatment plan?

§482.61(e) Standard: Discharge Planning and Discharge Summary

B133

§482.61(e) The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and

Guidance §482.61(e)

The record of each patient who has been discharged should indicate the extent to which goals established in the patient's treatment plan have been met.

As part of discharge planning, staff consider the discharge alternatives addressed in the psychosocial assessment and the extent to which the goals in the treatment plan have been met.

The surveyor should refer to hospital policy for discharge timeframes.

The discharge summary should contain a recapitulation of the patient's hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan. This summary includes the reasons for admission, treatment achieved during hospitalization, a baseline of the psychiatric, physical and social functioning of the patient at the time of discharge, and evidence of the patient/family response to the treatment interventions.

B134

§482.61(e) recommendations from appropriate services concerning follow-up or aftercare

Guidance §482.61(e)

The patient's discharge summary should describe the services and supports that are appropriate to the patient's needs and that will be effective on the day of discharge.

Examples include:

- A complete description of arrangements with treatment and other community resources for the provision of follow-up services. Reference should be made to prior verbal and written communication and exchange of information;

- A plan outlining psychiatric, medical/physical treatment and the medication regimen as applicable;

- Specific appointment date(s) and names and addresses of the service provider(s);
- Description of community housing/living arrangement;
- Economic/financial status or plan, i.e., supplemental security income benefits;
- Recreational and leisure resources; and
- A complete description of the involvement of family and significant others with the patient after discharge.

Probes §482.61(e)

How does the discharge planning process verify appointment source(s), dates and addresses?

How was the patient involved in the discharge and aftercare planning process?

Were discharge related documents made available to the patient, family, community treatment source and/or any other appropriate sources?

Is there indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-hospital treatment entity?

Is there evidence that contact with the post-hospital treatment entity included communication of treatment recommendations (including information regarding the patient's medications)?

Is a contact person named, and does the patient have a specific appointment date and time for the initial follow-up visit?

B135

§482.61(e) a brief summary of the patient's condition on discharge.

Guidance §482.61(e)

The patient's discharge planning process should address anticipated problems after discharge and suggested means for intervention, i.e., accessibility and availability of community resources and support systems including transportation, special problems related to the patient's functional ability to participate in aftercare planning.

The discharge summary and/or plan should contain information about the status of the patient on the day of discharge, including psychiatric, physical and functional condition.

B136

§482.62 Condition of Participation: Special Staff Requirements for Psychiatric Hospitals

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.

Guidance §482.62

The purpose of this Condition of Participation is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients.

Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, patient and staff injury reports, for indications that staffing is an issue.

Adequate numbers are defined to mean the numbers, and deployment, of staff with qualifications to evaluate, plan, implement and document active treatment.

Do not look at numbers alone. The hospital is responsible for organizing its available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment and patient assignments to wards and groups in such a way that results in patients achieving the maximum therapeutic benefit.

Survey Procedure §482.62

Assess the adequacy of the Special Staffing Condition by:

1. Observing sampled patients and others during structured sessions and in unstructured settings. You should be able to observe behavioral evidence of a rational organization of resources.

2. Next, interview patients and staff to determine whether or not necessary treatment modalities and other services are being provided in a timely manner.

3. Next review the medical records of patients in the sample to ascertain if necessary active treatment assessments, treatments, evaluations and activities have been conducted and documented.

4. Also, review other records such as restraint and seclusion records, incident reports, medication error reports, reports of patient/staff injuries, etc., to determine the extent to which staffing levels or deployment contributed to negative patient outcomes.

5. Evaluate all outcome data in light of the success or failure observed during the survey relevant to each patient receiving active treatment, and achieving desired outcomes of care. This is the primary basis for evaluating the adequacy of the hospital's staffing under this Special Condition.

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§482.62(a) Standard: Personnel

§482.62(a) The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

B137

§482.62(a)(1) Evaluate Patients

Probes §482.62(a)(1)

Is there adequate staff to assure that the admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner?

Is there evidence that there is continuing evaluation of the patient's progress and response to treatment?

Are evaluations delayed or absent?

B138

§482.62(a)(2) Formulate written individualized, comprehensive treatment plans;

Guidance §482.62(a)(2)

Staffing must be sufficient so that members of the patient's treatment team and others responsible for evaluation and assessment can contribute their respective data for consideration in the formulation of the treatment plan.

Probes §482.62(a)(2)

Was there sufficient discipline participation at the treatment team meeting to assure formulation of a treatment plan that meets the patient's individualized needs?

What problems prevent staff members from attending treatment meetings? Do they relate to staffing?

Are the assessments/evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment?

B139

§482.62(a)(3) Provide active treatment measures;

Guidance §482.62(a)(3)

Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Although the active treatment process must be identifiable in documentation, it must be first and foremost observable and evident in daily practice.

Treatment interventions need to be individualized, in that the patient receives assistance with resolving or ameliorating the problems/circumstances that led to hospitalization. Expect to see treatment focused on the unique needs of individual patients. For example, several patients may be referred to "Anger Management Group," but the focus of discussion and therapeutic intervention may differ depending on the individual patient's particular issue regarding managing anger.

Whether structure must be imposed by staff or whether the patient can direct his or her own activities for periods of time (without staff supervision), is based on the patient's ability to engage in constructive, appropriate behavior (without engaging in harm to self or others). Be certain that the patient's time on the unit is maximized toward the further development of appropriate desired outcomes, including but not limited to leisure and recreation.

Probes §482.62(a)(3)

Through observation, interviews and record reviews, can you determine that patients receive active treatment?

Is the distribution of staff consistent with particular patient needs? Is appropriate staffing sufficient to carry out treatment plans?

Does the patient attend therapies that are relevant to the identified problems that brought the patient to the hospital?

Are staff absences and/or vacancies preventing the patient from receiving active treatment? Are patients not attending therapeutic activities off the unit because there is no staff to escort them? Are therapeutic groups not available on the unit for patients who are not able to go off the unit?

Are patients observed not engaged in activities while staff attend to administrative tasks?

Are active treatment sessions or activities carried out at discrete time intervals exclusively? Or is active treatment implemented as the patient's needs emerge during the course of the day, as well?

Does a review of quality assurance data reveal a pattern of serious incidents occurring on particular shifts and/or days of the week?

What do patients report to the surveyor are their treatment modalities?

Do patient interviews indicate that patients believe the treatment being provided is helpful?

Does the scheduling of activities and their content relate directly to the patient's treatment objectives or are the activities/content generalized, non-therapeutic "time-fillers"?

Can staff describe how their activities relate to the patient's treatment objectives?

At any point in time, in any of the patient's experiences in the hospital is the thrust of the patient's treatment plan observable during the staff and/or patient interactions?

Is there a consistent, observable pattern of evidence that hospital staff provide, reinforce and otherwise implement measures to achieve active treatment objectives?

B140

§482.62(a)(4) Engage in discharge planning;

Guidance §482.62(a)(4)

The patient together with all relevant professionals caring for the patient should be expected to participate in the discharge planning process. Staffing should be sufficient to facilitate this outcome, to the maximum extent possible.

Probes §482.62(a)(4)

Do patients participate in their discharge planning process? If not, why?

Do staff interviews elicit information that staff working with patients are aware of the discharge plans for those patients?

Do record review and interviews indicate that all relevant staff have participated in discharge planning?

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§482.62(b) Standard: Director of Inpatient Psychiatric Services; Medical Staff

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B141

§482.62(b) Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.

Guidance §482.62(b)

Inpatient psychiatric services include the following functions: admission interviews, assessments and evaluations; psychiatric and medical work-ups; treatment team leadership; medication management; on-call provision of emergency psychiatric and medical treatment; provision of individual, group and family therapies; provision of clinical supervision to other professionals and paraprofessionals; provision of medical and psychiatric educational workshops and conferences for all staff; and provision of consultation to staff for clinical and/or administrative matters.

The clinical director is ultimately responsible for the medical and psychiatric care that is provided to patients. The clinical director should ascertain that quality improvement programs are in place to monitor all areas of patient care, and should implement educational programs for all levels of staff.

Survey Procedure §482.62(b)

Just prior to the end of the survey, schedule a meeting with the clinical director. By the time of this meeting, you should already have conducted required observation, interviews and record reviews for at least a majority of the patients in the sample. Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the clinical director; the leadership exhibited for the scope of psychiatric/medical treatment programs needed by patients; and the rationale for medical staffing coverage. If necessary, follow-up on letters of complaint previously reported serious problems, discrepancies with Data Collection Medical Staff Coverage (CMS-729).

B142

§482.62(b) The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

Guidance §482.62(b)

The number of full-time, part-time and consulting staff, who are board certified within each category and their availability to the hospital must be adequate to provide psychiatric services, as described above. Adequacy is considered in light of the following:

1. Number of admissions, discharges and current patients by treatment units;

2. Size of the hospital;

3. Geographic proximity of the wards and units;

4. Organization and kinds of treatment services rendered to the patients;

5. Availability of the physician coverage on evening, nights and weekends;

6. Availability of physicians to participate in treatment planning;

7. Availability of psychiatrists to consult with non-psychiatric physicians about psychotropic medication regimens; and

8. Availability of physicians to consult with multi-disciplinary staff about treatment issues.

Probes §482.62(b)

How many staff are board certified? Fully trained? How many full-time/part-time specialties are represented?

How are medical staff deployed? To what programs/units are they assigned? Why?

How much time do physicians spend on the units? Based on observations, interviews, and medical record reviews is coverage adequate to meet the needs of sampled patients? To meet the needs of other patients observed during the survey?

B143

§482.62(b)(1) The clinical director, service chief or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.

Guidance §482.62(b)(1)

A physician is qualified to take the examinations for board certification upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology.

Survey Procedures §482.62(b)(1)

Review the clinical director's personnel folder or ask the clinical director if he/she has one of the following:

a. Certification of the American Board of Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry.

b. If no certification, evidence that the person took the Boards would satisfy that the person had the training and equivalency to be admitted to the board examination.

c. If indicated, medical school and residency training

d. Length of time he has been employed at the facility; length of time he has been at his position

To be admitted to the American Board Examinations the following conditions must be met:

1. License without restrictions

2. Graduation from a medical school approved by either the Medical Osteopathic Association or the American Medical Association.

3. A successful completion of an approved residency-training program for at least 3 years before 1988 that the America Council on Graduate Medical Education (ACGME) approves. After 1988, it has to be a four year accredited program.

B144

§482.62(b)(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

Guidance §482.62(b)(2)

Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice.

In states that allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient's treatment.

Probes §482.62 (b)(2)

What mechanisms does the director use to monitor and evaluate the work of the medical staff (personal interviews? Quality Improvement reports? incident reports?)?

When problems are discovered by the clinical director, how are they corrected?

Are services, notes, and reports timely?

Are medications used appropriately for the patient's diagnosis?

§482.62(c) Standard Availability of Medical Personnel

B145

§482.62(c) Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

Guidance §482.62(c)

Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients. Review the medical and surgical services provided by the hospital during the interview with the clinical director. Discuss contract or arrangements with the clinical director for services provided off grounds.

Probes §482.62(c)

How did the hospital meet the medical/surgical/diagnostic needs represented by each patient in the sample? Were these done timely? Appropriately?

If contracts are not current or available, how are these services provided for the patient, if needed? Is there evidence of negative outcomes as a result of these arrangements?

Are reports from other services such as pharmacy, radiology, and clinical laboratory timely? Appropriate?

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§482.62(d) Standard: Nursing Services

B146

§482.62(d) The hospital or unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

Guidance §482.62(d)

Psychiatric nursing functions may include the following: supervision of paraprofessional staff; assessment, planning, provision, and evaluation of psychiatric nursing care to patients; medication teaching; management of the therapeutic milieu; provision of mandatory and voluntary in-service training to all staff; and provision of specialized treatments and therapies, such as individual, group and family therapies, that require the clinical expertise of a professional psychiatric nurse.

Expect to see evidence of orientation programs as well as ongoing continuing education programs for Licensed Practical Nurses and mental health workers that stress individualized treatment interventions.

Determine that there is a qualified Director of Nursing (DON) providing the required leadership and supervision for the psychiatric nursing department.

B147

§482.62(d)(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill.

Guidance §482.62(d)(1)

During the interview with the DON, assess his/her educational background and psychiatric nursing and leadership skills. If the DON has less than a Master's Degree in Psychiatric Nursing, expect to see evidence of experience and on-going training in psychiatric nursing. Documented consultation from a nurse with a Master's in Psychiatric Nursing constitutes on-going training.

Probes §482.62(d)(1)

Are nursing assessments completed on all patients?

Do the multidisciplinary treatment plans reflect nursing input which include specific nursing interventions for nursing problems (e.g. violence toward self/others, physical/medical crises)?

Is nursing care evaluated by an R.N., with changes in the care based on the patient's progress or lack thereof?

Are intrusive techniques (e.g. seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g. medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with hospital policy, State statutes and safe nursing practice?

Are nursing personnel observed relating to patients in a therapeutic manner?

B148

§482.62(d)(1) The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished

Guidance §482.62(d)(1)

Based on structured observations of the patients in the sample and other patients in the hospital, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice

Information obtained from the DON should include: implementation of continuous quality improvement programs; provision of orientation, in-service and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention and management of violence, CPR and Universal Precautions.

B149

§482.62(d)(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day.

B150

§482.62(d)(2) There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

Guidance §482.62(d)(2)

The evaluation of sufficient numbers and level of RNs, LPNs and mental health workers is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the hospital, patient interviews, and as evidenced in medical records and other data related to patients (e.g. incident reports, seclusion/restraint reports). Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care.

There should be evidence that all nursing personnel have education, experience and/or training in psychiatric care. Mental health workers spend the majority of their workday interacting with patients. Expect to see evidence that they are receiving on-going supervision and training. Mental health workers should be assigned patient care duties and therapeutic modalities that reflect their educational level, psychiatric training, and experience.

Survey Procedure §482.62(d)(2)

The nursing staffing patterns should be reviewed on a sample of approximately 25% of the certified wards. The staffing, including levels of nursing personnel, should be reviewed for the day(s) of the survey and evaluated based on the level of needs presented by the patients. Additional staffing patterns shall be reviewed if a problem or concern is evidenced. Decisions regarding extent of additional data (number of wards and dates) to be reviewed shall be based on the degree of problem/concern. Patient need assessment/patient acuity shall be reviewed for any wards as deemed necessary based on problems/concerns found in the sampling review.

If your observations and/or interviews indicate a staffing problem, you may want to consider the following variables in assessing adequacy of nursing personnel coverage:

1. Organization and types of services provided to patients by the nursing department;4

2. Number and levels of nursing care needs of patients, including average length of stay, acuity of patients and nursing care requirements;

3. Number and levels of nursing personnel based on the roles and functions required of nursing;

4. Number of suicidal/assaultive patients;

5. Seclusion/restraint incidents;

6. Number of admissions and discharges;

7. Number and type of accidents and/or injuries;

8. Amount and complexity of medication regimens;

9. Medication errors;

10. Use of P.R.N. (as needed) medications;

11. Medical (physical) procedures;

12. Assignment and utilization of "pool" nursing personnel (those staff who are hired through a contract service and are not employees of the hospital). Contractual staff should receive orientation and training necessary for assigned functions, and should be supervised by employees of the hospital;

13. Availability of RNs to supervise/consult with nursing/non-nursing personnel about patient care;

14. Availability of RNs to assess and implement care in crisis situations;

15. Availability of RNs to interact with patients in structured activities; and

16. Involvement of patients with personnel.

Probes §482.62(d)(2)

Are personnel interacting with patients? Are patients involved in structured activities? Are patients lying in beds/on floors, sitting alone, fighting and arguing?

When interviewing/observing staff, do they interact therapeutically with patients? If unclear, request rationale from staff.

Why have nursing staff been deployed in the manner that they have?

§482.62(e) Standard Psychological Services

B151

§482.62(e) The hospital must provide or have available psychological services to meet the needs of the patients.

Guidance §482.62(e)

Psychology services may include the following: diagnostic testing and diagnostic formulations on request from physicians; provision of individual, group and family therapies; participation in multi-disciplinary treatment conferences; and program development and evaluation.

The number of full-time, part-time and consulting psychologists must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided.

Probes §482.62(e)

Did the patients in the sample have a need for psychological services or testing? Were they provided in a timely manner and with sufficient intensity?

Did any of the patients in the sample indicate a need for psychological services, but none were requested?

What types of psychological services are offered? (e.g., assessments, therapy)

Do certain groups of patients receive testing routinely? Dementia?, Children?, Adolescents? Why?

Once tests are performed, are results reported in sufficient time to be integrated in the patient's active treatment and treatment plan?

How does the hospital or Psychological Service Department determine whether or not: it meets the needs of patients? Its services are underutilized or over-utilized?

Why have psychological services staff been deployed in the manner that they have?

§482.62(f) Standard: Social Services

B152

§482.62(f) There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.

Guidance §482.62(f)

Social work functions may include the following functions: Intake or admission screening, psychosocial assessment of a newly admitted patient; developing an update or detailed re-assessment of the patient; high-social risk case finding; contact with family and others significant in the patient's life. Such functions may include patient and family education, support, and advocacy; providing coordination/liaison with community-based social and mental health agency(ies) regarding the pre-admission status of the patient; participating as a member of the treatment team in development of treatment planning and subsequent planned interventions (modalities). Such modalities may include supportive, individual, couple, family, or group therapy, aimed at meeting specified goals identified in the treatment plan.

Continuity of care is an important social work principle and may be demonstrated through case management and a major role in discharge planning. Activities, in conjunction with the patient wishes, may include contact with patient's family, identifying and assisting in referral of the patient to community-based agency(ies) at the time of discharge. Finally, post-discharge follow-up may be done to assure that linkage of the patient with community resources has occurred to reduce re-hospitalization.

Determine who completed the assessment required by §482.61(a)(4) and initiated preliminary discharge planning. When staff other than a Social Worker perform these duties, the Director of Social Work or a Master's level social worker (MSW) qualified supervisory staff member should be involved to oversee the quality and appropriateness of service provided.

Patient and staff interviews, structured observations and review of selected medical records yield the information necessary to determine how well social work has met the needs of the patients. The surveyor should evaluate these data to determine adequacy of qualified and support staff deployed to patient areas and their duties.

The social work policies for service provision to the patient should describe: the organizational structure of the department (program) and the range of services performed by the department.

Survey Procedure §482.62(f)

Just prior to the end of the survey, schedule a meeting with the Director of Social Work. By the time of the meeting, you should already have conducted required observations, interviews and record reviews for at least a majority of the patients in the sample. Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the director; the leadership exhibited for the scope of services needed by the patient; and the rationale for social work staffing coverage.

Probes §482.62(f)

How does the director periodically audit the quality of social work services furnished?

What are the outcomes of audits conducted? What percentage of psychosocial assessments was completed and available in written form at the time of the interdisciplinary treatment plan? How does the patient's social needs as addressed by the social worker in the psychosocial assessment compare against the goals developed in the interdisciplinary treatment plan?

Has social work staff provided active treatment in accordance with the patient's treatment plan?

B153

§482.62(f) The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

Guidance §482.62(f)

Accepted standards of practice are based on policy statements adopted by the National Association of Social Workers and a definition of social work practice in health care adapted by the Consortium of Health Care Social Work Organizations. Staff should adhere to the facility's personnel requirements.

B154

§482.62(f)(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree in social work, at least one staff member must have this qualification.

Guidance §482.62(f)(1)

The duties, functions, and responsibilities of the director of social services/social work should be clearly delineated and documented in the facility's policies and procedures. If the director is not MSW qualified and at least one staff member is MSW qualified, verify the duties, functions, and responsibilities of the MSW.

Probes §482.62(f)(1)

What are the director's qualifications, experience and scope of duties within this position?

If a MSW staff member, other than the director, is performing any of these duties, what are this staff member's experience and scope of duties performed? Why were these duties delegated?

To what extent is the director's knowledge of the social work needs of the various wards?

Why has the social work staff and services provided throughout the hospital been deployed in the manner it has?

B155

§482.62(f)(2) Social service staff responsibilities must include, but are not limited to, participating in discharge, planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

Guidance §482.62(f)(2)

Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission. High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated. The treatment team should consider, for possible inclusion into the patient's treatment plan, the anticipated social work role and expected interventions as recommended in the psychosocial assessment . Treatment and discharge planning activities, liaison/follow-up efforts should be based upon the goals, including discharge goals, and staff responsibilities specified in the treatment plan.

Probes §482.62(f)(2)

Are social work staff routinely involved in providing services to the patient that are identified in the treatment plan?

To what extent do social work staff provide discharge planning services to the patient in the way of: supportive individual, couple, family, or group therapy focused on discharge goals of the patient? Carrying out a liaison role with community resource providers?

Have social work staff assured that adequate information is provided to post-hospital patient service providers?

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§482.62(g) Standard: Therapeutic Activities

B156

§482.62(g) The hospital must provide a therapeutic activities program.

Guidance §482.62(g)

A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patients. Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient's functioning. In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences. A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients the priority need may be for leisure education and activities.

B157

§482.62(g)(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

Guidance §482.62(g)(1)

The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs.

The selection of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling. There are other disciplines that also serve paients. Consultants include but are not limited to the following: educational instructors, registered occupational therapist/certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and

registered physical therapist. The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or the work adjustment specialist.

B158

§482.62(g)(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

Guidance §482.62(g)(2)

Qualified staff should complete their respective discipline assessments for use in multidisciplinary treatment planning. Specific role(s) and modalities to be implemented by rehabilitative staff must be determined by goals set in the patient's treatment plan.

Qualified therapists who provide clinical services and administrative staff should utilize established monitoring and evaluation mechanisms to conduct consistent timely review of the quality and appropriateness of therapeutic and rehabilitative services delivered to patients.

Probes §482.62(g)(2)

Is there evidence that sampled patients and staff are familiar with the goals and staff interventions described in the patient's treatment plan? Are these observed interventions being carried out? What is the patient's response? Are these interventions and activities of sufficient frequency and intensity to achieve maximum therapeutic benefit?

What are the qualifications, experience, duties and responsibilities of the Therapeutic Activities Director and discipline supervisor(s)?

How is the program organized?

Did the patients in the sample have a need for any therapeutic activities? Were their needs met?

Did any of the patients in the sample indicate a need for therapeutic activities, but none were considered?

What kinds of services are provided to the patient population?

Are activity areas/sites accessible and available to meet the patient's individual needs? Are the facilities and resources adequate to enable implementation of goals set in the patient's treatment plan?

Does the program utilize available community resources to provide opportunities for socialization, leisure, and therapeutic and/or rehabilitation activities for patients who can participate outside the hospital setting?

Are current activity schedules clearly posted for patient and staff reference and use? Are the scheduled activities related to the particular patient area and specific treatment needs of patients?

Are patient needs met consistently at all times including evenings and weekends?

If a large number of patients are assigned to the same therapeutic activity, do patients have individualized goals within their treatment plans?

Why have therapeutic activities staff been deployed in the manner they have?

Regulations and Interpretive Guidelines for CAHs

C-0150

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretive Guidelines §485.608

Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result.

Refer or report suspected violations to the appropriate Federal, State, or local agency.

C-0151

§485.608(a) Standard: Compliance With Federal Laws and Regulations

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Survey Procedures §485.608(a)

Interview the CEO, or appropriate individual, to determine whether the CAH is in compliance with Federal laws related to patient health and safety. For example, if the CAH has been convicted of violating a Federal law such as denying people with disabilities access to care, verify that satisfactory corrections have been made to bring the CAH into compliance with that law.

Refer noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood borne pathogens, universal precautions, TB control to OSHA, hazardous chemical and waste issues to EPA, etc.)

C-0152

§485.608(b) Standard: Compliance With State and Local Laws and Regulations

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guidelines §485.608(b)

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function.

Survey Procedures §485.608(b)

Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

C-0153

§485.608(c) Standard: Licensure of CAH

The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

Survey Procedures §485.608(c)

Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

C-0154

§485.608(d) Standard: Licensure, Certification or Registration of Personnel

Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

Interpretive Guidelines §485.608(d)

All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators.

All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications; and
- Training/education requirements.

Survey Procedures §485.608(d)

- Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.
- Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.
- Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.
- Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

C-0160

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

This COP only applies to initial surveys unless the facility relocates. If the CAH moves the location of the CAH to another location, the status and relocation must be reassessed.

C-0161

§485.610(a) Standard: Status

The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

Interpretive Guidelines §485.610(a)

Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will reverify the status requirement prior to approving a CAH for Medicare certification.

C-0162

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.62(f) of this chapter;

(ii) The CAH is not deemed to be located in an urban area under §412.63(b) of this chapter; and

(iii) The CAH has not been classified as an urban CAH for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter, and is not among a group of CAHs that have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

Interpretive Guidelines §485.610(b)

"**Urban**" as defined at 42 CFR §412.62(f), means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget, or the following New England Counties: Litchfield County, Connecticut; York County, Maine; Merrimack County, New Hampshire; Newport County, Rhode Island; and Fagadahoe County, Maine.

"**Urban area**," as defined at 42 CFR §412.62 (f) and referenced in 42 CFR § 412.63(b), applies to CAHs located within an MSA or NECMA that crosses census division boundaries. In such cases, the MSA or NECMA in which the CAH is located is deemed to belong to the census divisions in which most of the CAHs within the MSA or NECMA are located.

A "**Metropolitan CAH**" is a CAH that is located within a MSA but is being treated as being located in a rural area. A CAH that wishes to convert to a CAH, and is located in an urban area, must be reclassified as a rural CAH by submitting an application, prior to conversion, to the regional office of CMS. Prior to conversion, the CAH must meet one of the following criteria and explain how they meet the criteria for reclassification as rural, including data and documentation necessary to support the request, in the application for reclassification. Reference 42 CFR §412.103.

- The CAH is located in a rural census tract of an MSA as determined under the most recent version of the Goldsmith Modification; or
- The CAH is located in an area designated as a rural area by any law or regulation of the State in which it is located; or
- The CAH is designated as a rural CAH by State law or regulation; or
- The CAH would qualify as a rural referral center or as a sole community hospital.

Survey Procedures §485.610(b)

Determine that a CAH meets the basic location requirement prior to scheduling the survey. The appropriate RO will reverify the location requirement prior to approving a CAH for Medicare certification.

C-0165

(Rev. 32, Issued: 01-18-08, Effective: 09-07-07, Implementation: 09-07-07)

§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guidelines §485.610(c)

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination.

C-0166

(Rev. 32, Issued: 01-18-08, Effective: 09-07-07, Implementation: 09-07-07)

§485.610(d) Standard: Relocation of CAHs With a Necessary Provider Designation

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii)Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

Interpretive Guidelines §485.610(d)

Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. However, as discussed in the adoption of this regulation (70 FR 47472), all newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities. The determination of whether or not CAHs with a necessary provider designation have met the requirements at §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.

C-0170

§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guidelines §485.612

This COP only applies to initial surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP to determine compliance, whether they are:

- A currently operating CAH; or
- A re-opened CAH; or
- A CAH that down-sized to become a clinic.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition, these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

C-0190

§485.616 Condition of Participation: Agreements

C-0191

§485.616(a) Standard: Agreements With Network Hospitals

In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for:

Interpretive Guidelines §485.616(a)

Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.

Survey Procedures §485.616(a)

- If the CAH is a member of a rural health network having a communications system, ask to see the agreement.
- How does the CAH participate with other hospitals and facilities in the network communications system?
    - Is a communications log kept at the facility?
    - Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays.
- How does the network's communications system compare with any available communications equipment in the CAH?
- When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?
- Review any policies and procedures related to the operation of any communications system.
- How is the CAH staff educated on the use of any communication system utilized in the facility?
- Review any written agreements with the local EMS service.

C-0192

§485.616(a)(1) Patient referral and transfer;

C-0193

§485.616(a)(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

C-0194

§485.616(a)(3) The provision of emergency and non-emergency transportation between the facility and the hospital.

C-0195

§485.616(b) Standard: Agreements for Credentialing and Quality Assurance

Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

Interpretive Guidelines §485.616(b)

Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities.

Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH.

Survey Procedures §485.616(b)

- Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH.
- Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

C-0200

§485.618 Condition of Participation: Emergency Services

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

Interpretive Guidelines §485.618

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH'S emergency services must be under the direction of a qualified member of the CAH'S medical staff. The CAH'S medical staff establishes criteria for the qualifications for the director of the CAH'S emergency services in accordance with State law and acceptable standards of practice.

The CAH'S medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QA activities. The CAH'S emergency services must be integrated into the CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needed to met its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- Each type of service provided by the CAH;
- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;
- Equipment assembly and operation;
- Safety practices, including infection control measures;
- Handling, storage, and dispensing of therapeutic gases;
- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;

- Administration of medications; and

- Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures §485.618

- Verify that emergency services are organized under the direction of a qualified member of the medical staff.

- Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.

- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care

- Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?

- Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.

- Verify that emergency services are provided in accordance with acceptable standards of practice.

- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:

    - Parenteral administration of electrolytes, fluids, blood and blood components;

    - Care and management of injuries to extremities and central nervous system;

    - Prevention of contamination and cross infection; and

    - Provision of emergency respiratory services.

- Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.

- Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.

- Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.

- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

C-0201

§485.618(a) Standard: Availability

Emergency services are available on a 24-hours a day basis.

Interpretive Guidelines §485.618(a)

The CAH "makes available 24-hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day.

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(a)

Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

C-0202

§485.618(b) Standard: Equipment, Supplies, and Medication

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

Interpretive Guidance §485.618(b)

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(b)

- How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?
- Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

C-0203

§485.618(b)(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Survey Procedures §485.618(b)(1)

- How does the CAH ensure that staff knows where drugs and biologicals are kept?
- How is the inventory maintained?
- Who is responsible for monitoring drugs and biologicals?
- How are drugs and biologicals replaced?

C-0204

§485.618(b)(2) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

Survey Procedures §485.618(b)(2)

- How does the CAH ensure that required equipment and supplies are readily available to staff?
- How does the CAH ensure that staff knows where emergency equipment and supplies are kept?

- How is the supply inventory maintained?
- Who is responsible for monitoring supplies?
- How are supplies replaced?
- When was the last time emergency supplies were used?
- Is there an equipment maintenance schedule (e.g., for the defibrillator)?
- Ask staff if equipment has ever failed to work when needed.
- Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
- Examine the oxygen supply system to determine functional capabilities.
- Check the force of the vacuum (suction) equipment to see that it is in operating condition.

C-0205

§485.618(c) Standard: Blood and Blood Products

The facility provides, either directly or under arrangements, the following--

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

Interpretive Guidelines §485.618(c)(1)

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The

provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"**Availability**" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

C-0206

§485.618(c)(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Survey Procedures §485.618(c)(2)

- If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?

- For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

C-0207

§485.618(d) Standard: Personnel

(1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner with training

or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(ii) of this

section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph (d)(2)(ii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

Interpretive Guidance § 485.618(d)

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Survey Procedures §485.618(d)

- Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.

- Interview staff to determine how the CAH staff knows who is on call.

- What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, or registered nurse (as allowed under (d)(2)) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

C-0209

§485.618(e) Standard: Coordination With Emergency Response Systems

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Interpretive Guidelines §485.618(e)

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Survey Procedures §485.618(e)

- Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?

- What evidence demonstrates that the procedures are followed and evaluated for effectiveness?

- Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

C-0210

§485.620 Condition of Participation: Number of Beds and Length of Stay

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C-0211

(Rev. 34; Issued: 04-04-08; Effective/Implementation Dates: 04-04-08)

§485.620(a) Standard: Number of Beds

Except as permitted for CAHs having *distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.*

Interpretive Guidelines §485.620(a)

Section 1820(c)(2)(B)(iii) of the Social Security Act, codified at 42 USC 1395i-4(c)(2)(B)(iii) limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds.

Observation Services

Observation beds are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.

Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have been avoided, had the beneficiary been properly admitted as an inpatient. This is the case because, as CAHs are not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs are also not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

*Observation services are **NOT** appropriate:*

- *As a substitute for an inpatient admission;*
- *For continuous monitoring;*
- *For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;*
- *For patients awaiting nursing home placement;*
- *To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;*

- *For routine prep or recovery prior to or following diagnostic or surgical services; or*

- *As a routine "stop" between the emergency department and an inpatient admission.*

*Observation services **BEGIN** and **END** with an order by a physician or other qualified licensed practitioner of the CAH.*

- *The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "admit for observation."*

- *Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.*

- *Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care.*

Medicare generally will not pay for observation services lasting more than 48 hours. However, some States may have more stringent limits in their licensure or other regulatory requirements, e.g., 24 hours. In such cases the more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for admission to, and discharge from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this would suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question, but would violate the CAH's provider agreement. (See 42 CFR 489.53(c)(2).)

CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH

observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25 inpatient bed limit include:

- *Examination or procedure tables;*
- *Stretchers;*
- *Operating room tables;*
- *Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;*
- *Beds in an obstetric delivery room used exclusively for OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth);*
- *Newborn bassinets and isolettes used for well-baby boarders;*
- *Stretchers in emergency departments; and*
- *Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.*

Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

- *Count the number of inpatient beds the CAH maintains, excluding any DPU beds.*
- *Ask the CAH how frequently it uses observation services, and for its policies and procedures governing use of observation services.*

- *Verify that patients are never pre-registered for observation services; there should be no scheduled observation stays.*

- *Check to see if the CAH has specific clinical criteria for admission to and discharge from the observation service, and that these clinical criteria are clearly distinguishable from those used for inpatient admission and discharge.*

- *If there is a separate unit of observation beds, ask the CAH for evidence of how its criteria for admission to the observation unit differ from admission criteria for an inpatient bed. Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater is the CAH's burden to prove these are not being used as inpatient beds. Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater is the CAH's burden to prove these are not being used as inpatient beds.*

- *Review the medical records for patients who are in observation status at the time of survey. Verify that the medical record includes an order to place the patient in observation status, including the clinical reason for observation, as "Place patient in observation to rule out possible myocardial infarction (MI)."*

- *Select a sample of closed medical records for patients who were in an observation status. Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.*

Verify through medical record review that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department.

C-0212

§485.620(b) Standard: Length of Stay

The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

Interpretive Guidelines §485.620(b)

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

C-0220

§485.623 Condition of Participation: Physical Plant and Environment

Interpretive Guidelines §485.623

This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S QA program and be in compliance with the QA requirements.

C-0221

§485.623(a) Standard: Construction

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

Interpretive Guidelines §485.623(a)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §485.623(a)

Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

C-0222

§485.623(b) Standard: Maintenance

The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

Interpretive Guidelines §485.623(b)(1)

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH'S QA plan.

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies must be maintained to ensure an acceptable level of safety and quality.

Equipment must be maintained to ensure an acceptable level of safety and quality.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person, must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services.

Survey Procedures §485.623(b)(1)

- Verify that the condition of the CAH is maintained in a manner to ensure the safety and well being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

- Review the CAH'S routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

- Interview the person in charge of medical equipment and determine if there is an adequate periodical maintenance and repair program.

- Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.

- Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

C-0223

§485.623(b)(2) There is proper routine storage and prompt disposal of trash;

Interpretive Guidelines §485.623(b)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials.

Survey Procedures §485.623(b)(2)

Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.

C-0224

§485.623(b)(3) Drugs and biologicals are appropriately stored;

Survey Procedures §485.623(b)(3)

What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

C-0225

§485.623(b)(4) The premises are clean and orderly; and

Interpretive Guidelines §485.623(b)(4)

"**Clean and orderly**" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems.

C-0226

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.); and
- Laboratory locations.

There must be adequate lighting in all the patient care, food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into CAH policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §485.623(b)(5)

- Verify that all food and medication preparation areas are well lit.
- Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving

treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.

- Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.

- Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.

- Verify that each operating room has temperature and humidity control mechanisms.

- Review temperature and humidity tracking logs to ensure that appropriate temperature and humidity levels are maintained.

C-0227

§485.623(c) Standard: Emergency Procedures

The CAH assures the safety of patients in non-medical emergencies by--

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

Survey Procedures §485.623(c)(1)

- How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?

- Ask facility staff what they are supposed to do in case of an emergency such as a tornado or a blizzard.

- Review staff training documents and inservice records to validate training.

- Review the CAH'S written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.

- Verify that CAH staff reported all fires as required to State officials.

- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

C-0228

§485.623(c)(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

Interpretive Guidelines §485.623(c)(2)

The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

Survey Procedures §485.623(c)(2)

Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

C-0229

§485.623(c)(3) Providing for an emergency fuel and water supply; and

Interpretive Guidelines §485.623(c)(3)

The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures §485.623(c)(3)

- Review the system used by CAH staff to determine the CAH'S emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.

- Determine the source of emergency gas and water, both the quantity of these supplies readily available at the CAH, and that are needed within a short time through additional deliveries.

- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.

C-0230

§485.623(c)(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

Interpretive Guidelines §485.623(c)(4)

Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The CAH must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The CAH must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will ensure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- Differences needed for each location where the certified CAH operates;

- The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);

- Security of patients and walk-in patients;

- Security of supplies from misappropriation;

- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;

- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);

- Communication among staff within the CAH itself;

- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;

- Identification, availability and notification of personnel that are needed to implement and carry out the CAH'S emergency plans;

- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;

- Provisions for gas, water, electricity supply if access is shut off to the community;

- Transfer or discharge of patients to home or other healthcare settings

- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures §485.623(c)(4)

Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and well being of patients during local emergency situations.

C-0231

§485.623(d) Standard: Life Safety From Fire

(1) Except as otherwise provided in this section, the CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capital Street NW, Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

Interpretive Guidelines §485.623(d)(1)

Medicare-participating CAHs, regardless of size or number of beds, must comply with the Hospital/healthcare Life Safety Code requirements for all inpatient care locations. CAH departments and locations such as emergency departments, outpatient care

locations, etc. must comply with Hospital/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99: Health Care Facilities.

This revision adopts the 2000 edition of the LSC and deletes provisions for the use of roller latches in the facility.

Survey Procedures §482.41(b)(1)

- There is a separate survey form, (CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. (Life Safety Code Guidelines and a copy of the 1985 Life Safety Code Addendum are contained in SOM Appendix I.)

- Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.

C-0232

§485.623(d)(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

Interpretive Guidelines §485.623(d)(2)

This revision deletes "grandfathering" of older editions of the LSC and allows the use of a State code if approved by CMS.

C-0233

§485.623(d)(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(d)(3)

Life Safety Code waivers may be recommended by the State survey agency but only CMS (at the regional office level) may grant those waivers for Medicare or Medicaid-participating CAHs.

Survey Procedures §485.623(d)(3)

Consideration, assessment and recommendation for waivers of specific Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.

C-0234

§485.623(d)(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Survey Procedures §485.623(d)(4)

Examine copies of inspection and approval reports from State and local fire control agencies.

C-0235

§485.623(d)(5) A critical access CAH must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2 exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

Interpretive Guidelines §485.623(d)(5)

§ 485.623(d)(1) states, "Chapter 19.3.6.3.2 exception number 2 of the adopted edition of the Life Safety Code does not apply to CAH." The wording in § 485.623(d)(5) and § 485.623(d)(5)(i) when used together means that after March 13, 2006 a CAH may no longer continue to keep in service existing roller latches even when these roller latches have been demonstrating the ability to keep the door closed against 5lbf.

Medicare-participating CAHs must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101 beginning March 13, 2006. Exception number 2 of chapter 19.3.6.3.2 will not be allowed in Medicare-participating CAHs.

CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006.

Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101.

This section gives facilities until March 13, 2006, to replace roller latches and to replace 1 hour batteries with 1-1/2 hour batteries in emergency lighting systems that use batteries as power sources.

After March 13, 2006 a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).

C-0240

§485.627 Condition of Participation: Organizational Structure

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C-0241

§485.627(a) Standard: Governing Body or Responsible Individual

The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

Interpretive Guidelines §485.627(a)

The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment

Survey Procedures §485.627(a)

- Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.
- Review documentation and verify that the governing body (or responsible individual) has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.
- Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?
- What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?
- Evaluate records of medical staff appointments to substantiate the governing body’s (or responsible individual’s) involvement in appointments of medical staff members.

- Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

- Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).

- Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.

- Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.

- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medial staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body (or responsible individual) for the quality of services provided.

- Verify that there are written criteria for staff appointments to the medical staff.

- Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.

- Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

C-0242

§485.627(b) Standard: Disclosure

The CAH discloses the names and addresses of--

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

Survey Procedures §485.627(b)(1)

- Review CAH policy for reporting changes of ownership.
- How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency?

C-0243

§485.627(b)(2) The person principally responsible for the operation of the CAH; and

Survey Procedures §485.627(b)(2)

How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

C-0244

§485.627(b)(3) The person responsible for medical direction

Survey Procedures §485.627(b)(3)

How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

C-0250

§485.631 Condition of Participation: Staffing and Staff Responsibilities

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C-0251

§485.631(a) Standard: Staffing

(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

Interpretive Guidelines §485.631(a)(1)

A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.

Survey Procedures §485.631(a)(1)

- Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff.

- Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

C-0252

§485.631(a)(2) Any ancillary personnel are supervised by the professional staff.

Survey Procedures §485.631(a)(2)

Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

C-0253

§485.631(a)(3) The staff is sufficient to provide the services essential to the operation of the CAH.

Survey Procedures §485.631(a)(3)

- How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)?

- Review staffing schedules and daily census records.

C-0254

§485.631(a)(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

Interpretive Guidelines §485.631(a)(4)

Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physicians office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a

practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.

Survey Procedures §485.631(a)(4)

- If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.

- What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

C-0255

§485.631(a)(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

Survey Procedures §485.631(a)(5)

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

C-0256

§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

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C-0257

485.631(b)(1) The doctor of medicine or osteopathy--

(i) Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff;

Interpretive Guidelines §485.631(b)(1)(i)

A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions.

Survey Procedures §485.631(b)(1)(i)

What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

C-0258

§485.631(b)(1)(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

Survey Procedures §485.631(b)(1)(ii)

- What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services?
- How does the CAH ensure that an MD/DO periodically reviews these policies?

C-0259

§485.631(b)(1)(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

Survey Procedures §485.631(b)(1)(iii)

- How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients?
- What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

C-0260

§485.631(b)(1)(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

Interpretive Guidelines §485.631(b)(1)(iv)

The CAH MD/DO(s) must review and sign all medical records for patients cared for by mid-level practitioners at the CAH.

Survey Procedures §485.631(b)(1)(iv)

Select a sample of inpatient and outpatient records, including both open and closed records, and verify that a **MD/DO has reviewed and signed all records for patients cared for by mid-level practitioners.**

C-0261

§485.631(b)(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

Interpretive Guidelines §485.631(b)(2)

An MD/DO must visit a CAH often enough to provide medical oversight for all patient services provided at the CAH in accordance with the scope of services provided.

Survey Procedures §485.631(b)(2)

- What documentation shows that an MD/DO visits the facility at least once every two weeks?

- How does the CAH ensure that an MD/DO is available by telephone or radio contact for consultation, assistance and/or patient referral?

C-0262

§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

C-0263

485.631(c)(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

Survey Procedures §485.631(c)(1)(i)

- Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.

- Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

C-0264

485.631(c)(1)(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Survey Procedures §485.631(c)(1)(ii)

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

C-0265

§485.631(c)(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH'S policies.

Survey Procedures §485.631(c)(2)(i)

- Review policies and procedures.
- Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

C-0267

§485.631(c)(2)(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

Survey Procedures §485.631(c)(2)(ii)

Verify that there are policies and procedures for transferring patients to other facilities.

C-0268

§485.631(c)(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

Interpretive Guidelines §485.631(c)(3)

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §485.631(c)(3)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.

- Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.

- Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.

- If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

C-0270

§485.635 Condition of Participation: Provision of Services

C-0271

§485.635(a) Standard: Patient Care Policies

(1) The CAH'S health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Survey Procedures §485.635(a)(1)

- Review CAH health care services policies and sampled records.

- Observe staff delivering health care services to patients.

- What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with applicable State law?

C-0272

§485.635(a)(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

Interpretive Guidelines §485.635(a)(2)

A CAH with a full time MD/DO is not required to have a mid-level practitioner on staff and would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies.

Survey Procedures §485.635(a)(2)

- Review any meeting minutes to determine group composition and to ascertain the extent of the group's interactions with the CAH.

- Interview the Director of Nursing to determine the extent of his/her interactions with this group concerning policy development.

C-0273

§485.635(a)(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

Policies should clearly explain what types of health care services are available at the CAH and which services are furnished through agreements or arrangements. For example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided) would satisfy this requirement.

Arrangement and agreements include services provided through formal contracts, joint ventures, informal agreements, or lease arrangements.

Additional services furnished through referral should be clearly described in statements such as: "arrangements have been made with Hospital X for CAH patients to receive the

following services" (with a specific list of specialized diagnostic and laboratory testing, or specialized therapy).

C-0274

§485.635(a)(3)(ii) Policies and procedures for emergency medical services.

Interpretive Guidelines §485.635(a)(3)(ii)

Policies should show how the CAH would meet all of its emergency services requirements.

C-0275

§485.635(a)(3)(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

Interpretive Guidelines §485.635(a)(3)(iii)

Guidelines for the medical management of health problems should include a description of the scope of medical acts that may be performed by the mid-level practitioners. Guidelines represent an agreement between the MD/DO providing the CAH'S medical direction and the CAH'S mid-level practitioners relative to the privileges and limits of those acts of medical diagnosis and treatment that may be undertaken with direct MD/DO supervision.

Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management when consultation or referral is required. Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements:

- They should be comprehensive enough to cover most health problems that patients usually refer to a MD/DO;
- They should describe the medical procedures available to the PA, NP and/or CNS;
- They should describe the medical conditions, signs, or developments that require consultation or referral; and
- They should be compatible with State laws.

Survey Procedures §485.635(a)(3)(iii)

- What evidence demonstrates that the CAH'S guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility?

- What evidence demonstrates that the guidelines are followed?

C-0276

§485.635(a)(3)(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guidelines §485.635(a)(3)(iv)

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles include compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations such as the American Society of Health-System Pharmacists.

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate CAH staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a CAH uses to maintain professional principles include:

- Policies and procedures have been developed and are being followed;

- Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

- Employees provide pharmaceutical services within their scope of license and education;

- Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the CAH through dispensation/administration;

- The pharmacy maintains controls over drugs and medications in all CAH locations, including floor stock;

- Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;

- Ensuring that drugs are being dispensed only by a licensed pharmacist; and

- Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Pharmaceutical services at a CAH can be provided either as direct services or through an agreement. The direction of pharmaceutical services may not require continuous on-premise supervision at the CAH'S pharmacy but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service whether employed by the CAH or obtained through agreement. The pharmacist must be responsible for developing, supervising, and coordinating all the activities of the CAH-wide pharmacy service and must be thoroughly knowledgeable about CAH pharmacy practice and management.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Pharmacists and pharmacy technicians must perform their duties within the scope of their license and education. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there may be an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

The CAH must have a system that ensures that medication orders get to the pharmacy and drugs get back to patients promptly.

Record System

Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- Records trace the movement of scheduled drugs throughout the service.

The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

The CAH system should be capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Facility policies and procedures should minimize scheduled drug diversion.

Receipt and Distribution of Drugs

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical safety and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate CAH staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of

pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices, and biologicals.

All prescribers' medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.

Appropriate monitoring of medication therapy should be conducted. Medication-therapy monitoring includes an assessment of:

- Therapeutic appropriateness of a patient's medication regimen;
- Therapeutic duplication in the patient's medication regimen;
- Appropriateness of the route and method of administration;
- Medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects; and
- Physical signs and clinical symptoms relevant to the patient's medication therapy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in CAH decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines. The evaluation and monitoring should include the potential for medication errors.

Dispensation of Drugs

Medications must be prepared safely. Safe preparation procedures could include:

- Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).
- Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.

- Wherever medications are prepared, staff uses techniques to ensure accuracy in medication preparation.

- Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include, but are not limited, to the following:

    - Using clean or sterile technique as appropriate;

    - Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;

    - Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and

    - Visually inspecting the integrity of the medications.

Drug Storage

All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals.

All drugs and biologicals must be stored in a manner to prevent access by unauthorized individuals. Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the CAH would not be considered as in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts

When not in use, nursing medication carts, anesthesia carts, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. When carts are not in use, locked carts that contain drugs or biologicals must be stored in a locked room, monitored area, or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with state and Federal law and CAH policy has legal access to the drugs and biologicals in the cart.

That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

System for Labeling and Management of Outdated Drugs

The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures §485.635(a)(3)(iv)

- Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

- Is the staff familiar with the medication-related policies and procedures?

- Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?

- Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?

- Determine whether the pharmacist is a full-time or part-time employee or employed on a consultative basis.

- Review the implementation of the chief pharmacist's responsibilities by:

    - Reviewing written status reports;

    - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;

    - Reviewing schedules, time logs, etc.; and

    - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision, and coordination of all the activities of pharmacy services.

- Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

- Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. Review any agreements.

- Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

- Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

- Determine that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Review the records to determine that they trace the movement of scheduled drugs throughout the service.

- Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the CAH system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

- Is access to concentrated solutions (e.g. potassium chloride, sodium chloride Solutions greater than 0.9%) restricted?

- Identify and assess the quality assurance procedures for the preparation of sterile products.

- Is appropriate monitoring of medication therapy being conducted?

- Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.

- Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

- Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:

    - Reviewing policies and procedures;

    - Interviewing pharmacy and CAH staff to determine how drugs and biologicals are dispensed;

    - Observing on-site dispensing operations;

    - Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and

    - Inspecting drug storage areas.

- Verify through interviews of pharmacy and CAH staff, observation of on-site dispensing operations and review of pharmacy records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws.

- Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.

- Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

- Determine if the facility identifies what personnel may have access to medications.

- Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:

    - Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed.

Appropriate accessory and cautionary statements are included as well as the expiration date.

- Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, and expiration date.

- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.

- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.

- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.

- Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.

- Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

- Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the CAH.

- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

- Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?

- Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

C-0277

§485.635(a)(3)(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guidelines §485.635(a)(3)(v)

Written procedures should require that medication errors and adverse drug reactions be reported immediately to the practitioner who ordered the drug. An entry, including the medication administered and the drug reaction, should be entered into the patient's medical record. Unexpected or significant adverse drug reactions should also be reported to the Food and Drug Administration in accordance with the MedWatch program. There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program.

It is important to flag new types of mistakes as they occur and create systems to prevent their recurrences. The system should work through those mistakes and continually improve and refine things, based on what went wrong.

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture “near misses” and suspected ADRs as well as actual medication errors and ADRs.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to: checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines.

One example of a definition is the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error.

> “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

The facility must have a method by which to measure the effectiveness of its reporting system so as to identify whether or not its system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their CAH. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

The facility should have immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

The CAH should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include:

- Direct observation of medication administration;
- Review of patient's clinical records; and
- Identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies.

The CAH should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include; Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The CAH pharmacy must ensure that drug orders are accurate and that medications are administered as ordered. When medications are returned unused, the pharmacy should determine the reason the medication was not used. For example, did the patient refuse the medication, was there a clinical reason the medication was not used, was the medication not used due to error?

Policies and procedures to minimize drug errors should include:

- High-alert medications with dosing limits, administration guidelines, packaging, labeling and storage;
- Limiting the variety of medication-related devices and equipment. For example, limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise such as having a pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Standardization of prescribing and communication practices;
- Avoidance of certain abbreviations;
- All elements of the order such as dose, strength, units (metric), route, frequency, and rate;
- Alert systems for look-alike and sound-alike drug names;
- Use of facility approved pre-printed order sheets whenever possible;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Medication recalls;
- Policies and procedures are reviewed and amended secondary to facility-generated reports of adverse drug events.

Survey Procedures §485.635(a)(3)(v)

- Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.

- Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

- Review the pharmaceutical policies and procedures, the CAH'S formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.

- Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors.

- Are there policies and procedures to minimize drug errors?

- Are policies and procedures reviewed and amended secondary to facility-generated reports of adverse drug events?

- Determine that the CAH has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

- Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

- Determine if the facility's definition of an adverse drug reaction and medication error will generate sufficient number of reports.

- Review QA activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.

- Determine if the number of medication errors and adverse drug reactions reported is consistent with the size and scope of services provided by the CAH.

- Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facilities policy on reporting and documentation of medication errors and adverse drug reactions.

- Is there a process to report serious adverse drug reactions to the Federal MedWatch program?

C-0278

§485.635(a)(3)(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §485.635(a)(3)(vi)

The CAH must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the CAH. There must be a mechanism to evaluate the effectiveness of the program and to provide corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases as recommended by organizations such as the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc.).

The active infection control program should have policies that address the following:

- Definition of nosocomial infections and communicable diseases;
- Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;
- Measures for assessing and identifying patients and health care workers, including CAH personnel, contract staff (e.g., agency nurses, housekeeping staff),and volunteers, at risk for infections and communicable diseases;
- Methods for obtaining reports of infections and communicable diseases on inpatients and health care workers, including all CAH personnel, contract such as agency nurses, housekeeping staff, and volunteers, in a timely manner;
- Measures for the prevention of infections, especially infections caused by organisms that are antibiotic resistant or in other ways epidemiologically important; device-related infections (e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc.); surgical site infections; and those infections associated with tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;
- Measures for prevention of communicable disease outbreaks, especially tuberculosis;

- Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;

- Isolation procedures and requirements for infected or immunosuppressed patients;

- Use and techniques for standard precautions;

- Education of patients, family members and caregivers about infections and communicable diseases;

- Methods for monitoring and evaluating practices of asepsis;

- Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean from dirty, as well as other means for limiting the spread of contagion;

- Authority and indications for obtaining microbiological cultures from patients;

- A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children;

- Orientation of all new CAH personnel to infections, communicable diseases, and to the infection control program;

- Measures for the screening and evaluation of health care workers, including all CAH staff, contract workers such as agency nurses, housekeeping staff, and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;

- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work;

- A procedure for meeting the reporting requirements of the local health authority;

- Procedures for working with local, State, and Federal health authorities in emergency preparedness situations;

- Policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and

- Provision for program evaluation and revision of the program, when indicated.

Designated Infection Control Officer

The CAH must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers.

An infection control committee may delegate responsibility for infection functions, in accordance with CAH policy.

The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases.

The infection control officer(s) is responsible for:

- Implementing policies governing asepsis and infection control;

- Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and CAH personnel, including contract staff and volunteers;

- Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and CAH personnel, including contract staff and volunteers, especially those occurring in clusters;

- Preventing and controlling the spread of infections and communicable diseases among patients and staff;

- Cooperating with CAH-wide orientation and inservice education programs;

- Cooperating with other departments and services in the performance of quality assurance activities; and

- Cooperating with disease control activities of the local health authority.

It is recommended that the infection control officer or officers maintain a log of all incidents related to infections and communicable diseases, including those identified through employee health services. The log is not limited to nosocomial infections. All incidents of infection and communicable disease should be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non patient care, employees, contract staff and volunteers).

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the CAH-wide Quality Assurance (QA) program and staff inservice training programs address problems identified through the infection control program.

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Survey Procedures §485.635(a)(3)(vi)

- Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and CAH personnel, including contract workers and volunteers.

- Determine that this system is an active program, that it is both CAH-wide and program-specific, and that it is implemented correctly.

- Throughout the CAH, observe the environment of care, noting the cleanliness of horizontal surfaces, bedside equipment, and air inlets, etc, because infectious organisms may spread from these places.

- Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.

- Review the personnel file of the infection control officer(s) to verify that he/she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

- Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.

- Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.

- Verify that the infection control officer(s) maintains a log of all incidents related to infections and communicable diseases, including those identified through employee health services.

- Determine that the CAH'S QA program and staff inservice training programs address problems identified by the infection control officer(s).

- Determine that problems identified are reported to the medical staff, nursing, and administration, and addressed in the CAH'S quality assurance and inservice training programs.

C-0279

§485.635(a)(3)(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) is met with respect to inpatients receiving post CAH SNF care.

Interpretive Guidelines §485.635(a)(3)(vii)

A CAH is not required to prepare meals itself and is free to obtain meals under contract with another supplier, but the CAH is responsible for the quality of arranged services on the same basis as if CAH employees had provided those services.

The food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and recognized dietary practices.

Policies and Procedures for Dietary Services

The CAH should have written policies and procedures that address at least the following:

- Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;
- Frequency of meals served;
- System for diet ordering and patient tray delivery;
- Accommodation of non-routine occurrences such as enteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.;
- Integration of the food and dietetic service into the CAH-wide QA and Infection Control programs;
- Guidelines for acceptable hygiene practices of food service personnel; and
- Guidelines for kitchen sanitation.

Compliance with Recognized Dietary Practices

The CAH must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

Director of Food and Dietetic Services

The CAH must have an employee (either on staff or contracted) who–

- Serves as director of the food and dietetic services;
- Is responsible for daily management of the dietary services; and
- Is qualified by experience or training.

The service director must be either an employee on staff or under contract, who has been granted the authority and delegated responsibility by the CAH'S governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following:

- Safety practices for food handling;
- Emergency food supplies;
- Orientation, work assignments, supervision of work and personnel performance;
- Menu planning, purchasing of foods and supplies, and retention of essential records such as cost, menus, personnel, training records, QA reports, etc.; and
- Dietary service QA program.

Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operation.

Qualified Dietitian

A qualified dietitian must supervise the nutritional aspects of patient care. The dietitian can be part of the CAH staff or work under contract (may be full or part time) and is responsible for all inpatient nutrition including swing bed services. The dietitian must be licensed if required by State law. The dietitian's responsibilities include, but are not limited to:

- Approving patient menus and nutritional supplements;
- Patient, family, and caretaker dietary counseling;
- Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;

- Collaborating with other CAH services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients; and

- Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.

If the qualified dietitian does not work full-time, and when the dietitian is not available, the CAH must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.

Dietary Support Staff

There must be administrative and technical personnel competent in their respective duties.

This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that each staff member is competent in their respective duties.

Recognized Dietary Practices

Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner responsible for the care of the patients.

Recognized dietary practices include following current national standards for recommended dietary allowances such as the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council.

Menus provided by the CAH must be nutritionally balanced and meet the needs of the patients. In order to ensure that the CAH is meeting the nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. If a patient is identified as an altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);

- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;

- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.); and

- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).

Therapeutic diets must be prescribed by the practitioner responsible for the care of the patient. Therapeutic diets should be:

- Prescribed in writing by a qualified practitioner or a qualified dietitian;

- Documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and

- Evaluated for nutritional adequacy.

A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Survey Procedures §485.635(a)(3)(vii)

- Review CAH personnel files to determine that staff is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.

- If the dietitian is part-time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the CAH makes adequate provisions for qualified consultant coverage when the dietitian is not available.

- Review personnel files for administrative and technical staff to determine if they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

- Ask the CAH to show you what national standard they are following in its menus to meet the nutritional needs of their patients.

- Review patient records to verify that diet orders are provided as prescribed by the practitioner responsible for the care of the patient.

- From the sample patient records, identify patients with special nutritional needs to determine:

- If their nutritional needs have been met;
- If appropriate therapeutic diets have been ordered; and
- If their dietary intake and nutritional status is being monitored, as appropriate.

- Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.
- Determine that the therapeutic diet manual is current and:
  - Has been approved by both the medical staff and a qualified dietitian;
  - Is readily available to MD/DOs, nursing and food service personnel;
  - Is in accordance with the current national standards, such as RDA or DRI;
  - Includes the different types of therapeutic diets routinely ordered at the CAH; and
  - Is consistently used as guidance for ordering and preparing patient diets.

C-0280

§485.635(a)(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Survey Procedures §485.635(a)(4)

Review the meeting notes and policy and procedure books to verify that the patient care policies are reviewed on an annual basis by the professional group

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C-0281

§485.635(b) Standard: Direct Services

(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity CAH outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guidelines §485.635(b)

The CAH must provide outpatient and emergency room services as direct services at the CAH campus through the use of CAH personnel. The CAH can choose the level of services to be offered. They may offer only the basic services required by this CoP and State law or they may offer a more complex range of services. However, all the outpatient and emergency services offered must be provided at the CAH campus as direct services.

Outpatient Services are a required direct service of the CAH. All outpatient services that the CAH provides to its patients must meet the needs of the patients, in accordance with acceptable standards of practice. The CAH must provide adequate services, equipment, staff, and facilities adequate to provide the outpatient services for the scope of practices appropriate to the scope and complexity of services offered. The outpatient services may be offered at specific times. The CAH is not required to offer outpatient services 24/7 except for emergency room services.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Medical Association, American College of Radiology, American College of Surgeons, etc.

The CAH'S outpatient services must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia services, other diagnostic services, etc), as appropriate to the outpatient services offered. The CAH must have written policies in place to ensure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

The outpatient services department must be accountable to a single individual who directs the overall operation of the department. The CAH should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include, necessary education, experience and specialized training, consistent with State law, and acceptable standards of practice.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the CAH'S outpatient department. The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients.

Rehabilitation Services

Rehabilitation services are optional CAH services and can include physical therapy, occupational therapy, audiology, and/or speech pathology services. If a CAH provides any degree of rehabilitative services to its patients, either directly or under arrangement,

either inpatient or outpatient, the services must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.

Acceptable standards of practice include any standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, and the American Medical Association etc.

If rehabilitative services are provided, the CAH must provide, or ensure, the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the CAH in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the CAH, both directly or under contract, should be defined in written policies and procedures and approved by the Medical staff. Each service, whether provided directly or through a contract, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.

The rehabilitation service must be accountable to an individual that directs the overall operation of the service. The director of the services must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service. The director may be part-time, full-time, and/or under contract. If part-time, the time spent directing the service should be appropriate with the scope of services provided.

The medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered. Qualifications should include the necessary education, experience, specialized training, and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law.

At least one qualified professional, of the applicable discipline, must be on site when needed to:

- Perform an initial evaluation of each patient for whom rehabilitative services were ordered;

- Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and

- Supervise supportive personnel when they furnish services.

Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must:

- Be established by the practitioner ordering the service in collaboration with an individual qualified to provide the services;
- Be based on the patient's individualized assessment;
- Include the type, amount, frequency and duration of services;
- Include measurable short-term and long-term goals;
- Incorporate patient, family and caregiver goals; and
- Be reviewed and revised as necessary reflect changes in the patient's response to therapeutic intervention. Updated treatment goals should reflect the changes in the patient's status.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders.

The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.

Survey Procedures §485.635(b)(1)

- Determine the types of outpatient services provided.
- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.
- Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.
- Verify that the CAH has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care.

- Review medical records of outpatients who were later admitted to the CAH in order to determine that pertinent information from the outpatient record has been included in the inpatient record.

- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.

- Verify that one person is assigned by the governing body (or responsible individual) to manage and be responsible for outpatient services.

- Review the position description and personnel file of the individual responsible for the outpatient services to ensure that he/she meets the qualifications, in accordance with State law, acceptable standards of practice and CAH policy.

- Review personnel files to verify that the staff qualifications, including education, experience, certifications, current licensure, where appropriate, and competencies are appropriate for assigned responsibilities.

- Verify that sufficient staff are available to provide care.

- Verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care and the complexity of services offered.

- Determine if the CAH provides any degree of rehabilitation services.

- Review the CAH'S policies and procedures to verify that the scope of rehabilitation services offered, either directly or under contract, is defined in writing.

- Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.

- Determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment.

- Review medical records to verify that a qualified professional evaluates the patient and initiates the treatment under medical orders and direction for each episode.

- Verify that each patient has a plan of treatment established in writing and that the plan is established by the practitioner ordering the service and is documented in the patient record along with treatment outcomes achieved.

- If the director of the service does not work full-time, determine that the number of hours spent working is appropriate to the scope of services provided.

- Interview the director to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

C-0282

§485.635(b)(2) Laboratory Services

The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guidelines §485.635(b)(2)

Basic laboratory services must be provided directly at the CAH campus by CAH staff in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed.

The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement. The CAH must maintain or have available laboratory services, either directly or through arrangement, whenever its patients need those services. The CAH may maintain laboratory services at the CAH or may make laboratory services available through contractual agreements except for the required basic services. The scope and complexity of the CAH laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual must be provided in accordance with CLIA requirements. Every CAH laboratory must be operating under a current CLIA certificate appropriate to the level of services performed.

The CAH must provide basic emergency laboratory services 24 hours a day, 7 days a week. The medical staff should determine which laboratory services are to be

immediately available to meet the emergency laboratory needs of patients who may be currently at the CAH or those patients who may arrive at the CAH in an emergency condition and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH'S operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Survey Procedures §485.635(b)(2)

- Determine which services are provided directly by the facility and which are provided through contractual agreements.
- Determine if the referral laboratory is CLIA certified for the appropriate test specialty.
- Verify that all laboratory services are operating under a current CLIA certificate.
- Examine records and determine if the services, including emergency services, are provided in accordance with the CAH'S policies.
- Review the written description of the emergency laboratory services.
- Review records such as worksheets and test reports to verify the 24 hour availability of emergency services and that those services are provided when required.
- Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). Verify that the description of services is accurate and current.
- Verify that the laboratory has the appropriate CLIA certificate or waiver for the tests performed in the CAH laboratory.
- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
- Verify that the CAH has written policies and procedures to ensure that all laboratory results are recorded in the medical record.

C-0283

§485.635(b)(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiological services must be provided by the CAH as direct services at the CAH campus by CAH staff. The CAH must maintain and have available diagnostic radiological services to meet the needs of their patients. These services must be available at all times. The CAH can choose the level of services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine) according to the needs of the patients of the CAH. While the CAH must directly provide all radiology services in the CAH, the interpretation of roentgenograms may be contracted out.

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, American College of Radiology, etc.

The CAH must adopt policies and procedures that provide safety for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least:

- Adequate radiation shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the CAH;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;

- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and

- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must have a system in place and qualified employees to correct hazards. The CAH must be able to demonstrate current inspection and proper correction of all hazards.

There must be written policies developed and approved by the medical staff to designate which radiological tests must be interpreted by a radiologist.

Supervision of the radiology services includes, but is not limited, to the following:

- Enforcing safety standards;

- Ensuring that radiology reports are signed by the practitioner who interpreted them;

- Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;

- Enforcing infection control standards;

- Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;

- Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and

- Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

The CAH must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The CAH should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records.

Survey Procedures §485.635(b)(3)

- Verify that the CAH maintains, or has available, organized radiology services that meet the needs of the patients, are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.

- Verify that patient shielding (aprons, etc) are properly maintained and routinely inspected.

- Verify that the CAH requires periodic tests of all radiology personnel and that the personnel are knowledgeable about radiation exposure.

- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

- Verify that hazardous materials are stored properly in a safe manner.

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and CAH policy.

- Determine that any problems identified are properly corrected in a timely manner.

- Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges authorized by the medical staff and the governing body (or responsible individual) to order radiological services, consistent with State law.

- Review records to determine that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist.

- Verify that supervision of the radiology services is restricted to an individual who is credentialed by the medical staff.

- Review radiological records to determine that reports are signed by the practitioner who reads and evaluates the roentgenogram.

- Verify through observation and document review that radioactive materials, including radioactive waste, are properly stored and disposed of.

- Verify that the CAH maintains accurate records of the receipt and distribution of radio pharmaceuticals.

C-0284

§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

Survey Procedures §485.635(b)(4)

Review policies and procedures for the provision of emergency services.

C-0285

§485.635(c) Standard: Services Provided Through Agreements or Arrangements

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

Interpretive Guidelines §485.635(c)(1)

Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.

The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by arrangement. The governing body must take actions through the CAH'S QA program to: assess the services furnished directly by CAH staff and those services provided under arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.

Survey Procedures §485.635(c)(1)

Ascertain that all contractor services provided in the CAH are in compliance with the CoP for CAHs.

C-0286

§485.635(c)(1)(i) Inpatient CAH care;

Survey Procedures §485.635(c)(1)(i)

How does the CAH ensure that it has arrangements or agreements with one or more facilities to provide inpatient care to its patients?

C-0287

§485.635(c)(1)(ii) Services of doctors of medicine or osteopathy;

Survey Procedures §485.635(c)(1)(ii)

How does the CAH ensure that it has arrangements or agreements with one or more MD/DOs to meet its requirements at §485.631(b)?

C-0288

§485.635(c)(1)(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

Interpretive Guidelines §485.635(c)(1)(iii)

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493 of this chapter. These laboratories will be surveyed separately for compliance with Part 493.

Survey Procedures §485.635(c)(1)(iii)

How does the CAH ensure through arrangements or agreements that it can obtain specialized diagnostic and clinical laboratory services?

C-0289

§485.635(c)(1)(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Survey Procedures §485.635(c)(1)(iv)

If the CAH has an outside contract for nutritional services, how does the CAH ensure that it has arrangements or agreements for the provision of nutritional services that meet this requirement?

C-0290

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Survey Procedures §485.635(c)(2)

- Review a sample of medical records of patients who were treated and transferred from the CAH. What documentation shows that:
    - Transferred patients were accepted and provided with inpatient care, as needed, at CAHs to which they were transferred?
    - Patients referred for diagnostic and/or laboratory tests had these tests performed as requested by the practitioner responsible for the patient?
    - MD/DOs and/or suppliers of services are providing services for the CAH in the manner described in the arrangement or agreement?

C-0291

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Survey Procedures §485.635(c)(3)

- Review the list of contracted services and verify that there is a delineation of contractor responsibility.
- Review any arrangements or agreements to determine if the nature and scope of services defined is being provided to CAH patients and is in compliance with the CAH CoPs.

C-0292

§485.635(c)(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

Survey Procedures §485.635(c)(4)(i)

How does the CAH ensure, (e.g., through operating policies and procedures, by-laws etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements?

C-0293

§485.635(c)(4)(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

Survey Procedures §485.635(c)(4)(ii)

How does the CAH ensure that contracted services meet all of the CAH Conditions of Participation and standards for contracted services?

C-0294

§485.635(d) Standard: Nursing Services

Nursing services must meet the needs of patients.

Interpretive Guidelines §485.635(d)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH and under the direction of a registered nurse.

The CAH and the director of the nursing service are responsible for the clinical activities of all nursing to include the clinical activities of all non-CAH nursing personnel (contract, agency, or volunteer). The CAH and the director of nursing service ensure that all CAH nursing staff and each non-CAH nursing staff person is adequately trained and oriented, is adequately supervised, that their clinical activities are evaluated, and that all nursing personnel know the CAH policies and procedures. An appropriately qualified CAH-employed RN should conduct the supervision and evaluation of the clinical activities of each non-CAH nursing staff.

Survey Procedures §485.635(d)

- Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, accident and investigative reports, staffing schedules, nursing policies and procedures, credentialing and training files (including contracted staff), and QA activities and reports.

- Review the method for orienting non-CAH staff to CAH policies and procedures. The orientation should include at least the following:

    - The CAH and the unit;

    - Emergency procedures;

    - Nursing services policies and procedures; and

    - Safety policies and procedures.

C-0295

485.635(d)(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guidelines §485.635(d)(1)

The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being serviced.

An RN must make all patient care assignments. The director of the nursing service and the CAH are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Survey Procedures §485.635(d)(1)

- Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient care needs and the competence and specialized qualifications of the nursing staff.

- Determine that there are written staffing schedules that correlate to the number and acuity of patients.

- Verify that there is supervision of personnel performance and nursing care for each nursing unit.

- Interview the registered nurse responsible for supervising the nursing care of the patients and ask the following--

    - How are the specialized needs of patients determined? Who makes this determination?

    - How is staff assigned?

    - How is staff monitored to ensure that appropriately qualified staff provides the care needed?

    - How does the CAH ensure that care provided meets the needs of each patient?

    - If temporary nursing staff is utilized, how are these staff oriented and supervised relative to CAH nursing procedures?

- Interview one or more temporary staff, if available, to determine if they are adequately familiar with CAH nursing requirements.

C-0296

485.635(d)(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

Interpretive Guidelines §485.635(d)(2)

An RN (or PA where State law permits) must supervise and evaluate the nursing care for each patient. Evaluation would include assessing the patient's care needs as well as the patient's response to interventions.

Survey Procedures §485.635(d)(2)

- Determine that a registered nurse (or PA where State law permits) supervises and evaluates the nursing care for each patient?

- Interview the RN (or PA where State law permits) who is responsible for supervising and evaluating the nursing care for CAH patients.

- Ask to see staffing schedules as needed to verify information
- Observe the care provided by any non-CAH staff
    - Do they know and adhere to CAH policies?
    - Do they know appropriate emergency procedures?
    - Are they adequately supervised by an appropriately experienced CAH employed RN (or PA where State law permits)?
    - Are their clinical activities being evaluated adequately?
    - Are they licensed in accordance with State law?
- Confirm with the director of nurses that a non-CAH nurse's performance is evaluated at least annually.

C-0297

485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guidelines §485.635(d)(3)

All drugs and biologicals and intravenous medications must be administered by or under the supervision of a RN, MD, DO or where permitted by State law a PA, in accordance with written or signed orders, accepted standards of practice, and Federal and State laws. As permitted by State law and CAH policy, LPN's may administer medications if they are under the supervision of an RN, MD, DO or if permitted by State law a PA.

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care.

Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.

All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible

for the care of the patient. All entries in the medical record must be legible, timed, dated and authenticated.

A telephone or verbal order is written in the medical record by a nurse or other professional in accordance with State law and CAH policy as being able to accept verbal orders. The written verbal order must be legible and includes the date, time, the order, the name of the ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time he or she signs the order and must sign a verbal order as soon as possible which would be the earlier of the following:

- The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record, or

- The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and CAH policy.

The content of verbal orders should be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be reduced immediately to writing and signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible.

We recognize that in some instances, the ordering practitioner may not be able to authenticate his or her verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering practitioner to co-sign the verbal order of the ordering practitioner. The signature indicates that the covering practitioner assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the CAH'S policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a MD/DO's verbal order or otherwise authenticate a medical record entry for the MD/DO who gave the verbal order.

When used, verbal orders must be used infrequently. Therefore, it is not acceptable to allow covering practitioners to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the CAH.

Verbal orders are orders for medications, treatments, intervention or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone.

Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible.

CAHs should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal orders;
- Provide a mechanism to ensure validity/authenticity of the prescriber;
- List the elements required for inclusion in a complete verbal order;
- Describe situations in which verbal orders may be used;
- List and define the individuals who may send and receive verbal orders; and
- Provide guidelines for clear and effective communication of verbal orders.

CAHs should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication.

Elements that should be included in any verbal medication order include:

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants)
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Purpose or indication;
- Specific instructions for use; and
- Name of prescriber.

Survey Procedures §485.635(d)(3)

- Select patients from the patient sample. Review their medication orders, medication administration records, and appropriate medication documentation in the medical record. Observe the preparation and administration of medications to those patients. Are medications prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and CAH policy?

- Ascertain that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Ascertain that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.

- Review a sample of medication administration records to see that they conform to the practitioner's order and that the order is current, and that drug and dosage are correct and administered as ordered.

- Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Are patients addressed by name and/or identiband checked? Does the nurse remain with the patient until medication is taken?

- Verify that nursing staff administering drugs have completed appropriate training courses.

- Check the QA activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors and corrective action taken.

- Determine that all drug orders, including verbal orders, are written in the patient charts and signed by the practitioner caring for the patient. Have verbal orders been signed or initialed by the prescribing practitioner as soon as possible?

- Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized CAH personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so.

- Read the CAH'S policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?

- Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

C-0298

485.635(d)(4) A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guidelines §485.635(d)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for discharge to meet post-CAH needs. A nursing care plan is based on assessing the patient's nursing care needs and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the requirements for patient records.

Survey Procedures §485.635(d)(4)

Select a sample of nursing care plans (6-12 as appropriate)

- Are the plans initiated as soon as possible after admission for each patient?
- Does the plan describe patient goals and appropriate physiological and psychosocial factors and patient discharge planning?
- Is the plan consistent with the attending practitioner's plan for medical care?
- Are the plans revised as the needs of the patient change?
- Are the plans implemented?

C-0300

§485.638 Condition of Participation: Clinical Records

C-0301

§485.638(a) Standard: Records System

(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

Interpretive Guidelines §485.638(a)(1)

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature.

There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps.

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries.

The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or

treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures §485.638(a)(1)

- Verify that a medical record is maintained for each person receiving care.
- Verify that written procedures ensure the integrity of authentication and protect the security of patient records.
- Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.
- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.
- Verify that there is an established system that addresses at least the following activities of the medical records services:
    - Timely processing and retrieval of records;
    - Protecting the confidentiality of medical information;
    - Compiling and retrieval of data of quality assurance activities.
- Verify that the system policies and procedures are reviewed and revised as needed.
- Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.
- Are medical records promptly completed in accordance with State law and CAH policy?
- Select a sample of past patients of the CAH (inpatient and/or outpatient). Request those patient's medical records. Can the CAH promptly retrieve those records?

C-0302

§485.638(a)(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(2)

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures §485.638(a)(2)

For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and outpatients records, if appropriate.

C-0303

§485.638(a)(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(3)

The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.

Survey Procedures §485.638(a)(3)

- Verify that the CAH employs adequate medical record personnel.
- Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

C-0304

§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

> **(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;**

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;

- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary.

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

Survey Procedures §485.638(a)(4)(i)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.
- Verify that consent forms are properly executed.
- Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.

- Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH policy. The sample should be at least 10 percent of the average daily census, as appropriate.

C-0305

§485.638(a)(4)(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guidelines §485.638(a)(4)(ii)

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures §485.638(a)(4)(ii)

- Determine that the bylaws require a physical examination and medical history be done for each patient.

- For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

C-0306

§485.638(a)(4)(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

Interpretive Guidelines §485.638(a)(4)(iii)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);

- All nursing notes;

- All reports of treatment (including complications and CAH-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.

Survey Procedures §485.638(a)(4)(iii)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

C-0307

§485.638(a)(4)(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guidelines §485.635(a)(4)(iv)

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The CAH has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.

- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.

- The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §485.635(a)(4)(iv)

- Verify that entries are authenticated.

- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

- Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.

- Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

- Examine the CAH'S policies and procedures for using the system, and determine if documents are being authenticated after transcription.

- For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

C-0308

§485.638(b) Standard: Protection of Record Information

(1) The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guidelines §485.638(b)(1)

The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §485.638(b)(1)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.

- Verify that the CAH has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.

- Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.

- Verify that copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.

- Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.

- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

C-0309

§485.638(b)(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guidelines §485.638(b)(2)

The CAH'S patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures §485.638(b)(2)

- Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

- If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

C-0310

§485.638(b)(3) The patient's written consent is required for release of information not required by law.

C-0311

§485.638(c) Standard: Retention of Records

The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

Interpretive Guidelines §485.638(c)

Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA).

Survey Procedures §485.638(c)

Determine that records are retained for at least 6 years, or more if required by State or local laws.

C-0320

§485.639 Condition of Participation: Surgical Services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH provides any degree of surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and

guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the quality of the CAH'S outpatient surgical services must be consistent with the CAH'S inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the medical staff.

Supervision in the OR

The operating room (inpatient and outpatient) must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies.

If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures

Policies governing surgical care should contain:

- Aseptic surveillance and practice, including scrub techniques
- Identification of infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
    - Preoperative work-up
    - Patient consents and releases
    - Clinical procedures
    - Safety practices

    - Patient identification procedures

- Duties of scrub and circulating nurse
- Safety practices
- The requirement to conduct surgical counts in accordance with accepted standards of practice
- Scheduling of patients for surgery
- Personnel policies unique to the OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.
- Sterilization and disinfection procedures
- Acceptable operating room attire
- Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
    - Level of activity
    - Respirations
    - Blood pressure
    - Level of consciousness
    - Patient color
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register

The register should include at least the following information:

- Patient's name
- Patient's CAH identification number
- Date of the operation
- Inclusive or total time of the operation
- Name of the surgeon and any assistant(s)
- Name of nursing personnel (scrub and circulating)
- Type of anesthesia used and name of person administering it
- Operation performed
- Pre and post-op diagnosis
- Age of patient

Operative Report

The operative report would include at least:

- Name and CAH identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;

- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and

- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:

    - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;

    - The conformance to aseptic and sterile technique by all individuals in the surgical area;

    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

    - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;

    - That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and

    - That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

- If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.

- Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.

- Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.

- Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

- Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

- Check to determine that the operating room suite has available the items listed.

    - On-call system

    - Cardiac monitor

    - Resuscitator

    - Defibrillator

    - Aspirator (suction equipment)

    - Tracheotomy set (a cricothyroidotomy set is not a substitute)

- Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.

- Verify that the CAH has provisions for post-operative care.

- Determine that there are policies and procedures that govern the recovery room area.

- Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

- Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

C-0321

§485.639(a) Standard: Designation of Qualified Practitioners

The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

Interpretive Guidelines §485.639(a)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.

The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term “supervision” would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures §485.639(a)

- Review the CAH’S method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

C-0322

§485.639(b) Standard: Anesthetic Risk and Evaluation

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk

- Anesthesia, drug and allergy history
- Any potential anesthesia problems identified
- Patient's condition prior to induction of anesthesia

The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum:

- Cardiopulmonary status;
- Level of consciousness;
- Any follow-up care and/or observations; and
- Any complications occurring during post-anesthesia recovery.

Survey Procedures §485.639(b)

- Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery.
- Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

C-0323

§485.639(c) Standard: Administration of Anesthesia

The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

Interpretive Guidelines §485.639(c)(1)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH'S credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit; and
- Is prepared to immediately conduct hands-on intervention if needed; and
- Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed

Survey Procedures §485.639(c)(1)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

C-0324

§485.639(c)(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

C-0325

§485.639(d) Standard: Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines §485.639(d)

Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record.

Survey Procedures §485.639(d)

Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

C-0326

§485.639(e) Standard: State Exemption

(1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the

CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

C-0330

§485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review

Interpretive Guidelines §485.641

While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as:

- Tell me about this practice.
- Is the practice a requirement or standard of practice?
- What is your source for this requirement, activity or standard of practice?
- Show me your source material for this practice.

If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH'S policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH'S actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

C-0331

§485.641(a) Standard: Periodic Evaluation

(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

Survey Procedures §485.641(a)(1)

- How is information obtained to be included in the periodic evaluation?
- How does the CAH conduct the periodic evaluation?
- Who is responsible for conducting the periodic evaluation?

C-0332

§485.641(a)(1)(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

Survey Procedures §485.641(a)(1)(i)

How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

C-0333

§485.641(a)(1)(ii) A representative sample of both active and closed clinical records; and

Interpretive Guidelines §485.641(a)(1)(ii)

"A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records.

Survey Procedures §485.641(a)(1)(ii)

- Who is responsible for the review of both active and closed clinical records?
- How are records selected and reviewed in the periodic evaluation?
- How does the evaluation process ensure that the sample of records is representative of services furnished?
- What criteria are utilized in the review of both active and closed records?

C-0334

§485.641(a)(1)(iii) The CAH'S health care policies.

Survey Procedures §485.641(a)(1)(iii)

What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

C-0335

§485.641(a)(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

Survey Procedures §485.641(a)(2)

- How does the CAH use the results of the yearly program evaluation?
- Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

C-0336

§485.641(b) Standard: Quality Assurance

The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

Interpretive Guidelines §485.641(b)

There is nothing in this requirement to preclude a CAH from obtaining QA through arrangement. Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements for QA must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contact. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff.

"An effective quality assurance program" means a QA program that includes:

- Ongoing monitoring and data collection;
- Problem prevention, identification and data analysis;

- Identification of corrective actions;
- Implementation of corrective actions;
- Evaluation of corrective actions; and
- Measures to improve quality on a continuous basis.

Survey Procedures §485.641(b)

Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

C-0337

§485.641(b)(1) All patient care services and other services affecting patient health and safety, are evaluated;

Survey Procedures §485.641(b)(1)

- Who is responsible to evaluate CAH patient care services?
- How are patient care services evaluated?
- What other services are evaluated?
- How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

C-0338

§485.641(b)(2) Nosocomial infections and medication therapy are evaluated;

Survey Procedures §485.641(b)(2)

- What methodology does the CAH use to evaluate nosocomial infections and medications therapy?
- Review committee meeting minutes for current issues or projects, etc.

C-0339

§485.641(b)(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

Survey Procedures §485.641(b)(3)

- How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?
- How is clinical performance of mid-level practitioners evaluated?
- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?
- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?
- What follow-up actions are called for in the QA plan?

C-0340

§485.641(b)(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

C-0341

§485.641(b)(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

C-0342

§485.641(b)(5)(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

Survey Procedures §485.641(b)(5)(ii)

- How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program?
- Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

C-0343

§485.641(b)(5)(iii) The CAH documents the outcome of all remedial action.

Survey Procedures §485.641(b)(5)(iii)

How does the CAH document the outcome of any remedial action?

C-0344

§485.643 Condition of Participation: Organ, Tissue, and Eye Procurement

The CAH must have and implement written protocols that:

Interpretive Guidelines §485.643

The CAH must have written policies and procedures to address its organ procurement responsibilities.

C-0345

§485.643(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

Interpretive Guidelines §485.643(a)

The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH;
- Includes a definition of "imminent death";
- Includes a definition of "timely notification";
- Addresses the OPO's responsibility to determine medical suitability for organ donation;
- Specifies how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s);
- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;
- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH;
- Permits the OPO, tissue bank, and eye bank access to the CAH'S death record information according to a designated schedule, e.g., monthly or quarterly;
- Includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and
- The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH'S medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH'S care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures.

Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; **AND**
- Has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**
- MD/DOs are evaluating a diagnosis of brain death; **or**
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH'S OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

"**Timely notification**" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any

other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

- As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (i.e., medical **or** pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.

Survey Procedures §485.643(a)

- Review the CAH'S written agreement with the OPO to verify that it addresses all required information.

- Verify that the CAH'S governing body has approved the CAH'S organ procurement policies.

- Review a sample of death records to verify that the CAH has implemented its organ procurement policies.

- Interview the staff to verify that they are aware of the CAH'S policies and procedures for organ, tissue and eye procurement.

- Verify that the organ, tissue and eye donation program is integrated into the CAH'S QA program.

C-0346

§485.643(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretive Guidelines §485.643(b)

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §485.643(b)

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

C-0347

§485.643(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §485.643(c)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the CAH will decide together how and by whom the family will be approached.

The individual designated by the CAH to initiate the request to the family must be a designated requestor.

A "**designated requestor**" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.

The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §485.643(c)

- Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.

- Review training schedules and personnel files to verify that all designated requestors have completed the required training.

- How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

C-0348

§485.643(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors;

Interpretive Guidelines §485.643(d)

Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff's perception that a family's grief, race, ethnicity, religion or

socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §485.643(d)

- Interview a CAH-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the facility complaint file for any relevant complaints.

C-0349

§485.643(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

§485.643(f) For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guidelines §485.643(e)

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH'S QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH'S donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §485.643(e)

- Review inservice training schedules and attendance sheets.
- How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?
- Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
- Determine how confidentiality is ensured.
- Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.
- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

C-0350

§485.645 Special Requirements for CAH Providers of Long-Term Care Services ("Swing-Beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guidelines §485.645

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.

There must be discharge orders from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same facility or transfers to another facility. If the patient does not change facilities, the same chart can be utilized but the swing-bed section of the chart must be separate with appropriate admission orders, progress notes, and supporting documents.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes.

Medicare reimbursement requires a 3-day qualifying stay in any CAH or CAH prior to admission to a swing-bed. The swing-bed stay must fall within the same spell of illness as

the qualifying stay. This requirement does not apply to patients who are not receiving Medicare reimbursement.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

C-0351

§485.645(a) Eligibility

A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

C-0352

§485.645(b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted..

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

C-0355

§485.645(c) Payment

Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.

C-0360

§485.645(d) SNF Services

The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h), (i), (j)(1)(vii) and (viii), (1), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

C-0361

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

§483.10(a) Exercise of Rights

(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

§483.10(b) Notice of Rights and Services

(1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right--

> **(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and**
>
> **(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.**

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

Interpretive Guidelines §483.10(b)

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits. These rights include the resident's right to:

- Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6));
- Choose a MD/DO (§483.10(d));
- Participate in decisions about treatment and care planning (§483.10(d));
- Have privacy and confidentiality (§483.10(e));
- Work or not work (§483.10(h));
- Have privacy in sending and receiving mail (§483.10(i));
- Visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii));
- Retain and use personal possessions (§483.10(l));
- Share a room with a spouse (§483.10(m)).

"**Total health status**" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

Survey Procedures §483.10(b)

- Look for on-going efforts on the part of facility staff to keep residents informed.

- Look for evidence that information is communicated in a manner that is understandable to residents.

- Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis?

- Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?

C-0362

§483.10(b)(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of this section; and

Interpretive Guidelines §483.10(b)(4)

"**Treatment**" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"**Experimental research**" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

"**Advance directive**" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.

A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

Survey Procedures §483.10(b)(4)

If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? The requirement at §483.75(c) Relationship to Other HHC Regulations may apply, see 45 CFR Part 46, Protection of Human Subjects of Research). "Although these regulations at §483.75(c) are not in themselves considered requirements under this part,

their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds."

C-0363

§483.10(b)(5) The facility must--

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of--

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

Interpretive Guidelines: §483.10(b)(5-6)

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident.

- Telephone;
- Television/radio for personal use;
- Personal comfort items including smoking materials, notions, novelties, and confection;
- Cosmetic and grooming items and services in excess of those for which payment is made;
- Personal clothing;

- Personal reading matter;
- Gifts purchased on behalf of a resident;
- Flowers and plants;
- Social events and entertainment offered outside the scope of the activities program;
- Non-covered special care services such as privately hired nurses or aides;
- Private room, except when therapeutically required, for example, isolation for infection control;
- Specially prepared or alternative food requested;

NOTE: 42 CFR §483.10(b)(8), containing advance directive requirements, guidelines, procedures and probes, is contained below.

§483.10(b)(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.

Interpretive Guidelines §483.10(b)(8)

This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:

- Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care;

- Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;

- Document in the resident's medical record whether or not the individual has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- Ensure compliance with requirements of State law regarding advance directives;

- Provide for educating staff regarding the facility's policies and procedures on advance directives; and

- Provide for community education regarding issues concerning advance directives.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object.

The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audiotapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.

Survey Procedures §483.10(b)(8)

Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.

- Determine to what extent the facility educates its staff regarding advance directives.

- Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

C-0364

§483.10(d) Free Choice

The resident has the right to--

(1) Choose a personal attending MD/DO;

Interpretive Guidelines §483.10(d)(1)

The right to choose a personal MD/DO does not mean that the MD/DO must serve the resident. If the MD/DO of the resident's choosing fails to fulfill a given requirement, such as frequency of MD/DO visits, the facility will have the right, after informing the resident, to seek alternate MD/DO participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own MD/DO. If a resident does not have a MD/DO, or if the resident's MD/DO becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another MD/DO. A resident can choose his/her own MD/DO, but cannot have a MD/DO who does not have swing-bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal MD/DO from among those who have practice privileges.

C-0365

§483.10(d)(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

Interpretive Guidelines §483.10(d)(2)

"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

C-0366

§483.10(d)(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

Interpretive Guidelines §483.10(d)(3)

"Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment.

Survey Procedures §483.10(d)(3)

- Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes.

- If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.

- If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

C-0367

§483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when--

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

Interpretive Guidelines §483.10(e)

"**Right to personal privacy**" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes.

For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Survey Procedures §483.10(e)

Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.

Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.

C-0368

§483.10(h) Work

The resident has the right to--

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when--

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

Interpretive Guidelines §483.10(h)

All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, the resident must agree to a therapeutic work assignment. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated.

The "**prevailing rate**" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.

Survey Procedures §483.10(h)

- Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)?

- Pay special attention to the possible work activities of residents with mental retardation or mental illness.

- If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team?

C-0369

§483.10(i) Mail

The resident has the right to privacy in written communications, including the right to--

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

Interpretive Guidelines §483.10(i)

"**Promptly**" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

C-0370

§483.10(j) Access and Visitation Rights

(1) The resident has the right and the facility must provide immediate access to any resident by the following:

> **(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and**
>
> **(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.**

Interpretive Guidelines §483.10(j)(1)(vii)-(viii)

The facility may set reasonable hours for visitation.

If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

C-0371

§483.10(l) Personal Property

The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Interpretive Guidelines §483.10(l)

The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded.

The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.

Survey Procedures §483.10(l)

If residents' rooms have few personal possessions, ask residents and families if--

- They are encouraged to have and to use personal items;
- Their personal property is safe in the facility.

C-0372

§483.10(m) Married Couples

The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

Interpretive Guidelines §483.10(m)

The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.

C-0373

§483.12 Admission, Transfer and Discharge Rights

§483.12(a) Transfer and Discharge

(1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

Interpretive Guidelines §483.12(a)(1)

The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

C-0374

§483.12(a)(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless--

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

Interpretive Guidelines §483.12(a)(2)

If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs.

If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.

Survey Procedures §483.12(a)(2)

During closed record review, determine the reasons for transfer/discharge.

- Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine?

- Did the resident's MD/DO document the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility?

- Did a MD/DO document the record if residents were transferred because the health of individuals in the facility is endangered?

- Do the records of residents who are transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?

- If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's MD/DO justify why the facility could not meet the needs of this resident.

C-0376

§483.12(a)(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's MD/DO when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A MD/DO when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines §483.12(a)(3)

A physician extender may complete documentation of the transfer/discharge unless prohibited by State law or facility policy.

C-0377

§483.12(a)(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must--

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

C-0378

§483.12(a)(5) Timing of the notice.

(i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when--

(A) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

C-0379

§483.12(a)(6) Contents of the notice. The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii)The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

C-0380

§483.12(a)(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

Interpretive Guidelines §483.12(a)(7)

"**Sufficient preparation**" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns.

Survey Procedures §483.12(a)(7)

During resident reviews, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

C-0381

§483.13 Resident Behavior and Facility Practices

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Interpretive Guidelines §483.13(a)

The intent of this requirement is for each person to reach his/her highest practicable well being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

"**Physical restraints**" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body.

"**Chemical Restraint**" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

"**Discipline**" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"**Convenience**" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest.

Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

Survey Procedures §483.13(a)

- Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints.

- Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated.

- Did the team institute measures in the care plan to address reversal of any decline in health status?

- Determine the intended use of any restraints. Was the use for convenience or discipline?

C-0382

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Interpretive Guidelines §483.13(b)

The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

"**Abuse**" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"**Verbal abuse**" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.

"**Sexual abuse**" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"**Physical abuse**" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints.

"**Mental abuse**" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

"**Involuntary seclusion**" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

Survey Procedures §483.13(b)

- Offsite, pre-survey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

- Report and record **any** instances where the survey team **observes** an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.

- If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.

- If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions:

    - What are the symptoms that led to the consideration of the separation?

    - Are these symptoms caused by failure to:

        - Meet individual needs;

        - Provide meaningful activities;

        - Manipulate the resident's environment?

    - Can the cause(s) be removed?

    - If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?

    - Does the facility use the separation for the least amount of time?

- To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?

- Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?

- If residents are temporarily separated in secured units, staff should carry keys to these units at all times.

- If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

C-0383

§483.13(c) Staff Treatment of Residents

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must--

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

Interpretive Guidelines §483.13(c)

The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.

"**Misappropriation of resident's property**" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

C-0384

§483.13(c)(1)(ii) Not employ individuals who have been--

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or
(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Interpretive Guidelines §483.13(c)(1-4)

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions.

“Found guilty...by a court of law” applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere.

“**Finding**” is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.

Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

Survey Procedures §483.13(c)(1-4)

During Sample Selection--

- If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request--
    - A copy of the facility's policies and procedures regarding abuse prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey;
    - Reports of action(s) by a court of law against employees;
    - Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property;
    - Reports of the results of these investigations; and
    - Records of corrective actions taken.
- Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.
- Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected.
- Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources.
    - Was the administrator notified of the incident and when?
    - Did investigations begin promptly after the report of the problem?
    - Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses?

- Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)?

- Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report?

- What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)?

- What actions were taken as a result of the investigation?

- What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

C-0385

§483.15(f) Activities

(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who--

(i) Is a qualified therapeutic recreation specialist or an activities professional who--

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

Interpretive Guidelines §483.15(f)

A "**recognized accrediting body**" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

The activities program should be multi-faceted and reflect individual resident's needs on their care plan. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.

In a Critical Access Hospital, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

Survey Procedures §483.15(f)

- Observe individual, group and bedside activities.
    - Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities?
    - If residents sit for long periods of time with no apparently meaningful activities, is the cause:
        - The resident's choice;
        - Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;
        - Lack of assistance with ambulation;
    - Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or
    - Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?
    - For residents selected for review, determine to what extent the activities resident's assessment.

- Review the activity calendar for the month prior to the survey to determine if the formal activity program:
    - Reflects the schedules, choices and rights of the residents;
    - Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);
    - Reflects the cultural and religious interests of the resident population; and
    - Would appeal to both men and women and all age groups living in the facility.
- Review clinical records and activity attendance records of residents to determine if:
    - Activities reflect individual resident history indicated by the comprehensive assessment;
    - Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
    - Activities occur as planned; and
    - Outcomes/responses to activities interventions are identified in the progress notes of each resident.
- If there are problems with provision of activities, determine if qualified staff provide these service.

C-0386

§483.15(g) Social Services

(1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) Qualifications of social worker. A qualified social worker is an individual with--

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

Interpretive Guidelines §483.15(g)

The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.

"**Medically-related social services**" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include:

- Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;
- Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;
- Assisting staff to inform residents and those they designate about the resident's health status and health care choices;
- Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
- Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);
- Providing or arranging provision of needed counseling services;

- Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;

- Finding options that meet the physical and emotional needs of each resident;

- Meeting the needs of residents who are grieving; and

- Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.

Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.

Survey Procedures §483.15(g)

For residents selected for review:

- How do facility staff implement social services interventions to assist the resident in meeting treatment goals?

- How do staff that are responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?

- How does the care plan link goals to psychosocial functioning/well being?

- Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative?

- What attempts does the facility make to access services for Medicaid recipients when a Medicaid State Plan does not cover those services?

- Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

C-0388

§483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(b) Comprehensive assessment.

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts.

Interpretive Guidelines §483.20(b)(1)

The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's MD/DO, family members, or outside consultants and review of the resident's record.

C-0389

§483.20(b)(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

> **(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)**

Interpretive Guidelines §483.20(b)(2)

The intent of this regulation is to assess residents in a timely manner.

"**Admission**" to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A "return stay" applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility.

A "**readmission**" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave.

Items in (b)(2) of this section would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; or done on an annual review. These assessments need to be in the final discharge summary.

C-0390

> **§483.20(b)(2)(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's**

physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires inter-disciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

Interpretive Guidelines §483.20(b)(2)(ii)-(iii)

A "**significant change**" may include, but is not limited to, any of the following, or may be determined by a MD/DO's decision if uncertainty exists.

- Deterioration in two of more activities of daily living (ADLs), or any combination of deterioration in two or more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke.

- Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush, or comb. Temporary loss of ability, such as during an acute illness, is not included.

- Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention.

- Deterioration in a resident's health status, where this change places the resident's life in danger (e.g., stroke, heart disease, metastatic cancer); where the change is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or change that is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time (e.g., Alzheimer's disease or diabetes); or the onset of significant, unplanned weight loss (5% in the last 30 days, 10% in the last 180 days).

C-0395

§483.20(k) Comprehensive Care Plans

(1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following--

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and

(ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guidelines §483.20(k)(1)

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care.

The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and plan of care.

However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record.

Survey Procedures §483.20(k)(1)

- Does the care plan address the needs, strengths and preferences identified in the comprehensive assessment?

- Is the care plan oriented toward preventing avoidable declines in functioning or functional levels?

- How does the care plan attempt to manage risk factors?
- Does the care plan build on resident strengths?
- Do treatment objectives have measurable outcomes?
- Does the care plan reflect standards of current professional practice?
- Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents; especially those identified as refusing treatment.
- Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.
- If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?

C-0396

§483.20(k)(2) A comprehensive care plan must be--

(i) Developed within 7 days after the completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending MD/DO, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

Interpretive Guidelines §483.20(k)(2)

"**Interdisciplinary**" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) are at the discretion of the facility.

The MD/DO must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

Survey Procedures §483.20(k)(2)

- Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities?

    - For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?

    - Do the dietitian and the speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident?

    - Is there evidence of MD/DO involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)?

- In what ways does staff involve residents and families, surrogate, and/or representatives in care planning?

- Does staff make an effort to schedule care plan meetings at the best time of the day for residents and their families?

- Do facility staff attempt to make the process understandable to the resident/family?

- Is the care plan evaluated and revised as the resident's status changes?

- Ask in your resident interviews, "Have you had concerns or questions about your care and brought them to the attention of facility staff?" If yes, "What happened as a result?"

C-0397

§483.20(k)(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality; and

Interpretive Guidelines §483.20(k)(3)(i)

The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality and are provided by appropriate qualified persons (e.g., licensed, certified).

"**Professional standards of quality**" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

Survey Procedures §483.20(k)(3)(i)

Question those practices that have a negative outcome or have a potential negative outcome.

- Do nurses notify MD/DOs, as appropriate, and show evidence of discussions of acute medical problems?
- Are residents with acute conditions promptly hospitalized, as appropriate?
- Are there errors in medication administration?
- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and care plan?
- Are MD/DOs' orders carried out, unless otherwise indicated by an advanced directive?
- Can staff describe the care, services and expected outcomes of the care they provide?

C-0398

§483.20(k)(3)(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

C-0399

§483.20(l) Discharge Summary

When the facility anticipates discharge a resident must have a discharge summary that includes--

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines §483.20(l)

The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider.

"**Post discharge plan of care**" means the discharge planning process that includes assessing continuing care needs and developing a plan designed to ensure that the individual's needs will be met after discharge from the facility into the community.

When the facility "**anticipates discharge**" the discharge is not an emergency discharge (e.g., hospitalization for an acute condition) and is not due to the resident's death.

"**Adjust to his or her living environment**" means that the post discharge plan should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

Survey Procedures §483.20(l)

- Does the discharge summary have information pertinent to continuing care for the resident?

- Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?

- Do discharge plans address necessary post discharge care?

- Has the facility aided the resident and his/her family in locating and coordinating post discharge services?

- What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

C-0400

§483.25(i) Nutrition

Based on a resident's comprehensive assessment, the facility must ensure that a resident:

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

Interpretive Guidelines §483.25(i)(1)

Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should consider the loss or gain in light of the individual's former life style as well as the current diagnosis.

C-0401

§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.

Interpretive Guidelines §483.25(i)(2)

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The following formula determines percentage of loss:

% of body weight loss = (usual weight - actual weight x 100) divided by usual weight

In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?

Suggested laboratory values are:

Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion) Plasma Transferrin >60 yr.:180 - 380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

Hemoglobin	Males	14-17 g/dl
	Females:	12-15 g/dl
Hematocrit	Males:	41 - 53
	Females	36 - 46
Potassium	3.5 - 5.0 mEq/L	
Magnesium	1.3 - 2.0 mEq/L	

Some laboratories may have different "normals." Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect

laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.

NOTE: There is no requirement that facilities order the tests referenced above.

Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, and swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

Risk factors for malnutrition are--

- Drug therapy that may contribute to nutritional deficiencies such as--
    - Cardiac glycosides;
    - Diuretics;
    - Anti-inflammatory drugs;
    - Antacids (antacid overuse);
    - Laxatives (laxative overuse);
    - Psychotropic drug overuse;
    - Anticonvulsants;
    - Antineoplastic drugs;
    - Phenothiazines;
    - Oral hypoglycemics;
- Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;
- Depression or dementia;
- Therapeutic or mechanically altered diet;
- Lack of access to culturally acceptable foods;
- Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and
- Cancer.

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to--

- Refusal to eat and refusal of other methods of nourishment;
- Advanced disease (i.e., cancer, malabsorption syndrome);
- Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);
- Radiation or chemotherapy;
- Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;
- Gastrointestinal surgery; and
- Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice.

"Therapeutic diet" means a diet ordered by a MD/DO as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

Survey Procedures §483.25(i)(2)

Determine if residents selected for a comprehensive review, or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?

For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable--

- Did the facility identify factors that put the resident at risk for malnutrition?
- What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)?
- Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?
- Was this care provided consistently?

- Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

C-0402

§483.45 Specialized Rehabilitative Services

§483.45(a) Provision of Services

If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must--

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

Interpretive Guidelines §483.45(a)

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide **specialized rehabilitative services** if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.

For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or mental retardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individuals needs.

"Mental health **rehabilitative services** for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and MR may include, but are not limited to—

- Consistent implementation during the resident's daily routine and across settings, of systematic plans that are designed to change inappropriate behaviors;

- Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;

- Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);

- Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;

- Crisis intervention services;

- Individual, group, and family psychotherapy;

- Development of appropriate personal support networks; and

- Formal behavior modification progress.

Survey Procedures §483.45(a)

Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

1. **Physical Therapy**

    - What did the facility do to improve the resident's muscle strength? The resident's balance?

- What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?

- If the resident has an assistive device, is he/she encouraged to use it on a regular basis?

- What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?

- What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

2. Occupational Therapy

- What did the facility do to decrease the amount of assistance needed to perform a task?

- What did the facility do to decrease behavioral symptoms?

- What did the facility do to improve gross and fine motor coordination?

- What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?

- What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

3. Speech, Language Pathology

- What did the facility do to improve auditory comprehension?

- What did the facility do to improve speech production?

- What did the facility do to improve expressive behavior?

- What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiology evaluation?

- For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

4. Rehabilitative Services For MI And MR

- What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior?

- What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?

- What did the facility do to develop and maintain necessary daily living skills?

- How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR?

- Questions to ask individuals with MI or MR--

    - Who do you talk to when you have a problem or need something?

    - What do you do when you feel happy? Sad? Can't sleep at night?

    - In what activities are you involved, and how often?

C-0403

§483.45(b) Qualifications

Specialized rehabilitative services must be provided under the written order of a MD/DO by qualified personnel.

Interpretive Guidelines §483.45(b)

A qualified professional provides specialized rehabilitative services for individuals under a MD/DO's order. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.

"**Qualified personnel**" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.

Survey Procedures §483.45(b)

- Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

- Determine from the care plan and record that qualified personnel provide rehabilitative services under the written order of a MD/DO. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it might be necessary to validate the care provider's qualifications.

- If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

C-0404

§483.55 Dental Services

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

Interpretive Guidelines §483.55

This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. It can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.

C-0405

§483.55(a) Skilled Nursing Facilities

A facility--

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

Interpretive Guidelines §483.55(a)(1-2)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

C-0406

§483.55(a)(3) Must if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(a)(3-4)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?

- Are residents missing teeth and may be in need of dentures?

- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?

- Are resident's dentures intact? Properly fitted?

NOTE: §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.

C-0407

§483.55(b) Nursing Facilities

The facility

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental service (to the extent covered under the State plan); and

(ii) Emergency dental services;

Interpretive Guidelines §483.55(b)(1)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

C-0408

§483.55(b)(2) Must, if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(b)(2-3)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
- Are residents missing teeth and may be in need of dentures?
- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
- Are resident's dentures intact? Properly fitted?

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R34SOM	04/04/2008	Revision to Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs)”	04/04/2008	N/A
R32SOM	01/18/2008	Revisions to Chapter 2, “Critical Access Hospitals (CAHs) and Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs”	09/2007	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A

STATE OF GEORGIA)
)
COUNTY OF _____)

AFFIDAVIT RE: PERSONAL IDENTIFICATION FOR LICENSURE/REGISTRATION

PERSONALLY APPEARED before the undersigned officer, duly authorized to administer oaths, came the undersigned, who after having been duly sworn, states under oath, the following:

1. That my name is _____and that I am who I say I am;

2. That my address is_____;

3. That I have presented sufficient personal identification to the notary that is true and accurate;

4. That I am legally in the United States of America;

5. That I am applying to the Georgia Department of Community Health, Healthcare Facility Regulation Division, to operate a business/activity that is subject to regulation by the Department of Community Health; and that this affidavit is a material part of the application; and

6. That if the Department subsequently determines that the material information contained in this affidavit is false, I will be in violation of licensing/registration requirements, which may result in revocation of my license or registration.

Sworn to and subscribed before me)
This _____day of _____,___.)
)
)
)_____
_____) Affiant
NOTARY PUBLIC)
STATE OF GEORGIA)

My commission expires:_____.

LIST B

Documents That Establish Identity

For individuals 18 years of age or older

- Driver's license or ID card issued by a state or outlying possession of the United States provided it contains a photograph or information such as name, date of birth, sex, height, eye color, and address
- ID card issued by federal, state, or local government agencies or entities provided it contains a photograph or information such as name, date of birth, sex, height, eye color, and address (including U.S. Citizen ID Card [INS Form I-197] and ID Card for use of Resident Citizen in the U.S. [INS Form 1-179])
- School identification card with photograph
- Voter's registration card
- United States military card or draft record
- Military dependent's identification card
- United States Coast Guard Merchant Mariner Card
- Native American tribal document
- Driver's license issued by a Canadian government authority

Source: http//uscis.gov/graphics/lawsregs/handbook/hand_emp.pdf US Handbook for Employers, page 23.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office for Civil Rights (OCR)

Civil Rights Information Request For Medicare Certification

Form Approved: OMB No. 0990-0243

Expiration Date: 10/31/2010

Instructions: Complete all fields and return this form, with the required documents, to your State Health Department, along with your other Medicare Application Materials.

I. Healthcare Provider Information

CMS Medicare Provider Number:

Name of Facility:

Address: _____
Street Number and Name

_____ - _____
City or Town *State or Province* *Zip Code*

Administrator's Name: _____ Contact Person: _____

Telephone: ( ) - TDD: ( ) -

FAX: ( ) - E-mail: _____

Type of Facility: _____ Number of employees: _____

Corporate Affiliation: _____ Reason for Application: Circle One
Initial Medicare Certification or Change of Ownership

II. Documents Required for Submission

(Additional guidance is available at: (www.hhs.gov/ocr/crclearance.html)

1.	**Two signed and completed originals of the form HHS-690, Assurance of Compliance.**
2.	**Your Nondiscrimination Policy that provides for admission and services without regard to race, color, national origin, disability, or age, as required by Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 (see example).**
3.	**Description of methods used to disseminate your nondiscrimination policies/notices (e.g., describe where you post your Nondiscrimination Policy, and include brochures, postings, ads, etc.).**
4.	**Facility admissions policy that describes eligibility requirements for your services.**
5.	**Copies of brochures, pamphlets, etc. with general information about your services.**
6.	**Procedures to effectively communicate with persons who are limited English proficient (LEP), including (see example):** **a) Process for how you identify individuals who need language assistance;** **b) Procedures to provide services (interpreters, written translations, bilingual staff, etc.). Include the name(s) and telephone number(s) of your interpreter(s) and/or interpreter service(s);** **c) Methods to inform LEP persons that language assistance services are available at no cost to the person being served;** **d) Appropriate restrictions on the use of family and friends as LEP interpreters;** **e) A list of all written materials in other languages, if applicable. Examples may include consent and complaint forms, intake forms, written notices of eligibility criteria, nondiscrimination notices, etc.**
7.	**Procedures used to communicate effectively with individuals who are deaf, hard of hearing, blind, have low vision, or who have other impaired sensory, manual or speaking skills, including (see example):** **a) Process to identify individuals who need sign language interpreters or other assistive services;** **b) Procedures to provide interpreters and other auxiliary aids and services. Include the name(s) and telephone number(s) of your interpreter(s) and/or interpreter service(s);** **c) Procedures used to communicate with deaf or hard of hearing persons over the telephone, including the telephone number of your TTY/TDD or State Relay System;** **d) A list of available auxiliary aids and services;** **e) Methods to inform persons that interpreter or other assistive services are available at no cost to the person being served;** **f) Appropriate restrictions on the use of family and friends as sign language interpreters.**

Office for Civil Rights (OCR)

Civil Rights Information Request
For Medicare Certification

Form Approved: OMB No. 0990-0243

Expiration Date: 10/31/2010

8.	**Notice of Program Accessibility and methods used to disseminate information to patients/clients about the existence and location of services and facilities that are accessible to persons with disabilities (see example).**
9.	**For healthcare providers with 15 or more employees: the name/title and telephone number of the Section 504 coordinator.**
10.	**For healthcare providers with 15 or more employees: copy of your procedures used for handling disability discrimination grievances (see example).**
11.	**A description/explanation of any policies or practices restricting or limiting your facility's admissions or services on the basis of age. In certain narrowly defined circumstances, age restrictions are permitted.**

III. Certification

I certify that the information provided to the Office for Civil Rights is true, complete, and correct to the best of my knowledge.

Name and Title of Authorized Official	Signature	Date
_____	_____	_____

ASSURANCE OF COMPLIANCE

ASSURANCE OF COMPLIANCE WITH TITLE VI OF THE CIVIL RIGHTS ACT OF 1964, SECTION 504 OF THE REHABILITATION ACT OF
1973, TITLE IX OF THE EDUCATION AMENDMENTS OF 1972, AND THE AGE DISCRIMINATION ACT OF 1975

The Applicant provides this assurance in consideration of and for the purpose of obtaining Federal grants, loans, contracts, property, discounts
or other Federal financial assistance from the Department of Health and Human Services.

THE APPLICANT HEREBY AGREES THAT IT WILL COMPLY WITH:

1. Title VI of the Civil Rights Act of 1964 (Pub. L. 88-352), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 80), to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

2. Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 84), to the end that, in accordance with Section 504 of that Act and the Regulation, no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

3. Title IX of the Educational Amendments of 1972 (Pub. L. 92-318), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 86), to the end that, in accordance with Title IX and the Regulation, no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any education program or activity for which the Applicant receives Federal financial assistance from the Department.

4. The Age Discrimination Act of 1975 (Pub. L. 94-135), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 91), to the end that, in accordance with the Act and the Regulation, no person in the United States shall, on the basis of age, be denied the benefits of, be excluded from participation in, or be subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

The Applicant agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the Applicant, its successors, transferees and assignees for the period during which such assistance is provided. If any real property or structure thereon is provided or improved with the aid of Federal financial assistance extended to the Applicant by the Department, this assurance shall obligate the Applicant, or in the case of any transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. If any personal property is so provided, this assurance shall obligate the Applicant for the period during which it retains ownership or possession of the property. The Applicant further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the Applicant to the above provisions.

_____ _____
Date Signature and Title of Authorized Official

_____
Name of Applicant or Recipient

_____
Street

_____
City, State, Zip Code

Mail Form to:
DHHS/Office for Civil Rights
Office of Program Operations
Humphrey Building, Room 509F
200 Independence Ave., S.W.
Washington, D.C. 20201

Form HHS-690
5/97

Office for Civil Rights

Civil Rights Information Request
For
Medicare Certification

Technical Assistance

Go to http://www.hhs.gov/ocr/crclearance.html for more information, including links to the full regulations.

Nondiscrimination Policies and Notices

The regulations implementing Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 require health and human service providers that receive Federal financial assistance from the Department of Health and Human Services to provide notice to patients/residents, employees, and others of the availability of programs and services to all persons without regard to race, color, national origin, disability, or age.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.6(d) Information to beneficiaries and participants. Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation.

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§ 84.8 Notice. (a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to **§**84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

Age Discrimination Act: 45 CFR Part 91

§ 91.32 Notice to subrecipients and beneficiaries. (b) Each recipient shall make necessary information about the Act and these regulations available to its program beneficiaries in order to inform them about the protections against discrimination provided by the Act and these regulations.

See Policy Example Section for examples of Nondiscrimination Policies.

Communication with Persons Who Are Limited English Proficient

In certain circumstances, the failure to ensure that Limited English Proficient (LEP) persons can effectively participate in, or benefit from, federally-assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, and the Title VI regulations against national origin discrimination. Specifically, the failure of a recipient of Federal financial assistance from HHS to take reasonable steps to provide LEP persons with a meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS's implementing regulations. It is therefore important for recipients of Federal financial assistance, including Part A Medicare providers, to understand and be familiar with the requirements.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.3 Discrimination prohibited.

(a) General. No person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this part applies.
(b) Specific discriminatory actions prohibited. (1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit under the program;
(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;
(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;
(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;
(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;
(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as an employee but only to the extent set forth in paragraph (c) of this section).
(vii) Deny a person the opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.

Resources

For further guidance on the obligation to take reasonable steps to provide meaningful access to LEP persons, see HHS' "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.hhs.gov/ocr/lep/. This guidance is also available at http://www.lep.gov/, along with other helpful information pertaining to language services for LEP persons.

Technical Assistance for Medicare and Medicare+Choice organizations from the Centers for Medicare and Medicaid for Designing, Conducting, and Implementing the 2003 National Quality Assessment and Performance

Improvement (QAPI) Program Project on Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services- http://www.cms.hhs.gov/healthplans/quality/project03.asp

Examples of Vital Written Materials

Vital written materials could include, for example:

- Consent and complaint forms.
- Intake forms with the potential for important consequences.
- Written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services, actions affecting parental custody or child support, and other hearings.
- Notices advising LEP persons of free language assistance.
- Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required.
- Applications to participate in a recipient's program or activity or to receive recipient benefits or services.

Nonvital written materials could include:

- Hospital menus.
- Third party documents, forms, or pamphlets distributed by a recipient as a public service.
- For a non-governmental recipient, government documents and forms.
- Large documents such as enrollment handbooks (although vital information contained in large documents may need to be translated).
- General information about the program intended for informational purposes only.

Auxiliary Aids and Services for Persons with Disabilities

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§84.3 Definitions

(h) Federal financial assistance – means any grant, loan … or any other arrangement by which [DHHS] makes available … funds; services …

(j) Handicapped person – means any person who has a physical or mental impairment which substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.

(k) Qualified handicapped person means - (4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

§84.4 Discrimination prohibited

(1) General. No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

Discriminatory actions prohibited –

(1) A recipient, in providing any aid, benefits, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded other;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

Subpart F – Health, Welfare and Social Services

§84.51 Application of this subpart

Subpart F applies to health, welfare, or other social service programs and activities that receive or benefit from Federal financial assistance …

§84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered non-handicapped persons;

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in **§** 84.4(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) Notice. A recipient that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) ***Auxiliary aids.*** (1) A recipient with fifteen or more employees "shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such person an equal opportunity to benefit from the service in question." (2) Pursuant to the Department's discretion, recipients with fewer than fifteen employees may be required "to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services." (3) "Auxiliary aids may include brailed and taped material, interpreters, and other aids for persons with impaired hearing or vision."

504 Notice

The regulation implementing Section 504 requires that an agency/facility "that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified disabled persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their disability." **(45 CFR §84.52(b))**

Note that it is necessary to note each area of the consent, such as:

1. Medical Consent
2. Authorization to Disclose Medical Information
3. Personal Valuables
4. Financial Agreement
5. Assignment of Insurance Benefits
6. Medicare Patient Certification and Payment Request

Resources:

U.S. Department of Justice at www.ada.gov

ADA Business Brief: Communicating with People Who are Deaf or Hard of Hearing in Hospital Settings at http://www.ada.gov/business.htm

A new on-line library of ADA documents is now available on the Internet. Developed by Meeting the Challenge, Inc., of Colorado Springs with funding from the National Institute on Disability and Rehabilitation Research, this website makes available more than 3,400 documents related to the ADA, including those issued by Federal agencies with responsibilities under the law. It also offers extensive document collections on other disability rights laws and issues. By clicking on one of the general categories in the left column, for example, you will go to a catalogue of documents that are specific to the topic. http://www.dbtac.vcu.edu/adaportal//

Requirements for Facilities with 15 or More Employees

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973:

45 CFR Part 84§84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

Age Discrimination Act Requirements

The Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) has the responsibility for the Age Discrimination Act as it applies to Federally funded health and human services programs. The general regulation implementing the Age Discrimination Act requires that age discrimination complaints be referred to a mediation agency to attempt a voluntary settlement within sixty **(60)** days. If mediation is not successful, the complaint is returned to the responsible Federal agency, in this case the Office for Civil Rights, for action. OCR next attempts to resolve the complaint through informal procedures. If these fail, a formal investigation is conducted. When a violation is found and OCR cannot negotiate voluntary compliance, enforcement action may be taken against the recipient institution or agency that violated the law.

The Age Discrimination Act permits certain exceptions to the prohibition against discrimination based on age. These exceptions recognize that some age distinctions in programs may be necessary to the normal operation of a program or activity or to the achievement of any statutory objective expressly stated in a Federal, State, or local statute adopted by an elected legislative body.

Applicable Regulatory Citations:

45 CFR Part 91: Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance From HHS

§ 91.3 To what programs do these regulations apply?

(a) The Act and these regulations apply to each HHS recipient and to each program or activity operated by the recipient which receives or benefits from Federal financial assistance provided by HHS.
(b) The Act and these regulations do not apply to:
(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:
(i) Provides any benefits or assistance to persons based on age; or
(ii) Establishes criteria for participation in age-related terms; or
(iii) Describes intended beneficiaries or target groups in age-related terms.

Subpart B-Standards for Determining Age Discrimination

§ 91.11 Rule against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§91.13 and 91.14 of these regulations.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.
(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of:
(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance.
(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal

financial assistance.
(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 91.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and
(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and
(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and
(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 91.11 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 91.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 91.13 and 91.14 is on the recipient of Federal financial assistance.

Policy Examples

The next few pages contain examples of policies that you could use as guidance in developing civil rights policies and procedures for your facility. You may modify them to best reflect your procedures and methods.

Examples of Nondiscrimination Policies

Example One (for posting in the facility and inserting in advertising or admissions packages):

NONDISCRIMINATION POLICY

As a recipient of Federal financial assistance, (insert name of provider) does not exclude, deny benefits to, or otherwise discriminate against any person on the ground of race, color, or national origin, or on the basis of disability or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by (insert name of provider) directly or through a contractor or any other entity with which (insert name of provider) arranges to carry out its programs and activities.

This statement is in accordance with the provisions of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Regulations of the U.S. Department of Health and Human Services issued pursuant to these statutes at Title 45 Code of Federal Regulations Parts 80, 84, and 91.

In case of questions, please contact:

Provider Name:

Contact Person/Section 504 Coordinator:

Telephone number:

TDD or State Relay number:

Example Two (for use in brochures, pamphlets, publications, etc.):

(Insert name of provider) does not discriminate against any person on the basis of race, color, national origin, disability, or age in admission, treatment, or participation in its programs, services and activities, or in employment. For further information about this policy, contact: (insert name of Section 504 Coordinator, phone number, TDD/State Relay).

Example of a Policy and Procedure for Providing Meaningful Communication with Persons with Limited English Proficiency

POLICY AND PROCEDURES FOR COMMUNICATION WITH PERSONS WITH LIMITED ENGLISH PROFICIENCY

POLICY:

(Insert name of your facility) will take reasonable steps to ensure that persons with Limited English Proficiency (LEP) have meaningful access and an equal opportunity to participate in our services, activities, programs and other benefits. The policy of (***Insert name of your facility)*** is to ensure meaningful communication with LEP patients/clients and their authorized representatives involving their medical conditions and treatment. The policy also provides for communication of information contained in vital documents, including but not limited to, waivers of rights, consent to treatment forms, financial and insurance benefit forms, etc. ***(include those documents applicable to your facility)***. All interpreters, translators and other aids needed to comply with this policy shall be provided without cost to the person being served, and patients/clients and their families will be informed of the availability of such assistance free of charge.

Language assistance will be provided through use of competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation or translation services, or technology and telephonic interpretation services. All staff will be provided notice of this policy and procedure, and staff that may have direct contact with LEP individuals will be trained in effective communication techniques, including the effective use of an interpreter.

(Insert name of your facility) will conduct a regular review of the language access needs of our patient population, as well as update and monitor the implementation of this policy and these procedures, as necessary.

PROCEDURES:

1. IDENTIFYING LEP PERSONS AND THEIR LANGUAGE

(Insert name of your facility) will promptly identify the language and communication needs of the LEP person. If necessary, staff will use a language identification card (or "I speak cards," available online at www.lep.gov) or posters to determine the language. In addition, when records are kept of past interactions with patients (clients/residents) or family members, the language used to communicate with the LEP person will be included as part of the record.

2. OBTAINING A QUALIFIED INTEPRETER

(Identify responsible staff person(s), and phone number(s)) is/are responsible for:

(a) Maintaining an accurate and current list showing the name, language, phone number and hours of availability of bilingual staff ***(provide the list)****;*

(b) Contacting the appropriate bilingual staff member to interpret, in the event that an interpreter is needed, if an employee who speaks the needed language is available and is qualified to interpret;

(c) Obtaining an outside interpreter if a bilingual staff or staff interpreter is not available or does not speak the needed language.
(*Identify the agency(s) name(s) with whom you have contracted or made arrangements)* have/has agreed to provide qualified interpreter services. The agency's (or agencies') telephone number(s) is/are **(*insert number (s)),*** and the hours of availability are (***insert hours)***.

Some LEP persons may prefer or request to use a family member or friend as an interpreter. However, family members or friends of the LEP person will not be used as interpreters unless specifically requested by that individual and **after** the LEP person has understood that an offer of an interpreter at no charge to the person has been made by the facility. Such an offer and the response will be documented in the person's file. If the LEP person chooses to use a family member or friend as an interpreter, issues of competency of interpretation, confidentiality, privacy, and conflict of interest will be considered. If the family member or friend is not competent or appropriate for any of these reasons, competent interpreter services will be provided to the LEP person.

Children and other clients/patients/residents will **not** be used to interpret, in order to ensure confidentiality of information and accurate communication.

3. PROVIDING WRITTEN TRANSLATIONS

(a) When translation of vital documents is needed, each unit in ***(insert name of your facility)*** will submit documents for translation into frequently-encountered languages to ***(identify responsible staff person).*** Original documents being submitted for translation will be in final, approved form with updated and accurate legal and medical information.

(b) Facilities will provide translation of other written materials, if needed, as well as written notice of the availability of translation, free of charge, for LEP individuals.

(c) ***(Insert name of your facility)*** will set benchmarks for translation of vital documents into additional languages over time.

4. PROVIDING NOTICE TO LEP PERSONS

(Insert name of your facility) will inform LEP persons of the availability of language assistance, free of charge, by providing written notice in languages LEP persons will understand. At a minimum, notices and signs will be posted and provided in intake areas and other points of entry, including but not limited to the emergency room, outpatient areas, etc. ***(include those areas applicable to your facility)***. Notification will also be provided through one or more of the following: outreach documents, telephone voice mail menus, local newspapers, radio and television stations, and/or community-based organizations ***(include those areas applicable to your facility)***.

5. MONITORING LANGUAGE NEEDS AND IMPLEMENTATION

On an ongoing basis, ***(insert name of your facility)*** will assess changes in demographics, types of services or other needs that may require reevaluation of this policy and its procedures. In addition, ***(insert name of your facility)*** will regularly assess the efficacy of these procedures, including but not limited to mechanisms for securing interpreter services, equipment used for the delivery of language assistance,

complaints filed by LEP persons, feedback from patients and community organizations, etc. ***(include those areas applicable to your facility)***.

Example of a Policy and Procedure for Providing Auxiliary Aids for Persons with Disabilities

AUXILIARY AIDS AND SERVICES FOR PERSONS WITH DISABILITIES

POLICY:

(Insert name of your facility) will take appropriate steps to ensure that persons with disabilities, including persons who are deaf, hard of hearing, or blind, or who have other sensory or manual impairments, have an equal opportunity to participate in our services, activities, programs and other benefits. The procedures outlined below are intended to ensure effective communication with patients/clients involving their medical conditions, treatment, services and benefits. The procedures also apply to, among other types of communication, communication of information contained in important documents, including waivers of rights, consent to treatment forms, financial and insurance benefits forms, etc. (***include those documents applicable to your facility)****.* All necessary auxiliary aids and services shall be provided without cost to the person being served.

All staff will be provided written notice of this policy and procedure, and staff that may have direct contact with individuals with disabilities will be trained in effective communication techniques, including the effective use of interpreters.

PROCEDURES:

1. Identification and assessment of need:

(Name of facility) provides notice of the availability of and procedure for requesting auxiliary aids and services through notices in our ***(brochures, handbooks, letters, print/radio /televison advertisements, etc.)*** and through notices posted ***(in waiting rooms, lobbies, etc****.).* When an individual self-identifies as a person with a disability that affects the ability to communicate or to access or manipulate written materials or requests an auxiliary aid or service, staff will consult with the individual to determine what aids or services are necessary to provide effective communication in particular situations.

2. Provision of Auxiliary Aids and Services:

(Insert name of your facility) shall provide the following services or aids to achieve effective communication with persons with disabilities:

A. For Persons Who Are Deaf or Hard of Hearing

(i) For persons who are deaf/hard of hearing and who use sign language as their primary means of communication, the ***(identify responsible staff person or position with a telephone number*****)** is responsible for providing effective interpretation or arranging for a qualified interpreter when needed.

In the event that an interpreter is needed, the ***(identify responsible staff person)*** is responsible for:

Maintaining a list of qualified interpreters on staff showing their names, phone numbers, qualifications and hours of availability ***(provide the list)*;**

Contacting the appropriate interpreter on staff to interpret, if one is available and qualified to interpret; or

Obtaining an outside interpreter if a qualified interpreter on staff is not available. **(Identify the agency(s) name with whom you have contracted or made arrangements)** has agreed to provide interpreter services. The agency's/agencies' telephone number(s) is/are **(insert number(s) and the hours of availability)**.**[Note: If video interpreter services are provided via computer, the procedures for accessing the service must be included.]**

(ii) Communicating by Telephone with Persons Who Are Deaf or Hard of Hearing

[Listed below are three methods for communicating over the telephone with persons who are deaf/hard of hearing. Select the method(s) to incorporate in your policy that best applies/apply to your facility.]

(*Insert name of facility)* utilizes a Telecommunication Device for the Deaf (TDD) for external communication. The telephone number for the TDD is ***(insert number***). The TDD and instructions on how to operate it are located ***(insert location*)** in the facility; OR

(Insert name of provider) has made arrangements to share a TDD. When it is determined by staff that a TDD is needed, we contact ***(identify the entity e.g., library, school or university, provide address and telephone numbers*)**; OR

(Insert name of facility) utilizes relay services for external telephone with TTY users. We accept and make calls through a relay service. The state relay service number is ***(insert telephone for your State Relay)***.

(iii) For the following auxiliary aids and services, staff will contact ***(responsible staff person or position and telephone number)***, who is responsible to provide the aids and services in a timely manner:
Note-takers; computer-aided transcription services; telephone handset amplifiers; written copies of oral announcements; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning; telecommunications devices for deaf persons (TDDs); videotext displays; or other effective methods that help make aurally delivered materials available to individuals who are deaf or hard of hearing.

(iv) Some persons who are deaf or hard of hearing may prefer or request to use a family member or friend as an interpreter. However, family members or friends of the person will not be used as interpreters unless specifically requested by that individual and *after* an offer of an interpreter at no charge to the person has been made by the facility. Such an offer and the response will be documented in the

person's file. If the person chooses to use a family member or friend as an interpreter, issues of competency of interpretation, confidentiality, privacy and conflict of interest will be considered. If the family member or friend is not competent or appropriate for any of these reasons, competent interpreter services will be provided.
NOTE: Children and other residents will *not* be used to interpret, in order to ensure confidentiality of information and accurate communication.

B. For Persons Who are Blind or Who Have Low Vision

(i) Staff will communicate information contained in written materials concerning treatment, benefits, services, waivers of rights, and consent to treatment forms by reading out loud and explaining these forms to persons who are blind or who have low vision **[in addition to reading, this section should tell what other aids are available, where they are located, and how they are used]**.

The following types of large print, taped, Brailled, and electronically formatted materials are available: **(d*escription of the materials available)*.** These materials may be obtained by calling **(*name or position and telephone number*)**.

(ii) For the following auxiliary aids and services, staff will contact ***(responsible staff person or position and telephone number),*** who is responsible to provide the aids and services in a timely manner:
Qualified readers; reformatting into large print; taping or recording of print materials not available in alternate format; or other effective methods that help make visually delivered materials available to individuals who are blind or who have low vision. In addition, staff are available to assist persons who are blind or who have low vision in filling out forms and in otherwise providing information in a written format.

C. For Persons With Speech Impairments

To ensure effective communication with persons with speech impairments, staff will contact ***(responsible staff person or position and telephone number),*** who is responsible to provide the aids and services in a timely manner:
Writing materials; typewriters; TDDs; computers; flashcards; alphabet boards; communication boards; ***(include those aids applicable to your facility)*** and other communication aids.

D. For Persons With Manual Impairments

Staff will assist those who have difficulty in manipulating print materials by holding the materials and turning pages as needed, or by providing one or more of the following:
note-takers; computer-aided transcription services; speaker phones; or other effective methods that help to ensure effective communication by individuals with manual impairments. For these and other auxiliary aids and services, staff will contact ***(responsible staff person or position and telephone number)*** who is responsible to provide the aids and services in a timely manner.

Example of a Notice of Program Accessibility for Describing that your Program is Accessible to Persons with Disabilities

Section 504 Notice of Program Accessibility

The regulation implementing Section 504 requires that an agency/facility "*…adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by disabled persons.*" **(45 C.F.R. §84.22(f))**

(Insert name of facility) and all of its programs and activities are accessible to and useable by disabled persons, including persons who are deaf, hard of hearing, or blind, or who have other sensory impairments. Access features include:

- Convenient off-street parking designated specifically for disabled persons.
- Curb cuts and ramps between parking areas and buildings.
- Level access into first floor level with elevator access to all other floors.
- Fully accessible offices, meeting rooms, bathrooms, public waiting areas, cafeteria, patient treatment areas, including examining rooms and patient wards.
- A full range of assistive and communication aids provided to persons who are deaf, hard of hearing, or blind, or with other sensory impairments. There is no additional charge for such aids. Some of these aids include:
    - Qualified sign language interpreters for persons who are deaf or hard of hearing.
    - A twenty-four hour (24) telecommunication device (TTY/TDD) which can connect the caller to all extensions within the facility and/or portable (TTY/TDD) units, for use by persons who are deaf, hard of hearing, or speech impaired.
    - Readers and taped material for the blind and large print materials for the visually impaired.
    - Flash Cards, Alphabet boards and other communication boards.
    - Assistive devices for persons with impaired manual skills.

If you require any of the aids listed above, please let the receptionist or your nurse know.

Example of a Section 504 Grievance Procedure that Incorporates Due Process Standards

Section 504 GRIEVANCE PROCEDURE

It is the policy of ***(insert name of facility/agency)*** not to discriminate on the basis of disability. **(*Insert name of facility/agency*)** has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) or the U.S. Department of Health and Human Services regulations implementing the Act. Section 504 states, in part, that "no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance." The Law and Regulations may be examined in the office of ***(insert name, title, tel. no. of Section 504 Coordinator)***, who has been designated to coordinate the efforts of ***(insert name of facility/agency)*** to comply with Section 504***.***

Any person who believes she or he has been subjected to discrimination on the basis of disability may file a grievance under this procedure. It is against the law for ***(insert name of facility/agency)*** to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.

Procedure:

Grievances must be submitted to the Section 504 Coordinator within (insert timeframe) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
The Section 504 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it must be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 504 Coordinator will maintain the files and records of ***(insert name of facility/agency)*** relating to such grievances.
The Section 504 Coordinator will issue a written decision on the grievance no later than 30 days after its filing.
The person filing the grievance may appeal the decision of the Section 504 Coordinator by writing to the ***(Administrator/Chief Executive Officer/Board of Directors/etc.)*** within 15 days of receiving the Section 504 Coordinator's decision.
The ***(Administrator/Chief Executive Officer/Board of Directors/etc.)*** shall issue a written decision in response to the appeal no later than 30 days after its filing.
The availability and use of this grievance procedure does not prevent a person from filing a complaint of discrimination on the basis of disability with the U. S. Department of Health and Human Services, Office for Civil Rights.

*(**Insert name of facility/agency**)* will make appropriate arrangements to ensure that disabled persons are provided other accommodations if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing interpreters for the deaf, providing taped cassettes of material for the blind, or assuring a barrier-free location for the proceedings. The Section 504 Coordinator will be responsible for such arrangements.

Office for Civil Rights

Medicare Certification

Nondiscrimination Policies and Notices

Please note that documents in PDF format require Adobe's Acrobat Reader.

The regulations implementing Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 require health and human service providers that receive Federal financial assistance from the Department of Health and Human Services to provide notice to patients/residents, employees, and others of the availability of programs and services to all persons without regard to race, color, national origin, disability, or age.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.6(d) Information to beneficiaries and participants. Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation.

Go to 45 CFR Part 80 for the full regulation.

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§ 84.8 Notice. (a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to §84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in

recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

Go to 45 CFR Part 84 for the full regulation.

Age Discrimination Act: 45 CFR Part 91

§ 91.32 Notice to subrecipients and beneficiaries. (b) Each recipient shall make necessary information about the Act and these regulations available to its program beneficiaries in order to inform them about the protections against discrimination provided by the Act and these regulations.

Go to 45 CFR Part 91 for the full regulation.

Policy Examples

Example One (for posting in the facility and inserting in advertising or admissions packages):

NONDISCRIMINATION POLICY

As a recipient of Federal financial assistance, (insert name of provider) does not exclude, deny benefits to, or otherwise discriminate against any person on the ground of race, color, or national origin, or on the basis of disability or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by (insert name of provider) directly or through a contractor or any other entity with which (insert name of provider) arranges to carry out its programs and activities.

This statement is in accordance with the provisions of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Regulations of the U.S. Department of Health and Human Services issued pursuant to these statutes at Title 45 Code of Federal Regulations Parts 80, 84, and 91.

In case of questions, please contact:

Provider Name:

Contact Person/Section 504 Coordinator:

Telephone number:

TDD or State Relay number:

Example Two (for use in brochures, pamphlets, publications, etc.):

(Insert name of provider) does not discriminate against any person on the basis of race, color, national origin, disability, or age in admission, treatment, or participation in its programs, services and activities, or in employment. For further information about this policy, contact: (insert name of Section 504 Coordinator, phone number, TDD/State Relay).

Medicare Certification

Communication with Persons Who Are Limited English Proficient

Please note that documents in PDF format require Adobe's Acrobat Reader.

In certain circumstances, the failure to ensure that Limited English Proficient (LEP) persons can effectively participate in, or benefit from, federally-assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, and the Title VI regulations against national origin discrimination. Specifically, the failure of a recipient of Federal financial assistance from HHS to take reasonable steps to provide LEP persons with a meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS's implementing regulations. It is therefore important for recipients of Federal financial assistance, including Part A Medicare providers, to understand and be familiar with the requirements.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.3 Discrimination prohibited.

(a) General. No person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this part applies.
(b) Specific discriminatory actions prohibited. (1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit under the program;
(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;
(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;
(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;
(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;
(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as

an employee but only to the extent set forth in paragraph (c) of this section).
(vii) Deny a person the opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.

Go to 45 CFR Part 80 for the full regulation.

Resources

For further guidance on the obligation to take reasonable steps to provide meaningful access to LEP persons, see HHS' "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.hhs.gov/ocr/lep/. This guidance is also available at http://www.lep.gov/, along with other helpful information pertaining to language services for LEP persons.

"I Speak" Language Identification Flashcard (PDF) From the Department of Commerce, Bureau of the Census, the "I Speak" Language Identification Flashcard is written in 38 languages and can be used to identify the language spoken by an individual accessing services provided by federally assisted programs or activities.

Technical Assistance for Medicare and Medicare+Choice organizations from the Centers for Medicare and Medicaid for Designing, Conducting, and Implementing the 2003 National Quality Assessment and Performance Improvement (QAPI) Program Project on Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services-
http://www.cms.hhs.gov/healthplans/quality/project03.asp

Examples of Vital Written Materials

Vital written materials could include, for example:

- Consent and complaint forms.
- Intake forms with the potential for important consequences.
- Written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services, actions affecting parental custody or child support, and other hearings.

- Notices advising LEP persons of free language assistance.
- Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required.
- Applications to participate in a recipient's program or activity or to receive recipient benefits or services.

Nonvital written materials could include:

- Hospital menus.
- Third party documents, forms, or pamphlets distributed by a recipient as a public service.
- For a non-governmental recipient, government documents and forms.
- Large documents such as enrollment handbooks (although vital information contained in large documents may need to be translated).
- General information about the program intended for informational purposes only.

Medicare Certification

Auxiliary Aids and Services for Persons With Disabilities

Please note that documents in PDF format require Adobe's Acrobat Reader.

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§84.3 Definitions

(h) Federal financial assistance – means any grant, loan … or any other arrangement by which [DHHS] makes available … funds; services …

(j) Handicapped person – means any person who has a physical or mental impairment which substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.

(k) Qualified handicapped person means - (4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

§84.4 Discrimination prohibited

(1) General. No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

Discriminatory actions prohibited –

(1) A recipient, in providing any aid, benefits, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded other;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any

class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

Subpart F – Health, Welfare and Social Services

§84.51 Application of this subpart

Subpart F applies to health, welfare, or other social service programs and activities that receive or benefit from Federal financial assistance …

§84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered non-handicapped persons;

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in **§** 84.4(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) Notice. A recipient that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) ***Auxiliary aids.*** (1) A recipient with fifteen or more employees "shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such person an equal opportunity to benefit from the service in question." (2) Pursuant to the Department's discretion, recipients with fewer than fifteen employees may be required "to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services." (3) "Auxiliary aids may include brailed and taped material, interpreters, and other aids for persons with impaired hearing or vision."

Go to 45 CFR Part 84 for the full regulation.

504 Notice

The regulation implementing Section 504 requires that an agency/facility "that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified disabled persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their disability." **(45 CFR §84.52(b))**

Note that it is necessary to note each area of the consent, such as:

1. Medical Consent

2. Authorization to Disclose Medical Information

3. Personal Valuables

4. Financial Agreement

5. Assignment of Insurance Benefits

6. Medicare Patient Certification and Payment Request

Resources:

U.S. Department of Justice Document:

ADA Business Brief: Communicating with People Who are Deaf or Hard of Hearing in Hospital Settings

ADA Document Portal

A new on-line library of ADA documents is now available on the Internet. Developed by Meeting the Challenge, Inc., of Colorado Springs with funding from the National Institute on Disability and Rehabilitation Research, this website makes available more than 3,400 documents related to the ADA, including those issued by Federal agencies with responsibilities

under the law. It also offers extensive document collections on other disability rights laws and issues. By clicking on one of the general categories in the left column, for example, you will go to a catalogue of documents that are specific to the topic.

Medicare Certification

Requirements for Facilities with 15 or More Employees

Please note that documents in PDF format require Adobe's Acrobat Reader.

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973:

45 CFR Part 84§84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

Go to 45 CFR Part 84 for the full regulation.

Policy Example

The following procedure incorporates appropriate minimum due process standards and may serve as a model or be adapted for use by recipients in accordance with the Departmental regulation implementing Section 504 of the Rehabilitation Act of 1973.

SECTION 504 GRIEVANCE PROCEDURE

It is the policy of (**insert name of facility/agency**) not to discriminate on the basis of disability. (**Insert name of facility/agency**) has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) or the U.S. Department of Health and Human Services regulations implementing the Act. Section 504 states, in part, that "no otherwise qualified handicapped individual...shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance..." The Law and Regulations may be examined in the office of (**insert name, title, tel. no. of Section 504 Coordinator**), who has been designated to coordinate the efforts of (**insert name of facility/agency**) to comply with Section 504.

Any person who believes she or he has been subjected to discrimination on the basis of disability may file a grievance under this procedure. It is against the law for (**insert name of facility/agency**) to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.

Procedure:

- Grievances must be submitted to the Section 504 Coordinator within (**insert time frame**) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
- A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
- The Section 504 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it must be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 504 Coordinator will maintain the files and records of (**insert name of facility/agency**)

relating to such grievances.

- The Section 504 Coordinator will issue a written decision on the grievance no later than 30 days after its filing.
- The person filing the grievance may appeal the decision of the Section 504 Coordinator by writing to the (**Administrator/Chief Executive Officer/Board of Directors/etc.**) within 15 days of receiving the Section 504 Coordinator's decision.
- The (**Administrator/Chief Executive Officer/Board of Directors/etc.**) shall issue a written decision in response to the appeal no later than 30 days after its filing.
- The availability and use of this grievance procedure does not prevent a person from filing a complaint of discrimination on the basis of disability with the U. S. Department of Health and Human Services, Office for Civil Rights.

(**Insert name of facility/agency**) will make appropriate arrangements to ensure that disabled persons are provided other accommodations if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing interpreters for the deaf, providing taped cassettes of material for the blind, or assuring a barrier-free location for the proceedings. The Section 504 Coordinator will be responsible for such arrangements.

Medicare Certification

Age Discrimination Act Requirements

Please note that documents in PDF format require Adobe's Acrobat Reader.

The Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) has the responsibility for the Age Discrimination Act as it applies to Federally funded health and human services programs. The general regulation implementing the Age Discrimination Act requires that age discrimination complaints be referred to a mediation agency to attempt a voluntary settlement within sixty **(60)** days. If mediation is not successful, the complaint is returned to the responsible Federal agency, in this case the Office for Civil Rights, for action. OCR next attempts to resolve the complaint through informal procedures. If these fail, a formal investigation is conducted. When a violation is found and OCR cannot negotiate voluntary compliance, enforcement action may be taken against the recipient institution or agency that violated the law.

The Age Discrimination Act permits certain exceptions to the prohibition against discrimination based on age. These exceptions recognize that some age distinctions in programs may be necessary to the normal operation of a program or activity or to the achievement of any statutory objective expressly stated in a Federal, State, or local statute adopted by an elected legislative body.

Applicable Regulatory Citations:

45 CFR Part 91: Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance From HHS

§ 91.3 To what programs do these regulations apply?

(a) The Act and these regulations apply to each HHS recipient and to each program or activity operated by the recipient which receives or benefits from Federal financial assistance provided by HHS.
(b) The Act and these regulations do not apply to:
(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:
(i) Provides any benefits or assistance to persons based on age; or
(ii) Establishes criteria for participation in age-related terms; or
(iii) Describes intended beneficiaries or target groups in age-related terms.

Subpart B-Standards for Determining Age Discrimination

§ 91.11 Rule against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§91.13 and 91.14 of these regulations.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.
(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of:
(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance.
(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.
(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 91.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and
(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and
(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and
(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 91.11 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 91.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions

outlined in §§ 91.13 and 91.14 is on the recipient of Federal financial assistance.

For the full regulation, go to 45 CFR Part 91.

FORM APPROVED
OMB No. 0938-0832

HEALTH INSURANCE BENEFIT AGREEMENT

(Agreement with Provider Pursuant to Section 1866 of the Social Security Act,
as Amended and Title 42 Code of Federal Regulations (CFR)
Chapter IV, Part 489)

AGREEMENT

between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
and

_____

doing business as (D/B/A) _____

In order to receive payment under title XVIII of the Social Security Act,_____
_____
D/B/A _____ as the provider of services, agrees to conform to the provisions of section of 1866 of the Social Security Act and applicable provisions in 42 CFR.

This agreement, upon submission by the provider of services of acceptable assurance of compliance with title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 as amended, and upon acceptance by the Secretary of Health and Human Services, shall be binding on the provider of services and the Secretary.

In the event of a transfer of ownership, this agreement is automatically assigned to the new owner subject to the conditions specified in this agreement and 42 CFR 489, to include existing plans of correction and the duration of this agreement, if the agreement is time limited.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or make any false, fictitious or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than 5 years or both (18 U.S.C. section 1001).

Name _____ Title _____

Date _____

ACCEPTED FOR THE PROVIDER OF SERVICES BY:

NAME *(signature)*

TITLE	DATE

ACCEPTED BY THE SECRETARY OF HEALTH AND HUMAN SERVICES BY:

NAME *(signature)*

TITLE	DATE

ACCEPTED FOR THE SUCCESSOR PROVIDER OF SERVICES BY:

NAME *(signature)*

TITLE	DATE

OMB Number: 0990-0243
Expiration Date: 06/30/2007

Medicare Certification Civil Rights Information Request Form

Please return the completed, signed Civil Rights Information Request form and the required attachments with your other Medicare Provider Application Materials.

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT THE FACILITY:

a. **CMS Medicare Provider Number:**_____

b. **Name and Address of Facility:** _____

_____

_____

c. **Administrator's Name** _____

d. **Contact Person** _____
(If different from Administrator)

e. **Telephone** _____ **TDD** _____

f. **E-mail** _____ **FAX** _____

g. **Type of Facility** _____
(e.g., Home Health Agency, Hospital, Skilled Nursing Facility, etc.)

h. **Number of employees:** _____

i. **Corporate Affiliation** _____ (if the facility is now or will be owned and operated by a corporate chain or multi-site business entity, identify the entity.)

j. **Reason for Application** _____
(Initial Medicare Certification, change of ownership, etc.)

PLEASE RETURN THE FOLLOWING MATERIALS WITH THIS FORM.

To ensure accuracy, please consult the technical assistance materials (www.hhs.gov/ocr/crclearance.html) **in developing your responses.**

√	No.	REQUIRED ATTACHMENTS
	1.	Two original signed copies of the form HHS-690, Assurance of Compliance (www.hhs.gov/ocr/ps690.pdf). *A copy should be kept by your facility.*
Nondiscrimination Policies and Notices Please see Nondiscrimination Policies and Notices (www.hhs.gov/ocr/nondiscriminpol.html) for the regulations and technical assistance.		
	2.	A copy of your written notice(s) of nondiscrimination, *that provide for admission and services without regard to race, color, national origin, disability, or age, as required by Federal law. Generally, an EEO policy is not sufficient to address admission and services.*
	3.	A description of the methods used by your facility to disseminate your nondiscrimination notice(s) or policy. *If published, also identify the extent to which and to whom such policies/notices are published (e.g., general public, employees, patients/residents, community organizations, and referral sources) consistent with requirements of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.*
	4.	Copies of brochures or newspaper articles. *If publication is one of the methods used to disseminate the policies/notices, these copies must be attached.*
	5.	A copy of facility admissions policy or policies.
Communication with Persons Who Are Limited English Proficient (LEP) Please see Communication with Persons Who Are Limited English Proficient (LEP) (www.hhs.gov/ocr/commune.html) for technical assistance. For information on the obligation to take reasonable steps to provide meaningful access to LEP persons, including guidance on what constitutes vital written materials, and HHS' "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at www.hhs.gov/ocr/lep . This guidance is also available at http://www.lep.gov/ , along with other helpful information pertaining to language services for LEP persons.		
	6.	A description (or copy) of procedures used by your facility to effectively communicate with persons who have limited English proficiency, including: 1. *How you identify individuals who are LEP and in need of language assistance.* 2. *How language assistance measures are provided (for both oral and written communication) to persons who are LEP, consistent with Title VI requirements.* 3. *How LEP persons are informed that language assistance services are available.*
	7.	A list of all vital written materials provided by your facility, and the languages for which they are available. *Examples of such materials may include consent and complaint forms; intake forms with the potential for important consequences; written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services; applications to participate in a recipient's program or activity or to receive recipient benefits or service; and notices advising LEP persons of free language assistance.*

√	No.	REQUIRED ATTACHMENTS
Auxiliary Aids and Services for Persons with Disabilities Please see Auxiliary Aids and Services for Persons with Disabilities (www.hhs.gov/ocr/auxaids.html) for technical assistance.		
	8.	A description (or copy) of the procedures used to communicate effectively with individuals who are deaf, hearing impaired, blind, visually impaired or who have impaired sensory, manual or speaking skills, including: 1. *How you identify such persons and how you determine whether interpreters or other assistive services are needed.* 2. *Methods of providing interpreter and other services during all hours of operation as necessary for effective communication with such persons.* 3. *A list of available auxiliary aids and services, and how persons are informed that interpreters or other assistive services are available.* 4. *The procedures used to communicate with deaf or hearing impaired persons over the telephone, including TTY/TDD or access to your State Relay System, and the telephone number of your TTY/TDD or your State Relay System.*
	9.	Procedures used by your facility to disseminate information to patients/residents and potential patients/residents about the existence and location of services and facilities that are accessible to persons with disabilities.
Requirements for Facilities with 15 or More Employees Please see Requirements for Facilities with 15 or More Employees (www.hhs.gov/ocr/reqfacilities.html) for technical assistance.		
	10.	For recipients with 15 or more employees: the name/title and telephone number of the Section 504 coordinator.
	11.	For recipients with 15 or more employees: A copy or description of your facility's procedure for handling disability discrimination grievances.
Age Discrimination Act Requirements Please see Age Discrimination Act Requirements (www.hhs.gov/ocr/agediscrim.html) for technical assistance, and for information on permitted exceptions.		
	12.	A description or copy of any policy (ies) or practice(s) restricting or limiting admissions or services provided by your facility on the basis of age. *If such a policy or practice exists, please submit an explanation of any exception/exemption that may apply. In certain narrowly defined circumstances, age restrictions are permitted.*

After review, an authorized official must sign and date the certification below. Please ensure that complete responses to all information/data requests are provided. Failure to provide the information/data requested may delay your facility's certification for funding.

Certification: **I certify that the information provided to the Office for Civil Rights is true and correct to the best of my knowledge.**

Signature of Authorized Official: _____

Title of Authorized Official: _____

Date: _____