

---

# An Analysis and Evaluation of Certificate of Need Regulation in Georgia

---

Final Report to the Georgia General Assembly and Governor Perdue



**Commission on the Efficacy  
of the Certificate of Need Program**

**December 29, 2006**

---

Daniel W. Rahn, M.D.  
Chair

Richard Holmes  
Vice Chair

# Commission Membership

The Commission is comprised of eleven members:

Chairman Daniel W. Rahn, MD  
President, Medical College of Georgia  
*(Ex Officio)*

Vice-Chairman Richard L. Holmes  
Chairman, Board of the Department of Community Health  
*(Ex Officio)*

Senator Don Balfour  
Chair, Senate Rules Committee  
*(Appointed by Senate President Pro Tempore)*

Melvin Deese, MD  
Orthopedic Surgeon, Summit Sports Clinic  
*(Appointed by House Speaker)*

Donna Johnson, Esq.  
President, Donna L. Johnson, P.C.  
*(Appointed by Governor Perdue)*

Robert Lipson, MD *(deceased)*  
President and CEO, WellStar Health Systems, Inc.  
*(Appointed by Governor Perdue)*

Dan Maddock  
President, Taylor Regional Hospital and Healthcare Group  
*(Appointed by Governor Perdue)*

Rhonda M. Medows, MD  
Commissioner, Department of Community Health  
*(Ex Officio)*

Ronnie Rollins  
President & CEO, Community Health Systems  
*(Appointed by Governor Perdue)*

Joseph R. Ross, Esq.  
Senior Vice President & General Counsel, Memorial Health  
*(Appointed by Senate President Pro Tempore)*

Representative Austin Scott  
Chair, Government Affairs Committee  
*(Appointed by House Speaker)*

***Dr. Robert Lipson attended every meeting of the Commission and contributed to discussion in a meaningful and significant fashion until his untimely death in early November 2006. Dr. Lipson was not present at the final consensus meeting of the Commission and did not take part in voting on final recommendations; therefore, his position on any issue is not reflected throughout the report.***

***Dr. Lipson was not replaced on the Commission following his death.***

# Table of Contents

## **Executive Summary**

## **Prologues**

General Background of Certificate of Need	i
Background of CON Commission	v
The Existing Healthcare Environment	xii

## **Legal and Regulatory Issues**

Chapter 1: Administration and Organization	1
Chapter 2: Process and Procedure	12
Chapter 3: Exemptions	27
Chapter 4: Miscellaneous	38

## **Acute Care Services**

Chapter 5: Medical/Surgical	43
Chapter 6: Cardiovascular Services	64
Chapter 7: Perinatal and Obstetrical Services	83
Chapter 8: Inpatient Psychiatric Services	99

## **Long Term Care**

Chapter 9: Skilled Nursing	114
Chapter 10: Home Health	128
Chapter 11: Assisted Living	141
Chapter 12: Inpatient Rehabilitation	151
Chapter 13: Traumatic Brain Injury	163

## **Special and Other Services**

Chapter 14: Ambulatory Surgery	170
Chapter 15: Radiation Therapy	196
Chapter 16: Diagnostic Imaging	207

# EXECUTIVE SUMMARY

## An Analysis and Evaluation of Certificate of Need in Georgia

### An Executive Summary

The Commission has been able to reach consensus on a number of ways to improve upon Georgia's Certificate of Need Program. However, sharp disagreement remains with regard to a number of areas of regulation, most notably, regulation of ambulatory surgery centers and free-standing imaging centers.

Although the Commission's deliberations have been informed by data, previous research and the experiences of other states, the particular areas of disagreement are linked tightly to the financial operating environment for both physicians and hospitals in Georgia at the present time. For this reason, experiences of other states or at different points in time in which the operating environment was and are different from that experienced by providers in Georgia at present can only provide a certain amount of guidance.

The following Executive Summary outlines the key recommendations of the Commission.



## Legal & Regulatory: Administration and Organization

### Recommendation 1.0 *(Unanimous)*

*Move the healthcare-related licensing functions of the Office of Regulatory Services from the Department of Human Resources to the Department of Community Health.*

In order to consolidate inter-related functions, the Commission recommends that the healthcare-related licensing functions of the Office of Regulatory Services be relocated from the Department of Human Resources to the Department of Community Health. Non-healthcare-related licensing functions of ORS, such as the licensure of childcare facilities should remain with the Department of Human Resources.

### Recommendation 1.1 *(Unanimous)*

*Amend the licensure statute to permit detailed licensure standards on a clinical service level.*

Current licensure standards in Georgia are developed and applied at a facility level. The Commission recommends that the licensure statute be amended to permit the development and application of detailed licensure standards on a clinical service level. This recommendation would improve the quality of care, and in certain instances where the Commission has recommended the removal of Certificate of Need regulation (for example, Level 1 perinatal services and diagnostic cardiac catheterization), implementation of this recommendation will ensure a level of regulatory oversight of the service. Implementation of this recommendation will provide the licensing agency with the authority to preclude a facility from offering a particular service if quality standards are not met. Currently, the licensing agency has no recourse on a service level; rather, the agency must take action against a facility as a whole.

### Recommendation 1.2 *(Unanimous)*

*Add a statutory provision allowing the Department of Community Health to place moratoria on new and emerging services for a time period not to exceed 6 months, which may be renewed once for an additional 3 months.*

Because of the substantial delay in the rule-making process from the time that a new health care service is identified and a final rule is adopted, many entities, upon learning that the Department is developing a new rule, rush to develop services before the Department has defined standards or review criteria. As a result, this means that by the time a final rule is adopted, any party wishing to offer a service may have already developed the service. For this reason, the Commission recommends that the Department be empowered by statute to issue temporary moratoria during the development of rules and standards. Any such moratorium should be issued by the Commissioner of the Department of Community Health with the authorization of the Board of Community Health. Upon the expiration of the moratorium, if the Department of Community Health had not finalized detailed standards, any project which had been subject to the moratorium would be reviewable under the general statutory considerations.

### Recommendation 1.3 *(Unanimous)*

*Revise the statutory functions of the Health Strategies Council to make the Council advisory in nature.*

The Health Strategies Council's statutory functions should be revised to provide that the Health Strategies Council's role from a rule making perspective is only advisory in nature. The Health Strategies Council would not be responsible for updating the component parts of the State Health Plan nor



would it be responsible for reviewing and approving the Department's health planning rules. Rather, the Health Strategies Council would serve as an advisory body. As an advisory body, the Department would seek input of the Council whenever it is interested in updating rules and regulations and the state health plan components. However, the development of such rules and components would not rely on the actions of the Council. The Commission feels that the implementation of this regulation will allow for more proactive and timely development of rules and standards.

Recommendation 1.4 (Unanimous)

*Decrease the statutory membership of the Health Strategies Council.*

The current size of the Health Strategies Council (27 gubernatorial appointees) is unwieldy because it is difficult to obtain consensus amongst the various representatives. Rather than 27, the Commission recommends that the membership of the Council consist of one member from each congressional district. In addition to representing a district, each Council member should represent one of the following groups:

- Urban Hospital
- Rural Hospital
- Private Insurance Industry
- Primary Care Physician
- Physician in a Board Certified Specialty
- Freestanding Ambulatory Surgery Center
- Nursing Home
- Home Health Agency
- Healthcare Needs of Women and Children

- Healthcare Needs of Disabled and Elderly
- Healthcare Needs of Indigent
- Mental Healthcare Needs
- Business

The statute should provide that with the addition of congressional districts to the state, additional members should be added representing local or county governments.

Recommendation 1.5 (Unanimous)

*Amend the statute to require meetings of the Health Strategies Council at least once bi-monthly.*

Currently, the Health Strategies Council meets at least once quarterly as required by statute. However, health care is a quickly changing market, and quarterly meetings do not provide for the timely advisement of the Department in regards to rules and policy. Therefore, the Commission recommends that the statute be amended to require meetings of the Council at least once bi-monthly.

Recommendation 1.6 (Unanimous)

*Amend the statute to alter provisions relating to the removal of Health Strategies Council members.*

Currently, the Certificate of Need Statute proscribes certain circumstances that would result in the removal of a Council member by the Governor, such as incompetence or neglect of duty. Members of the Commission believe the Governor should be allowed to remove members for any reason without cause. In addition, the statute should be amended to provide for the automatic removal (without an action by the Governor) of any member who is absent from more than ¾ of the meetings in any calendar year.



Recommendation 1.7 (Unanimous)

*Increase the statutory fine for failure to obtain a Certificate of Need to \$5,000 per day for the first month, \$10,000 per day for the second month, and \$25,000 per day for subsequent months.*

There has been substantial testimony that entities that fail to obtain a certificate of need frequently view the maximum fine of \$5,000 per day as a cost of doing business. Amending the current statutory language to allow for a progressively increasing fine will serve as more of a deterrent for those who begin offering new institutional health services without first obtaining a certificate of need.

Recommendation 1.8 (Unanimous)

*Permit the Department to levy fines of \$500 per day for the first month and \$1,000 per day for subsequent months and to revoke Certificates of Need for failure to provide annual and periodic data surveys.*

Currently, there are no sanctions that the Department may pursue if an entity fails to submit annual data. Incomplete data has a negative impact on the projections the Department issues for service needs because the Department relies on utilization and other data from annual surveys to calculate projections for future needs. There is evidence that a number of providers fail to provide basic information to the Department through submission of annual surveys. Therefore, the Commission recommends that the Certificate of Need statute be amended to empower the Department to levy fines and to revoke certificates of need/authorization to offer health care services (for those facilities which have been grandfathered) when an entity fails to provide data accurately and timely. The fine for failure to submit data timely and accurately should be \$500 per day for every day that data is not timely and accurately submitted, increasing to \$1,000 per day for every day that data is not timely and accurately submitted beyond

the 30<sup>th</sup> day. The Department should have statutory authority to revoke a certificate of need/authorization to offer health care services once data is more than 180 days late.

Recommendation 1.9 (Unanimous)

*Amend the statute to allow the Department the authority to issue conditional Certificates of Need and to revoke CONs when such conditions are not met by the certificate holder.*

Currently, the Certificate of Need Statute only specifically authorizes the Department to place two conditions on Certificates: (1) that the applicant will provide indigent and charity care and (2) that the applicant will participate in the Medicaid program. Violation of either of these conditions currently does not result in revocation of the Certificate of Need; rather, the Statute only authorizes the Department to levy a fine for such violations. The Commission recommends that the Statute be revised to specifically allow the Department by rule and by application to place conditions on a Certificate of Need, such as minimum volumes, quality standards, limitations on services, etc. The Department should have the ability to revoke Certificates of Need if such conditions are not met. The Commission recommends that the authority to revoke be limited to those instances where substantial compliance has not been met. To implement this recommendation, the statute should authorize the Department to develop rules defining “substantial compliance.”

Recommendation 1.10 (Unanimous)

*Permit the Department to have the authority to revoke parts of Certificates of Need.*

Certificates of Need are often issued for units of service, such as hospital beds or operating rooms, some of which are never put into service or built. Applicants who have been approved for more than they ultimately implement have the potential to create access problems for because of the adverse effect this skewed inventory has on planning area need projections. If



the Department had the authority to revoke CON approval for those units of service that are not timely implemented, they could be potentially awarded to another applicant who is willing to develop and offer the service. For this reason, the Commission recommends that the statute specifically empower the Department to revoke parts of Certificates of Need. This provision should only be applied to Certificates of Need issued after the effective date of the statutory change and should not be applied retroactively.

## Legal & Regulatory: Process and Procedure

### Recommendation 2.0 *(Unanimous)*

*Batch applications by clinical health service.*

Under current statutory provisions, CON applications may be submitted at any time, and there are only two methods of comparative review: the batching of nursing home and home health applications and joinder of closely-related applications filed and deemed complete within a 30-day period. Other than home health and nursing home services, this submission and review process may lead to mal-distribution of health care services because the current process is one of “first come, first served.” Therefore, the Commission recommends that all applications for clinical health services be competitively reviewed through a batching process. Under this recommended approach, the application process would begin with the filing of letters of intent, in which all intended applicants announce their proposed project. Applications would then be submitted at least twice annually for any particular clinical health service, whether the application is to fulfill a predetermined calculated need or not (e.g. the application is for an exception to need). The applications would be reviewed to determine the best applicant(s) and to ensure the best distribution and access to health care services. Additionally, the Department would determine set times during the year when applications would be due for capital projects (those projects which

are being reviewed solely because they are over the capital or equipment thresholds). The statute should provide for the Department to create rules to define the appropriate times during the year for submission of applications.

### Recommendation 2.1 *(Unanimous)*

*Increase the review timeframe to 120 days and allow the Department of Community Health to develop rules and regulations defining the intermediate review time periods.*

With the change to a batching approach to application submission, the application review time frame should be extended to 120 days. The statute should be amended to this effect and should also delineate the following intermediate review steps: Submission of Written Opposition, Applicant Review Meeting (currently “60-day meeting”), Submission of Supplemental Information, Submission of Supplemental Written Opposition, and Opposition Meeting (as discussed in Recommendation 2.2). The statute should authorize the Department, by rule, to define the appropriate time frame during the 120-day review process for each of these intermediate review steps.



Recommendation 2.2 (Unanimous)

*Provide for opposition meetings during the review cycle.*

Currently opposing parties may submit written documentation to the Department in opposition to projects but are not given the opportunity to formally present their opposition arguments to the Department in a public forum. The recommendation of the Commission is to allow an opposition meeting for those who are opposed to projects. Attendance and participation in an opposition meeting would be required to have standing to appeal a project.

Recommendation 2.3 (Unanimous)

*Abolish the Health Planning Review Board and model the appeals process on the Administrative Procedure Act.*

There has been substantial testimony that the current administrative appeals process is lengthy and costly. Currently, the Health Planning Review Board, a body separate and apart from the Department of Community Health, is composed of 9 gubernatorial appointees who have no direct interest in health care entities. The Review Board Chair or Vice Chair is responsible for assigning hearing officers to oversee initial administrative hearings regarding whether or not a Certificate of Need should have been issued by the Department. Once a Hearing Officer has made a decision, the Hearing Officer's Order can be appealed to the full Health Planning Review Board, which issues a final administrative order after brief oral arguments. There has been consensus among all participants during the Commission's deliberations that the arguments before the entire Health Planning Review Board rarely result in a change to a hearing officer's order and are therefore unnecessary. For this reason, the Commission recommends that the current structure of the Health Planning Review Board be modified using a modified APA-like appeals process. Under this process, requests for appeals of Certificates of Need either issued or denied will be addressed to the Commissioner of the Department. The Commissioner would be

responsible for assigning a Hearing Officer to hold a *de novo* hearing. (The Department should not be required to use the Office of State Administrative Hearings for Certificate of Need appeals because there already exists a body of knowledge relating to Certificate of Need and health planning in the hearing officers who have currently been appointed by the Health Planning Review Board). At the conclusion of the initial administrative hearing, the Hearing Officer assigned to the case by the Commissioner would make an initial order. Any party to the hearing, including the Department, who disputes the initial order, would have the right to request review of the initial order by the Commissioner, or his/her designee, within 30 days of the initial order of the Hearing Officer. Furthermore, the Department should be statutorily authorized to create rules and regulations regarding the conduct of its administrative hearings.

Recommendation 2.4 (Unanimous)

*Require appellants to contribute to a Hearing Funds Pool at the time of requesting an initial administrative appeal.*

Currently, the State pays all hearing officer costs and administrative costs of appeals, except for preparation of transcripts and the administrative record, the costs for which are divided equally amongst the parties. In order to maintain a degree of separation from the Department, Hearing Officers are paid from dedicated funds from the Department of Administrative Services. The funds allocated for such appeals routinely expire long before the beginning of the next fiscal year. For this reason, the Commission recommends that appellants contribute to a Hearing Funds Pool at the time of their requests for initial administrative appeal. The statute should empower the Department to develop rules to establish an appropriate fee schedule for such appeals.



Recommendation 2.5

*(Unanimous)*

*Require losing parties in appeals to pay for the entire cost of the appeal, including hearing officer fees and preparation of the record, etc.*

The Commission has reviewed documentation that the success rate for most appeals is extremely low. Yet, the number of appeals sought belies this fact. Therefore, the Commission recommends that the statute be amended to provide that the losing party pay the entire cost of the appeal including hearing officer fees and preparation of the record. In combination with Recommendation 2.4, this would mean that if the actual costs of the hearing exceeded the costs contributed into the Hearing Funds Pool by the appellant(s), the losing appellant would be required to pay additional funds up to the total cost of the appeal. In addition, at the judicial level, losing parties would be required to pay all administrative fees.

Recommendation 2.6

*(Unanimous)*

*Amend provisions of the statute relating to judicial appeal in a fashion similar to Workers' Compensation Statute.*

The Commission voted in favor of amending the statutory provisions relating to judicial review of final agency decisions on Certificate of Need applications. In particular, the Commission recommended the adoption of a process similar to the appeal of final awards from the Board of Worker's Compensation set forth in O.C.G.A. § 34-9-105(b), which was designed to expedite the disposition of worker's compensation claims that have been appealed to the courts of this state. See Felton Pearson Co. v. Nelson, 260 Ga. 513 (1990). Section 34-9-105(b) provides that a party to a worker's compensation dispute may appeal a final award within 20 days from the date of the final order of the Board of Worker's Compensation to superior court. Once the Board of Worker's Compensation has transmitted the record to the superior court,

*The case so appealed may then be brought by either party upon ten days' written notice to the other before the superior court for a hearing upon such record, subject to an assignment of the case for hearing by the court; provided, however, if the superior court does not hear the case within 60 days of the date of docketing in the superior court, the decision of the board shall be considered affirmed by operation of law unless a hearing originally scheduled to be heard within the 60 days has been continued to a date certain by order of the court.*

In addition, if the superior court does not enter an order on the merits within 20 days of the date of the hearing, the decision of the Board of Worker's Compensation is considered affirmed by operation of law. In the event a decision of the Board is affirmed by operation of law under this provision, subsection (d) provides that a party may seek an appeal to the court of appeals through O.C.G.A. § 5-6-35.



## Legal & Regulatory: Exemptions

### Recommendation 3.0 *(Unanimous)*

*Authorize the Department to require Notification of Items Exempt from Review for certain exemptions.*

The Commission has heard testimony from the Department and other stakeholders that occasionally a provider will undertake a task that it believes to be exempt from CON but later learns that a CON was required. In order to prevent such occurrences, the Commission recommends that the statute specifically authorize the Department to have the ability to determine (by rule) which exemptions rise to a level that would require notification to the Department and/or advance approval by the Department. Specifically, the Commission recommends that once so empowered, the Department require advance notification and approval for exemptions related to exempt ambulatory surgery centers (if the exemption remains) and equipment purchased below threshold.

### Recommendation 3.1 *(Unanimous)*

*Raise the capital expenditure threshold from the current \$1.495 million to \$1.75 million and maintain the provision relating to an annual adjustment of this dollar amount.*

After thoroughly reviewing the dollar thresholds of other CON states and neighboring southern states, the Commission recommends that the dollar threshold for capital expenditures be increased to \$1,750,000. In addition, the Commission recommends that the statute continue to provide for annual adjustments to this dollar threshold.

### Recommendation 3.2 *(Unanimous)*

*Maintain the existing provisions relating to the amount of the Equipment Expenditure threshold.*

Currently, the dollar amount applicable to expenditures on equipment is \$823,934 as adjusted annually. After reviewing similar equipment expenditure thresholds in comparison states, the Commission recommends maintaining the existing dollar threshold for such equipment.

### Recommendation 3.3 *(Unanimous)*

*Modify the existing list of exempt projects and activities to exempt non-clinical projects, such as parking decks, medical office buildings, and improvements of physical plant infrastructure, etc., and modify or delete certain current exemptions.*

Certain projects currently require Certificates of Need even though they do not involve clinical health services and are routinely approved. The review of these projects requires time and resources that would otherwise be available to focus on clinical health services. Therefore, the Commission recommends that the list of statutory exemptions be modified by adding the following: parking lots, parking decks, or parking facilities; computer systems, software, and other information technology; medical office buildings, both construction and addition of space; state mental health facilities; and renovation of physical infrastructure where clinical health services are not being added or affected. In addition, the Commission recommends that the current exemption relating to repair of physical plant be modified. Currently, the exemption is limited to repairs of physical plant which do not cost more than the capital expenditure threshold. Any repair of physical plant should be exempt regardless of cost.

The Commission also recommends removing the exemption for “Christian Science Sanatoriums.”



Recommendation 3.4 (Unanimous)

*Add a statutory exemption for relocation of an existing facility within a limited distance.*

Currently, there is no exemption from Certificate of Need regulation regarding the relocation of an existing facility. This has proved a hardship on entities that may need to relocate for reasons beyond their control, such as a fire or expiration of a lease. This is also a particular concern for older facilities, which are in need of being replaced and which are otherwise prevented from replacing or expanding on site. Therefore, the Commission recommends that the list of statutory exemptions be modified to add “replacement of existing facilities within a defined distance and which would have no adverse impact on other existing providers.”

**Legal & Regulatory: Miscellaneous**

Recommendation 4.0 (Unanimous)

*Add a review criterion regarding the quality of health care services to be offered or which are offered in the health care facility.*

Currently, the Department's rules for specific services mandate minimum quality standards, such as JCAHO accreditation, minimum volumes, quality improvements and assurance practices, utilization review practices, etc. Therefore, the Commission recommends that a specific general review consideration be added to the statute relating to quality. In addition, the Commission recommends that the statutory goals of the program be redefined to include “ensuring access to quality services.”

*agrees to provide an underrepresented service in addition to the service for which application was made.*

The Commission has heard evidence regarding the underrepresentation of certain services in the state, largely because of lack of funding sources. As a means to encourage the offering of such services, the Commission recommends the addition of a specific review criterion relating to the potential for the project to provide or enhance the provision of an underrepresented service, e.g. inpatient psychiatric care, trauma, etc. The Department would create rules relating to this criterion such that it would annually define the underrepresented services for the upcoming year and would also develop rules to allow an advantage to equally qualified applicants who agree to provide an underrepresented service in addition to the project for which it has applied.

Recommendation 4.1 (Unanimous)

*Statutorily provide for the Department to give favorable consideration to projects and applicants where the applicant*



Recommendation 4.2 (Unanimous)

*Recommend that the Department's Health Planning functions be adequately staffed and supplied with the appropriate resources.*

Many of the recommendations of the Commission require that the Division of Health Planning increase staffing and resources in order to plan proactively and to monitor health care facilities and services that have been awarded certificates of need. Therefore, the Commission recommends that the budget and staffing of the Division of Health Planning be reviewed to ensure that the appropriate resources are available for these additional activities.

Recommendation 4.3 (Unanimous)

*Recommend that the Department adopt and follow a proactive and prospective approach to need methodologies and emerging technologies by addressing such factors annually in its annual report.*

Currently, the CON statute requires the Health Strategies Council to submit an annual report concerning health planning. Because the Commission has recommended that the Health Strategies Council's role be advisory in nature, the Commission recommends that the responsibility for an annual report be delegated to the Department of Community Health. The Commission further recommends that the Department adopt a proactive and prospective approach to need methodologies and access to health care services by undertaking an annual analysis of such issues in the annual report.



## Acute Care Services: General Hospitals

*NOTE: The Commission did not reach consensus on the regulation of general, short stay, acute care hospitals.*

### Recommendation 5.0 (3 Agree, 2 Disagree, 5 Abstain)

*Maintain existing CON regulation of Short Stay General Hospital Beds.*

Because data shows that there is a surplus of nearly 5,600 too many medical/surgical beds at the State's hospitals, some members of the Commission believe that CON regulation of medical and surgical beds should be maintained, particularly given the high costs of medical construction. These members maintain that the current regulation of short stay general hospital beds is effective and ensures access for those needing these services.

Other members of the Commission disagree. These members of the Commission feel that there is no need to regulate the addition of beds to established facilities as it hinders the delivery of health care when a facility has to wait for the completion of the review process in order to expand. Furthermore, the current manner in which the Department's rules forecast need for new beds is institution specific (i.e. the forecast relies on an institution's own historic utilization). They also feel that money that should be used to deliver health services is taken out of the system if money has to be dedicated to resources (i.e. attorneys, consultants, etc.) needed to file and/or fight an appeal if the project is denied by the Department or opposed by another party.

### Recommendation 5.1 (3 Agree, 4 Disagree, 3 Abstain)

*Deregulate Short Stay General Hospital Beds by not requiring a Certificate of Need for the expansion of Short-Stay beds, but still requiring a CON for the establishment of new hospitals.*

The members who agree with this recommendation disagreed with Recommendation 5.0 and for similar reasons. The members who disagree with this recommendation agree with Recommendation 5.0 and for the same reasons.

### Recommendation 5.2 (4 Agree, 2 Disagree, 4 Abstain)

*Amend the exemption for the addition of beds to short stay hospitals to allow expansion of such facilities without obtaining a CON when the facility has reached a utilization of 75% for the prior 12 months. Under the amended exemption, the facility would be able to expand by 10 beds or 10%, whichever is greater, once every two years.*

Currently, the statute has an exemption allowing a short stay hospital to increase its beds once every two years when it has demonstrated an 85% utilization rate for the prior twelve months. If this utilization is achieved, the facility may expand by 10 beds or ten percent, whichever is less, without obtaining a Certificate of Need.

The members of the Commission who agree with this recommendation feel that because of the cost of construction involved with adding additional beds and because of seasonal fluctuations in utilization rates, the statutory exemption should be broadened. Such members maintain that the utilization rate should be lower because a facility may have an average annual utilization rate of 75%, but that the facility may still exceed 100% utilization during seasonal periods such as winter. In addition, these members support increasing the



number of beds by which hospitals who have obtained the utilization can expand. Such members support such a recommendation based on the economies of scale. Oftentimes it may be cost prohibitive to expand a facility to add 10 beds or fewer, the limit of the current statutory exemption. For this reason, these members recommend that the exemption permit the addition of up to 10% more beds.

Those members who are opposed to this recommendation are so opposed because they believe that exemptions which allow existing facilities to expand may have a tendency to promote monopolies in the healthcare market.

## Acute Care Services: Cardiovascular Services

*NOTE: The Commission did not reach consensus on the regulation of cardiac catheterization, but did achieve consensus on the regulation of open heart surgery.*

### Recommendation 6.0 (4 Agree, 1 Disagrees, 5 Abstain)

*Deregulate diagnostic cardiac catheterization and require therapeutic catheterizations to be performed only by providers approved to offer open heart surgery.*

The members of the Commission who support the deregulation of adult diagnostic cardiac catheterization maintain that deregulating diagnostic cardiac catheterization will allow for the proliferation of these services in the market assuring access to residents in all areas of the state. Such members feel that this service is a valuable service to the citizens of the state and has been shown to save lives, particularly in states such as Georgia with high rates of coronary disease. These members feel that the regulation of the quality of this service could be managed by Licensure.

One member of the Commission disagrees. This member feels that this service should continue to be regulated by Certificate of Need. Because cardiac catheterization is such a specialized service, certain quality standards must be met to achieve the best possible outcomes. Because the American College of Cardiology recommends that minimum volumes be maintained to ensure the quality of the service, this member feels the Certificate of Need process ensures that there will not be a proliferation of low volume providers who won't maintain the same quality as high volume providers.

Several members of the Commission report that this recommendation should only apply to hospital-based cardiac catheterization and not to freestanding cath programs.

### Recommendation 6.1 (Unanimous)

*Maintain existing CON regulation of open heart surgery.*

Members of the Commission agree that open heart surgery services should continue to be regulated by CON because of the technical nature of the service and the highly-skilled labor



force that is required to perform the service. They also agreed that licensure standards should be added to routinely monitor the quality of open heart surgical programs.

Recommendation 6.2 (Unanimous)

*Maintain existing CON regulation of pediatric cardiac catheterization and open heart surgery.*

The Commission unanimously agrees that Certificate of Need regulation of pediatric cardiovascular services be maintained because of the complex and highly-skilled nature of these services and the concentrated demographic that utilizes these services.

**Acute Care Services: Perinatal Services**

*NOTE: The Commission did not reach full consensus on the regulation of perinatal and obstetrical services.*

Recommendation 7.0 (6 Agree, 1 Disagrees, 3 Abstain)

*Deregulate Level I perinatal services and continue regulation of Level II and Neonatal Intensive Care.*

Most members of the Commission recommend that Level I perinatal services be deregulated because these services are already provided by most hospitals in the state and do not require specialized labor. These members believe that access to perinatal and obstetrical care will be enhanced by their recommendation. The fact that federal law already requires a facility to treat a woman in active labor further supports this recommendation. The members who make this recommendation maintain that Level II and Level III services should continue to be regulated by CON because of the highly-skilled nature of these services and the workforce that is required to support them. One member of this group further believed that Level II should be deregulated in addition to Level I.

One member of the Commission made the recommendation to maintain existing CON regulation for this service. This member believes that maintaining Certificate of Need regulation of Level I perinatal services will address the problem of large fixed costs incurred by facilities that provide these services and the shortage of skilled workforce.

Several members of the Commission report that this recommendation should be limited to Level 1 perinatal services at hospitals and should not be construed as a recommendation regarding freestanding facilities.



## Acute Care Services: Inpatient Psychiatry and Substance Abuse

### Recommendation 8.0

*Maintain existing CON regulation of inpatient psychiatric and substance abuse services.*

The Commission members agree that inpatient psychiatric and substance abuse services should continue to be regulated by Certificate of Need.

## Long Term Care Services: Skilled Nursing

### Recommendation 9.0

*(Unanimous)*

*Maintain existing CON regulation of skilled nursing facilities.*

The members of the Commission unanimously recommend maintaining CON regulation of skilled nursing facilities. As the state's population of elderly citizens grows, there will be an increased need for skilled nursing services. CON works to ensure that there will be an adequate number of services to meet that need. CON also serves as a gatekeeper to ensure the quality of skilled nursing service market entrants.

### Recommendation 9.1

*(Unanimous)*

*Deregulate CCRCs as long as the nursing beds remain sheltered.*

Commission members agreed unanimously to exempt Continuing Care Retirement Communities (CCRC) from Certificate of Need regulation because these facilities have been routinely approved by the Department in large part because they have already been approved by the Department of Insurance before applying for a Certificate of Need. The Commission recommends that CCRCs continue to comply with Department rules that their skilled nursing beds remain sheltered to prevent any inaccuracies in projecting need for other skilled nursing beds throughout the State. Therefore, the Commission recommends that only CCRCs that maintain sheltered nursing beds be added to the list of statutorily-exempt services and facilities.



## Long Term Care Services: Home Health

Recommendation 10.0                      *(Unanimous)*

*Maintain existing CON regulation of home health services.*

The Commission unanimously recommends that home health services continue to be regulated by CON. Members of the Commission believe that CON regulation adequately determines need and assesses quality in this area. Committee members considered the concerns expressed by home health agency stakeholders regarding indigent and charity care commitment stated in the service-specific rules. They decided to leave the issue of determining the proper indigent and charity care requirement to the Department and its rulemaking authority.

## Long Term Care Services: Assisted Living

Recommendation 11.0                      *(Unanimous)*

*Deregulate personal care homes except for Medicaid-Certified personal care homes.*

The Commission unanimously recommends that CON regulation of personal care homes be discontinued except for those personal care homes that seek Medicaid certification. This recommendation requires that all Medicare-certified personal care homes, including those with 24 or fewer beds, be regulated by CON because they receive reimbursement from the State. In order to encourage personal care homes as an alternative to skilled nursing facilities, the Commission recommends that all non-Medicaid personal care homes be exempt from the Certificate of Need process and regulation.



## Long Term Care Services: Rehabilitation

Recommendation 12.0 *(6 Agree, 1 Disagrees, 3 Abstain)*

*Maintain existing CON regulation of Comprehensive Inpatient Physical Rehabilitation.*

A majority of the Commission recommends that comprehensive inpatient physical rehabilitation (CIPR) services continue to be regulated by CON. In addition, these members of the Commission recommend that the need methodology for CIPR services be based on set-up-and-staffed beds and not on authorized beds. Such members agreed that this change to the need methodology will allow the Department to accurately project need and allow new providers to enter the market, increasing access to CIPR services. Such members did not recommend the deregulation of this service because they felt that the service required a highly-skilled workforce and that deregulation may drain the workforce from existing facilities, thereby lowering quality of care.

One member of the Commission disagreed with this recommendation. This member supports the deregulation of CIPR services to promote access and competition.

## Long Term Care Services: Rehabilitation Services

Recommendation 13.0 *(Unanimous)*

*Deregulate traumatic brain injury facilities as long as detailed licensure standards are developed.*

The Commission unanimously supports the deregulation from Certificate of Need of Traumatic Brain Injury facilities.

Evidence demonstrates that there have been no applications for new or expanded facilities in recent years. In addition Licensure already has detailed licensure standards for such services as Traumatic Brain Injury Facility is a specific licensure classification. Therefore, as long as these service-specific licensure standards are maintained, the Commission supports the deregulation of these facilities.



## Special and Other Services: Ambulatory Surgery

*NOTE: The Commission did not reach full consensus on the regulation of ambulatory surgery, except for the current regulation of freestanding multi-specialty centers.*

### Recommendation 14.0 (Unanimous)

*Maintain existing CON regulation of freestanding multi-specialty ambulatory surgery services.*

The Commission recommends that the existing regulation of freestanding multi-specialty ambulatory surgery services should be maintained.

### Recommendation 14.1 (5 Agree, 1 Disagrees, 4 Abstain)

*Treat General Surgery in a consistent manner as all other single specialties.*

The majority of the Commission recommends that General Surgery be treated in a manner consistent with all other single specialties, regardless of the regulatory requirement for single specialty facilities.

One member disagrees and maintains that general surgery should be treated as a multi-specialty because of the complex nature of the cases that a general surgeon may perform.

### Recommendation 14.2 (5 Agree, 3 Disagree, 2 Abstain)

*Abolish entirely the exemption for freestanding single specialty, office-based, physician-owned ambulatory surgery centers and require physician-owned limited purpose ambulatory surgery centers to obtain a Certificate from the Department. Upon application, such applicants would not be required to address*

*need criteria but would be required to make indigent and charity care commitments, to accept Medicaid, to supply data to the Department of Community Health, and to verify that all its physicians are members of a hospital staff and are willing to accept emergency room coverage.*

The membership of the Commission was sharply divided on the issue of physician-owned single specialty ambulatory surgery centers, which are currently exempt from Certificate of Need if the center can be established for a dollar amount less than approximately \$1.6 million. One contingent of the Commission agrees with the recommendation that the current exemption be abolished and that limited-purpose, physician-owned ambulatory surgery centers (“ASC”) obtain a Certificate, although such centers would be free from an objective need methodology. Such ASCs would be required to commit to the provision of indigent and charity care at a level of 3 percent of adjusted gross revenues. In addition, this contingent recommends that these ASCs agree to accept Medicaid, if at all possible, and provide services as a minimum community standard, that such facilities agree to provide annual data to the Department, and that all physicians who perform procedures at the facility be required to hold hospital staff privileges, if possible, and to accept ER coverage. The members who agree with this recommendation do so because freestanding single-specialty ambulatory surgery centers have been shown to be high quality and low cost alternatives. These members who argue for less regulatory control contend that to artificially restrain these services raises costs reduces efficiency, and prevents physicians from billing facility fees.

Other members disagreed with this recommendation and maintain that the exemption for physician-owned ambulatory surgery centers should be abolished and that such centers should be required to obtain a Certificate of Need addressing



all applicable review criteria including a determination of need. These members are concerned that if ambulatory surgery centers are allowed to proliferate significantly, hospitals will not have a financially sustainable business model. Mainly, these members maintain that ambulatory surgery centers take low acuity, paying patients, and leave hospitals to treat the complex cases and individuals without the ability to pay.

The CON Commission has been unable to reach consensus with regard to the best policy to address this difficult issue because its root causes involve complex factors relating to reimbursement and costs that are beyond the CON program's purview. A real and sustainable solution to this dilemma will require a health policy approach that corrects the cost and payment problems for both professional services and hospital-based services, particularly with respect to the under-insured and uninsured.

Recommendation 14.3 *(3 Agree, 3 Disagree, 4 Abstain)*

*Abolish the exemption for physician-owned, office-based, single specialty ambulatory surgery centers and require such facilities to obtain a Certificate of Need under the exact same standards as all other ambulatory surgery centers.*

The original recommendation of the Specialized Services Sub-Committee was to abolish the current ASC exemption and require all ASCs to obtain a Certificate of Need without exception. The full Commission discussed this recommendation, but was sharply divided and no final conclusion was reached on the recommendation.

Recommendation 14.4 *(Unanimous)*

*Require all providers of ambulatory surgical services to make indigent and charity care commitments, to accept Medicaid patients, and to supply data to the Department (even if some remain exempt).*

The Commission recommends unanimously that all providers of ambulatory surgical services share the burden of caring for those who have the inability to pay for services. The Commission further recommends that it is in the best interest of the state's health planning efforts to have complete data regarding ambulatory surgical services, regardless of the level of CON regulation.



## Special and Other Services: Radiation Therapy

### Recommendation 15.0 (Unanimous)

*Maintain existing CON regulation of radiation therapy services.*

All Commission members agree that the existing regulation of radiation therapy services is sufficient and should be maintained because of the cost of the equipment used to deliver the services and the complex nature and highly-skilled workforce required to deliver radiation therapy.

## Special and Other Services: Imaging Services

*NOTE: The Commission did not reach full consensus on the regulation of imaging services. The equipment expenditure threshold is addressed in Recommendation 3.2.*

### Recommendation 16.0 (4 Agree, 3 Disagree, 3 Abstain)

*Maintain existing CON regulation of Positron Emission Tomography.*

A majority of the Commission recommends that Certificate of Need regulation of Positron Emission Tomography (PET) services be maintained. These members maintain that the high cost of PET equipment necessitates a higher degree of regulation. PET also requires a trained workforce such as dosimetrists, physicists, etc.

Another portion of the Commission maintains that PET services should be deregulated. These members maintain that PET services have great potential in saving lives and that the deregulation of the service would improve access to the citizens of the state. In addition, these members have concern about the perceived accessibility problems in Georgia associated with PET.

In relation to other neighboring states, Georgia has fewer PET scanners per capita.

### Recommendation 16.1 (Unanimous)

*Require statutorily-exempt providers of diagnostic or therapeutic equipment to make a commitment to indigent and charity care as a condition of the exemption.*

Members of the Commission unanimously recommend that freestanding providers of diagnostic imaging should provide indigent and charity care. Therefore, the Commission recommends that the statutory exemption be modified to specifically require providers to make an indigent and charity care commitment as a condition of the exemption.

### Recommendation 16.2 (Unanimous)

*Require statutorily exempt providers of diagnostic or therapeutic equipment to provide data to the Department as a condition of the exemption.*



The lack of data from all providers of healthcare in the state adversely impacts the state's health planning functions. Therefore, the Commission unanimously recommends that all exempt providers of diagnostic imaging services commit to provide data to the Department annually as a condition of being exempt.

Recommendation 16.3 (5 Agree, 1 Disagree, 4 Abstain)

*Modify the exemption for equipment below threshold to require all freestanding diagnostic imaging centers to obtain a Certificate of Need for equipment regardless of costs, except for de minimis x-ray equipment. Physician offices and hospitals and other health care facilities would still be able to obtain equipment under threshold, but freestanding imaging centers would require a Certificate of Need.*

A majority of the Commission recommends that the exemption for equipment below threshold should not apply to Freestanding Imaging Centers. Under this recommendation, Freestanding Imaging Centers would need to obtain a Certificate of Need regardless of the cost of the equipment being acquired and used in the facility, except that such facilities would be permitted to obtain *de minimis* x-ray equipment without obtaining a Certificate of Need. The members who make this recommendation do so because of concerns over the quality of freestanding imaging centers and the potential for over-utilization of imaging services at freestanding imaging centers, which has been substantially documented.

Those who oppose this recommendation maintain that the equipment threshold should be applicable to freestanding imaging centers as for all other providers of imaging services because the cost of freestanding imaging centers to the patient and to insurers is substantially less than the cost of hospital-based imaging.



## Final CON Commission Recommendations Matrix

In general, the 3 *ex officio* members of the Commission abstained from voting on all issues except Ambulatory Surgery.

LEGAL AND REGULATORY OPTIONS	Yes	No	Abstain*
<b>Licensure</b>			
<i>Move the healthcare-related licensing functions of the Office of Regulatory Services from the Department of Human Resources to the Department of Community Health forming a consolidated licensure and Certificate of Need unit.</i>	7	0	3
<i>Amend the Licensure statute to permit detailed licensure standards on a clinical service-level.</i>	7	0	3
<b>Rule Making Process</b>			
<i>Recommend the addition of a statutory provision allowing the Department of Community Health to place moratoria on new and emerging services for a time period not to exceed 6 months, which may be renewed once for an additional 3 months.</i>	7	0	3
<b>Health Strategies Council</b>			
<i>Revise the functions of the Health Strategies Council to make the Council advisory in nature.</i>	7	0	3
<i>Decrease the membership of the Health Strategies Council.</i>	7	0	3
<i>Amend the statute to require meetings of the Health Strategies Council more frequently than Quarterly.</i>	7	0	3
<i>Amend the statute to alter provisions relating to the removal of members.</i>	7	0	3
<b>Sanctions</b>			
<i>Increase the statutory fine for failure to obtain a Certificate of Need to \$5,000 per day for the first month, \$10,000 for the 2<sup>nd</sup> month, and \$25,000 subsequently.</i>	7	0	3
<i>Permit the Department to levy fines and to revoke Certificates of Need for failure to provide annual and periodic data surveys.</i>	7	0	3
<i>Amend the statute to allow the Department the authority to issue conditional Certificates of Need and to revoke CONs when such conditions are not met by the certificate holder.</i>	7	0	3
<i>Permit the Department to have the authority to revoke parts of Certificates of Need.</i>	7	0	3
<b>Review Competitiveness</b>			
<i>Batch applications by clinical health services.</i>	7	0	3



Review Timeframe			
<i>For batched reviews, increase the review timeframe to 120 days</i>	7	0	3
<i>Allow the Department of Community Health to develop rules and regulations defining the time periods for review of applications within the 120 day review cycle.</i>	7	0	3
Opposition			
<i>Provide for opposition hearings during the review cycle.</i>	7	0	3
Administrative Appeals			
<i>Abolish the Health Planning Review Board and model the appeals process on the Administrative Procedure Act.</i>	7	0	3
<i>Require appellants during the Administrative Process to pay into a Hearing Funds pool which will pay for hearing officers and other administrative costs.</i>	7	0	3
<i>Require losing parties in appeals to pay for the entire cost of the appeal including hearing officer fees and preparation of the record, etc.</i>	7	0	3
Judicial Review			
<i>Amend provisions relating to judicial appeal in fashion similar to Workers' Comp Statute.</i>	7	0	3
Review Thresholds			
<i>Raise the Capital Expenditure Threshold from the current \$1.495 M to \$1.75 million and maintain provision for annual adjustment.</i>	7	0	3
<i>Maintain the existing provisions relating to the amount of the Equipment Expenditure Threshold--\$823,934.</i>	7	0	3
Exemptions			
<i>Authorize the Department to require Notification of Items Exempt from Review for certain exemptions.</i>	7	0	3
<i>Modify the existing list of exempt projects and activities to exempt non-clinical projects, such as parking decks, medical office buildings, improvements to physical plant infrastructure.</i>	7	0	3
<i>Add a statutory exemption for relocation of an existing facility within a limited distance.</i>	7	0	3
Review Criteria			
<i>Add a review criterion regarding the quality of health care services to be offered or which are offered in the health care facility.</i>	7	0	3
<i>Statutorily provide for the Department to give an advantage to projects and applicants under certain situations, such as the provision of an underrepresented service.</i>	7	0	3



Miscellaneous			
<i>Recommend to the General Assembly that the Department's Health Planning functions be adequately staffed and supplied with the appropriate resources.</i>	7	0	3
<i>Recommend that the Department follow a proactive and prospective approach to need methodologies and emerging technologies by addressing such factors annually in its annual report.</i>	7	0	3
ACUTE CARE OPTIONS			
	Yes	No	Abstain*
Short Stay General Hospitals			
<i>Maintain existing CON regulation.</i>	3	2	5
<i>Deregulate expansions but require CON for new hospitals.</i>	3	4	3
<i>Amend the exemption for addition of beds to short stay hospitals to allow expansion of such facilities without obtaining a CON when the facility has reached a utilization of 75% for the prior 12 months. Under the amended exemption, the facility would be able to expand by 10 beds or 10%, whichever is greater, once every two years.</i>	4	2	4
Cardiac Catheterization			
<i>Deregulate diagnostic cardiac catheterization and require therapeutic catheterizations to only be performed by providers approved to offer open heart surgery.</i>	4	1	5
Open Heart Surgery			
<i>Maintain existing CON regulation of open heart surgery.</i>	7	0	3
Pediatric Cardiac Cath and Open Heart Surgery			
<i>Maintain existing CON regulation of pediatric cardiac catheterization and open heart surgery.</i>	7	0	3
Perinatal Services			
<i>Deregulate Level 1 perinatal services and maintain regulation of Levels 2 and 3.</i>	6	1	3
Inpatient Psychiatric Care			
<i>Maintain existing CON regulation of inpatient psychiatric and substance abuse services.</i>	7	0	3
LONG TERM CARE OPTIONS			
	Yes	No	Abstain*
Skilled Nursing			
<i>Maintain existing CON regulation of skilled nursing facilities.</i>	7	0	3
CCRC			
<i>Deregulate CCRCs: as long as the nursing beds remain sheltered, the facility would be exempt from CON.</i>	7	0	3



Home Health			
<i>Maintain existing CON regulation of home health.</i>	7	0	3
Personal Care Home			
<i>Deregulate personal care homes: Only Medicaid-Certified Personal Care Homes would require a Certificate of Need.</i>	7	0	3
Inpatient Physical Rehabilitation			
<i>Maintain existing CON regulation of comprehensive inpatient physical rehabilitation services.</i>	6	1	3
Traumatic Brain Injury Facilities			
<i>Deregulate traumatic brain injury facilities from Certificate of Need as long as detailed licensure standards are developed.</i>	7	0	3
Hospice			
<i>Increase licensure standards for these facilities but do not require a Certificate of Need.</i>	7	0	3
<b>SPECIAL AND OTHER OPTIONS</b>			<b>Yes No Abstain*</b>
Freestanding Multi-Specialty Ambulatory Surgery			
<i>Maintain existing CON regulation of freestanding multi-specialty ambulatory surgery services.</i>	7	0	3
ASC Exemption			
<i>Abolish entirely the exemption for freestanding single specialty office based physician-owned ambulatory surgery centers, and require physician-owned limited purpose ambulatory surgery centers to obtain a Certificate. Upon application, such applicants would not need to address need criteria but would be required to make indigent and charity care commitments, to accept Medicaid, to supply data to the Department, and all physicians would be required to be on a hospital staff.</i>	5	3	2
<i>Abolish the exemption for physician-owned, office-based, single specialty ambulatory surgery centers and require such facilities to obtain a Certificate of Need under the exact same standards as all other ambulatory surgery centers.</i>	3	3	4
<i>Treat General Surgery in a consistent manner as all other single specialties.</i>	5	1	4
<i>Require all providers of ambulatory surgical services (even if some remain exempt) to make indigent and charity care commitments, to accept Medicaid, and to supply data to the Department.</i>	9	0	1
Radiation Therapy			
<i>Maintain existing CON regulation of radiation therapy services.</i>	7	0	3
Imaging			
<i>Maintain existing CON regulation of PET.</i>	4	3	3



<i>Require statutorily exempt providers of diagnostic or therapeutic equipment to make a commitment to indigent and charity care as a condition on the exemption.</i>	6	0	4
<i>Require statutorily exempt providers of diagnostic or therapeutic equipment to provide data to the Department as a condition of the exemption.</i>	6	0	4
<i>Modify the exemption for equipment below threshold to require all freestanding imaging centers to obtain a CON for equipment regardless of cost, except for de minimis x-ray equipment. The equipment threshold would still be available to physician offices and to hospitals and other health care facilities.</i>	5	1	4



## General Background

### A Summary of the Certificate of Need Law

#### Certificate of Need Overview

Government involvement in enforced planning for health facilities has an extensive and well-documented history. As far back as 1946, with the Hill-Burton Act, the federal government has provided the means for developing health planning agencies. Certificate of Need regulations, or "CON laws," were the pinnacle of federal and state legislation advocating government-mandated health planning efforts. Federal regulations provided enabling legislation and enforcement provisions, while program development and implementation generally took place on the state or local level.

#### Development of Federal Regulations

The Hill-Burton Act of 1946 was the first modern legislation to regulate the distribution of federal assistance to states through grants-in-aid. The Act was intended to assure adequate distribution of health service facilities in each state. In order to receive the funding, each state was required to develop plans (Hill-Burton Plans) that established priorities for the allocation of these monies. In addition, each state was required to provide a certain level of uncompensated care to people unable to pay. Healthcare facilities then had to meet state requirements to make certain that

renovating or adding new facilities "fit" into the state plan, which then would be submitted to the federal level.

In order to monitor this program of planning regulation, Congress passed the Comprehensive Health Planning and Public Service Amendments of 1966, which created a single federal agency to regulate and administer the health planning program.

Two other pieces of federal legislation were essential to the growth of CON programs. Section 1122 of the 1972 Social Security Act Amendments and the National Health Planning and Resources Development Act (NHPDA) of 1974 formed the framework for future CON programs.

Similar to CON in many ways, Section 1122 forced states to review all capital expenditures when they exceeded \$100,000, when bed capacity changed, or when a "substantial" change in services took place. States that failed to comply could be denied Medicare and Medicaid cost reimbursement. Hospitals could proceed with construction of new facilities without review, however, if another source of funding could be found. Professional Standards Review Organizations (PSROs) were also established by the 1972 Social Security Amendments to control utilization of



services and to review procedures according to professional standards.

Then, in 1974, the National Health Planning and Resources Development Act pushed CON regulations to the forefront of government healthcare cost containment efforts. This legislation encouraged states to enact CON regulatory programs by guaranteeing federal funding for those states enacting CON review programs and tying certain healthcare funds to the enactment of those programs. State CON programs were required to meet federal guidelines in order to receive federal money. The law required development of comprehensive health plans in accordance with national health planning priorities and standards. The law required each state to designate health planning agencies. These agencies would be responsible for creating plans outlining the needs of different health services throughout the state. Each State Health Planning and Development Agency (SHPDA) performed certificate-of-need reviews and any facility seeking federal funding was required to first seek approval from the Agency. Because of this legislative structure, each of these Agencies became solely responsible for determining whether or not proposed projects "fit" within the state's plan for providing health services. Federal legislation had firmly-established public sanctions for states that failed to comply with mandates for CON review programs. Correspondingly, most states dropped their Section 1122 review provisions and replaced them with a CON regulatory apparatus. By 1980 almost every state developed some form of CON review program under these guidelines.

In 1979, the National Health Planning and Resource Development Act was amended to clarify Congress' assertion that the healthcare industry had been suffering from a phenomenon described as "supply creating demand" and purported to address this concern through government intervention in the market. These comments explicitly expressed a lack of faith in market forces as a primary means of cost control in the healthcare industry. Although some states had developed CON programs prior to the advent of national legislation, it is clear that these federal laws were the key stimulus for most state CON programs. States who later

questioned the wisdom of CON still followed federal guidelines. Some states even reverted back to the voluntary review provisions in Section 1122 when their CON programs were allowed to expire.

The primary driving force for the enactment of CON programs developed out of the perception of and growing concerns for rapidly increasing healthcare costs. In the 1980s, however, the politics of deregulation caught on and set the tone for the elimination of CON provisions on a federal level. The free market argument had begun to garner support among legislators, in the face of growing criticism of CON regulations as being ineffective in lowering costs as well as restricting delivery access and impeding quality enhancements for patient care. The status of federal legislation advocating CON regulations changed dramatically in 1986 when the National Health Planning and Resources Development Act of 1974 was repealed. States would no longer receive federal funding for their CON programs. The Act had, however, already imparted a strong regulatory body in many states which kept their CON regulations intact. Nevertheless, over the period of years from 1983 to 2001, sixteen states either repealed and abandoned CON, or modified the scope and extent of its application.

### Georgia's CON Experience

Georgia began reviewing health care projects under Section 1122 regulations in 1975. The State Health Planning Agency (SHPA), then called the State Health Planning and Development Agency (SHPDA), was established to administer the program. Section 1122 reviews continued until 1987. Georgia's CON program was established by the General Assembly in 1979 (O.C.G.A. Title 31, Chapter 6). SHPDA began reviewing projects under the new CON regulations in that same year. In 1999, Governor Roy Barnes signed legislation creating the Georgia Department of Community Health. The State Health Planning Agency became the Division of Health Planning in the new department.

The number of projects reviewed under the two health planning programs in Georgia is exhibited in Figure A-1.



FIGURE A-1

Program	Number of Projects	Time Period
Projects reviewed under 1122 regulations only	1,081	1975-1987
Projects reviewed under CON regulations only	2,469	1979-2006
Projects reviewed under both programs	1,171	1979-1987

Source: Georgia Department of Community Health, Project Reporting and Management System (PRAMS) as of 12/8/2006.

#### Initial Purpose and Goals of Certificate of Need Law

The above-described history of CON legislation outlines how the regulation began, but a more important aspect is why it was enacted. There are three reasons for the original CON legislation and its continued existence in many states. The first and second reasons for the legislation are closely related. The **first reason** was to control the addition and duplication of facilities and services in a community. The **second reason** is an extension of the first and was to curtail escalating costs to the community (caused by unnecessary facilities and services). Specifically, the government was originally concerned about the development of health services and gradually changed its emphasis to planning to avoid overbuilding and the accompanying increase in health care service expenditures.

In developing the legislation, the federal government assumed that in order to control the potential for escalating costs and to guarantee access, some regulatory measure was needed. This regulatory measure was to control the market "supply" with CON

laws. The idea behind controlling the supply was tiered. The concept was to control the supply of healthcare construction (and technology) and healthcare services to the market, thereby limiting the additional construction/technology costs that providers would incur. Once these additional costs were controlled, there would be no additional costs to pass on to consumers. The end result would be that if no additional costs were passed on to the consumer, costs would not escalate.

Another rationalization of the CON legislation was that if providers were allowed to build new buildings, purchase new technology, or provide new services, they would have to induce more need. Furthermore, if providers had to compete, they might provide "unnecessary services" to the community, thereby causing a community's healthcare prices to escalate. By limiting the construction and services that healthcare providers could provide to the community, it was assumed that there would be less need to "compete" for patients. Therefore, if the state controlled who provided services, there would be no unnecessary duplication of services and thus, costs would not spiral out of control. In fact, as



technology improved, CON laws were helpful in curbing the 'technology arms race' which occurred in many communities in which each provider felt it needed to have the latest medical equipment to compete, regardless of whether the particular market could support the addition of new service providers.

The **third reason** for creation of the initial CON legislation was to achieve equal access to quality health care at a reasonable cost. Specifically, the government wanted to ensure that the distribution of health services was equitable to all regions of the states with a particular emphasis on rural areas. By controlling the market "supply" with CON laws, in addition to eliminating duplicate facilities and controlling costs, the government was also able to control the distribution of health services to different regions of the state.

Once enacted, the CON laws were designed to achieve three goals, which were closely tied to the three reasons the laws were enacted. The **three goals** were: (1) to measure and define need, (2) to control costs, and (3) to guarantee access. In order to accomplish these goals, CON laws focused on many of the "costly" projects, such as buildings and technology.

The agencies responsible for issuing certificates of need are extremely involved with the entry of new competition into the healthcare market. In addition, the agencies are also highly involved in monitoring the current system. By maintaining this authority over facilities and projects, the theory is that the agencies are able to control costs and monitor need by deciding if services are needed or if services are duplicative of existing services in the market. Further expanding this theory, limitation on new or expanding services "controls" the additional costs added to the healthcare system, thereby attempting to ensure that healthcare costs remain low for the community. In addition, the agency has the ability to monitor patient access through the CON programs. Many state agencies have the authority to make certificate-of-need approvals conditional by requiring that the facility or service provide care to indigent patients or patients who may require

specialized care. In this way, the agencies accomplish the third goal of CON laws, which is to guarantee all individuals access to healthcare.



## General Background

### A Summary of the Work of the State Commission on the Efficacy of the CON Commission

#### Overview

During the fiscal year 2005, the General Assembly passed a law, codified at OCGA § 31-6-90 through 95, which created the State Commission on the Efficacy of the Certificate of Need Program. The commission's purpose is to study and collect data and information relating to the effectiveness of the Certificate of Need Program in the state of Georgia. This goal is achieved by ensuring that adequate and cost effective health care services are available to meet the needs of all Georgians, develop services in an orderly and economical manner, and avoid unnecessary duplication of services.

#### Statutory Duties

The statutory duties of the Commission include studying and evaluating the effectiveness and efficiency of the Certificate of Need Program, undertaking a comprehensive review of the Certificate of Need Program to include the effectiveness in accomplishing original policy objectives, the program's costs, the benefits of continuing or discontinuing the program, the financial impact of continuing or discontinuing the program, and the impact on quality, availability, and cost of health care if the program is either continued or discontinued. Additionally, the Commission is

responsible for evaluating and considering the experiences of other states which utilized the Certificate of Need Program, as well as those states which have abolished the Certificate of Need Program to identify findings and conclusions and make recommendations for proposed legislation.

#### Commission Composition

The Commission is comprised of eleven members:

Chairman Daniel W. Rahn, MD  
President, Medical College of Georgia  
(*Ex Officio*)

Vice-chairman Richard L. Holmes  
Chairman, Board of the Department of Community Health  
(*Ex Officio*)

Senator Don Balfour  
Chair, Senate Rules Committee  
(*Appointed by Senate President Pro Tempore*)



Melvin Deese, MD  
Orthopedic Surgeon, Summit Sports Clinic  
*(Appointed by House Speaker)*

Donna Johnson, Esq.  
President, Donna L. Johnson, P.C.  
*(Appointed by Governor Perdue)*

Robert Lipson, MD *(deceased)*  
President and Chief Executive Officer, WellStar Health Systems,  
Inc.  
*(Appointed by Governor Perdue)*

Dan Maddock  
President, Taylor Regional Hospital and Healthcare Group  
*(Appointed by Governor Perdue)*

Rhonda M. Medows, MD  
Commissioner, Department of Community Health  
*(Ex Officio)*

Ronnie Rollins  
President and Chief Executive Officer, Community Health  
Systems  
*(Appointed by Governor Perdue)*

Joseph R. Ross, Esq.  
Senior Vice President and General Counsel, Memorial Health  
*(Appointed by Senate President Pro Tempore)*

Representative Austin Scott  
Chair, Government Affairs Committee  
*(Appointed by House Speaker)*

## Work Plan

The initial meeting of the State Commission on the Efficacy of the CON Program was held on June 27, 2005. At that meeting, the Commission members were welcomed by Governor Sonny Perdue. Governor Perdue thanked the members for their service and stressed that the decisions made by the Commission are to be in the best interest of the citizens of the state of Georgia. Dr. Daniel Rahn, the Commission Chair, led the discussion regarding the charge of the Commission and the scope of their work. This discussion and resulting points for further review laid the foundation for subsequent Commission meetings.

Starting in August 2005, the Commission met on a monthly basis until the end of calendar year 2005. During those meetings, the Commission heard testimony and presentations from several stakeholders in Georgia's healthcare industry and Department of

Community Health staff. *(A timeline of Commission meeting highlights follows.)* Commission members engaged in discussion surrounding various aspects of the CON policy and its implications. At each meeting, Commission members discussed the need for data from several sources to aid in their decision making process. They frequently made data requests to Department staff and other entities and suggested the idea of retaining data consultants for external consultative support. In November 2005, the Commission voted to approve the formation of a Data Subcommittee which would identify data the Commission could use in their deliberations.

In 2006, the Commission continued receiving public comments and hearing stakeholder testimonies. In April 2006, the Commission began to solidify its work plan and decided to



incorporate a subcommittee structure in order to streamline its work process. At that time, the Commission agreed to issue a Request for Proposal (RFP) to consultants to provide additional data support.

## Sub-Committee Structure

The statutory duties and mission of the Commission are addressed by four sub-committees, including the Acute Care Subcommittee, the Long Term Care Subcommittee, the Special and Other Services Subcommittee, and the Legal and Regulatory Issues Subcommittee. The first three sub-committees focus on respectively defined health care services, whereas the Legal and Regulatory Issues Sub-Committee focuses on issues directly related to specific elements of the legislative and regulatory process and procedure. The responsibility of overseeing the subcommittees' functions and processes are designated among the various members of the CON Commission, who serve as co-chairs of each subcommittee. The sub-committees have met regularly since May 2006 to address any issues or concerns regarding their relevant health care services.

The sub-committee structure is advantageous because it allows each sub-committee to focus on a defined area of services and it is a natural progression of the fashion in which the Commission has conducted its proceedings to date. Additionally, the structure facilitates a review of some of the perceived shortcomings of the statute, regulations, and program inconsistencies, including but not limited to statutory confusion, content limitations, program redundancy, inconsistent treatment, lack of quality review standards, and bureaucratic concerns.

The **Acute-Care Sub-Committee** is under the supervision of co-chair Maddock and co-chair Scott. This sub-committee focuses entirely on issues relating to acute care services. Regulated services include:

- Short stay hospital beds

- Adult cardiac catheterization
- Open heart surgery
- Pediatric catheterization and open heart surgery
- Perinatal services
- Freestanding birthing centers
- Psychiatric and substance abuse
- Currently, non-regulated services include:
- Organ transplant
- Burn units

The **Long-Term Care Sub-Committee** is under the supervision of co-chairs Deese and Rollins. This particular sub-committee focuses entirely on issues relating to long term care services. Regulated services include the following:

- Skilled nursing
- Home health
- Personal care home
- CCRCs
- Traumatic brain injury facilities
- Comprehensive inpatient physical rehabilitation
- Long term care hospitals

Currently, hospice is a non-regulated service.

- The **Special & Other Services Sub-Committee** is under the supervision of co-chair Johnson and co-chair Ross. This sub-committee focuses on issues relating to special and other services. Regulated services include:
- Ambulatory surgery centers (CON & LNR)
- Positron emission tomography
- Radiation therapy services
- Magnetic resonance imaging
- Computed tomography

Currently, non-regulated services include renal dialysis and refractive eye centers.

The **Legal & Regulatory Issues Sub-Committee** is under the supervision of co-chairs Lipson and Balfour. This sub-committee



focuses entirely on issues relating to legal and regulatory matters. These matters include:

- Appeals process
- Advice and rule making process
- Definitions
- Sanctions and enforcement
- Statutory exemptions (other than ASC)
- Statutory review considerations
- Process and procedure
- Thresholds
- Indigent and charity care provisions

## Process

The work of the CON Commission and its subcommittees is directed by a clearly defined work process. The four-phase plan includes: plan and define, data collection and analysis, strategy and policy development, and recommendations and reporting.

Phase I (Plan and Define) of the process consists of assessing data needs and requirements, identifying comparison points, defining the scope of consultant engagement, developing RFP, selecting consultant(s), and developing a work plan with the consultant(s). The ultimate outcome of this phase is the engagement of the economist/data consultant(s).

Phase II (Data Collection and Analysis) of the process includes collecting external data, reviewing internal data, and analyzing in detail both internal and external data by service where applicable. At the conclusion of this phase, the sub-committees and the consultant(s) will have developed and finalized the following work products: utilization trends, economic trends, payment and reimbursement data, supply and distribution data, quality indicators, provider workforce trends, and provider financial status and trends.

Phase III (Strategy and Policy Development) of the work plan allows for the sub-committees to develop strategies and policy

options by taking into consideration the data collected and analyzed in Phase II. This phase includes developing options and strategies for modification of legislation, regulation, and policy by service where applicable.

Finally, Phase IV (Recommend and Report) of the process consists of adopting interim recommendations, drafting proposed legislation, recommending detailed modifications to regulations, and issuing a final report.

## Outside Data Assistance

In June 2006, after narrowing down the responses to the RFP, and hearing presentations from the two finalists, the Commission chose to select the Georgia Health Policy Center as its data consultant.

The Georgia Health Policy Center (GHPC) is a nonpartisan forum for consensus building among diverse interest groups. GHPC's fundamental mission is to improve the health status of all Georgians through research, policy development, and program design and evaluation. GHPC frequently collaborates with Georgia State University faculty and other organization representatives to assist in formulating policy at the state and national levels on health care quality, access, and cost. Dr. William Custer and Dr. Patricia Ketsche are GHPC's principal researchers for its work with the Commission.

Dr. William Custer is an expert in the areas of employee benefits, health care financing and health insurance. He ran his own research firm in Washington, D.C. and also has been the director of research at the Employee Benefit Research Institute (EBRI) in D.C., as well as serving as an economist in the Center for Health Policy Research at the American Medical Association. He authored numerous articles and studies on the health care delivery system, insurance, retirement income security, and employee benefits. Dr. Custer is the Director of the Center for Health Services Research and holds a joint appointment in the



Department of Risk Management and Insurance at Georgia State University.

Dr. Patricia Ketsche has done extensive research work for various public and private organizations using the Census Bureau's Current Population Survey data and the Medical Expenditure Panel Survey data to evaluate the existing distribution of health insurance in the population and the effect of policy proposals on that coverage. She has also participated in projects relating to cost containment for Medicaid and assistance for rural health care providers by analyzing claims data and utilization patterns of various populations. She participated in early evaluation of health care quality and cost containment under Georgia Better Health Care for the Department of Medical Assistance, State of Georgia. Dr. Ketsche coordinated data collection and production of the national Institute of Health care Management's Health Care System DataSource, published in November 1998.

Dr. Custer and Dr. Ketsche, along with Glenn Landers, Program Director for GHPC attended subcommittee and full Commission meetings in an effort to collect and respond to data requests from Commission members. The data consultants were charged with gathering data from various sources to analyze the effect of CON on the cost, quality, and access of health care. In their research, the consultants compared CON in Georgia to regulatory mechanisms in ten other states (Colorado, Florida, Iowa, Maine, Massachusetts, Oregon, Utah, Washington, West Virginia, and Wisconsin). In alignment with the Commission's work plan schedule, the data consultants issued their findings in September 2006, with a final report following in October. The team at GHPC continues to work with the Commission to provide data support to aid the Commission in finalizing its recommendations to modify Georgia's CON program.



## Timeline

### 2005

#### June 27<sup>th</sup> – First Meeting

Discussion of Commission's charge and scope of work  
The Commission begins to request data from Department staff

#### August 8<sup>th</sup> – The Commission hears presentations from:

Kurt Stuenkel, FACHE of the Georgia Alliance of Community Hospitals  
C. Richard Dwozan of the Georgia Hospital Association  
Houston Payne, MD of the Georgia Society of Ambulatory Surgery Centers  
Deborah Winegard, JD of the Medical Association of Georgia

#### September 13<sup>th</sup> – The Commission hears presentations from:

Genia Ryan, Ex. Director of Georgia Assisted Living Federation of America  
Judy Adams, Ex. Director of Georgia Association for Home Health Agencies, Inc.  
Walter Coffey, President of Georgia Association of Homes and Services for the Aging, Inc.  
Fred Watson, President, Georgia Healthcare Association

#### October 24<sup>th</sup> – The Commission hears presentations from the Department (Letters of Non-Reviewability and Mandamus actions) and from Dr. Thomas Gadacz, Governor of the Georgia Chapter of the American College of Surgeons, and Dr. Chris Smith, President

of the Georgia Chapter of the Society of General Surgeons

#### November 21<sup>st</sup> – The Commission hears presentation from Department staff on the rules for Specialized Services and from James Connolly, Director of Reimbursement Services on the work of the Department's Hospital Advisory Committee. The Commission forms a Data Subcommittee to identify its data needs.

#### December 14<sup>th</sup> – The Commission hears presentations from the Department on the rules for Specialized Services and the data collected by the Department

### 2006

#### February 27<sup>th</sup> – A recommendation is made to complete the Commission's work by the end of calendar year 2006 in time for consideration by the 2007 General Assembly

The Commission agrees on a number consensus points, namely to modify rather than abolish the CON program

#### April 27<sup>th</sup> – The Commission forms four subcommittees, and outlines its four-phase work plan

The Commission agrees to issue a Request for Proposal (RFP) for an external data consultant



**June 12<sup>th</sup>** - In a closed session, the Commission hears presentations from the respondents to the RFP, and selects the Georgia Health Policy Center as its data consultant

**July 28<sup>th</sup>** - The Commission hears presentations from Carie Summers, CFO of the Department of Community Health on Medicaid Reimbursement and from Martin Rotter of the Department of Human Resources on licensure

The data consultants at GHPC give an update on their work plan; they plan to present their findings by October

**August 17<sup>th</sup>** – The Commission hears presentations from:  
Ben Robinson, Ex. Director of the Ga. Board for Physician Workforce  
John Fox, President and CEO of Emory Healthcare  
James Peoples, Director of Health Policy and Strategy, DCH  
Jimmy Lewis, CEO, HomeTown Health

**September 20<sup>th</sup>** – The Department presents topics for further discussion based on input from stakeholders and other external parties

**October 20<sup>th</sup>** – The data consultants present their findings to the Commission



## Overview of Healthcare in Georgia

### A Summary of the Existing Healthcare Environment in Georgia and Issues Intertwined with CON

#### Existing Healthcare Environment

The healthcare industry is one of the nation's largest economic driving forces. It faces a number of issues that are unique among other industries in the economic landscape. Some of those issues include shortages in its specialized workforce, the ongoing financial struggle between general hospitals and specialty physician-owned ambulatory centers, and the dilemma of delivering adequate trauma care in an increasingly precarious environment.

#### Cross-Subsidization and Financing Issues

A critical battleground in the ongoing conflict between regulation and markets as vehicles of reform in U.S. health care is the community hospital. The key to these hospitals' financial viability is cross-subsidization. Patients with private insurance underwrite under- and uncompensated care for Medicaid patients and the indigent, and profits from well-compensated services, such as cardiac care and orthopedic surgery, support services operating at a loss, such as emergency rooms and substance abuse counseling.

With nearly 1.7 million uninsured people in the state, community hospitals are dependent upon the financial balance brought in by

privately insured patients, which helps to keep staffing and equipment dollars available. Over the past decade or more, hospital reimbursement for publicly insured patients (Medicare and Medicaid) has not kept pace with costs. At the present time, Medicaid is based on 85.6% of costs for inpatient hospital services. Hospitals collect on average 10% of charges (or 20% of cost for a typical hospital with a 50% cost to charge ratio) for care of the uninsured. This is particularly problematic for trauma services. In order for a hypothetical hospital with a case mix of 40% Medicare, 15% Medicaid, 10% uninsured, and 35% commercially insured patients to cover expenses, it must cross-subsidize the care of the Medicare, Medicaid and uninsured patients from some other funding source. Traditionally, two federal/state matching programs: the upper payment limit (UPL) and disproportionate share hospital (DSH) programs have provided funds to partially cover the losses associated with care of Medicaid and uninsured patients. The future of these programs has become uncertain at present. This leaves cost shifting to privately or commercially insured patients as the primary means of maintaining financial stability. This cost shifting has primarily involved the highest margin services, in particular imaging services and ambulatory surgery services. Hospital leaders are concerned that if they lose their ability to cross-subsidize from these services, they will no longer be able to cover the fixed losses associated with inpatient Medicaid services and care of the uninsured.



For this reason, hospitals, whether nonprofit or proprietary, urban or rural, have wanted to see CON rules maintained or tightened in order to maintain regulatory control over the provision of these services in non-hospital-based settings.

A concurrent change in the finances of professional practice has affected physicians significantly. Reimbursement for most professional services provided by physicians has been reduced or has not kept pace with inflation while practice-related expenses have increased. This has led physicians to take advantage of technological advances and seek to perform previously-hospital-based services in practice-based settings (including ambulatory surgery and imaging studies), thus capturing the ability to bill for services that were previously the exclusive domain of hospitals. Services provided in practice-based settings can often be provided at lower cost and with greater efficiency for both patients and physicians than when provided in hospital-based settings. At the present time in Georgia, there are 201 single-specialty ambulatory surgery centers, 46 CON-authorized ambulatory surgery centers (those which have obtained a Certificate of Need), and an unknown number of free-standing imaging centers. The current CON regulations permit the issuance of a letter of non-reviewability for construction of a single-specialty ambulatory surgery center with a total cost that is below a specified cost threshold and operated by physicians from a specified set of single surgical/procedural specialties. The list of allowable single specialties has excluded the specialty of General Surgery. The CON rules also allow free-standing imaging so long as the cost of equipment is below a specified cost threshold. The Con program has not been directly linked to either the licensure of these centers or monitoring of the volume or quality of services provided through them. This has meant that health planning has proceeded with an incomplete set of data regarding services currently being provided in a planning region. Many physicians would like to see CON regulation of free-standing imaging centers and ambulatory surgery centers eliminated, arguing that it will improve access,

reduce costs and be more patient-centered to allow these services to be provided in non-hospital settings.

When viewed in a vacuum, analysis has shown a relatively weak effect of CON, but the CON program is being used as a regulatory device in an environment involving much stronger forces. The hospital leadership concern is that if CON is changed significantly or if imaging and low intensity surgical services continue to migrate to non-hospital based settings, hospitals will not have a financially sustainable business model. Physicians who advocate for less regulatory control argue that to artificially restrain where these services can be provided in a way that raises costs and reduces efficiency and leaves them with only the ability to bill for professional services creates an inefficient, high cost environment and leaves them with an unsustainable business model.

The CON Commission has been unable to reach consensus with regard to the best policy to address this difficult issue because its root causes involve complex factors relating to reimbursement and costs that are beyond the CON program's purview. A real and sustainable solution to this dilemma will require a health policy approach that corrects the cost and payment problems for both professional services and hospital-based services, particularly with respect to the under-insured and uninsured.

## Healthcare Workforce Shortages

### *Physicians.*

There has been recent growth of the physician workforce in Georgia which aids in removing the obstacles many Georgians face with getting quality healthcare. For example, between 2002 and 2004 the number of new physicians obtaining licenses in the state and practicing was almost 40% than the previous license renewal cycle. There is, however, growing evidence that concerns persist owing to the current capacity and growth trends in Georgia's physician workforce. These concerns also address the



future of the delivery of medical care in the state. Some of those concerns are:

- Georgia's population is growing at a rapid rate and will require an equally rapid introduction of new physicians, just to maintain current capacity
- Growth in important specialties (e.g. OB/GYN, General Surgery, etc.) is minimal or negative
- Even as demand for physicians is expected to rise, their average work effort is expected to decline
- Diversity in the workforce still lags the diversity seen in the population

To create effective responses to these concerns, state leaders must understand the driving force behind them. The Georgia Board for Physician Workforce suggests a multi-pronged approach to address and remedy these and other issues:

- Understand the problem
- Take the necessary steps to maintain current physician capacity
- Promote increased physician productivity
- Increase diversity of the workforce
- Ensure practice in underserved areas
- Increase the overall numbers of physicians practicing in the state
- Right size the medical education system
- Ensure adequate funding for medical education
- Maintain a focus on Family Medicine
- Build appropriate capacity in all levels of the medical education system, and

- Expand research capacity

#### *Non-Physician Workforce.*

Georgia and the nation may be facing the worst shortage of non-physician health care professionals in history. Evidence from numerous sources indicates that the system's ability to meet current needs for health care services is in jeopardy. If trends in workforce dynamics are not addressed, the country could witness a substantial shrinkage in the number of nurses, allied health and behavioral health professionals while experiencing an explosion in the demand for health care services that is the product of substantial population growth and longevity. Vacancy rates in hospitals, nursing homes and public sector programs are ranging between 10% and 20%. More disturbing is the outlook for the future.

In past shortages, a few factors could be isolated and addressed to provide for simple, quick and effective responses. The current shortage lacks this simplicity. As with previous shortages, demand is rising as the population grows in size and health care systems become more sophisticated and diverse. Further, the growth in population has additional components that complicate matters involving the workforce. More people are living longer, increasing the demand for health care services more markedly than pure population growth might suggest. In addition to demand factors, issues concerning the supply of health care professionals may have long-term impact. Evidence shows that the workforce may already be staffed at levels too low to meet current demand. Adding to this problem is the fact that the current health care workforce is aging rapidly, and younger, potential replacements are seeking work outside of health care. The output of key health care professional education programs, with dropping numbers of new recruits and graduates, validates this concern. Finally, with decreasing revenues and staffing shortfalls, the workplace itself appears to be a growing liability and may be driving potential recruits as well as veteran health care professionals away from health care.



Shortages in critical staff in the health care environment impact the quality of care. Low staffing levels will result in poor care, leading to increased complications, reduced benefits from successful interventions and, most importantly, increased mortality. In a study that was issued by the Health Resources and Services Administration in February 2001, entitled *Nurse Staffing and Patient Outcomes in Hospitals*, researchers identified solid evidence that indicates that the quality of care is affected by nurse staffing levels. They identified a “strong and consistent relationship . . . between nurse staffing variables and . . . patient outcomes (in pneumonia, length of stay, upper gastrointestinal bleeding, shock . . . and failure to rescue.” Better outcomes were associated with higher levels of nurse staffing. Lower levels of staffing may be linked to poor outcomes. These outcomes can impact individual lives in increased discomfort and complications that result from inadequate care. Because length of stay appears to increase with lower staffing levels, the overall cost of providing care rises. Health care quality costs have long-term social and economic impact.



## Administration and Organization

### An Analysis and Evaluation of the Administration and Organization of the Certificate of Need Program in Georgia

#### Overview

#### Department of Community Health and Division of Health Planning

The Department of Community Health, Division of Health Planning (DHP) is the division of state government responsible for administering the Certificate of Need Program, which evaluates proposals for new or expanded healthcare services or facilities under Georgia's Health Planning Statute, O.C.G.A. Title 31, Chapter 6. The Department of Community Health was created in 1999 and the administration of the CON Program was placed within the Department. Prior to 1999, the Certificate of Need Program was administered by the State Health Planning Agency.

The health planning functions of the Department include the following:

- to conduct the health planning activities of the State and, within appropriations made available by the General Assembly and consistent with the laws of the State of Georgia, to implement such parts of the State Health Plan as may relate to State government;
- to prepare and revise a draft State Health Plan for submission to the Health Strategies Council for adoption and submission to the Board of Community Health;
- to assist the Health Strategies Council in its functions;
- to adopt, promulgate, and implement rules and procedures necessary to carry out the provisions of O.C.G.A. § 31-6 in accordance with O.C.G.A. § 50-13, the "Georgia Administrative Procedure Act."
- to define the form, content, schedules, fees, and procedures for submission of applications for Certificates of Need and periodic reports;
- to establish time periods and procedures consistent with O.C.G.A. § 31-6 to hold hearings and to obtain the viewpoints of interested persons prior to issuance or denial of a Certificate of Need;



- to provide for such payment as may be necessary to share the costs of preparing the record for Certificate of Need appeals before the Review Board;
- to provide for a reasonable and equitable fee schedule for Certificate of Need applications; and
- to grant, deny, suspend, rescind, cancel, or revoke a Certificate of Need as applied for or as amended.
- to impose civil penalties as permitted or required by law for violation of these Rules and O.C.G.A. § 31-6.

The day-to-day functions of administering the health planning laws are the responsibility of the Division of Health Planning. The Division of Health Planning's day-to-day workload is divided into three main areas: Data Services, Regulatory Review, and Planning. Data Services is responsible for preparing annual surveys sent to health care providers. The information obtained from such providers is crucial in assisting the Department of Community Health in determining whether additional services are needed. Data Services uses the information obtained from these surveys to develop need projections for certain specialized health care services. The functions of the Regulatory Review Section of the Division consist of the actual review of Certificate of Need applications. The Regulatory Review Section thoroughly reviews applications and recommends denial or approval of such applications, recommendations which are based on the rules and regulations in place at the time of the review. The Planning Section of the Division is responsible for reviewing component plans and rules to ensure that they stay current with health care industry trends. Planning works closely with the Health Strategies Council in developing the overall state health plan and the individual rules and regulations for specialized services.

## The Health Strategies Council and the Rule-Making Process

The Health Strategies Council is responsible for developing Georgia's State Health Plan and addressing policy issues concerning access to health care services. The members of the Council are appointed by the Governor and represent a wide range of health care and consumer interests. The Council focuses on providing policy direction and health planning guidance for the Division of Health Planning and the Department of Community Health.

According to O.C.G.A. 31-6-21, the functions of the Council are to:

- Adopt the state health plan and submit it to the Board of Community Health for approval which include all of the council's functions and are regularly updated;
- Review, comment on and make recommendations to the Department on the proposed rules for the administration of the law;
- Conduct an ongoing evaluation of Georgia's existing health care resources for accessibility, including financial, geographic, cultural and administrative accessibility, quality, comprehensiveness and cost;
- Study long-term comprehensive approaches to providing health insurance to the entire population; and
- Perform other functions that the Department or Board may specify for the Council.



By statute, the Council must be composed of the following members, with at least one member representing each congressional district:

- 1 Representative of County Governments
- 1 Representative of Private Insurance Industry
- 11 Health Care Provider Representatives, including
  - 1 Rural Hospital Representative
  - 1 Urban hospital Representative
  - 1 Primary Care Physician
  - 1 Specialty Physician
  - 1 Registered Professional Nurse
  - 1 Certified Nurse Practitioner
  - 1 Nursing Home Representative
  - 1 Home Health Representative
  - 1 Primary Care Center Representative
  - 2 Primary Care Dentists
- 11 Consumer Representatives who have no financial interest in the health care industry, including
  - 1 Representative for Women's Health Care Needs
  - 1 Representative for Children's Health Care Needs
  - 1 Representative for Disabled Health Care Needs
  - 1 Representative for Elderly Health Care Needs
  - 1 Representative for Health Care Needs of Low-Income Persons

- 1 Representative for Small Business Health Care Needs
  - 1 Representative for Large Business Health Care Needs
  - 1 Representative for Health Care Needs of Labor Organizations
  - 3 Representatives of Populations with Special Health Care Access Problems
- 3 At-Large Members

The council holds quarterly public meetings.

The main function of the Health Strategies Council is to adopt the state health plan and submit it to the Board of Community Health; and to review, comment on and make recommendations to the department on proposed rules for the administration of the law. In this regard, the Health Strategies Council plays a large role in the rule-making process. While the Board of Community Health is the ultimate party responsible for the adoption of final rules and regulations relating to the Certificate of Need program, the Health Strategies Council plays a central role in updating and creating new rules and regulations, as well as component plans for specialized health care services.

The rule-making process generally is initiated during annual meetings of three standing committees of the Council: Acute Care Services, Long Term Care, and Special and Other Services. At the annual meeting of each standing committee, the Department reviews any issues that it has in implementing existing rules and regulations as well as whether it sees the need for any new regulations or rules. In addition, an opportunity is given for public comment to ascertain whether any additional changes are needed.



If the standing committees recommend new, additional or revised rules or regulations, the recommendation of the standing committee is made to the full Council at its next regularly scheduled quarterly meeting. If the full Council agrees with the recommendation, the Department, with the assistance of Council members, identifies certain individuals who have knowledge of the specialized service at issue and who may be interested in serving on a Technical Advisory Committee (TAC). Once an appropriate group of individuals has been identified, the full Council (at its next quarterly meeting) approved the TAC membership. At this point, the TAC can begin meeting. Depending on the whether the existing rules are fairly current or whether a new rule must be created in its entirety, the work and deliberations of TACs can take anywhere from 3 months to 12 months.

Once a TAC has made a final recommendation on proposed rules and regulations, the rules and regulations are presented to the Health Strategies Council at its next regularly scheduled quarterly meeting. If a majority of the Council approved the rules, they are forwarded with the recommendation of the Council to the Board of Community Health. The Board of Community Health may then adopt the rules as proposed and publish for public comment. Once public comment is received, the Board will then either approve the rules for final adoption or send the rules back to the Council for additional work and deliberation.

## Sanctions

The Department of Community Health only has two sanctioning and/or enforcement opportunities relating to health planning. If the Department determines that an entity is violating the statute by offering a new institutional health service without having obtained a certificate of need, the Department may issue cease and desist mandates and/or seek court injunctions to halt such violations. In addition, the Department may impose maximum fines of \$5,000 per day for every day a violation to the CON law exists. Any

imposition of fines is subject to appeal pursuant to the Administrative Procedure Act, and a fine may not be collected until such appeal is resolved.

In addition to the sanctioning abilities of the Department in relation to offering a health care service without having obtained a prior CON, the Department may also levy a fine of \$500 for each date that a transfer notification is late. The CON Statute requires any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means to notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within 45 days following the acquisition.

There are no additional sanction or enforcement actions that are available to the Department under the existing CON Statute.

## Department of Human Resources and Licensure

Licensure of Health Care facilities is the primary function of the Office of Regulatory Services (ORS) of the Department of Human Resources. The Department of Human Resources is precluded by law from issuing a license to a health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility. Licensure does not license individual services within a health care facility. For example, if a hospital seeks to offer open heart surgery, the ORS does not issue a license to the hospital to offer such a service.

Many of the functions of the ORS and the Division of Health Planning are heavily dependent on the functions of the other. For example, if a health care facility does not offer a clinical health service for 12 months, it no longer has a valid certificate of need. Licensure would then need to be notified to revoke the license of a facility to offer the service.



## Comparison States

### Rule-Making Process

A survey of a select group of states—Florida, Iowa, Maine, Massachusetts, Oregon, West Virginia, and Washington—indicates that none of these states have external bodies from the agency that regulates health planning making rules and regulations. Colorado, Utah, and Wisconsin do not have Certificate of Need laws per se. Outside of these states, there may be a few states that have purely advisory bodies that provide guidance on rules and regulations, but such bodies are not responsible for the adoption and approval of the state health plan and/or rules and regulations.

### Licensure

In many states of the survey states, including Florida, Maine, Massachusetts, West Virginia, Oregon, and Washington, licensure processes are contained in the same administrative agency as health planning and certificate of need. This is generally the case as there is much interaction and overlap between licensure and health planning. Wisconsin and Iowa do not license health care facilities. Colorado and Utah do not have Certificate of Need programs.

## Options

### Option 1.0: Licensure

*Maintain the existing organizational structure whereby the licensure of health care facilities is the responsibility of the Office of Regulatory Services at the Department of Human Resources and the issuance of certificates of need is the responsibility of the Division of Health Planning at the Department of Community Health.*

### Option 1.1: Licensure

*Move the healthcare-related licensing functions of the Office of Regulatory Services from the Department of Human Resources to the Department of Community Health.*

In this option, the functions of licensing health care facilities and issuing Certificates of Need would fall within the same state agency. This would allow for better coordination of the

two functions and may increase the accountability of health care facilities throughout the state.

### Option 1.2: Licensure

*Amend the licensure statute to permit detailed licensure standards on a clinical service-level.*

In this option, the functions of licensing health care facilities and issuing Certificates of Need would fall within the same state agency. This would allow for better coordination of the two functions and may increase the accountability of health care facilities throughout the state.

### Option 1.3: Rule Making Process

*Maintain the existing rule making process identified by statute.*



In this option, the current statutory process for rule making would be maintained. The Health Strategies Council would continue to play a pivotal role in developing and revising health planning rules for the Department.

#### Option 1.4: Rule Making Process

*Revise the existing statutory process for rule making by reducing or eliminating the role of the Health Strategies Council in the process.*

In this option, the current statutory process for rule making would be revised to reduce or eliminate the role of the Health Strategies Council in one of the following ways:

1.3A: The Health Strategies Council's statutory functions would be revised to state that the Health Strategies Council's role from a rule making perspective is simply as an advisory body. The Health Strategies Council would not be responsible for updating the component parts of the State Health Plan nor would it be responsible for reviewing and approving the Department's health planning rules. Rather, the Health Strategies Council would serve as an advisory body.

1.3B: The Health Strategies Council's role in developing and approving rules and creating components of the state health plan would be eliminated.

#### Option 1.5: Rule Making Process

*Recommend the addition of a statutory provision allowing the Department of Community Health to place moratoria on new and emerging services for a time period not to exceed 6 months, which may be renewed twice for an additional 3 months.*

Because of the substantial delay in the rule making process from the time that a new health care service is identified and a final rule is adopted, many entities, upon learning that the Department is developing a new rule, rush out to develop services for which the Department has no defined standards or review criteria. Occasionally, this means that by the time a final rule is adopted, any party wishing to offer a service may have already developed the service. This option would preclude parties from rushing to get a service initiated prior to having criteria and standards for a meaningful review by the Department.

#### Option 1.6: Health Strategies Council

*Maintain the existing configuration of the Health Strategies Council.*

#### Option 1.7: Health Strategies Council

*Abolish the Health Strategies Council and its functions.*

Under this option, the Health Strategies Council would be entirely abolished. If the Department needed guidance in developing component plans or rules, the Department could seek the input of experts in the industry on an informal basis. With the information gathered, the Department would then create and/or update component plans and rules on its own initiative.

#### Option 1.8: Health Strategies Council

*Revise the functions of the Health Strategies Council.*

The Health Strategies Council's statutory functions would be revised to state that the Health Strategies Council's role from a rule making perspective is simply as an advisory body. The



Health Strategies Council would not be responsible for updating the component parts of the State Health Plan nor would it be responsible for reviewing and approving the Department's health planning rules. Rather, the Health Strategies Council would serve as an advisory body.

#### Option 1.9: Health Strategies Council

*Decrease the membership of the Health Strategies Council.*

The current structure of the Health Strategies Council (27 gubernatorial appointees) may inhibit consensus in agreeing on component plans and rules. Furthermore, because each member serves as a representative of a particular health care segment, members may put the interest of their own facility above statewide interests.

#### Option 1.10: Health Strategies Council

*Amend the statute to require meetings of the Health Strategies Council more frequently than Quarterly.*

A timely rule making process is significantly inhibited by the current requirement that the Council meet quarterly.

#### Option 1.11: Health Strategies Council

*Amend the statute to alter provisions relating to the removal of members.*

#### Option 1.12: Sanctions

*Maintain the existing limited statutory authority of the Department to sanction entities violating the CON laws.*

#### Option 1.13: Sanctions

*Amend the statute to provide for general and broad sanctioning authority of the Department of Community Health.*

This option would allow the Department the broad statutory authority to develop rules enforcing the Certificate of Need laws.

#### Option 1.14: Sanctions

*Increase the statutory fine for failure to obtain a Certificate of Need.*

The current fine limit is \$5,000 per day. In addition to increasing the fine, an additional recommendation could be progressively increasing the fine amount based on continued violations.

#### Option 1.15: Sanctions

*Permit the Department to levy fines and to revoke Certificates of Need for failure to provide annual and periodic data surveys.*

Currently, there are no sanctions which the Department may pursue if an entity fails to submit annual data. Incomplete data has a negative impact on the projections the Department issues for service needs.

#### Option 1.16: Revocation

*Amend the statute to allow the Department the authority to issue conditional Certificates of Need and to revoke CONs when such conditions are not met by the certificate holder.*



This option would allow the Department by rule and by application to place conditions on a Certificate of Need, e.g. minimum volumes, quality standards, limitations on services, etc. The Department would have the ability to revoke CONs if such conditions are not met.

Option 1.17: Revocation in Part

*Permit the Department to have the authority to revoke parts of Certificates of Need.*

Certificates of Need are frequently issued for more beds or units of service than an entity has committed to implementing in its application. Under this option, the authorized capacity of such facilities would be amended to reflect the number of beds or units which have actually been implemented. Such “revoked” beds or units would then be available to other entities that are willing to offer the services.

## Recommendations

Recommendation 1.0 *(Unanimous)*

*Move the healthcare-related licensing functions of the Office of Regulatory Services from the Department of Human Resources to the Department of Community Health.*

In order to consolidate inter-related functions, the Commission recommends that the healthcare-related licensing functions of the Office of Regulatory Services be relocated from the Department of Human Resources to the Department of Community Health. Non-healthcare-related licensing functions of ORS, such as the licensure of childcare facilities should remain with the Department of Human Resources.

Recommendation 1.1 *(Unanimous)*

*Amend the licensure statute to permit detailed licensure standards on a clinical service level.*

Current licensure standards in Georgia are developed and applied at a facility level. The Commission recommends that the licensure statute be amended to permit the development and application of detailed licensure standards on a clinical service level. This recommendation would improve the quality of care, and in certain instances where the Commission has recommended the removal of Certificate of Need regulation (for example, Level 1 perinatal services and diagnostic cardiac catheterization), implementation of this recommendation will ensure a level of regulatory oversight of the service. Implementation of this recommendation will provide the licensing agency with the authority to preclude a facility from offering a particular service if quality standards are not met. Currently, the licensing agency has no recourse on a service level; rather, the agency must take action against a facility as a whole.



Recommendation 1.2 (Unanimous)

*Add a statutory provision allowing the Department of Community Health to place moratoria on new and emerging services for a time period not to exceed 6 months, which may be renewed once for an additional 3 months.*

Because of the substantial delay in the rule-making process from the time that a new health care service is identified and a final rule is adopted, many entities, upon learning that the Department is developing a new rule, rush to develop services before the Department has defined standards or review criteria. As a result, this means that by the time a final rule is adopted, any party wishing to offer a service may have already developed the service. For this reason, the Commission recommends that the Department be empowered by statute to issue temporary moratoria during the development of rules and standards. Any such moratorium should be issued by the Commissioner of the Department of Community Health with the authorization of the Board of Community Health. Upon the expiration of the moratorium, if the Department of Community Health had not finalized detailed standards, any project which had been subject to the moratorium would be reviewable under the general statutory considerations.

Recommendation 1.3 (Unanimous)

*Revise the statutory functions of the Health Strategies Council to make the Council advisory in nature.*

The Health Strategies Council's statutory functions should be revised to provide that the Health Strategies Council's role from a rule making perspective is only advisory in nature. The Health Strategies Council would not be responsible for updating the component parts of the State Health Plan nor would it be responsible for reviewing and approving the Department's health planning rules. Rather, the Health Strategies Council would serve as an advisory body. As an

advisory body, the Department would seek input of the Council whenever it is interested in updating rules and regulations and the state health plan components. However, the development of such rules and components would not rely on the actions of the Council. The Commission feels that the implementation of this regulation will allow for more proactive and timely development of rules and standards.

Recommendation 1.4 (Unanimous)

*Decrease the statutory membership of the Health Strategies Council.*

The current size of the Health Strategies Council (27 gubernatorial appointees) is unwieldy because it is difficult to obtain consensus amongst the various representatives. Rather than 27, the Commission recommends that the membership of the Council consist of one member from each congressional district. In addition to representing a district, each Council member should represent one of the following groups:

- Urban Hospital
- Rural Hospital
- Private Insurance Industry
- Primary Care Physician
- Physician in a Board Certified Specialty
- Freestanding Ambulatory Surgery Center
- Nursing Home
- Home Health Agency
- Healthcare Needs of Women and Children
- Healthcare Needs of Disabled and Elderly
- Healthcare Needs of Indigent



- Mental Healthcare Needs
- Business

The statute should provide that with the addition of congressional districts to the state, additional members should be added representing local or county governments.

Recommendation 1.5 (Unanimous)

*Amend the statute to require meetings of the Health Strategies Council at least once bi-monthly.*

Currently, the Health Strategies Council meets at least once quarterly as required by statute. However, health care is a quickly changing market, and quarterly meetings do not provide for the timely advisement of the Department in regards to rules and policy. Therefore, the Commission recommends that the statute be amended to require meetings of the Council at least once bi-monthly.

Recommendation 1.6 (Unanimous)

*Amend the statute to alter provisions relating to the removal of Health Strategies Council members.*

Currently, the Certificate of Need Statute proscribes certain circumstances that would result in the removal of a Council member by the Governor, such as incompetence or neglect of duty. Members of the Commission believe the Governor should be allowed to remove members for any reason without cause. In addition, the statute should be amended to provide for the automatic removal (without an action by the Governor) of any member who is absent from more than ¾ of the meetings in any calendar year.

Recommendation 1.7 (Unanimous)

*Increase the statutory fine for failure to obtain a Certificate of Need to \$5,000 per day for the first month, \$10,000 per day for the second month, and \$25,000 per day for subsequent months.*

There has been substantial testimony that entities that fail to obtain a certificate of need frequently view the maximum fine of \$5,000 per day as a cost of doing business. Amending the current statutory language to allow for a progressively increasing fine will serve as more of a deterrent for those who begin offering new institutional health services without first obtaining a certificate of need.

Recommendation 1.8 (Unanimous)

*Permit the Department to levy fines of \$500 per day for the first month and \$1,000 per day for subsequent months and to revoke Certificates of Need for failure to provide annual and periodic data surveys.*

Currently, there are no sanctions that the Department may pursue if an entity fails to submit annual data. Incomplete data has a negative impact on the projections the Department issues for service needs because the Department relies on utilization and other data from annual surveys to calculate projections for future needs. There is evidence that a number of providers fail to provide basic information to the Department through submission of annual surveys. Therefore, the Commission recommends that the Certificate of Need statute be amended to empower the Department to levy fines and to revoke certificates of need/authorization to offer health care services (for those facilities which have been grandfathered) when an entity fails to provide data accurately and timely. The fine for failure to submit data timely and accurately should be \$500 per day for every day that data is not timely and accurately submitted, increasing to \$1,000 per day for every



day that data is not timely and accurately submitted beyond the 30<sup>th</sup> day. The Department should have statutory authority to revoke a certificate of need/authorization to offer health care services once data is more than 180 days late.

Recommendation 1.9 (Unanimous)

*Amend the statute to allow the Department the authority to issue conditional Certificates of Need and to revoke CONs when such conditions are not met by the certificate holder.*

Currently, the Certificate of Need Statute only specifically authorizes the Department to place two conditions on Certificates: (1) that the applicant will provide indigent and charity care and (2) that the applicant will participate in the Medicaid program. Violation of either of these conditions currently does not result in revocation of the Certificate of Need; rather, the Statute only authorizes the Department to levy a fine for such violations. The Commission recommends that the Statute be revised to specifically allow the Department by rule and by application to place conditions on a Certificate of Need, such as minimum volumes, quality standards, limitations on services, etc. The Department should have the ability to revoke Certificates of Need if such conditions are not met. The Commission recommends that the authority to revoke be limited to those instances where substantial compliance has not been met. To implement this recommendation, the statute should authorize the Department to develop rules defining “substantial compliance.”

Recommendation 1.10 (Unanimous)

*Permit the Department to have the authority to revoke parts of Certificates of Need.*

Certificates of Need are often issued for units of service, such as hospital beds or operating rooms, some of which are never put into service or built. Applicants who have been approved for more than they ultimately implement have the potential to

create access problems for because of the adverse effect this skewed inventory has on planning area need projections. If the Department had the authority to revoke CON approval for those units of service that are not timely implemented, they could be potentially awarded to another applicant who is willing to develop and offer the service. For this reason, the Commission recommends that the statute specifically empower the Department to revoke parts of Certificates of Need. This provision should only be applied to Certificates of Need issued after the effective date of the statutory change and should not be applied retroactively.



## Process and Procedure

### An Analysis and Evaluation of Procedural Issues Associated with the Administration of Certificate of Need in Georgia

#### Overview

##### Submission of Application

The Georgia Certificate of Need process begins with the submission of an application. An original and one (1) copy of the application must be submitted along with a *certified check* made payable to the State of Georgia for the appropriate filing fee. The Department's official application is available at the Department's website and provides an instruction page for applicant's convenience and assistance in preparation. The Department's application must be used. Applications received after 3 P.M. are considered as accepted the following business day. The amount of a filing fee is determined by the cost of a proposed project according to the following schedule:

- \$1,000 is the minimum filing fee and covers projects costing zero to \$1,000,000;
- one-tenth of one percent (0.001) for projects costing more than \$1,000,000 with no filing fee exceeding \$50,000;

Filing fees must be paid with certified cashier's checks or money orders and are deposited into the State Treasury. These fees are *not refundable*.

##### Review for Completeness

A project review cannot begin until all relevant information has been provided to the Division of Health Planning and the application has been deemed complete. Following an application's initial submission, the Division of Health Planning has 10 business days from the day following receipt to declare the application complete or incomplete. *The Division of Health Planning will not begin the review process unless it has received and deemed complete all relevant surveys and questionnaires, such as the Annual Hospital Questionnaire, the Annual Nursing Home Questionnaire, and the Annual Indigent Care Survey.* An applicant is notified of the completeness status on or before the 10<sup>th</sup> day, and if an application is deemed incomplete, given an opportunity to provide additional information to complete the application. The application will be considered withdrawn if the requested, additional information, including surveys and questionnaires, etc. is not provided within two calendar months of the date of the



incompleteness letter. The applicant will receive written notification to confirm the beginning of a review.

### Evaluation of Application

In reviewing an application, the Division of Health Planning will take into account the general considerations specified in the CON Statute and the Rules and the appropriate, service-specific standards and criteria, if applicable.

The review period is 90 days and may be extended an additional 30 days, if necessary. In no event shall a review exceed 120 days. For certain projects that do not involve the review for clinical health services, such as a medical office building or parking lot, an expedited review may be allowed. These reviews are 45 days and must be requested on the Department's Expedited Certificate of Need Application, which is also available at the Department's website. All review periods commence from the date of completeness.

### Batching Review Process

Projects that involve home health agencies or the development of new intermediate care or skilled nursing home beds are subject to the batching review process. Under this review procedure, the acceptance of Certificate of Need applications for these service categories only are limited to designated times throughout the year. The Division of Health Planning makes need determinations every six months, in March and September, for these services. If there is a determined need for these services within any of the 12 State Service Delivery Regions, a Batching Notification is published and made available at the Department's website. The notifications include detailed information about the need projections, deadlines for the submission of letters of intent and Certificate of Need applications, and other review procedures. The length of the batching review cycle is 120 days. The batching review process does not apply to nursing home renovation or replacement projects, which do not involve additional beds.

The Division of Health Planning maintains a mailing list of interested parties who want to receive notifications about unmet need and upcoming batching cycles.

### Decision

A project application, if not withdrawn, is either approved or denied by the Division of Health Planning. If the application is approved, an official Certificate of Need and project evaluation analysis is provided to the applicant. If the project is denied a denial letter and project evaluation analysis is provided to the applicant.

### Implementation of Project

Following a favorable award of a CON from the Division of Health Planning, the applicant has 12 months from the date of approval to implement the proposed project.

Certificates awarded for the acquisition of equipment shall be effective for 12 months, by which date the applicant must be in possession of the equipment and the proposed location.

For projects that require construction or renovations the applicant has one year from the date of approval to demonstrate substantial performance with construction plans that have been approved by the state architect, a construction contract that has been signed and provides for beginning and completion dates and evidence that construction materials and equipment are on site.

All CON approved projects must comply with post-approval requirements. CON post-approval requirements and progress reporting forms are available at the Department's website. An applicant may download the progress report to submit to the Department. Progress reports are required to document timely project implementation, interim progress, and completion.

### Appeals and the Health Planning Review Board

CON decisions may be appealed by:



- The applicant;
- A competing applicant;
- A competing health care facility that notified the DHP about its opposition to a proposed project on or before the 60<sup>th</sup> day of the review cycle; or
- The county or municipal government where the project would be located.

Requests for an initial administrative appeal hearing before a hearing officer, or a request for intervention, must be filed with the Health Planning Review Board chair no later than 30 days after the Division of Health Planning decision. A hearing officer is appointed by Health Planning Review Board and holds a *de novo* hearing within 60 days of appointment unless agreed to by all parties. Generally the time frame is longer than 60 days because of scheduling difficulties between attorneys for the parties. The hearing officer issues a decision no later than 45 days after the close of the record in the hearing.

Any party, which disputes the hearing officer's decision, must file specific objections with the Review Board no later than 30 days after receiving the hearing officer's decision. The Review Board must hold a meeting to hear arguments within 60 days of the hearing officer's decision. The Review Board meeting consists of arguments of 20 minutes by each party. Based on the oral arguments and any written briefs, the Review Board issues a written order within 30 days after its meeting. By law, the Review Board's decision serves as the Department's final decision. The Department cannot appeal the Review Board's final decision even if the decision is contrary to the Department's initial decision.

Any party opposed to the Review Board's decision, except for the Department, may appeal the decision to the Superior Court within 30 days of the decision. Judicial review of the Review Board decision may proceed through the Court of Appeals to the Supreme Court of Georgia.

The Health Planning Review Board consists of nine Governor-appointed members (currently there are three vacancies). The Chair and Vice-Chair of the Board must be attorneys. The members of the Board must have no financial interest in, or represent or have any compensation arrangement with any health care facility. In addition, no member may serve on the Review Board if the person is required to be registered with the Secretary of State as a lobbyist or as a registered agent.



## Comparison States

### Review Process

#### *Submission of Application*

A Letter of Intent (“LOI”) for the state’s regular review process is required by six of the eight active CON programs. Massachusetts does not require an LOI. Letters of Intent are due between 15 days (West Virginia) and 90 days (Maine) before submitting an application. Maine requires that competitive applicants submit an LOI within ten days after the first LOI. Most programs require an LOI to be submitted at least 30 days prior to the application.

Georgia requires an LOI for batch reviews but not for normal reviews; therefore, Letters of Intent are only required for Skilled Nursing and Home Health services.

Fees for applying for a Certificate of Need may create entry barriers. While the fees associated with the application are not the only costs, they are measurable. Data on true costs, including application preparation and legal fees cannot be calculated, as the data have not been collected or reported in a consistent manner. States generally assess sliding application fees that adjust for the varying costs of each project. Every state sets a minimum fee for application, with the lowest fee being \$250 in Massachusetts. Other states with minimum fees of \$1,000 or less are Georgia (\$1,000) and Iowa (\$600). Washington and West Virginia, which both assess fees by proposal, assess fees for designated services at \$1,000 or less. Oregon and Florida assess the highest minimum fees at \$10,000. Maximum application fees range from \$15,000 (Oregon) to \$250,000 (Maine). West Virginia has no stated maximum fee.

### *Completion and Application Review*

The level of assistance provided by CON staff can impact the approval or denial of an application as well as whether or not a potential applicant will proceed through the application process. Levels of technical assistance vary across the eight states. Maine provides the highest level of technical assistance to applicants and requires that applicants meet with CON staff to determine requirements for applying for a CON within 30 days of filing a Letter of Intent. In Georgia, if staff think the application might be denied, staff will meet with applicants within the first two months of the application process in order to go over any problems in the application and give the applicant an opportunity to amend the application. Massachusetts’s staff will assist applicants in completing their application and considers this assistance to be a part of their duties. Iowa will conduct a preliminary review of the application at the applicant’s request, and, if there are factors that may lead to the denial of the application, staff will inform the applicant.

Every state except Maine screens applications for completeness prior to beginning the formal review process. This screening period occurs within 15 days for all but Georgia (ten days) and Massachusetts (30 days). States notify applicants of any additional information that must be submitted for an application to be complete. Washington will review an incomplete application at the written request of the applicant.

States allow applicants differing amounts of time to submit missing information. Florida allows the least amount of time to submit missing information following notification that information is missing: 21 days. Washington allows 45 days but will hold an application open for 120 days, Georgia allows two calendar months, West Virginia allows 180 days, and Oregon allows one year for applicants to submit additional



information. Maine allows for revision of an application at any time prior to the date CON staff submit their final analysis to the Commissioner. Maine may also change the application cycle and treat the application as new. Washington will allow the submission of additional materials but treats this as an amendment to the application and assesses an additional fee. Timeframes for submitting additional materials were not found for Iowa and Massachusetts.

### *Types of Reviews*

A more competitive application process creates an entry barrier, and only one state (Iowa) does not do competitive, joined, or batched reviews for any proposal. Florida and Maine both do batched reviews and consider their process very competitive. Maine does not batch nursing facilities. However, Georgia and Washington batch reviews for nursing facilities, and Washington batches reviews for nursing homes, open-heart surgery, and a few other projects. Joining of applications that seek to provide a similar service in a similar market occurs for competitive or simultaneous review, even if batch reviews is standard in most states. Expedited and emergency reviews are also provided by all states.

Florida holds two batching review cycles per year in each project/service category. Maine holds two annual review cycles: one for large projects beginning on January 1 of each year and one for small projects beginning April 1 annually. In Massachusetts applications are batched and different filing dates are established based on service type.

### *Involvement of Outside Parties in Review Process*

An opportunity for outside parties to present information to the CON review agency during the evaluation process is allowed in every state. The most rigorous states hold opposition hearings on every application. Only two states build opposition hearings into the standard process. Iowa conducts

opposition hearings at least ten days before the Council meets to make a decision. Oregon conducts public opposition hearings at least 21 days before a decision is due. Washington has a standard public comment period during the first 35 days after an application is accepted. Opposing parties must submit documentation to the state at that time. The remaining five states and Washington conduct public and/or opposition hearings upon request.

The six states that require that public and/or opposition hearings be requested only allow them within certain constraints. The least amount of time for an opposition hearing request is in Florida 14 days after publication of notice of application. More time is allowed to submit a request for a public and/or opposition hearing in Maine (30 days), West Virginia (30 days), and Washington (35 days).

Most states (five) include only CON staff and a Council or Secretary for their Department of Health in the review decision. Maine, Massachusetts, and Washington involve parties outside of those related to Certificate of Need. Maine seeks input from Maine's Centers for Disease Control and Prevention Director to evaluate the application as well as the Bureau of Insurance for an impact on health insurance premiums.

Massachusetts and Washington consult other state agencies for information on licensure status and, if the applicant operates facilities in other states, Massachusetts contacts them to determine if there are complaints and sends the state a checklist so they can inform Massachusetts of any issues. Washington checks the same things as Massachusetts and reviews applicants' history of quality, Medicare certification, any fines or sanctions, and does a Department of Justice investigation. A credential check on key personnel who are individual license holders is also conducted.



### *Decision Timeframe*

The time it takes from submission of a Letter of Intent to application approval or denial (except in cases of expedited or emergency determinations), ranges from three to six months for most states (except for Massachusetts). Washington's statutes indicate that the review period is 90 days for regular reviews and 150 days for concurrent reviews. Massachusetts indicates that it takes approximately one year for a decision to be reached.

### *Issuance of Decision*

In most states, the agency responsible for the day-to-day operation of the Certificate of Need Program makes the final decision to issue or deny a Certificate of Need. However, in some states, a Council or other Body makes the initial decision or as an alternative makes the final decision based on an initial decision of the Agency.



FIGURE 2-1.

STATE	Batching Review Process?	Review Period	Issuing Body
Georgia	NO (Except Home Health and Nursing Home)	90 days (may be extended to 120 days)	Agency Review Analyst
Colorado	--	--	--
Florida	For Some Services	60 days	Agency
Iowa	No	90 days	State Health Facilities Council (5 members)
Maine	Yes (all services)	150 days	Agency
Massachusetts	For Some Services	1 year	Agency, Public Health Council if disagreement
Oregon	No	90 days	Agency
Utah	--	--	--
Washington	For Some Services	90 days	Agency Review Analyst
W. Virginia	No	58 days	Health Care Cost Review Board (3 members panel)
Wisconsin	No	45 days	Agency



## Appeals Process

Initial decisions are one step of the CON review process. Most states indicate that applicants, competitors, and taxpayers appeal decisions. An appellant must hold some standing in regard to the application being appealed. Standing varies across states, with the most lenient state (according to documentation available online) being West Virginia. Their statutes indicate that any person may request a reconsideration of a decision. Florida, Georgia, and Washington apply tighter restriction on who may appeal by requiring that appellants be applicants, competing applicants, or health care facilities. Washington requires that the appellant have participated in a public opposition hearing and requested to be informed of the decision.

In addition, Georgia and Oregon allow municipal, county, or civic governments to appeal decisions. Iowa, Maine, and Oregon have fairly lenient standards but do require either a group of taxpayers (Maine, Massachusetts) to appeal or that there be evidence that the appellant is an affected party and has, at minimum, attempted to participate in the review process (Iowa). Information on Oregon is based on the prior appeals process. Oregon has recently suspended the prior appeal process, and the current process is not yet clear. Massachusetts currently has no appeals process. Dissatisfied parties in Massachusetts must go through the court system to have their case heard.

A request for appeal is required within 30 days for Georgia and Maine, within 28 days for Washington, within 21 days for Florida, and within ten days for Oregon.

### *Appeal Cost*

No state assesses the appellant a fee for appealing a decision. Each party bears its own costs associated with preparing for

an appeal. In Georgia, the costs of reproducing the transcript and creating the hearing record are split equally between all parties. In Iowa, the CON program may be responsible for court costs if the state loses the appeal and the court decides to charge Iowa. In Washington, the CON program bears the cost (through chargeback to the program) for adjudicative proceedings. Washington recently performed a five-year audit and discovered that 24 percent of their department expenditures went to adjudicative proceedings or appeals.

### *Comparative Appeals Process*

Florida:

Within 21 days after publication of notice of the State Agency Action Report and Notice of Intent, any person authorized to participate in a hearing may file a request for an administrative hearing. The Agency shall assign proceedings requiring hearings to the Division of Administrative Hearings of the Department of Management Services within 10 days. Hearings shall commence within 60 days after the administrative law judge has been assigned. All parties, except the agency, shall bear their own expense of preparing a transcript. The administrative law judge only makes a recommended order, which must be submitted to the parties within 30 days after the hearing. The Agency has adopted procedures for administrative hearings which maximize the use of stipulated facts and provides for the admission of prepared testimony. Once the Agency has received the recommended order from the ALJ, it reviews the decision and issues its final order within 45 days after receipt of the recommended order. A party to an administrative hearing for an application for a certificate of need has the right, within not more than 30 days after the date of the final order, to seek judicial review in the District Court of Appeal.



Iowa:

Any dissatisfied party who is an affected person with respect to the application, and who participated or sought unsuccessfully to participate in the formal review procedure may request a rehearing from the Agency using the Administrative Procedure Act process for administrative hearings. If a rehearing is not requested or an affected party remains dissatisfied after the request for rehearing, an appeal may be taken to the judiciary.

Maine:

Any person directly affected by a review under the health planning statute may, for good cause shown, request in writing a hearing for the purpose of reconsideration of the decision of the department to issue or to deny a certificate of need within 30 days of the department's decision. The department conducts the reconsideration hearing itself and commences a hearing within 30 days of receipt of the request. The department does not hold a hearing if it determines that good cause for such a hearing has not been shown. A request for a hearing is considered to show good cause if it:

- Presents significant, relevant information not previously considered by the department;
- Demonstrates that there have been significant changes in factors or circumstances relied upon by the department in reaching its decision;
- Demonstrates that the department has materially failed to follow its adopted procedures in reaching its decision; or
- Provides other bases for a hearing that the department has determined constitute good cause.

A decision must be rendered within 60 days of the commencement of a hearing, except that the parties may agree to

a longer time period. Any person aggrieved by a final decision of the department is entitled to judicial review.

Massachusetts:

Any party may request a public hearing within 14 days after issuance of determination and file an appeal to the Health Facilities Appeals Board. The Board in considering any such appeal shall restrict itself to a review of materials on file with the department and to consideration of whether the determination appealed from was an abuse of discretion. Such appeal shall be heard by the Board or its designated hearing officer within 30 days after its filing. Within 30 days after a hearing by a hearing officer, the hearing officer must submit a recommended decision to the Board. The Board makes final decision. The Board, within 60 days after filing of the appeal, must issue a final decision either denying the appeal or remanding to the department for action consistent with the opinion of the Board; failure of the Board to issue a final decision within 120 days after filing of the appeal shall constitute a final decision affirming the action of the department and denying the appeal. The Board consists of 5 persons to be appointed for terms of 3 years by the governor, at least 3 of whom shall be consumers of health care services who are not officers or employees of, and do not bear any fiduciary relationship to a person or institution providing health care services. One such consumer member shall be a member of the bar of the commonwealth and shall be designated by the governor to serve as chairman of the board. Persons appointed to the board shall be knowledgeable in matters pertaining to the delivery of health care services.

Oregon:

Only a denied applicant is entitled to a contested case hearing or judicial review. A contested case hearing is conducted by the agency in accordance with APA.



Washington:

Any applicant denied a certificate of need or whose certificate of need has been suspended or revoked has the right to an adjudicative proceeding. The proceeding is conducted in accordance with the APA. Opposing parties may appeal but must have participated in a public hearing during the review process. The opposing party must demonstrate that it:

- provides services similar to the services provided by the applicant and under review pursuant to this subsection;
- is located within the applicant's health service area; and
- testified or submitted evidence at a public opposition hearing.

West Virginia:

Any person may request in writing a public hearing for purposes of reconsideration of a state agency decision. A request for a public hearing for purposes of reconsideration shall be considered to have shown good cause if, in a detailed statement, it:

- presents significant, relevant information not previously considered by the state agency, and demonstrates that with reasonable diligence the information could not have been presented before the state agency made its decision;
- demonstrates that there have been significant changes in factors or circumstances relied upon by the state agency in reaching its decision;
- demonstrates that the state agency has materially failed to follow its adopted procedures in reaching its decision; or
- provides such other bases for a public hearing as the state agency determines constitutes good cause.

A request for hearing shall be received within 30 days after the date of the state agency decision, and the hearing shall commence within 30 days of receipt of the request. Any such hearing is conducted in accordance with the APA, whereby the CON decision is reviewed by any other agency of the state designated by the Governor: The reviewing state agency shall make written findings which state the basis for its decision within 45 days after the conclusion of such hearing. A decision of the reviewing state agency following a reconsideration hearing shall be subject to judicial review.

Wisconsin:

Any applicant whose project is rejected may request a public hearing to review the department's initial finding if the request is submitted in writing within 10 days after the department's decision. The department shall commence the hearing within 30 days after receiving a timely request, unless all parties consent to an extension of this period. Each applicant at any such hearing has the burden of proving, by clear and convincing evidence, that the department's initial finding was contrary to the weight of the evidence on the record when considered as a whole, arbitrary and capricious or contrary to law. Any applicant adversely affected by a decision of the department may petition for judicial review of the decision. Competing facilities may not appeal the grant of a Certificate of Need.



## Options

### Option 2.0: Review Competitiveness

*Maintain the existing process for submission and review of CON applications.*

Under the current statutory provisions, CON applications may be submitted at any time. There are only two methods of comparative review: the batching of nursing home and home health applications and joinder of applications. Other than home health and nursing home services, this submission and review process may lead to mal-distribution of health care services because the current process is one of “first come, first served.”

### Option 2.1: Review Competitiveness

*Make no application subject to joinder or batching.*

### Option 2.2: Review Competitiveness

*Batch applications by clinical health services.*

Under this option, all applications for clinical health services would be competitively reviewed. Applications would be submitted once annually for the particular health service. The applications would be reviewed to determine the best applicant(s) and to ensure the best distribution and access to health care services.

### Option 2.3: Review Competitiveness

*Allow the Department to limit the times at which CON applications may be submitted.*

This option would not be an annual batching process, but rather, the Department would allow the submission of CON applications during set times of the year. For example, applications might be

submitted in January, April, July, and October. This would improve the competitiveness of the review process to a certain extent but would allow applications more frequently than once per year.

### Option 2.4: Review Timeframe

*Maintain the existing 90 day review cycle.*

### Option 2.5: Review Timeframe

*Increase or decrease the existing 90 day review cycle.*

### Option 2.6: Review Timeframe

*For batched reviews, increase the review timeframe to 120 days*

### Option 2.7: Review Timeframe

*Allow the Department of Community Health to develop rules and regulations defining the time periods for review of applications.*

2.7A: Statutorily define the time period for the completion of the review, but allow the Department to define the timeline by rule for intermediate steps of the review process.

2.7B: Statutorily define the time period for certain steps of the review process, but provide the Department with leeway for other steps.



#### Option 2.8: Opposition

*Provide for opposition hearings during the review cycle.*

Currently opposing parties may submit documentation to the Department in opposition to projects but are not given the opportunity to formally present their opposition arguments to the Department in a public forum.

#### Option 2.9: Administrative Appeals

*Maintain the current processes for appeals including the Health Planning Review Board.*

#### Option 2.10: Administrative Appeals

*Abolish the Health Planning Review Board and model the appeals process on the Administrative Procedure Act.*

2.10A: Use APA appeals process but exempt health planning appeals from the requirement of using OSAH. Under this approach, the Commissioner would assign a hearing officer to hear the issues and make a recommended order. The Commissioner of DCH would make the Final Order.

2.10B: Use APA process and require hearings to be heard before OSAH. The Commissioner would make the Final Order.

2.10C: Create an APA-like process with defined timelines and procedures.

#### Option 2.11: Administrative Appeals

*Modify the statutory definition of parties who have standing to appeal to remove the right to appeal from competing healthcare facilities.*

Under this option, only denied applicants would have the right to appeal.

#### Option 2.12: Administrative Appeals

*Limit the issues on appeal to whether the decision to deny or approve an application was arbitrary or capricious and to whether the decision lacked basis in law or fact based on the information that was presented to the Department.*

The existing hearing process requires a *de novo* hearing of the facts. In this option, hearing officers would be limited in their review standard and parties would be limited to information they had submitted to the Department during the review process (including opposing parties). Basically, the hearing officer would be limited to determining whether the Department made the correct decision based on the information that was presented to it.

#### Option 2.13: Administrative Appeals

*Require losing parties in appeals to pay for the entire cost of the appeal including hearing officer fees and preparation of the record, etc.*

#### Option 2.14: Judicial Review

*Amend provisions relating to judicial appeal in a fashion similar to the Workers' Compensation Statute.*



## Recommendations

### Recommendation 2.0

*(Unanimous)*

*Batch applications by clinical health service.*

Under current statutory provisions, CON applications may be submitted at any time, and there are only two methods of comparative review: the batching of nursing home and home health applications and joinder of closely-related applications filed and deemed complete within a 30-day period. Other than home health and nursing home services, this submission and review process may lead to mal-distribution of health care services because the current process is one of “first come, first served.” Therefore, the Commission recommends that all applications for clinical health services be competitively reviewed through a batching process. Under this recommended approach, the application process would begin with the filing of letters of intent, in which all intended applicants announce their proposed project. Applications would then be submitted at least twice annually for any particular clinical health service, whether the application is to fulfill a predetermined calculated need or not (e.g. the application is for an exception to need). The applications would be reviewed to determine the best applicant(s) and to ensure the best distribution and access to health care services. Additionally, the Department would determine set times during the year when applications would be due for capital projects (those projects which are being reviewed solely because they are over the capital or equipment thresholds). The statute should provide for the Department to create rules to define the appropriate times during the year for submission of applications.

### Recommendation 2.1

*(Unanimous)*

*Increase the review timeframe to 120 days and allow the Department of Community Health to develop rules and regulations defining the intermediate review time periods.*

With the change to a batching approach to application submission, the application review time frame should be extended to 120 days. The statute should be amended to this effect and should also delineate the following intermediate review steps: Submission of Written Opposition, Applicant Review Meeting (currently “60-day meeting”), Submission of Supplemental Information, Submission of Supplemental Written Opposition, and Opposition Meeting (as discussed in Recommendation 2.2). The statute should authorize the Department, by rule, to define the appropriate time frame during the 120-day review process for each of these intermediate review steps.

### Recommendation 2.2

*(Unanimous)*

*Provide for opposition meetings during the review cycle.*

Currently opposing parties may submit written documentation to the Department in opposition to projects but are not given the opportunity to formally present their opposition arguments to the Department in a public forum. The recommendation of the Commission is to allow an opposition meeting for those who are opposed to projects. Attendance and participation in an opposition meeting would be required to have standing to appeal a project.



Recommendation 2.3 (Unanimous)

*Abolish the Health Planning Review Board and model the appeals process on the Administrative Procedure Act.*

There has been substantial testimony that the current administrative appeals process is lengthy and costly. Currently, the Health Planning Review Board, a body separate and apart from the Department of Community Health, is composed of 9 gubernatorial appointees who have no direct interest in health care entities. The Review Board Chair or Vice Chair is responsible for assigning hearing officers to oversee initial administrative hearings regarding whether or not a Certificate of Need should have been issued by the Department. Once a Hearing Officer has made a decision, the Hearing Officer's Order can be appealed to the full Health Planning Review Board, which issues a final administrative order after brief oral arguments. There has been consensus among all participants during the Commission's deliberations that the arguments before the entire Health Planning Review Board rarely result in a change to a hearing officer's order and are therefore unnecessary. For this reason, the Commission recommends that the current structure of the Health Planning Review Board be modified using a modified APA-like appeals process. Under this process, requests for appeals of Certificates of Need either issued or denied will be addressed to the Commissioner of the Department. The Commissioner would be responsible for assigning a Hearing Officer to hold a *de novo* hearing. (The Department should not be required to use the Office of State Administrative Hearings for Certificate of Need appeals because there already exists a body of knowledge relating to Certificate of Need and health planning in the hearing officers who have currently been appointed by the Health Planning Review Board). At the conclusion of the initial administrative hearing, the Hearing Officer assigned to the case by the Commissioner would make an initial order. Any party to the hearing, including the Department, who disputes the initial order, would have the right to request review of the initial order by the Commissioner, or his/her

designee, within 30 days of the initial order of the Hearing Officer. Furthermore, the Department should be statutorily authorized to create rules and regulations regarding the conduct of its administrative hearings.

Recommendation 2.4 (Unanimous)

*Require appellants to contribute to a Hearing Funds Pool at the time of requesting an initial administrative appeal.*

Currently, the State pays all hearing officer costs and administrative costs of appeals, except for preparation of transcripts and the administrative record, the costs for which are divided equally amongst the parties. In order to maintain a degree of separation from the Department, Hearing Officers are paid from dedicated funds from the Department of Administrative Services. The funds allocated for such appeals routinely expire long before the beginning of the next fiscal year. For this reason, the Commission recommends that appellants contribute to a Hearing Funds Pool at the time of their requests for initial administrative appeal. The statute should empower the Department to develop rules to establish an appropriate fee schedule for such appeals.

Recommendation 2.5 (Unanimous)

*Require losing parties in appeals to pay for the entire cost of the appeal, including hearing officer fees and preparation of the record, etc.*

The Commission has reviewed documentation that the success rate for most appeals is extremely low. Yet, the number of appeals sought belies this fact. Therefore, the Commission recommends that the statute be amended to provide that the losing party pay the entire cost of the appeal including hearing officer fees and preparation of the record. In combination with Recommendation 2.4, this would mean that if the actual costs of the hearing exceeded the costs contributed



into the Hearing Funds Pool by the appellant(s), the losing appellant would be required to pay additional funds up to the total cost of the appeal. In addition, at the judicial level, losing parties would be required to pay all administrative fees.

Recommendation 2.6 (Unanimous)

*Amend provisions of the statute relating to judicial appeal in a fashion similar to Workers' Compensation Statute.*

The Commission voted in favor of amending the statutory provisions relating to judicial review of final agency decisions on Certificate of Need applications. In particular, the Commission recommended the adoption of a process similar to the appeal of final awards from the Board of Worker's Compensation set forth in O.C.G.A. § 34-9-105(b), which was designed to expedite the disposition of worker's compensation claims that have been appealed to the courts of this state. See Felton Pearson Co. v. Nelson, 260 Ga. 513 (1990). Section 34-9-105(b) provides that a party to a worker's compensation dispute may appeal a final award within 20 days from the date of the final order of the Board of Worker's Compensation to superior court. Once the Board of Worker's Compensation has transmitted the record to the superior court,

*The case so appealed may then be brought by either party upon ten days' written notice to the other before the superior court for a hearing upon such record, subject to an assignment of the case for hearing by the court; provided, however, if the superior court does not hear the case within 60 days of the date of docketing in the superior court, the decision of the board shall be considered affirmed by operation of law unless a hearing originally scheduled to be heard within the 60 days has been continued to a date certain by order of the court.*

In addition, if the superior court does not enter an order on the merits within 20 days of the date of the hearing, the decision of the Board of Worker's Compensation is considered affirmed by operation of law. In the event a decision of the Board is affirmed by operation of law under this provision, subsection (d) provides that a party may seek an appeal to the court of appeals through O.C.G.A. § 5-6-35.



## Exemptions

### An Analysis and Evaluation of Statutory Exemptions from Certificate of Need Requirements in Georgia

#### Overview

##### Specific Projects Requiring Certificates of Need

Georgia's Health Planning Statute covers almost all health care facilities and many health care services. The statute is written to have a general and overriding requirement that a health care facility or service requires a Certificate of Need before it can be developed an/or offered. The statute specifically requires a Certificate of Need for the following:

- All public and private hospitals, including general, acute-care, and specialized hospitals;
- Nursing homes;
- Ambulatory surgical services or obstetrical facilities;
- Home health agencies;
- Personal care homes (with 25 or more beds);
- Inpatient rehabilitation facilities treating traumatic brain injury;
- Diagnostic, treatment and rehabilitation centers ("DTRC") (whether for-profit or not-for-profit); although, not all DTRCs require a CON. A reviewable DTRC is a facility

which either offers radiation therapy, outpatient surgery, cardiac catheterization, or biliary lithotripsy OR acquires or operates diagnostic or therapeutic equipment exceeding the CON equipment threshold.

- Major medical equipment purchases or leases (e.g. MRI, CT Scanners) that exceed the equipment threshold; the 2006 equipment threshold is set at \$823,934. The threshold is recalculated each April 1<sup>st</sup> and published at the Department's website.
- Major hospital renovations or other capital activities by any health care facility that exceeds the capital expenditure threshold. The 2006 capital expenditure threshold is set at \$1,483,083. The threshold is recalculated each April 1<sup>st</sup> and published at the Department's website.



A Certificate of Need is also required before a health care facility can:

- Offer a health care service which was not provided on a regular basis during the previous 12-month period; or
- Add additional beds.

Certificate of Need thresholds for medical equipment, construction or capital expenditure projects and limited-purpose physician-owned ambulatory surgery centers are established each year on April 1<sup>st</sup>. If the proposed project costs associated with any threshold falls below the established amount, the project is not subject to CON review and evaluation. Calculation of the thresholds is made using the U.S. Bureau of Economic Analysis' (BEA) Composite Annual Index. The equipment threshold and capital expenditure thresholds were added to the statute in 1992, and have been increased using the composite annual indices since then. The historical threshold amounts are depicted in Figure 3-1.



FIGURE 3-1.

<b>Georgia CON Thresholds Historically</b>					
<b>Effective Year</b>	<b>Date Effective</b>	<b>Date Released</b>	<b>Thresholds by Type</b>		
			<b>Equipment</b>	<b>Construction/ Capital Expenditures</b>	<b>Physician- Owned Ambulatory Surgery Centers</b>
2006	4/1/2006	3/10/2006	\$823,934	\$1,483,083	\$1,610,823
2005	4/1/2005	4/5/2005	\$775,103	\$1,395,186	\$1,515,356
2004	4/1/2004	4/15/2004	\$734,695	\$1,322,451	\$1,436,356
2003	4/1/2003	3/3/2003	\$711,225	\$1,280,204	\$1,390,470
2002	4/1/2002	3/6/2002	\$694,556	\$1,250,199	\$1,357,881
2001	4/1/2001	3/8/2001	\$667,201	\$1,200,960	\$1,304,401
2000	4/1/2000	3/7/2000	\$642,152	\$1,155,881	\$1,255,439
1999	4/1/1999	3/15/1999	\$618,053	\$1,112,494	\$1,208,315
1998	4/1/1998	3/11/1998	\$602,979	\$1,085,360	\$1,178,844
1997	4/1/1997	3/7/1997	\$586,555	\$1,055,798	\$1,146,735
1996	4/1/1996	3/15/1996	\$575,054	\$1,035,096	\$1,124,250
1995	4/1/1995	3/14/1995	\$535,469	\$996,243	<i>n/a</i>
1994	4/1/1994	3/14/1994	\$535,270	\$963,485	<i>n/a</i>
1993	4/1/1993	3/15/1993	\$518,170	\$932,706	<i>n/a</i>
1992	4/1/1992	3/17/1992	\$515,592	\$928,066	<i>n/a</i>
Prepared by: Data Resources and Analysis Section, Division of Health Planning					



## Specific Exemptions from CON

The statute specifically exempts the following projects from CON review:

- Repairs to a facility that fall below the CON review threshold;
- Acquisition of equipment that falls below the CON review threshold;
- Replacement of existing therapeutic or diagnostic equipment that received prior CON authorization;
- Projects that bring facilities into compliance with licensing requirements, life safety codes or standards of the Joint Commission on Accreditation of Healthcare Organizations;
- Cost overruns that represent less than 10 percent of the previously approved capital expenditure and do not exceed the CON review threshold; all cost overruns under \$300,000 are exempt from review;
- A hospital that maintains an occupancy rate greater than 85 percent for the preceding 12-month period may increase its capacity by 10 beds or 10 percent of its existing inventory (whichever is less) every two years without a CON unless the cost associated with the increase exceeds the capital threshold. The hospital must submit a written request for determination regarding exemption under this provision, and the request must document the facility's month-by-month occupancy; and
- An Ambulatory Surgery Facility that is physician owned, office-based, and single-specialty, the establishment and development of which does not exceed the limited-purpose physician-owned ambulatory surgery centers

threshold. The 2006 limited-purpose physician-owned ambulatory surgery center threshold is \$1,610,823. The threshold is recalculated each April 1 and published at the Department's website.

- Capital activities by any health care facility that is less than the capital expenditure threshold. The 2006 capital expenditure threshold is set at \$1,483,083. The threshold is recalculated each April 1<sup>st</sup> and published at the Department's website.
- Major medical equipment purchases or leases (e.g. MRI, CT Scanners) that are less than the equipment threshold; the 2006 equipment threshold is set at \$823,934. The threshold is recalculated each April 1<sup>st</sup> and published at the Department's website.

If a service, project, or facility is exempt from CON, the activity need not be reported to the Department of Community Health.

## Determinations and Letters of Non-Reviewability

As a service to the healthcare providers of this state, the Division of Health Planning has established a voluntary process where facilities and practitioners can make a formal inquiry to the Division as to whether or not a particular project will need to file a CON application. This basic issue occurs in a number of diverse circumstances as discussed below.

OCGA §31-6-47 delineates approximately 16 instances where listed projects are statutorily exempt from the requirements to obtain a certificate of need. This statute authorizes the Department to establish rules to expedite or waive reviews of certain projects expenditures when the project is exempt.



The Department has adopted two sets of rules establishing a process wherein a facility or provider can receive a written opinion from DHP as to the need to obtain a CON prior to implementing a project. These rules are primarily found at DCH Rule 111-2-2-10 and Rule 272-.07.

The three most common types of requests are: (1) Letters of Determination; (2) Letters of Non-Reviewability for Below Threshold Diagnostic or Therapeutic Equipment; and (3) Letters of Non-Reviewability for Physician-Owned, Single Specialty, Office-Based Ambulatory Surgery Facilities.

Letters of Determination are a tool that can be utilized by facilities and practitioners to receive a written opinion as to the applicability of certain CON statutes and rules to their particular situation. Examples are questions concerning the application of Department rules or statutory provisions to questions concerning reviewability, grandfathering, relocations, replacements and the application of a particular rule or statute to a particular project or proposed action. A Letter of Determination does not address general issues relating to policy and procedure.

Letters of Non-Reviewability for Below Threshold Diagnostic or Therapeutic Equipment assists a party in determining whether or not the project involving major medical equipment will exceed the statutory expenditure threshold of \$823,934. The question is simple, but the answer is often complicated. The statutes and rules provide that not only is the fair market value of the particular piece of equipment considered when calculating an aggregated total; but also all expenditures relating to new construction, renovation, furnishings and functionally related items of equipment that are associated with or simultaneously incurred along with the basic equipment cost. This process, though voluntary, provides a facility or practitioner with an opinion from the Department as to the reviewability of their project.

Letters of Non-Reviewability for Physician-Owned, Single Specialty, Office-Based Ambulatory Surgery Facilities. Any non-

hospital owned ambulatory surgery center (ASC) that is utilized either by general surgeons or physicians of multiple specialties or an ambulatory surgery center whose costs exceeds the statutory expenditure threshold of \$1,483,083 must receive a CON. The statutes and rules covering those facilities are found primarily at OCGA§31-6-2(14)(G)(iii) and DCH Rule 272-2-(15). Physician offices and physician-owned, single specialty ASC's costing below the threshold are exempt from review by the Department. However, in order for a physician-owned, single specialty ASC to obtain a license from the Department of Human Resources, that Department requires such facilities to first obtain a Letter of Non-Reviewability from DCH. When determining if the facility exceeds the threshold, the facility must provide DCH with documentation and sworn affidavits concerning issues such as physician ownership, the name and specialty of every physician in the practice group, construction costs documented in writing by a licensed Georgia architect, project schematics, fixed equipment expenditures, legal and various other administrative fees. A physician or group of single specialty physicians will seek a Letter of Non-Reviewability because it is a prerequisite to licensure, which is a prerequisite to receiving reimbursement from most insurers for facility fees.

Letters of Determination and Letters of Non-Reviewability are issued to a particular party, non-transferable, and site specific. Any equipment or ASC projects receiving approval through the LNR process must, upon completion, submit to the Department sworn affidavits and itemized statement sheets establishing that the actual total costs of the project did not exceed the threshold; otherwise the LNR may be rescinded.

The volume of these requests, the complexity necessary to apply the statutes and rules, as well as processing applicant appeals and third party challenges to projects, consumes an inordinate amount of Department staff time. Conversely, the Department is providing valuable and meaningful service to the applicants and the public.



## Comparison States

### Exemptions

Most of the review states have similar exemptions. However, there are two states which structure the statute to only apply to services and/or projects which are specifically defined in the statute. These statutes do not focus on exemptions for this reason; however, they contain a few exemptions to clarify those services/projects/facilities that are not covered when the possibility may arise that something that is specifically defined as being covered may be misconstrued.

### Review Thresholds

Of the 8 comparison states that have certificate of need programs, 5 have defined specific dollar amounts for review thresholds. Of these 5 states, four have threshold amounts set higher than in Georgia; however, three of these states have thresholds which do not adjust annually. Comparative review thresholds for the CON comparison states are listed in Figure 3-2 and for neighboring southern states in Figure 3-3.

**FIGURE 3-2.**

STATE	Capital Expenditure	Equipment	Adjusts Annually?
Georgia	\$1,483,083	\$823,934	Yes
Colorado	--	--	--
Florida	None	None	NA
Iowa	\$1,500,000	\$1,500,000	No
Maine	\$2,666,198	\$1,333,099	Yes
Massachusetts	\$12,516,300	\$1,333,072	Yes
Oregon	None	None	NA
Utah	--	--	--
Washington	Varies by Service	None	NA
W. Virginia	\$2,000,000	\$2,000,000	No
Wisconsin	\$1,000,000	\$600,000	No



FIGURE 3-3.

STATE	Capital Expenditure	Equipment	Adjusts Annually?
Georgia	\$1,483,083	\$823,934	Yes
Alabama	\$4,251,780	\$2,125,890	Yes
Arkansas	\$500,000 (SNF Only)	None (AR does not regulate equipment)	No
Florida	None	None	N/A
Kentucky	\$1,951,612	\$1,951,612	Yes
Mississippi	\$2,000,000	\$1,500,000	No
North Carolina	\$2,000,000	\$750,000	No
South Carolina	\$2,000,000	\$600,000	No
Tennessee	\$2,000,000	\$1,500,000	No
Virginia	\$5,000,000	Any Amount	No

### Determination of Reviewability

Five states readily provide information on submissions of requests to determine if projects are reviewable, and all states provide the service. A determination of reviewability is incorporated as part of the Letter of Intent (LOI) process in both Maine and Oregon. The LOI in Maine requires that the applicant request a ruling on whether a CON is needed. In Oregon, the LOI serves as the request for determining the need for review. Florida, Iowa, and Massachusetts do not specifically address this in available information. Georgia is the

only state that charges for the determination: \$250 per request, with each proposal requiring a separate determination.

Another factor associated with the determination of whether a project requires a CON is the applicant's ability to self-determine, based on available information, whether a project is reviewable. All states provide information online; however, the ease with which it is accessed varies across states. A review of states' CON statutes or rules is generally required to determine reviewability except for Georgia, Massachusetts,



and Washington. These states provide a listing of reviewable services either on a separate web page or in brief, more reader-friendly documents. It is most difficult to determine reviewability in Iowa and Oregon. Although some states provide information on reviewability online, most states have exceptions and specific considerations which require detailed review of statutes or rules.

Florida is the only state requiring a Letter of Non-Reviewability or exemption for certain proposals. Florida requires that

applicants request an exemption for each proposal and charges a fee of \$250 for each request.

## Options

### Option 3.0: Notification of Exemptions

*Require Notification of Items Exempt from Review.*

3.0A: Report projects that were CON exempt on annual survey(s) for those facilities with existing certificates of need. For those facilities that are new or that do not have a prior CON, require advance notification to the Department of the activity that the facility believes to be exempt. Require a response from DCH regarding the non-reviewability of the projects.

3.0B: Report projects that were CON exempt on annual survey(s) for those facilities with existing certificates of need. For those facilities that are new or that do not have a prior CON, require advance notification to the Department of the activity that the facility believes to be exempt. Do not require a response from DCH regarding the non-reviewability of the projects.

3.0C: Report projects that were CON exempt on annual survey(s) for those facilities with existing certificates of need. For those facilities that are new or that do not have a prior CON, require advance notification to the Department of the activity that the facility believes to be exempt. Do not require a

response from DCH regarding the non-reviewability of the projects for facilities with existing certificates of need, but require an advance response from DCH for those facilities that are new or that do not have a prior CON.

3.0D: Require notification to the Department of a specified list of exempt items, activities, or facilities only. The Department would not be required to provide advance approval.

3.0E: Require notification to the Department of a specified list of exempt items only. The Department would be required to provide advance approval.

### Option 3.1: Review Thresholds

*Maintain existing review thresholds.*

### Option 3.2: Review Thresholds

*Raise the capital expenditure threshold \$1.75 Million.*

3.2A: Annually adjusted

3.2B: Not annually adjusted



### Option 3.3: Review Thresholds

*Abolish capital expenditure threshold except for those expenditures directly associated with clinical health services.*

Under this option all capital improvement projects would be exempt from review unless the space was for clinical health services.

### Option 3.4: Review Thresholds

*Abolish equipment thresholds.*

### Option 3.5: Review Thresholds

*Abolish both capital expenditure and equipment thresholds and write service-specific rules for all regulated health services.*

### Option 3.6: Exemptions

*Maintain existing list of exempt projects and activities.*

### Option 3.7: Exemptions

*Modify the existing list of exempt projects and activities.*

3.7A: Keep the existing list and add certain non-clinical projects from specified list, including parking lots, parking decks, or parking facilities; medical office buildings – construction or adding space; state mental health facilities; and renovation of physical infrastructure where clinical health services are not being added or affected.

3.7B: Delete some items from the existing list of exemptions and add certain non-clinical projects from specified list,

including parking lots, parking decks, or parking facilities; medical office buildings – construction or adding space; state mental health facilities; and renovation of physical infrastructure where clinical health services are not being added or affected.

### Option 3.8: Exemptions

Allow facilities or services to be relocated under certain circumstances (e.g. Acts of God) providing that there is no adverse impact on other existing providers. Statute would be modified to allow DCH to define the circumstances and conditions (e.g. within a planning area, county, etc.).

### Option 3.9: Statutory Framework

*Revise the statute to be structured as requiring a CON for only those items specified as opposed to the current structure where the general rule is that a CON is necessary unless an item is specifically exempted.*



## Recommendations

### Recommendation 3.0 *(Unanimous)*

*Authorize the Department to require Notification of Items Exempt from Review for certain exemptions.*

The Commission has heard testimony from the Department and other stakeholders that occasionally a provider will undertake a task that it believes to be exempt from CON but later learns that a CON was required. In order to prevent such occurrences, the Commission recommends that the statute specifically authorize the Department to have the ability to determine (by rule) which exemptions rise to a level that would require notification to the Department and/or advance approval by the Department. Specifically, the Commission recommends that once so empowered, the Department require advance notification and approval for exemptions related to exempt ambulatory surgery centers (if the exemption remains) and equipment purchased below threshold.

### Recommendation 3.1 *(Unanimous)*

*Raise the capital expenditure threshold from the current \$1.495 million to \$1.75 million and maintain the provision relating to an annual adjustment of this dollar amount.*

After thoroughly reviewing the dollar thresholds of other CON states and neighboring southern states, the Commission recommends that the dollar threshold for capital expenditures be increased to \$1,750,000. In addition, the Commission recommends that the statute continue to provide for annual adjustments to this dollar threshold.

### Recommendation 3.2 *(Unanimous)*

*Maintain the existing provisions relating to the amount of the Equipment Expenditure threshold.*

Currently, the dollar amount applicable to expenditures on equipment is \$823,934 as adjusted annually. After reviewing similar equipment expenditure thresholds in comparison states, the Commission recommends maintaining the existing dollar threshold for such equipment.

### Recommendation 3.3 *(Unanimous)*

*Modify the existing list of exempt projects and activities to exempt non-clinical projects, such as parking decks, medical office buildings, and improvements of physical plant infrastructure, etc., and modify or delete certain current exemptions.*

Certain projects currently require Certificates of Need even though they do not involve clinical health services and are routinely approved. The review of these projects requires time and resources that would otherwise be available to focus on clinical health services. Therefore, the Commission recommends that the list of statutory exemptions be modified by adding the following: parking lots, parking decks, or parking facilities; computer systems, software, and other information technology; medical office buildings, both construction and addition of space; state mental health facilities; and renovation of physical infrastructure where clinical health services are not being added or affected. In addition, the Commission recommends that the current exemption relating to repair of physical plant be modified. Currently, the exemption is limited



to repairs of physical plant which do not cost more than the capital expenditure threshold. Any repair of physical plant should be exempt regardless of cost.

The Commission also recommends removing the exemption for “Christian Science Sanatoriums.”

Recommendation 3.4 *(Unanimous)*

*Add a statutory exemption for relocation of an existing facility within a limited distance.*

Currently, there is no exemption from Certificate of Need regulation regarding the relocation of an existing facility. This has proved a hardship on entities that may need to relocate for reasons beyond their control, such as a fire or expiration of a lease. This is also a particular concern for older facilities, which are in need of being replaced and which are otherwise prevented from replacing or expanding on site. Therefore, the Commission recommends that the list of statutory exemptions be modified to add “replacement of existing facilities within a defined distance and which would have no adverse impact on other existing providers.”



## Miscellaneous

### An Analysis and Evaluation of Miscellaneous Legal and Regulatory Issues Associated with the Certificate of Need Program in Georgia

#### Overview

##### Department Discretion

The Georgia Supreme Court has limited the Department's ability to decide which services require a Certificate of Need and which do not. In fact, the Court has gone as far as to say that the Department has no statutory authority to exempt services/projects that are not already exempted by the statute. Since Health Care is a constantly changing environment, either the Department should be given this discretion by statute or the General Assembly would need to address these issues more frequently.

##### Conditional Approval

The Department has limited ability to issue conditional CONs under the statute. However, the Department may require that any applicant for a CON commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. § 31-6 which violates such an agreement, shall be liable to the

Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines.

##### Review Considerations

The CON Statute defines the review criteria that should be applicable to the review of each CON application by the Department. The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, is on the applicant. In conducting review and making findings for Certificates of Need, the Department must consider whether:

- the proposed new institutional health service is reasonably consistent with the relevant general goals and objectives of the State Health Plan. The goals and objectives related to issues addressed in the State Health Plan, which are relevant to the Certificate of Need



proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and in some respects may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan or any component thereof shall not supersede the Rules in such determination;

- the population residing in the area served, or to be served, by the new institutional health service has a need for such services. In analyzing this consideration, the Department must consider data and the Department has defined by rule the most appropriate data sources for such a determination. Population projections used by the Department are resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department. Updated resident population projections are utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data. The projection period or horizon year for need determinations is five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year is advanced to the next projection year or horizon year on or about April 1 of each year. Inpatient facilities are inventoried on the basis of bed capacity approved, grandfathered, or authorized through the certificate of need process regardless of the number of beds in operation at any given time or which may be licensed by the Office of Regulatory Services, Department of Human Resources. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends include, but are not limited to, the following:

- any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;
  - Cost reports submitted to fiscal intermediaries and the Department;
  - periodic special studies or surveys, as produced or formally adopted or used by the Department;
  - the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and
  - such other data sources utilized by the Department for measurement of community health status.
- existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid. In analyzing these criteria, the Department supports the concept of regionalization of those services for which a service-specific rule exists. Furthermore, the Department considers economies of scale where need exists for additional services or facilities.
  - the project can be financed adequately and is in the immediate and long term, financially feasible;
  - the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;



- the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;
- the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;
- the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;
- the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;
- the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;
- the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;
- the proposed new institutional health service meets the clinical needs of health professional training programs;

- the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance or cost effectiveness; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care; and
- the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations.

There is no specific review criteria related to the quality of the health care services delivered or proposed to be delivered.



## Comparison States

### Review Criteria

For the most part, the comparison states have similar review criteria to Georgia. However, many of the states have particular review criteria associated with the quality of health care services delivered or proposed to be delivered.

## Options

### Option 4.0: Review Criteria

*Add a review criterion regarding the quality of health care services to be offered or which are offered in the health care facility.*

### Option 4.1: Review Criteria

*Statutorily provide for the Department to give an advantage to projects and applicants under certain situations.*

4.1A: Provide an advantage to those projects which will improve hospital-physician relations

4.1B: Provide an advantage to those projects and applicants which agree to provide an underrepresented service, e.g. psychiatric, trauma, in addition to the service that they are applying for.

4.1C: Provide an advantage to applicants who exhibit exceptional preparedness for natural and man-made emergencies.



## Recommendations

### Recommendation 4.0 (Unanimous)

*Add a review criterion regarding the quality of health care services to be offered or which are offered in the health care facility.*

Currently, the Department's rules for specific services mandate minimum quality standards, such as JCAHO accreditation, minimum volumes, quality improvements and assurance practices, utilization review practices, etc. Therefore, the Commission recommends that a specific general review consideration be added to the statute relating to quality. In addition, the Commission recommends that the statutory goals of the program be redefined to include "ensuring access to quality services."

### Recommendation 4.1 (Unanimous)

*Statutorily provide for the Department to give favorable consideration to projects and applicants where the applicant agrees to provide an underrepresented service in addition to the service for which application was made.*

The Commission has heard evidence regarding the underrepresentation of certain services in the state, largely because of lack of funding sources. As a means to encourage the offering of such services, the Commission recommends the addition of a specific review criterion relating to the potential for the project to provide or enhance the provision of an underrepresented service, e.g. inpatient psychiatric care, trauma, etc. The Department would create rules relating to this criterion such that it would annually define the underrepresented services for the upcoming year and would also develop rules to allow an advantage to equally qualified applicants who agree to provide an underrepresented service in addition to the project for which it has applied.

### Recommendation 4.2 (Unanimous)

*Recommend that the Department's Health Planning functions be adequately staffed and supplied with the appropriate resources.*

Many of the recommendations of the Commission require that the Division of Health Planning increase staffing and resources in order to plan proactively and to monitor health care facilities and services that have been awarded certificates of need. Therefore, the Commission recommends that the budget and staffing of the Division of Health Planning be reviewed to ensure that the appropriate resources are available for these additional activities.

### Recommendation 4.3 (Unanimous)

*Recommend that the Department adopt and follow a proactive and prospective approach to need methodologies and emerging technologies by addressing such factors annually in its annual report.*

Currently, the CON statute requires the Health Strategies Council to submit an annual report concerning health planning. Because the Commission has recommended that the Health Strategies Council's role be advisory in nature, the Commission recommends that the responsibility for an annual report be delegated to the Department of Community Health. The Commission further recommends that the Department adopt a proactive and prospective approach to need methodologies and access to health care services by undertaking an annual analysis of such issues in the annual report.



## Medical/Surgical Services

### An Analysis and Evaluation of Short-Stay General Hospital Bed Services in Georgia

#### Overview

##### Background

During the mid-1980's, several changes occurred that impacted the delivery of inpatient hospital care. Among these changes were drastic modifications in the way hospitals were reimbursed for inpatient hospital care. The Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) changed its reimbursement mechanism to encourage the delivery of care in outpatient settings. Nationwide, this action resulted in the exponential growth of outpatient care services. Similarly, throughout the 1980's and 1990's, Georgia hospitals experienced decreased inpatient days and increased use of outpatient services. Beginning in the late 1990's, however, inpatient admissions nationwide began to increase and, according to data from the American Hospital Association, the level of inpatient admissions began to approach the level of outpatient visits in 2004.

Technological advances over the past two decades also greatly changed the way patient care was delivered. For example, as a result of technological innovations, more surgical procedures could be performed in shorter periods of time and fewer resources would be needed to support patients. Increasing penetration of Health

Maintenance Organizations (HMO), which advocated the use of primary and preventive health care services and the provision of health care services in outpatient settings, along with the utilization of support services including home health services and skilled nursing facilities further impacted the need for and duration of inpatient hospital services.

In the 2000's, hospitals began treating increasingly large numbers of sick patients. Long-range population trends project that people will be living longer but will be sicker and will consume greater healthcare resources. While there has been an increase in the provision of services to outpatient settings, hospital care still accounts for the largest portion of healthcare dollars. Much of this utilization can be attributed to hospital births, emergency room visits and a growing and aging population.

In response to the changes in hospital service delivery, hospitals downsized inpatient beds and shifted resources to outpatient settings between 1980 and 2000. Other hospitals completely closed their doors because of lower utilization and increased financial risks associated with new payment systems. Some hospitals leveraged resources by consolidating and becoming major hospital systems. Other smaller community hospitals,



particularly those hospitals in rural areas, were unable to absorb the financial impact of policy changes and reduced reimbursement rates for hospital care. Consequently, the number of hospitals and hospital beds-per-capita has fallen over the last 20 years.

Hospital use rates are dependent in part on the composition of the population. The American Hospital Association reports that increases in population and aging have the greatest impact on inpatient days. Data by the National Center for Health Statistics (NCHS) support findings that patients over 65 years of age use services at a significantly higher rate than other age groups. National discharge data shows that persons over the age of 65 years were three times more likely to use inpatient services than all other age groups in 2000. Growth of population in general is the most pressing force on inpatient demand. Increases in population have a greater impact on the utilization of inpatient services than any other factor. Other factors, such as per capita income, managed care, and outpatient surgeries, are all reported to decrease the number of inpatient days.

Emergency room visits are one of the main drivers for inpatient utilization. According to the *2000 National Hospital Ambulatory Medical Care Survey*, emergency room utilization in the United States has increased by 14 percent since 1997 and approximately 12 percent of emergency room visits result in hospitalization. The American Hospital Association reports that half of emergency departments are at or over capacity. Hospitals divert patients to other emergency departments when they can no longer accept all or specific types of patients by ambulance. In a survey conducted by the Lewin Group, an affiliate of the American Hospital Association, the most common reasons for emergency department diversions are the lack of critical care beds, staffing shortages and lack of general acute care beds. The emergency department is a point of critical access of care for most uninsured patients and diversions are a symptom of hospital capacity constraints. Emergency department services are recognized as critical services that should be accessible to all residents,

especially since the emergency department is a major point of access for inpatient care.

Another factor impacting hospitals' delivery of services is the health professional workforce shortage. The American Hospital Association reports that hospitals had an estimated 118,000 registered nurse vacancies as of December 2005. Many medical schools and nursing programs reported a decline in the number of enrollees and admission applications. Lack of general interest, increasing opportunities in the information technology field, competitive salary in other job sectors, and diminishing support in the workplace environment are all factors that have made the healthcare industry less appealing than it was twenty years ago. A major concern for hospitals is the supply of adequate staffing to support for current and future population needs.

Over the last two decades, Georgia hospitals have been impacted by many of the same national trends discussed above. Georgia hospitals have also experienced declines in staffing levels, decreases in reimbursements, multiple hospital closures, increases in outpatient volume, general decline in inpatient volume, increases in emergency room visits, and competition for a shrinking pool of private payers, and phenomenal growth in population and diversity. Moreover, Georgia's healthcare landscape presents some unique demographic characteristics that influence inpatient hospital services. It is comprised of 159 counties, has increased rates of morbidity and mortality from diseases, a populous metropolitan area encompassing almost 40% of the States' population, and concentrated economic resources. These indicators challenge Georgia policy makers to ensure the most efficient utilization of limited healthcare resources in a manner that is cost effective and accessible to all citizens of Georgia.



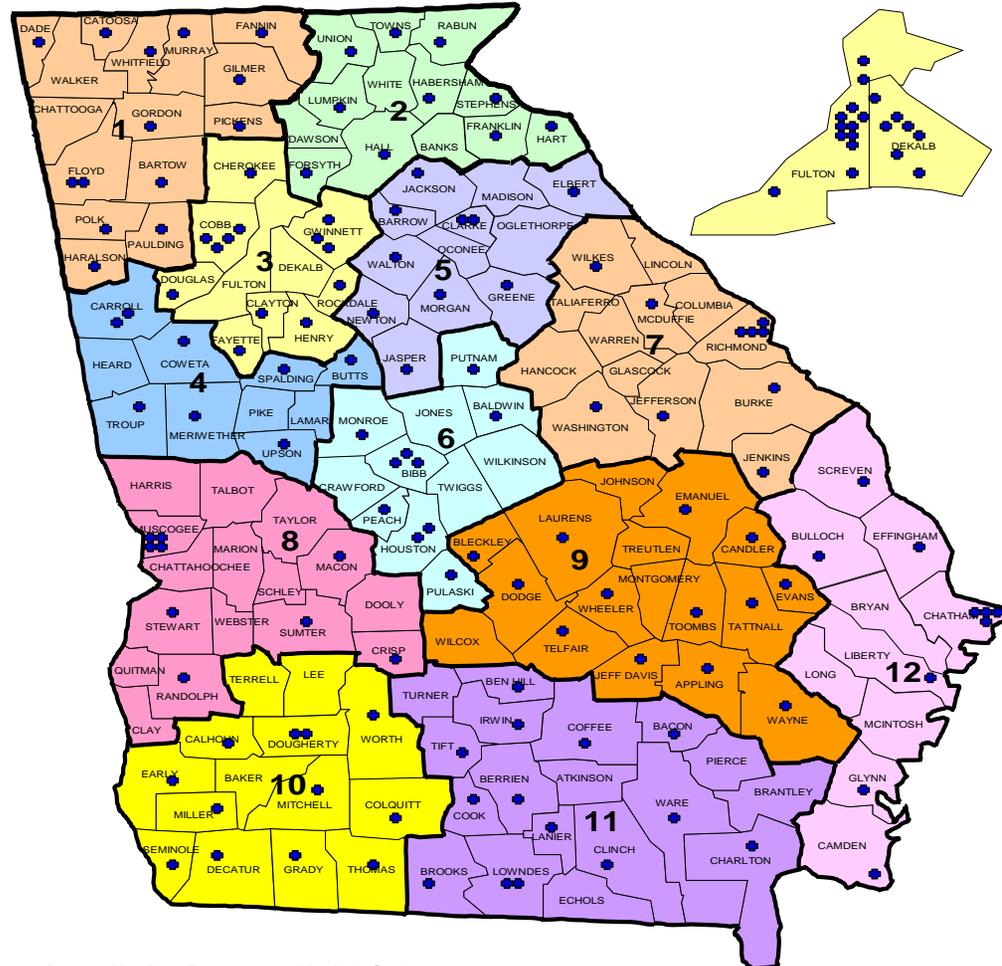
## Access, Supply and Distribution

As of 2004, there were 153 hospitals authorized to offer inpatient hospital services in Georgia. Figure 5-1 depicts the current distribution of hospitals and bed capacity around the state, by state service delivery region ("SSDR"). In addition, Figure 5-2 illustrates both the current number of hospitals and the number of beds per 1,000 persons by SSDR. SSDR 3, encompassing metro-Atlanta area, is the most populous region of the state. Although metro-Atlanta has the highest number of hospitals, it has a lower number of available beds per population (2.4 per 1,000) when compared to other less populated regions of the State. Area 7 has the largest number of available beds in the state (4.8 per 1,000) in comparison to its population.



Figure 5-1.

### General Acute Care Hospitals by State Service Delivery Region



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



Figure 5-2



Source: Official Agency Inventory, Georgia Department of Community Health, Division of Health Planning

The CON Commission’s consultants used 8 other states to conduct a comparative study to Georgia’s healthcare delivery system, including hospitals. Those states – Colorado, Florida, Iowa, Massachusetts, Maine, Oregon, Utah, Washington, Wisconsin, and West Virginia -- and the number of hospitals and beds per 1,000 are reflected on Figure 5-3. Georgia ranks fifth in the number of beds per 1,000 population among these comparison states.



Figure 5-3

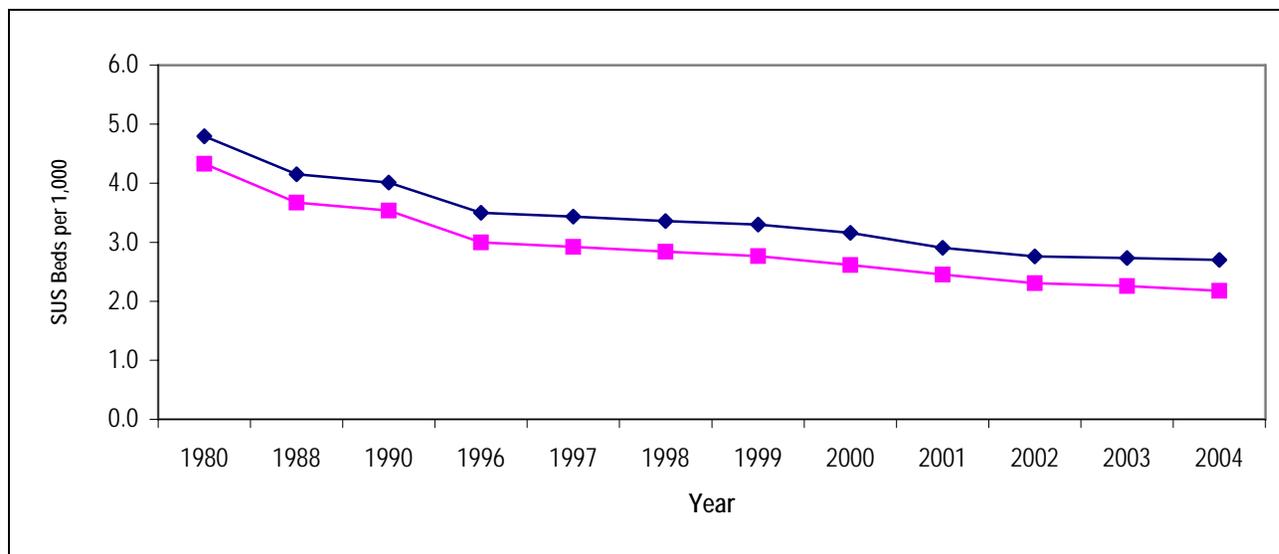
State	Beds per 1,000	
	General Hospitals	Persons
West Virginia	54	4.1
Iowa	122	3.7
Oregon	56	3.1
Florida	277	2.9
Georgia	153	2.8
Maine	37	2.7
Wisconsin	NR	2.7
Massachusetts	143	2.5
Colorado	81	2.0
Utah	52	1.9
Washington	93	1.8

Since 1980, 20 general acute care hospitals have closed and 5 hospitals have merged with other facilities. A listing of hospital closures in Georgia occurring since 1980 appears in Appendix 2. Total bed capacity decreased from 25,575 beds in 1980 to 23,913 beds in 2004, a 6.5% decrease in total beds. Since 1980, total inpatient days have decreased by 23% from 5,842,232 days in 1980 to 4,420,892 days in 2004.

In addition, set-up and staffed (SUS) bed capacity has declined from 4.3 bed per 1,000 population to 2.2 beds per 1,000 population in 2004, a 49% decrease in the rate of SUS beds to population. Total SUS beds decreased from 23,104 beds in 1980 to 19,305 in 2004, a decrease of 16% in total SUS bed capacity. Health planners believe that the decrease in SUS capacity has been impacted by both workforce shortage and population growth. Figure 5-4 illustrates the trend in total beds and set-up and staffed bed capacity since 1980.



**Figure 5-4: Set Up and Staffed Beds and Total Capacity Beds, 1980-2004.**

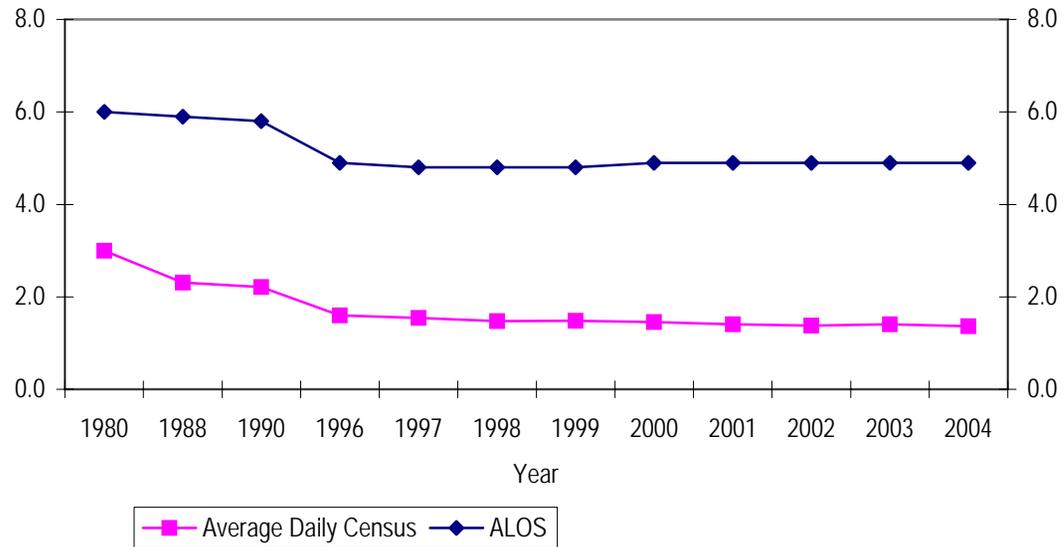


Source: Annual Hospital Questionnaire 1980-2004, Georgia Department of Community Health, Division of Health Planning

Average daily census and average length of stay have leveled but are significantly lower than they were during the 1980s. According to the American Hospital Association, average length of stay is hovering at 5.2 days per patient nationally. In 1980, the average length of stay in Georgia hospitals was 6 days per patient and average daily census was 3.0 patients per 1,000 population. In 2004, Georgia's average length of stay declined to 4.8 days per patient and the average daily census was 1.36 patients per 1,000 population.



**Figure 5-5: Trends in Average Daily Census and Average Length of Stay, 1980-2004.**



Source: Annual Hospital Questionnaire 1980-2004, Department of Community Health, Division of Health Planning

Over the past five years, short-stay general hospital bed admissions have increased in Georgia. In 2000, there were a total of 843,214 short-stay hospital bed admissions to Georgia hospitals. Data reported for the year 2004 indicate that the volume of admissions have increased to 928,987, a 9% increase since 2000. As depicted in Figure 5-5 above and Figure 5-6 below, average length of stay has changed only slightly between 2000 and 2004, from 4.9 days to 4.8 days.



Figure 5-6: Trends in the Utilization of Short-Stay General Hospital Beds, 2000-2004.

<b>Utilization Trends of Short-Stay General Hospitals, 2000-2004</b>						
	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>% Change</b>
<i>Number of Hospitals</i>	159	156	151	152	152	-4.40%
<i>Authorized Beds (existing &amp; pending)</i>	24,123	23,681	23,534	23,754	23,913	-0.87%
<i>Set Up &amp; Staffed Beds</i>	20,035	20,014	19,644	19,645	19,305	-3.64%
<i>Total Population</i>	8,186,453	8,354,887	8,523,607	8,692,390	8,861,063	8.24%
<i>Total Admissions</i>	841,404	875,522	892,108	924,962	928,987	10.41%
<i>Total Inpatient Days</i>	4,066,462	4,198,934	4,296,855	4,460,782	4,420,892	8.72%
<i>Average Length of Stay</i>	4.83	4.80	4.82	4.82	4.76	-1.53%
<i>Occupancy Rate-Total (existing &amp; pending) Beds</i>	46.18%	48.58%	50.02%	51.45%	50.65%	9.67%
<i>Average Daily Census-Total (existing &amp; pending) Beds</i>	11140.99	11503.93	11772.21	12221.32	12112.03	8.72%
<i>Occupancy Rate-Set Up &amp; Staffed Beds</i>	55.61%	57.48%	59.93%	62.21%	62.74%	12.83%
<i>ADC-Set Up &amp; Staffed Beds</i>	11140.99	11503.93	11772.21	12221.32	12112.03	8.72%
<i>Total Discharges</i>	807,913	856,546	874,739	917,215	917,016	13.50%
<i>Discharges per 1000 Population</i>	98.69	102.52	102.63	105.52	103.49	4.86%
<i>Patient Days per 1000 Population</i>	496.73	502.57	504.11	513.18	498.91	0.44%

Finally, many health planners view emergency room visits as a major driver of increases in the number of hospital admissions because the emergency department is one of the major points of access for inpatient care in short-stay general hospitals. Emergency departments are required to provide care to all presenting patients regardless of their ability to pay. Given such a mandate, they are often over-crowded.



Despite cost containment strategies, emergency department visits continue to increase in Georgia hospitals. This causes a drain on emergency room resources since care delivered in emergency rooms are provided by clinical specialists and represent among the highest level of service in hospital settings. In 2004, more than 45 percent of general hospital inpatient admissions originated in the emergency department. In 2000, the admission rate was 43.1% and even lower in 1999. According to data collected by the Department of Community Health/Division of Health Planning, over the past five years Georgia has experienced an increase in the number of patients that present to the emergency room for care. Emergency room visits and patients needing emergent care are expected to increase. Increasing rates of emergency room diversions also impacted hospitals' ability to provide appropriate services. The growing emergency room diversion crisis added to the committee's concern for patient safety and the need to provide adequate resources to serve local communities. Please see Figure 5-7.

**Figure 5-7: Emergency Room Visits Statewide and Admissions from ER Visits, 1998-2004.**

CY	ER Visits per 1,000	Percent Admissions from ER
1998	420	44.7%
1999	434	41.6%
2000	397	43.5%
2001	408	45.0%
2002	413	45.5%
2003	425	45.3%
2004	413	45.4%

Source: Annual Hospital Questionnaire, 1998-2004, Georgia Department of Community Health, Division of Health Planning



## Cost

Controlling the rising costs of healthcare is of grave concern to state and federal health officials. In an effort to ensure that resources are effectively allocated in the most efficient manner, health policy makers have attempted to implement strategies through CON guidelines and other legislative regulations. Because healthcare in the United States is a trillion dollar industry, monitoring healthcare costs is a major area of political discussion. The costs savings associated with DRG payments and managed care brought about new insights for regulators in the healthcare market. Although the delivery of care in outpatient services is increasing and hospital inpatient services have decreased, hospitals continue to represent the largest share of the health care dollar.

In the early 1990s, employers and insurers forced consumers into managed care plans. Managed care was credited for decreasing the double-digit healthcare inflation average experienced in the 1980s to single digit averages. The savings redeemed from managed care plans were attributed to streamlining consumer product choice and the provision of incentives that encouraged provider's to limit excess services by assigning primary care physicians as gatekeepers to specialized services. Reports document that there has been an inverse relationship between managed care penetration and the need for inpatient hospital services.

In the late 1990's consumers and providers began to rebel against tight restrictions placed on managed care policies that negatively impacted provider and patient relationships. Several changes

became evident: legislatures intervened by forcing insurance plans to provide basic types of coverage and to limit service constraints, consumers chose less stringent plans that offered more flexibility in choice of physicians and products, and managed care plans responded by becoming less restrictive on product types and expanding networks. These changes gave consumers more power and control when making healthcare choices. Comprehensive consumer rights laws empowered healthcare consumers to litigate changes in managed care planning and policy. There is a growing consensus that managed care plans can no longer produce health care savings that were experienced in the 1990s. Other forces, such as increases in an aging population, will drive up the demand and potentially the cost of inpatient care.

In Georgia, the average charge per case for short-stay general hospital bed admissions in Georgia in 2004 was \$19,205 (total general inpatient charges/inpatient admissions). The average charge per hospital ranged from \$2,671 at Phoebe Worth Medical Center to \$43,873 at Atlanta Medical Center. The average charges per case from 2000 to 2004 are displayed in Figure 5-8. In Figure 5-9, the amount of indigent and charity care, as a percentage of adjusted gross revenue, is depicted for 2000-2004, both for hospitals with indigent and charity care commitments and those without. Louis Smith Memorial Hospital in Lakeland, Georgia had the highest level of indigent and charity care as a percentage of Adjusted Gross Revenue in 2004, at 20.2 percent. Medical Center of Central Georgia in Macon, Georgia had the highest amount of uncompensated indigent and charity care charges reporting that \$74,340,479 in patient charges were written-off to indigent and/or charity care cases.



Figure 5-8: Average Charges per Case, 2000 to 2004

<b>Average Charge Per Case, Short-Stay General Hospitals, 2000-2004</b>			
<b>CY</b>	<b>Total Inpatient Charges</b>	<b>Inpatient Admissions</b>	<b>Average Charge/Case</b>
2000	\$10,752,543,151	841,404	\$12,779
2001	\$12,057,595,900	875,522	\$13,772
2002	\$13,674,973,264	892,108	\$15,329
2003	\$15,914,454,496	924,962	\$17,206
2004	\$17,841,269,218	928,987	\$19,205

Figure 5-9: Average Indigent and Charity Care Rate, 2000 to 2004

<b>Average Uncompensated Indigent and Charity Care Write-Off, Short-Stay General Hospitals, 2000-2004</b>			
<b>Year</b>	<b>Adjusted Gross Revenue</b>	<b>Uncompensated Indigent and Charity Care Charges</b>	<b>Indigent and Charity Care as % of AGR</b>
2000	\$12,745,850,926	\$607,800,891	4.8%
2001	\$14,207,969,901	\$756,523,686	5.3%
2002	\$15,758,790,973	\$822,672,638	5.2%
2003	\$17,868,625,453	\$969,596,073	5.4%
2004	\$19,563,508,580	\$1,070,777,730	5.5%



## Quality

Quality of care is important to healthcare consumers, providers and employers. Consumers and payers continue to raise questions about the quantity and quality of services that they receive for the dollars they are spending on healthcare. National attention is focused on quality of care and consumer report cards are popular tools for guiding consumer decision-making. Consumer product knowledge and direct-to-consumer advertising of pharmaceuticals and other medical advances add to healthcare expense. Consumer product knowledge increases as medical information and advice become more readily available via Internet access.

Currently, the Certificate of Need program does not monitor quality issues with respect to hospital on an ongoing basis. Certain quality control issues are addressed at the time a hospital applies to add beds, but there is currently no regulatory authority for the Department to assess quality performance indicators after the CON review process is complete.

The research literature and the results of the Commission's study by the Georgia Health Policy Center were mixed, some researchers finding significant volume and outcome difference among states with CON and others found little differences. Moreover, the researchers have found it difficult to detect a pattern related to CON from the available data in comparison states.



## Current Regulatory Scheme

### Georgia

#### *Department of Community Health.*

Under Georgia health planning law, the establishment of new, replacement or expanded short-stay general hospital beds requires Certificate of Need approval. To guide the development of all short-stay general hospital beds, the state health plan contains planning policies, a need projection, and criteria and standards for reviewing CON applications. The law and the rules of the Department of Community Health/Division of Health Planning, require a Certificate of Need (CON) prior to the establishment of a new, replacement or expanded hospital facility.

Need for short-stay general hospital beds are projected on an institutional rather than a regional or statewide basis, because these services are considered basic hospital services. The Department's current need projections, which reflect a base year of 2006 and a horizon year of 2011, show an overall statewide excess of short-stay general hospital beds. However, on an institutional level, there are 22 hospital facilities with projected need in 2011 for additional beds. Figures 5-10 and 5-11 depict the hospitals with projected need, as well as the overall short-stay hospital bed need projections by SDDR for 2011.



**Figure 5-10: Hospitals with Projected Need for Short-stay Beds in Horizon Year 2011.**

<b>Shortstay Hospital Bed Need Projection for 2011</b>					
<b>Hospitals with Projected Need</b>					
<b>Hospital Name</b>	<b>County</b>	<b>SSDR</b>	<b>Authorized Capacity Less LTCH Beds</b>	<b>Projected Beds Needed</b>	<b>Surplus/ (Deficit) Beds</b>
Brooks County Hospital	Brooks	11	25	31	(6)
Candler Hospital	Chatham	12	280	281	(1)
WellStar Cobb Hospital	Cobb	3	382	419	(37)
WellStar Kennestone Hospital	Cobb	3	633	666	(33)
Children's Healthcare at Egleston	DeKalb	3	250	258	(8)
Emory University Hospital	DeKalb	3	579	641	(62)
Piedmont Fayette Hospital	Fayette	3	106	117	(11)
Redmond Regional Medical Center	Floyd	1	230	244	(14)
Northside Hospital Forsyth	Forsyth	2	85	99	(14)
Emory Crawford Long Hospital	Fulton	3	481	482	(1)
Northside Hospital	Fulton	3	537	539	(2)
Piedmont Hospital	Fulton	3	458	549	(91)
Saint Joseph's Hospital of Atlanta	Fulton	3	410	447	(37)
Emory Eastside Medical Center	Gwinnett	3	200	223	(23)
Gwinnett Medical Center	Gwinnett	3	300	424	(124)
Joan Glancy Memorial Hospital	Gwinnett	3	111	121	(10)
Smith Northview Hospital	Lowndes	11	29	32	(3)
Mitchell County Hospital	Mitchell	10	23	25	(2)
Newton Medical Center	Newton	5	97	100	(3)
Mountainside Medical Center	Pickens	1	35	39	(4)
Rockdale Hospital and Health Systems	Rockdale	3	138	146	(8)
Wills Memorial Hospital	Wilkes	7	25	28	(3)
<b>Statewide</b>			<b>5,414</b>	<b>5,911</b>	<b>(497)</b>



**Figure 5-11: Short-stay Hospital Bed Need Projections by SSDR for 2011.**

<b>Shortstay Hospital Bed Need Projection for 2011 by State Service Delivery Region</b>				
<b>SSDR</b>	<b>Total Authorized Capacity</b>	<b>Capacity Less LTCH Beds</b>	<b>Projected Beds Needed</b>	<b>Surplus/ (Deficit) Beds</b>
1	1,473	1,453	1,163	290
2	1,090	1,090	874	216
3	8,659	8,559	7,623	936
4	978	978	766	212
5	989	989	675	314
6	1,506	1,472	1,176	296
7	2,145	2,145	1,290	855
8	1,355	1,325	810	515
9	906	906	448	458
10	1,489	1,489	980	509
11	1,263	1,263	850	413
12	1,684	1,644	1,412	232
<b>Statewide</b>	<b>23,537</b>	<b>23,313</b>	<b>18,067</b>	<b>5,246</b>

A Certificate of Need is required prior to the establishment of a new hospital, replacement of an existing hospital, or expansion of an existing hospital. These provisions do not apply to the following situations: (1) bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or (2) changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the applicable capital or equipment expenditure dollar threshold must be reviewed in accordance with the review considerations set forth in Rule 272-2.08.

An existing hospital seeking an expansion to be used for new institutional health services, including perinatal services, rehabilitation services, or psychiatric and substance abuse

services, must meet the applicable service specific rules and, as a threshold matter, meet the need standards set forth in 272-2-.09 (8)(c)(2)(iii) but shall not be required to meet the other requirements in Rule 272-2-.09(8).

A hospital that has been approved through the certificate of need process to use a certain number of short-stay hospital beds for long-term acute care (LTAC) beds shall have such LTAC beds removed from the official inventory of available short-stay beds once the LTAC is certified by Medicare; provided, however, that such beds will revert to the hospital's official inventory of available short-stay beds at any point that the LTAC ceases operation or is no longer certified by Medicare. An application to use existing short-stay hospital beds for LTAC beds shall not be subject to the guidelines in Rule 272-2-.09(8).



## Comparison States

Many states have deregulated Certificate of Need (CON) Laws that were set in place in 1979. Georgia is one of twenty-seven states that continue to comprehensively regulate hospital services. Today, many states are reviewing the effectiveness of the CON process. Those states that implemented sunset provisions in their CON laws have recently considered reversing their decisions in order to control the costly post-CON saturation of new hospitals, surgery centers, and diagnostic centers. States that have continued to regulate hospital expansions and construction are in the process of updating their CON guidelines to implement provisions that are more responsive to current industry trends and healthcare market forces.

A summary of eight comparison states and their regulation of hospitals is depicted in Figure 5-12.



FIGURE 5-12.

<b>Hospital Regulation</b>									
	<b>FL</b>	<b>GA</b>	<b>IA</b>	<b>ME</b>	<b>MA</b>	<b>OR</b>	<b>WA</b>	<b>WV</b>	<b>WI</b>
<i>Threshold</i>	Any amount	Capital: \$1,483,083; Equip: \$823,934, any bed increase	Any Amount	Capital:\$2,666,198; Equip: \$1,333,098; New Svc: \$121,880	Capital:\$12,516,300; Equip: \$1,335,272	Any amount (do not look at capital expenditures at all)	Any amount	Capital:\$2,000,000; Equip: \$2,000,000; New Svc or Facility: None	N/A
<i>New Hospitals</i>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
<i>Existing Hospitals, New Service, or Equipment</i>	Yes	Yes	Yes	Yes-over threshold	Yes-if it is considered innovative	Yes	Tertiary health services only	Yes	No
<i>Sale, Transfer, or Lease</i>	No	If from a subdivision of GA or equipment moved from 1 facility to another creates a new service	No	Yes	No	No	Yes	Yes-if currently operating as a health care facility	No
<i>Renovation</i>	No	Yes	No	Yes	No	No	No	Yes-if exceeds threshold	No
<i>Relocation, Replacement</i>	If more than 1 mile from current site	Yes-If more than 3m iles from current site	No-unless initiated by or for an HMO	Yes	No	Yes-if substantial increase or change in services	No	Yes-if exceeds threshold	No
<i>Beds</i>	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No
<i>Licensure, Regulation</i>	Does not issue licenses to facilities lacking CON or CON exemption	Reviews applicants' past licensure history. Must be nationally accredited	Not available	Must be licensed	Yes-original licensure must obtain CON	Dept of Human Svcs licenses. No info available on requirements	State licenses	Not available	No
<i>Moratoria, Caps</i>	No	No	None	New hospitals	Open heart surgery	No	No	Not available	N/A



## Federal Oversight

### *Medicare and Medicaid*

Medicare, Medicaid and public insurance reimbursement mechanisms are essential to the viability of hospitals in Georgia. In 2001, 89 hospitals were eligible for Disproportionate Share Hospital Payments under the Indigent Care Trust Fund. On average, Medicare beneficiaries compose 38.5% of patient admissions and Medicaid and PeachCare beneficiaries compose 17.7% of patient admissions.

## Strategic Options

### Option 5.0

*Maintain existing CON regulation.*

Under this option, hospitals would not need to obtain a CON for the addition of acute care medical/surgical beds or for the establishment of new facilities; however, licensure would create more detailed standards for the addition of beds.

### Option 5.1

*Deregulate acute care hospital beds from Certificate of Need.*

### Option 5.4

*Deregulate in part and maintain in part.*

### Option 5.2

*Deregulate and create a data reporting model.*

Under this option, the addition of general medical/surgical hospitals beds would not require a CON, but the establishment of a new hospital would still require a CON.

Under this option, hospitals would not need to obtain a CON for the addition of acute care medical/surgical beds or for the establishment of new facilities; however, hospitals would still be required to report data on a regular basis.

### Option 5.3

*Deregulate and create detailed licensure standards.*



## Recommendations

*NOTE: The Commission did not reach consensus on the regulation of general, short stay, acute care hospitals.*

### Recommendation 5.0 (3 Agree, 2 Disagree, 5 Abstain)

*Maintain existing CON regulation of Short Stay General Hospital Beds.*

Because data shows that there is a surplus of nearly 5,600 too many medical/surgical beds at the State's hospitals, some members of the Commission believe that CON regulation of medical and surgical beds should be maintained, particularly given the high costs of medical construction. These members maintain that the current regulation of short stay general hospital beds is effective and ensures access for those needing these services.

Other members of the Commission disagree. These members of the Commission feel that there is no need to regulate the addition of beds to established facilities as it hinders the delivery of health care when a facility has to wait for the completion of the review process in order to expand. Furthermore, the current manner in which the Department's rules forecast need for new beds is institution specific (i.e. the forecast relies on an institution's own historic utilization). They also feel that money that should be used to deliver health services is taken out of the system if money has to be dedicated to resources (i.e. attorneys, consultants, etc.) needed to file and/or fight an appeal if the project is denied by the Department or opposed by another party.

### Recommendation 5.1 (3 Agree, 4 Disagree, 3 Abstain)

*Deregulate Short Stay General Hospital Beds by not requiring a Certificate of Need for the expansion of Short-Stay beds, but still requiring a CON for the establishment of new hospitals.*

The members who agree with this recommendation disagreed with Recommendation 5.0 and for similar reasons. The members who disagree with this recommendation agree with Recommendation 5.0 and for the same reasons.

### Recommendation 5.2 (4 Agree, 2 Disagree, 4 Abstain)

*Amend the exemption for the addition of beds to short stay hospitals to allow expansion of such facilities without obtaining a CON when the facility has reached a utilization of 75% for the prior 12 months. Under the amended exemption, the facility would be able to expand by 10 beds or 10%, whichever is greater, once every two years.*

Currently, the statute has an exemption allowing a short stay hospital to increase its beds once every two years when it has demonstrated an 85% utilization rate for the prior twelve months. If this utilization is achieved, the facility may expand by 10 beds or ten percent, whichever is less, without obtaining a Certificate of Need.

The members of the Commission who agree with this recommendation feel that because of the cost of construction involved with adding additional beds and because of seasonal fluctuations in utilization rates, the statutory exemption should be broadened. Such members maintain that the utilization rate should be lower because a facility may have an average annual utilization rate of 75%, but that the facility may still exceed 100% utilization during seasonal periods such as



winter. In addition, these members support increasing the number of beds by which hospitals who have obtained the utilization can expand. Such members support such a recommendation based on the economies of scale. Oftentimes it may be cost prohibitive to expand a facility to add 10 beds or fewer, the limit of the current statutory exemption. For this reason, these members recommend that the exemption permit the addition of up to 10% more beds.

Those members who are opposed to this recommendation are so opposed because they believe that exemptions which allow existing facilities to expand may have a tendency to promote monopolies in the healthcare market.



## Specialized Cardiovascular Services

### An Analysis and Evaluation of Cardiovascular Services in Georgia

#### Overview

##### Background

According to the American Heart Association and the American Stroke Association, cardiovascular disease (CVD) is the leading cause of death in the United States. Data from *Heart and Disease Stroke Statistics-2006 Update* indicates that in 2003, over 13 million Americans suffer from coronary heart disease (CHD), coronary arteries narrowing that restricts oxygen and blood flow to the heart; it is the number one killer of both men and women in the United States. Scientists believe that many of these incidents could be prevented because CHD is related to certain aspects of lifestyle. Risk factors include high blood pressure, high blood cholesterol, smoking, obesity and a sedentary lifestyle. Although medical treatments for heart disease have improved tremendously over the years, controlling risk factors remains the key to preventing illness and death from CHD. Cardiac catheterizations and open heart surgical procedures are common diagnostic and therapeutic methods of diagnosis and treatment of this disease.

CVD is also the leading cause of death in Georgia, according to *Cardiovascular Disease in Georgia, 2005*, published by the Georgia Department of Human Resources, Division of Public Health and the American Heart Association, Southeast Affiliate.

This report also reports that Georgia death rates for CVD are 12% higher than the national rate, although from 1980 through 2003, the CVD mortality rate has declined in Georgia by an average of 2.4 percent annually. This decrease has been linked to changes in technology and overall lifestyle changes. Although the Georgia CVD death rate continues to decline, the rate of decline is slowing.

Race and gender disparities are strikingly obvious. In Georgia, men have higher CVD mortality rates than women, and blacks have higher rates than whites. In 2003, the risk of CVD was 20% higher for black males than white males and 27% higher for black females than white females; CVD is a major cause of costly hospitalization and disability, and resulted in 23,295 total deaths, of which 41 percent was from coronary heart disease. The mortality rate from coronary heart disease in Georgia has declined from 1980 through 2003 at an average of 3.5 percent annually, and is lower than the national rate. During 2003, there were 50,098 hospitalizations in Georgia as a result of coronary heart disease, and 142,336 hospitalizations due to total CVD-related conditions. Charges for these services have totaled \$3.347 billion. The average charge for a hospital stay was \$23,514.78.



The Department of Community Health regulates which facilities may expand or begin offering certain specialized cardiovascular services, including open heart procedures and adult and pediatric cardiac catheterizations. Open-heart surgery is a surgical procedure performed directly on the heart or its associated veins or arteries, during which a heart/lung bypass machine (extracorporeal pump) is utilized to perform the work of the heart and lungs. Coronary artery bypass graft surgery (CABG), also known as coronary revascularization, is the most commonly performed adult open-heart procedure. Cardiac catheterization is a medical, diagnostic or therapeutic procedure during which a physician inserts a catheter into a vein or artery of a patient. With the aid of x-rays and an electronic image intensifier, the physician then manipulates the free end of the catheter to travel along the course of the blood vessel into the chambers of the heart. For diagnostic purposes cardiac catheterizations are performed to detect and identify defects in the great arteries of the heart or abnormalities in the heart structure, whether congenital or acquired. Findings from cardiac catheterizations are important in determining whether therapeutic interventions are needed and, including open-heart surgery

The American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiovascular Angiography (SCAI) produce guidelines to address the full range of standards and criteria recommended by experts for the provision of quality care. The ACC/AHA Guidelines for Coronary Artery Bypass Graft (CABG) Surgery and the ACC/AHA/SCAI Guidelines for Percutaneous Coronary Interventions (PCI) are the guideposts for clinical care in specialized cardiovascular services. These documents outline specific strategies for cardiovascular disease management and procedures; they are intended to assist physicians in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management and prevention of specific diseases or conditions. The current component plan for specialized cardiovascular services in Georgia utilizes the guidelines released by the ACC, AHA, and the SCAI.

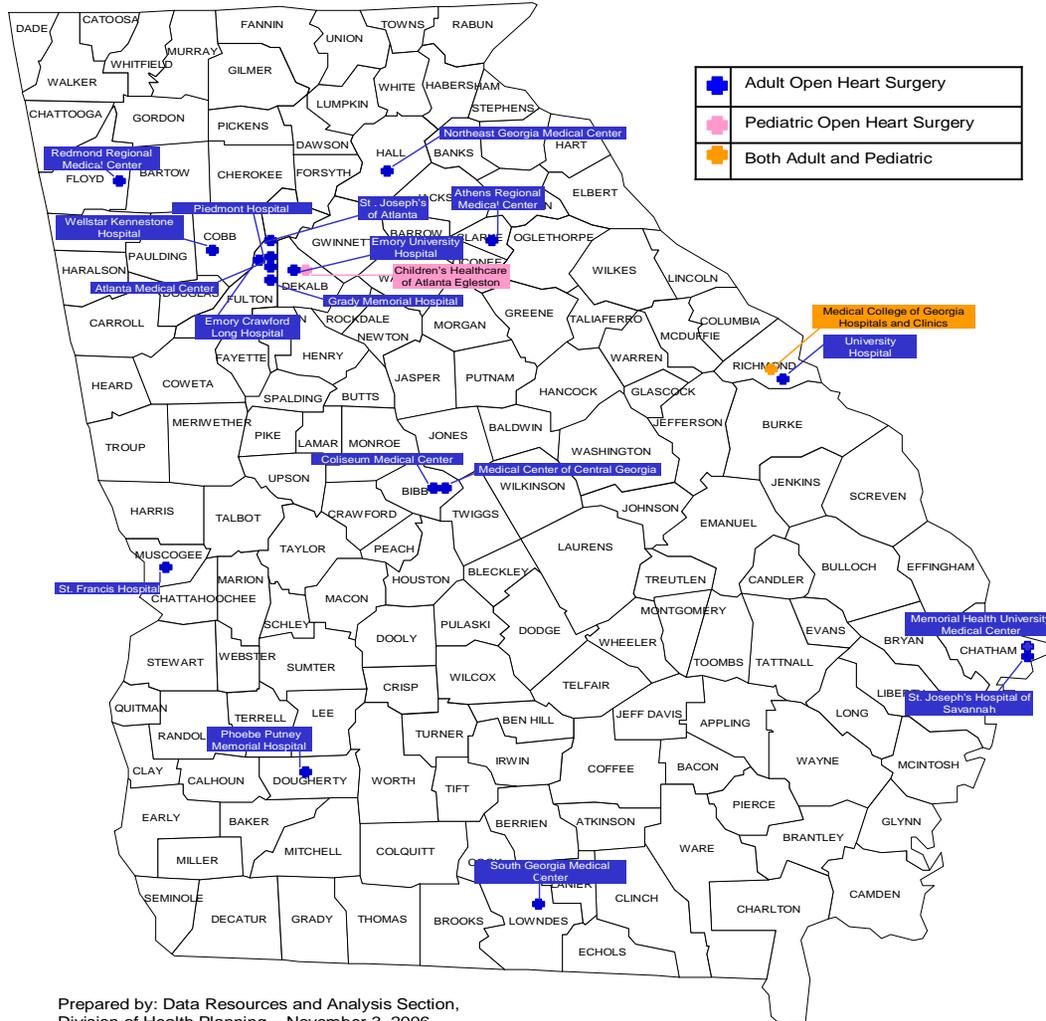
## Access, Supply and Distribution

Figures 6-1 and 6-2, which follow, show the distribution of adult and pediatric open heart surgery and cardiac catheterization providers in the entire state. Cardiac catheterization services are planned for on a regional basis. The majority of open heart surgery providers are located in the northern portion of Georgia, and mostly concentrated in the Atlanta metropolitan region. Facilities that offer adult cardiac catheterization services are more widely distributed throughout the state, and more providers are located in rural areas, although a large concentration is still found in the Atlanta area.



FIGURE 6-1.

Open Heart Surgery Services Providers

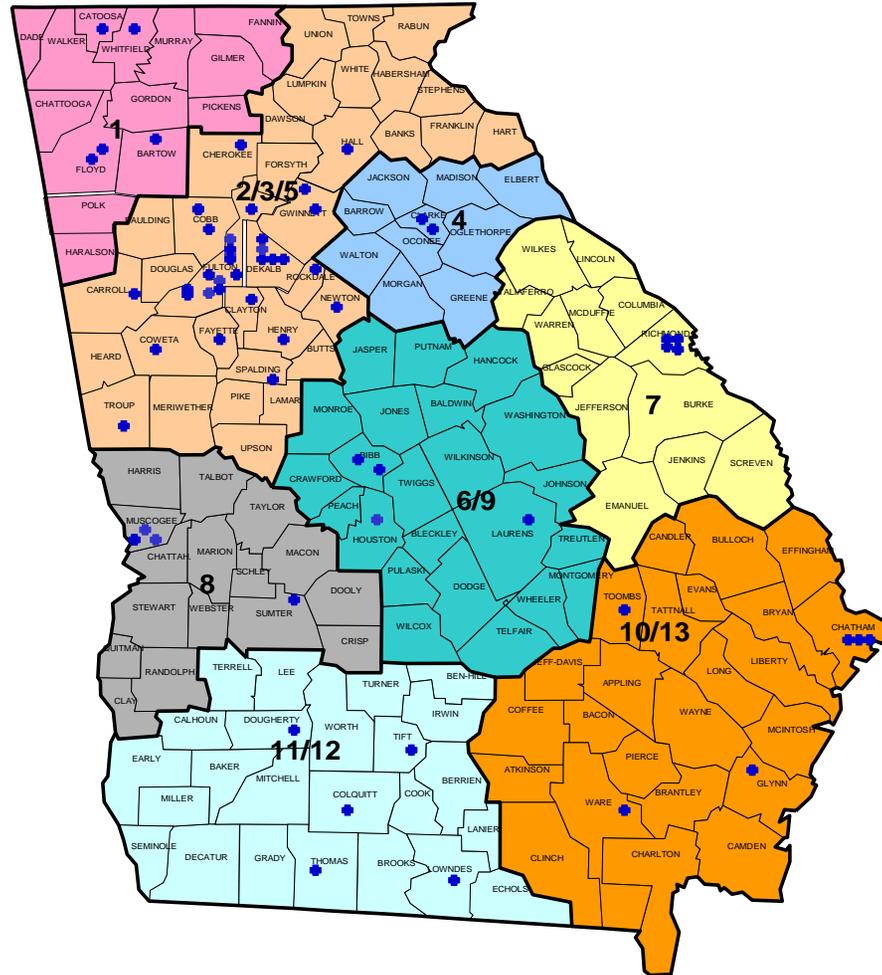


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 6-2.

Cardiac Catheterization Services Providers  
By Cardiac Catheterization Service Areas

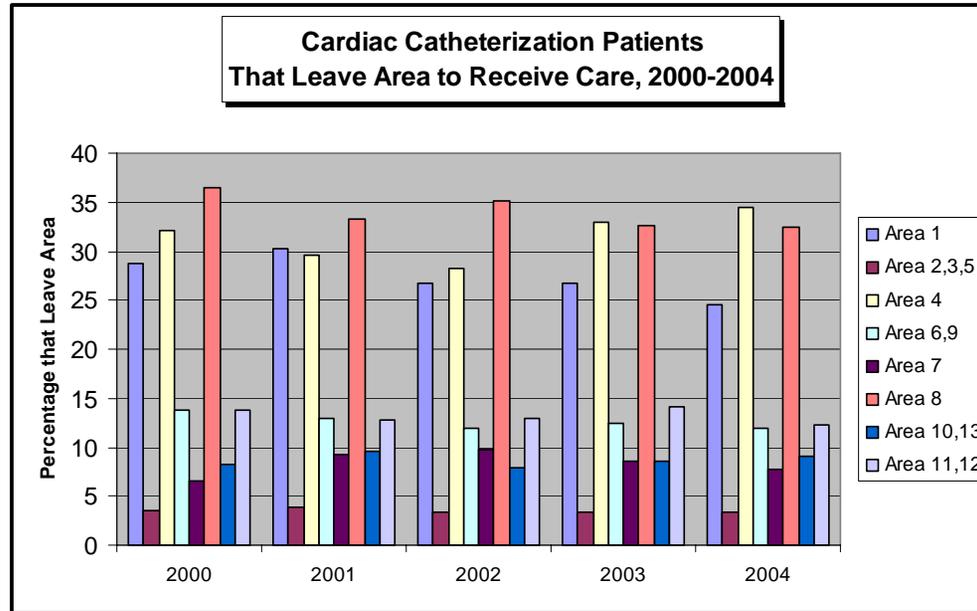


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



Although cardiac catheterization services are planned for on a regional basis, shown in the map above, many patients leave their cardiac planning area to receive care. Annually, patients that reside in cardiac planning areas 1, 4, and 8 consistently leave their region for catheterization services, at rates much higher than those in other areas. Please see Figure 6-3.

**FIGURE 6-3.**



Source: Cardiac Catheterization Survey, Georgia Department of Community Health, Division of Health Planning

The objective need methodology for open heart and cardiac catheterization services established by the Specialized Cardiovascular Services Component Plan allows the need for services in an area to be calculated based on aggregate utilization data, demand for services, and population projections. Since 2000, the number of open heart surgeries performed per capita has decreased, while the total number of diagnostic and

therapeutic cardiac catheterizations has increased, shown in the chart below. 1.07 persons per 1000 underwent an open heart surgery in 2004, a decrease of 15.08 percent from 2000. Cardiac catheterizations have grown 27.04 percent during the period of 2000 to 2004; according to most recent, complete data, in 2004 14.00 people per 1000 required a therapeutic or diagnostic cardiac catheterization. Refer to Figure 6-4.



FIGURE 6-4.

<b>Georgia Cardiovascular Procedure Rates Per Capita (1000)</b>		
<b>Year</b>	<b>Cardiac Catheterization Per Capita</b>	<b>Open Heart Surgery Per Capita</b>
2000	11.02	1.26
2001	11.76	1.20
2002	12.43	1.15
2003	12.59	1.13
2004	14.00	1.07

*Sources: Cardiac Catheterization & Open Heart Surveys, Georgia Department of Community Health, Division of Health Planning*

The number of open heart surgery providers in the state of Georgia has remained stable since 2001; 20 hospitals around the state currently offer the service. The number of freestanding facilities and hospitals that have cardiac catheterization laboratories has grown steadily, increasing 21.74 percent from 2000, for a 2004 total of 112 labs. However, many facilities are authorized to operate more than 1 laboratory on site, so there are considerably less providers than actual laboratories. In 2004, 61 different facilities offered cardiac catheterizations. Similar to the per capita rates, the average number of open heart surgeries performed per provider has decreased 26.38 percent from the year 2000, while the average number of catheterizations performed by each lab increased 12.92 percent. See Figure 6-5. State Service Delivery Region 3, in which much of the Atlanta metropolitan area resides, contained 42.33 percent of Georgia's total population in 2004; 53.08 percent of the open heart surgeries and 45.80 percent of cardiac catheterizations took place in this area.



FIGURE 6-5.

<b>Georgia Cardiovascular Procedure Average Rate Per Lab/Provider</b>						
<b>Year</b>	<b>Cardiac Catheterizations</b>	<b>Number of Labs</b>	<b>Catheterizations per Lab</b>	<b>Open Heart Surgeries</b>	<b>OHS Providers</b>	<b>OHS per Provider</b>
2000	90,240	92	980.87	10,348	16	646.75
2001	98,269	96	1023.64	9,985	20	499.25
2002	105,975	104	1018.99	9,848	20	492.4
2003	109,440	109	1004.04	9,887	20	494.35
2004	124,052	112	1107.61	9,523	20	476.15

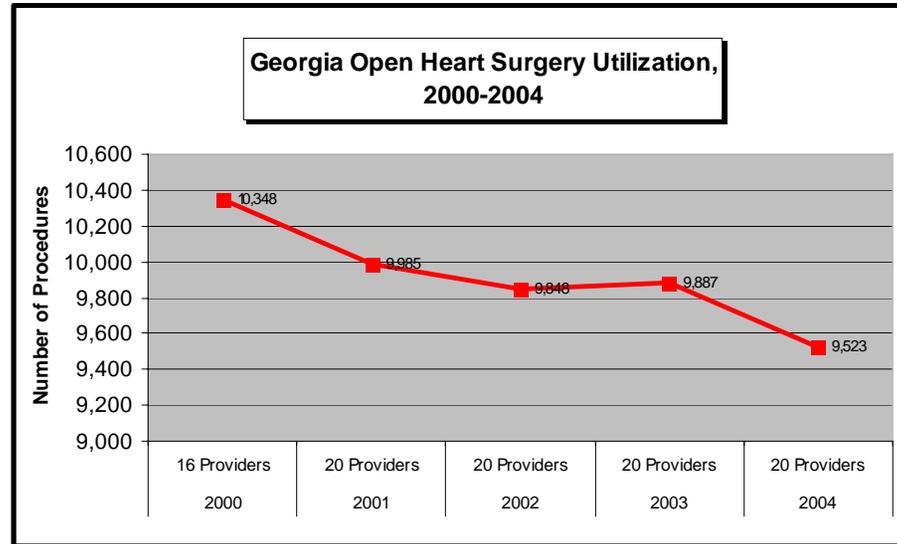
*Sources: Cardiac Catheterization & Open Heart Surveys, Georgia Department of Community Health, Division of Health Planning*

## Utilization

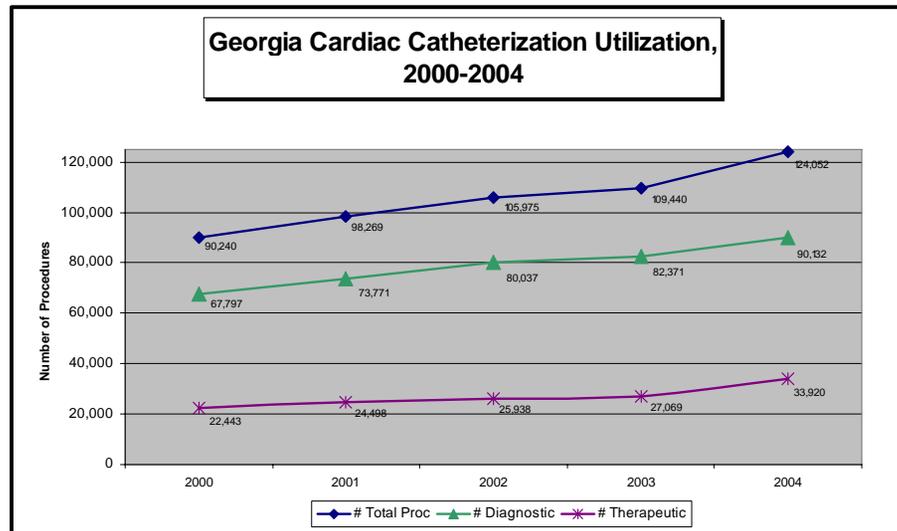
As was discussed in the previous section, and shown in the graphs below, the total number of open heart surgeries performed statewide has decreased 7.97 percent, while the cardiac catheterization use rate continues to grow overall, 37.47 percent during the 2000 to 2004 time period. Therapeutic catheterizations (angioplasties) have been utilized as a viable treatment option for coronary heart disease at a growing rate, increasing 51.14 percent over the past 5 years. During the same time period, diagnostic cardiac catheterizations have been performed at an increasing frequency, growing 32.94 percent. In 2004, diagnostic cardiac catheterizations accounted for 72.66 percent of total catheterizations in the state of Georgia. See Figures 6-6 and 6-7.



FIGURES 6-6 and 6-7.



Source: Open Heart Survey, Georgia Department of Community Health, Division of Health Planning



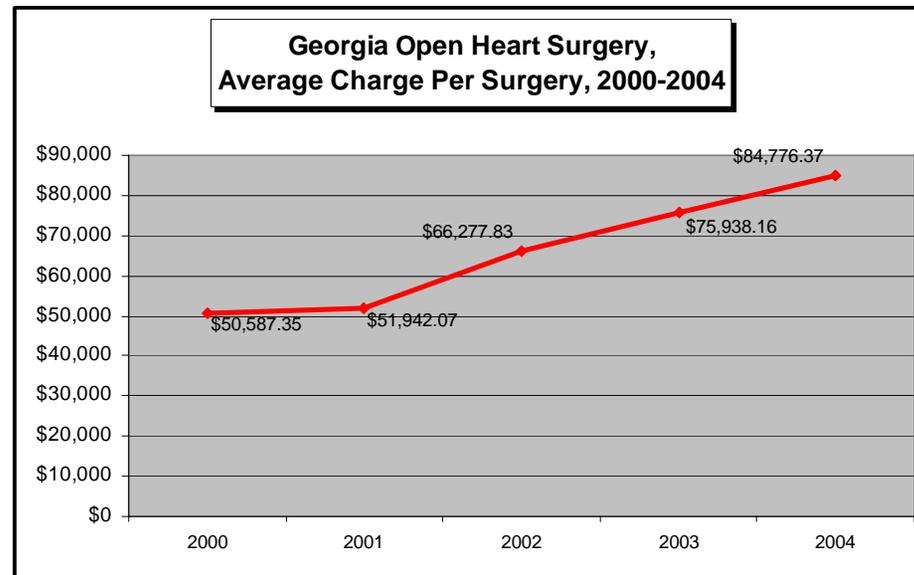
Source: Cardiac Catheterization Survey, Georgia Department of Community Health, Division of Health Planning



## Cost

While the actual number of open heart surgeries performed in Georgia has decreased, the average charge per surgery has risen dramatically. As shown in Figure 6-8, in 2004, the average charge for the state of Georgia for an open heart surgery was \$84,776.37. This represents a 67.58 percent increase in charges since 2000, when patients were charged an average of \$50,587.35 per open heart procedure.

**FIGURE 6-8.**

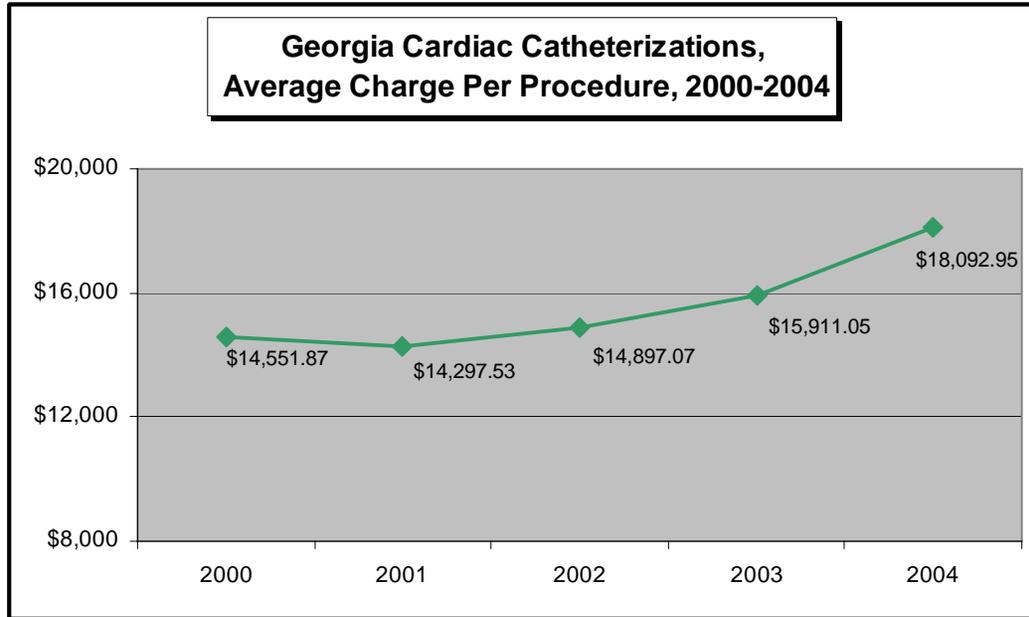


Source: Open Heart Survey, Georgia Department of Community Health, Division of Health Planning



As demonstrated in Figure 6-9, although the overall total of cardiac catheterizations performed per capita and per lab has been increasing, the average charge per procedure has not diminished. In 2004, the average charge for a catheterization was \$18,092.95, which increased 24.33 percent since 2000, when the average charge was \$14,551.87.

FIGURE 6-9.



Source: Cardiac Catheterization Survey, Georgia Department of Community Health, Division of Health Planning



## Quality

*ACC/AHA CABG Guidelines* The CABG (coronary artery bypass graft) guidelines, most recently published in 2004, provide a framework for patient outcomes, and delineate the core variables that were found to be predictive of mortality after CABG, which include such risk factors as urgency of operation, age, prior heart surgery, gender, left ventricular ejection fraction, percent stenosis of the left main coronary artery, the number of major coronary arteries with greater than 70% stenosis, and procedural volume. With regards to volume, the number of procedures has been correlated with patient outcomes. These guidelines suggest that after review of several national databases, a cut-off line of approximately 200 cases defines high and low-volume institutions. The AHA/ACC pointedly conclude that survival after CABG is negatively affected when carried out in institutions that perform fewer than the minimum threshold number (200) of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes. Because of the clear distinction with program results, the guidelines recommend outcome tracking and close monitoring of institutions or individuals that perform less than 100 cases annually.

*ACC/AHA/SCAI Angioplasty Guidelines* The angioplasty guidelines, most recently published in 2005, include factors related to clinician and facility volume, backup cardiac surgery capabilities of the facility, peer review standards, and outcome monitoring. Like CABG procedures, a volume-outcome relationship has been noted by many studies. The guidelines suggest that elective procedures be performed by high-volume facilities (more than 400 procedures) by operators with acceptable annual volume (at least 75 procedures); the guidelines also recommend that primary (emergency) procedures be performed by an operator who performs at least 75 elective and 11 primary percutaneous coronary interventions (PCI) procedures per year, at a facility that does 400 elective and at least 36 primary PCIs annually. The guidelines do not endorse the performance of elective PCIs in a facility without cardiac surgery capability; however, they do

recognize the difficult balance between emergent care in hospital-based settings without surgical back-up. They stressed the importance of ensuring that a mechanism for backup and bailout are in place to provide assistance should patients become unstable in a freestanding laboratory. Further, interventional procedures of any kind should not be performed in a freestanding facility. The guidelines also set standards for quality assurance, and focus on individual physicians and treatment teams that extend to the performance of the laboratory as a whole, and a continuous quality-improvement program should be included in the laboratory's overall design. It is important therefore to promote peer review and outcome monitoring that accounts for case mix and clinical anomalies.

In terms of quality, the most recent Specialized Cardiovascular Services Component Plan and rules recognize the guidelines recommended by the ACC, AHA, and SCAI. Both the open heart and cardiac catheterization rules set standards for applicants to meet based on volume, transfer agreements, adverse impact on existing providers, access (geographic, financial), and quality improvement plans (outcome monitoring, peer review). Specifically, applicants must show that they will be able to perform the following annually:

- Open Heart: 300 surgeries
- Adult Cardiac Catheterization: 1,040 catheterizations
- Pediatric Cardiac Catheterization: 150 catheterizations

The data analyses produced for the CON Commission by Georgia State University—Health Policy Center included information related to the quality of cardiovascular care and services and is depicted in Figure 6-10. The table below shows the percentage of markets in each state chosen for the study that failed the expected mortality rate for each condition included. The analysis of the mortality data based on markets did not reveal any apparent patterns with respect to CON regulation and no statistical correlation.



FIGURE 6-10.

Percentage of Markets that Fail Indicators				
State	CABG Mortality Rate (IQI 12)	Congestive Heart Failure Mortality Rate (IQI 16)	Acute Stroke Mortality Rate (IQI 17)	Acute Myocardial Infarction Mortality Rate (IQI 32)
Colorado	0%	0%	17%	0%
Florida	5%	0%	4%	0%
Georgia	25%	11%	6%	7%
Iowa	0%	12%	24%	6%
Maine	0%	25%	0%	0%
Massachusetts	0%	0%	0%	0%
Oregon	33%	17%	33%	0%
Utah	0%	0%	0%	0%
Washington	0%	0%	11%	0%
West Virginia	0%	14%	20%	20%
Wisconsin	0%	27%	27%	9%

Source: Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program

FIGURE 6-11.

In Figure 6-11, failure rates of 2 cardiovascular procedures are reported as a function of counties; these procedures have been identified as potentially over utilized. Georgia and West Virginia were not included in this analysis, as data were incomplete. Again, a pattern related to CON is difficult to detect.

Failure Rates as a Percentage of Counties Reporting		
State	CABG Rate (IQI 26)	PTCA Rate (IQI 27)
Colorado	22%	67%
Florida	58%	52%
Iowa	10%	10%
Maine	100%	67%
Massachusetts	33%	25%
Oregon	86%	50%
Utah	67%	40%
Washington	60%	33%
Wisconsin	62%	64%

Source: Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program



The report also included data related to cardiovascular disease-related hospital admissions which is depicted in Figure 6-12. The analyses found that of these 4 conditions listed in the table below, only the hypertension admission rate was positively correlated with presence of CON regulations.

**FIGURE 6-12.**

<b>Prevention Quality Indicators, Percentage of Counties with Greater Than Expected Rates</b>									
<b>Indicator</b>	<b>CO</b>	<b>FL</b>	<b>IA</b>	<b>ME</b>	<b>MA</b>	<b>OR</b>	<b>UT</b>	<b>WA</b>	<b>WI</b>
<i>Chronic Obstructive Pulmonary Disease Admission Rate (PQI 5)</i>	13%	33%	11%	27%	14%	0%	0%	3%	5%
<i>Hypertension Admission Rate (PQI 7)</i>	15%	29%	7%	0%	9%	0%	0%	0%	0%
<i>Congestive Heart Failure Admission Rate (PQI 8)</i>	5%	23%	2%	0%	7%	0%	5%	3%	3%
<i>Angina Without Procedure Rate (PQI 13)</i>	40%	37%	20%	27%	8%	0%	22%	22%	38%

*Source: Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program*



## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

The Georgia Department of Human Resources currently does not regulate specific cardiovascular services. The Office of Regulatory Services licenses and inspects hospitals that provide open heart and catheterization services; however, they do not regulate individual diagnostic centers that may be providing diagnostic cardiac catheterizations.

#### *Department of Community Health.*

The Georgia Department of Community Health currently has a component plan and specific review requirements and considerations that address three acute care cardiovascular services: adult cardiac catheterization services, open heart surgical services, and pediatric cardiac catheterization and open heart services; the most recent component plan for these services was issued in August 2001. In terms of setting standards for establishing or expanding cardiac catheterization or open heart services at a facility, the component plan utilizes certain guidelines set by the AHA, ACC, and SCAI related to quality of care. All entities that desire to expand their adult or pediatric catheterization or open heart services, or a facility that wishes to offer these services for the first time, must apply under these considerations, and address all of the rules. Under current regulations, a facility with no open heart back-up on-site may not be authorized to provide catheterizations which require this back-up, although it may offer diagnostic cardiac catheterizations, provided there exists a transfer agreement to a facility with open heart surgical services.

A current exception to facilities with no open heart back-up that are authorized to provide therapeutic catheterizations is the Atlantic Cardiovascular Patient Outcomes Research Team (C-Port) Trial. This trial allows selected hospitals to participate in a study protocol to offer primary and elective angioplasty without on-site open-heart surgical services. 36 hospitals in Georgia were eligible to participate, and 10 were selected; the program was launched in January, 2006, and is currently on-going. Figure 6-13 details study results so far.



FIGURE 6-13.

Summary of Georgia's Atlantic C-Port Trial Through October 25, 2006				
Hospital Name	County	Anticipated Volume Angioplasties	Elective PCI Patients	Primary PCI
<i>Archbold Memorial Hospital</i>	Thomas	177	63	30
<i>Southern Regional Medical Center</i>	Clayton	275	85	15
<i>Spalding Regional Medical Center</i>	Spalding	87	33	0
<i>Tift Regional Medical Center</i>	Tift	309	77	11
<i>Wellstar Cobb Hospital</i>	Cobb	165	119	11
<i>Tanner Health System</i>	Carroll	163	8	2
<i>Fairview Park Hospital</i>	Laurens	254	67	14
<i>West Georgia Health System</i>	Troup	126	41	12
<i>Hamilton Medical Center</i>	Whitfield	89	49	14
<i>Southeast Georgia Regional Health System</i>	Glynn	163	29	19
<b>Total</b>		<b>1808</b>	<b>571</b>	<b>128</b>
<b>Notes:</b>				
Elective PCI Patients represent the number recruited into the randomized trial as of October 25, 2006.				
Primary PCI Patients represent the number recruited into the Primary Percutaneous Coronary Intervention Registry as of October 25, 2006.				
Source: Sextant Database maintained by John Hopkins Medical Institute				

As shown Figure 6-14, applicants that propose to offer open heart surgical services are less successful at being granted a CON than those that desire to provide adult cardiac catheterization services; only 21.43 percent of open heart applicants were successful. Additionally, it is evident that very few applicants for pediatric cardiac catheterizations have applied for a CON. Applicants for adult cardiac catheterization services have a success rate of 74.47 percent of being granted a CON. 31.21 percent of adult cardiac catheterization and 52.38 percent of open heart applications were appealed.



FIGURE 6-14.

<b>Cardiovascular CON Applications, 1979 to Present, Final Findings</b>				
	<b>Approval</b>	<b>Denial</b>	<b>Withdrawal</b>	<b>Appeals</b>
<i>Adult Cardiac Catheterizations</i>	105	17	19	44
<i>Pediatric Cardiac Catheterizations</i>	3	0	0	1
<i>Open Heart Surgeries</i>	9	24	9	22

Sources: *Cardiac Catheterization & Open Heart Surveys, Georgia Department of Community Health, Division of Health Planning*

Comparison States

Unlike Georgia, not all states regulate the number and the facilities that provide specialized cardiovascular services such as cardiac catheterizations and open heart surgery services via a Certificate of Need Program. Oregon, with a CON program, and Wisconsin, Utah, and Colorado, with no CON programs, do not regulate either cardiovascular service in that capacity. Florida and Massachusetts regulate open heart surgical providers, but not those who offer cardiac catheterizations. All other comparison states have provisions in their CON regulations that govern providers of specialized cardiovascular services. This data is depicted in Figure 6-15.

FIGURE 6-15.

<b>Cardiovascular Services: CON Regulation</b>		
	<b>Open Heart</b>	<b>Cardiac Catheterization</b>
<i>Colorado</i>	No	No
<i>Florida</i>	Yes	No
<i>Georgia</i>	Yes	Yes
<i>Iowa</i>	Yes	Yes
<i>Maine</i>	Yes	Yes
<i>Massachusetts</i>	Yes	No
<i>Oregon</i>	No	No
<i>Utah</i>	No	No
<i>Washington</i>	Yes	Yes
<i>West Virginia</i>	Yes	Yes
<i>Wisconsin</i>	No	No

Source: *National Directory: State Certificate of Need Programs, Health Planning Agencies, American Health Planning Association*



## Federal Oversight

### *Medicare.*

On January 12, 2006, the US Department of Health and Human Services, Centers for Medicare and Medicaid Services repealed its policy of allowing national coverage of cardiac catheterizations in settings other than hospitals, based on Peer Review Organizations ceasing their reviews of freestanding facilities. Freestanding facilities may still receive reimbursement, if it has been reviewed by the appropriate Quality Improvement Organization. Other than in non-reviewed freestanding facilities, inpatient and outpatient therapeutic and diagnostic cardiac catheterizations, and open heart surgeries, are reimbursable services.

## Strategic Options

### Option 6.0

*Maintain existing CON regulation of cardiac catheterization.*

### Option 6.1

*Deregulate cardiac catheterization from Certificate of Need.*

### Option 6.2

*Deregulate cardiac catheterization and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for cardiac catheterization; however, hospitals would still be required to report data on a regular basis.

### Option 6.3

*Deregulate cardiac catheterization and create detailed licensure standards.*

Under this option, applicants would not need to obtain a CON for cardiac catheterization; however, licensure would create more detailed standards for cardiac catheterization.

### Option 6.4

*Deregulate diagnostic cardiac catheterization and require therapeutic catheterizations to only be performed by providers approved to offer open heart surgery.*

Under this option, applicants would not need to obtain a CON for diagnostic cardiac catheterization; however, any provider wishing to perform therapeutic catheterizations would be required to obtain an open heart surgery CON.



Option 6.5

*Deregulate diagnostic and therapeutic cardiac catheterization.*

Under this option, applicants would not need to obtain a CON for diagnostic or therapeutic cardiac catheterization.

Option 6.6

*Maintain existing CON regulation of open heart surgery.*

Option 6.7

*Deregulate open heart from Certificate of Need.*

Option 6.8

*Deregulate open heart and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for open heart surgery; however, hospitals would still be required to report data on a regular basis.

Option 6.9

*Deregulate open heart and create detailed licensure standards.*

Under this option, applicants would not need to obtain a CON for open heart surgery; however, licensure would create more detailed standards for open heart surgery.

Option 6.10

*Maintain existing CON regulation of pediatric cardiac catheterization and open heart surgery.*

Option 6.11

*Deregulate pediatric cardiac catheterization and open heart surgery from Certificate of Need.*

Option 6.12

*Deregulate pediatric cardiac catheterization and open heart surgery and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for pediatric cardiac catheterization and open heart surgery; however, hospitals would still be required to report data on a regular basis.

Option 6.13

*Deregulate cardiac catheterization and create detailed licensure standards.*

Under this option, applicants would not need to obtain a CON for pediatric cardiac catheterization and open heart surgery; however, licensure would create more detailed standards for such services.



## Recommendations

*NOTE: The Commission did not reach consensus on the regulation of cardiac catheterization, but did achieve consensus on the regulation of open heart surgery.*

### Recommendation 6.0 (4 Agree, 1 Disagrees, 5 Abstain)

*Deregulate diagnostic cardiac catheterization and require therapeutic catheterizations to be performed only by providers approved to offer open heart surgery.*

The members of the Commission who support the deregulation of adult diagnostic cardiac catheterization maintain that deregulating diagnostic cardiac catheterization will allow for the proliferation of these services in the market assuring access to residents in all areas of the state. Such members feel that this service is a valuable service to the citizens of the state and has been shown to save lives, particularly in states such as Georgia with high rates of coronary disease. These members feel that the regulation of the quality of this service could be managed by Licensure.

One member of the Commission disagrees. This member feels that this service should continue to be regulated by Certificate of Need. Because cardiac catheterization is such a specialized service, certain quality standards must be met to achieve the best possible outcomes. Because the American College of Cardiology recommends that minimum volumes be maintained to ensure the quality of the service, this member feels the Certificate of Need process ensures that there will not be a proliferation of low volume providers who won't maintain the same quality as high volume providers.

Several members of the Commission report that this recommendation should only apply to hospital-based cardiac catheterization and not to freestanding cath programs.

### Recommendation 6.1 (Unanimous)

*Maintain existing CON regulation of open heart surgery.*

Members of the Commission agree that open heart surgery services should continue to be regulated by CON because of the technical nature of the service and the highly-skilled labor force that is required to perform the service. They also agreed that licensure standards should be added to routinely monitor the quality of open heart surgical programs.

### Recommendation 6.2 (Unanimous)

*Maintain existing CON regulation of pediatric cardiac catheterization and open heart surgery.*

The Commission unanimously agrees that Certificate of Need regulation of pediatric cardiovascular services be maintained because of the complex and highly-skilled nature of these services and the concentrated demographic that utilizes these services.



## Perinatal Services

### An Analysis and Evaluation of Perinatal and Obstetrical Health Services in Georgia

#### Overview

##### Background

The health of infants is a high priority for the State of Georgia and the nation as a whole. Although Georgia policy makers have endeavored to improve perinatal health care to women and infants throughout the state, Georgia continues to rank near the bottom nationwide in infant health indicators, ranking 44<sup>th</sup> in 2005 with an infant mortality rate of 8.5 deaths per 1,000 live births, and 41<sup>st</sup> in the nation in 2003 for low birth weight babies. In 2004, 1 in 11 babies born in Georgia (9.3% of live births) were considered low birth weight infants, above the objective of no more than 5.0% of live births set by the United States Department of Health and Human Services. Low birth weight is viewed as a primary indicator of infant health by both health planners and economists.

The State of Georgia also is faced with alarming rates of teen pregnancies, unintended pregnancies and a great disparity between black/white infant health and survival rates. For example, in 2005, the infant mortality rate in Georgia varied from a low of 6.0 deaths per 1,000 live births for Hispanics to a high of 13.4 deaths for non-white Hispanic blacks. Black infants (13.1%) were about 2 times as likely as Hispanic infants (5.8%) to be born low birth weight during the 2001-2003 period. In addition, although the teen

pregnancy rate in Georgia has fallen over the past decade, Georgia is ranked 30<sup>th</sup> nationwide among states for teen pregnancies, with 53.4 teen births per 1,000 population, compared to a rate of 41.1 per 1,000 in the United States in 2004. These indicators are suggestive of the need for improved perinatal health care services.

Health planners believe that several factors contribute to poor infant health statistics. Among them are the lack of access to appropriate healthcare services, poor nutrition, poverty, lack of insurance, shortage of healthcare providers, rise in unintended pregnancies and substance abuse. Although medical technology in the United States today has far exceeded what was thought imaginable just a few decades ago, many women still do not have access to the full range of perinatal services.

*Sources: March of Dimes PeriStats, America's Health: State Health Rankings – 2004 and 2005 Editions from the United Health Foundation, Annie E. Casey Foundation's Kids Count database, Agency for Healthcare Research and Quality, CDC's National Vital Statistic Reports, Vo. 55, Number 1: Births: Final Data for 2004*



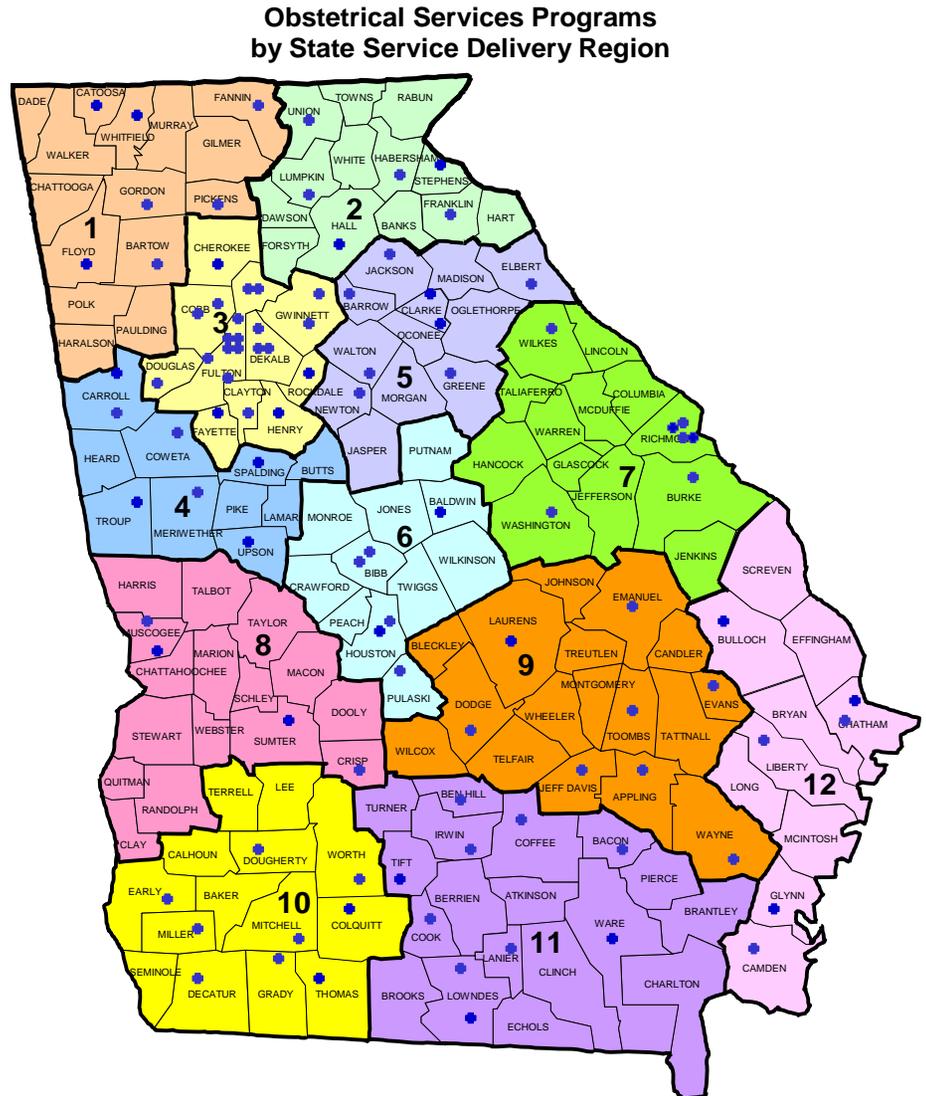
## Access, Supply and Distribution

As of 2004, 102 of Georgia's 153 general acute care hospitals facilities offered either Basic, Intermediate or Intensive Neonatal Care. (There is one licensed freestanding birthing center in Georgia, the Family Health and Birth Center in Rincon, Effingham County.) Of these hospitals, 50 offered Basic Perinatal Care (Level 1), 34 offered Neonatal Intermediate Care (Specialty/Level II), and 22 offered Neonatal Intensive Care (Sub-specialty/Level III). A "Basic Perinatal Hospital Services," as defined in the *Recommended Guidelines for Perinatal Care in Georgia*, published by the Council on Maternal & Infant Health in 1999 ("Guidelines"), offers basic inpatient care for pregnant women and newborns without complications. Intermediate Neonatal Care, or "Specialty Perinatal Hospital Service" under the Guidelines, provides basic perinatal care, as well as manages certain high-risk pregnancies and moderately ill newborns. Finally, a Neonatal Intensive Care hospital, or "Subspecialty Perinatal Hospital Service" under the Guidelines, has the highest level of technological capability in the state, as well as additional specialty staff to provide care for all maternal or fetal complications and a Neonatal Intensive Care Unit (NICU) equipped to treat critically ill newborns.

For Certificate of Need purposes, Basic Perinatal Services and Neonatal Intermediate Care Services are planned for on a regional basis, based on twelve State Service Delivery Regions ("SSDR"). Neonatal Intensive Care Services have larger regional planning areas, dividing the State into five NICU Planning Areas. The majority of the Level III/Subspecialty NICUs are located in the northern portion of Georgia, and are mostly concentrated in the metropolitan Atlanta area. (15 of the State's 22 NICUs are in NICU Planning Area 1.) The maps below, Figures 7-1, 7-2, and 7-3, depict the distribution of perinatal services throughout the State.



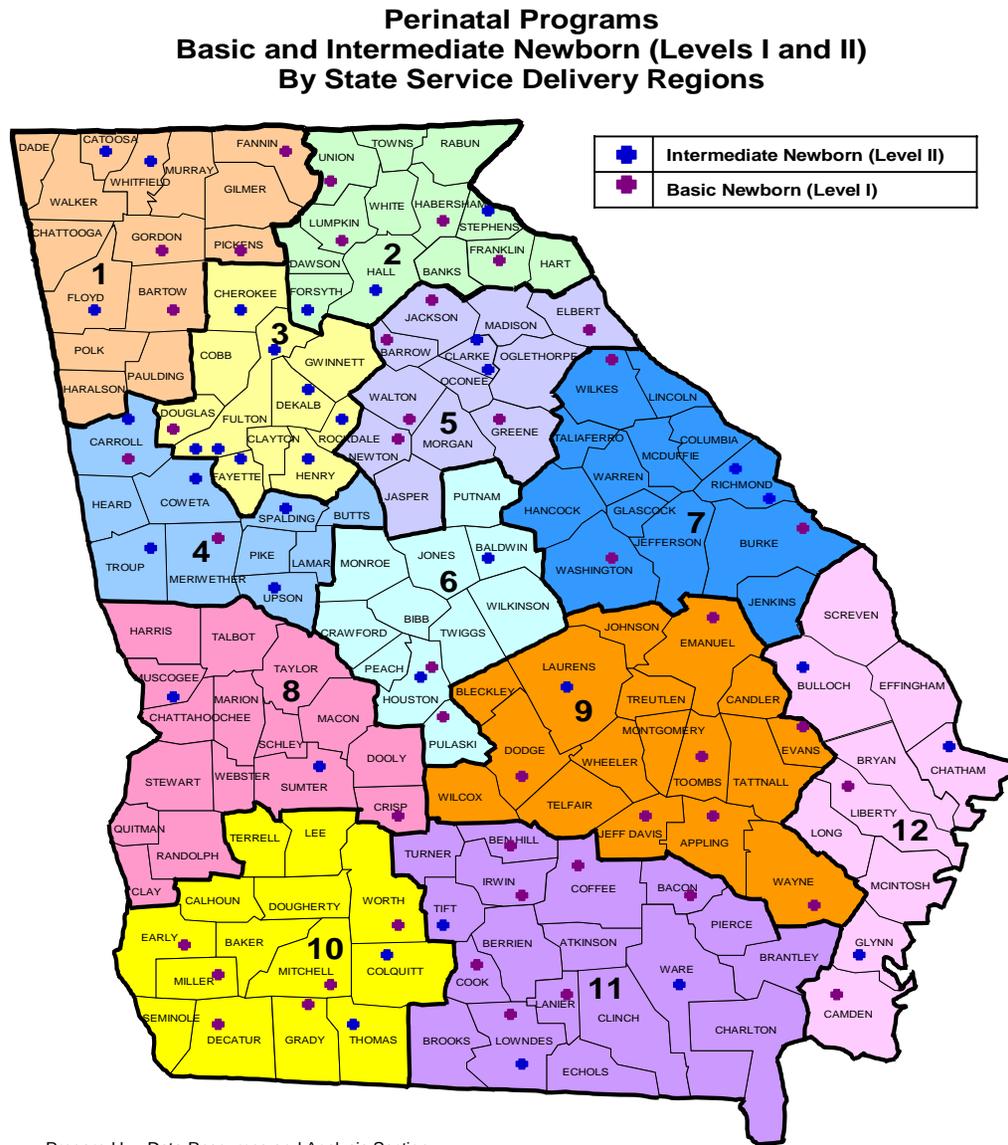
FIGURE 7-1: Distribution of Basic Neonatal Services in Georgia, 2006



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 7-2: Distribution of Intermediate Neonatal Services in Georgia, 2006

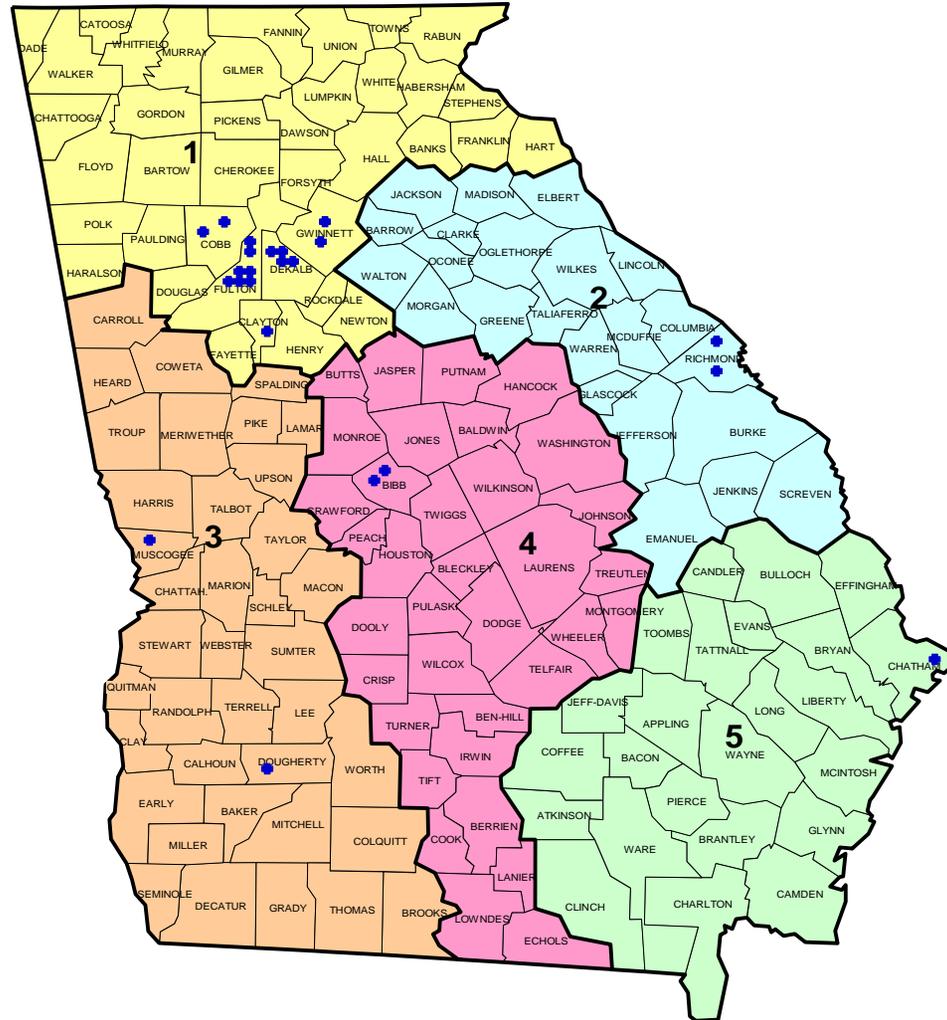


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 7-3: Distribution of NICU Services in Georgia, 2006

Perinatal Programs (Level III Newborn)  
Neonatal Intensive Care Units (NICU)  
By NICU Planning Areas



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



In the five year period between 2000 and 2004, the number of providers offering basic perinatal services, as well as the total number of basic perinatal beds, has declined, from 50 providers with a total of 1828 basic newborn beds, to 46 providers with a total of 1803 newborn beds. Conversely, the number of intermediate and NICU providers has stayed virtually the same from 2000 to 2004, but the number of authorized neonatal intermediate and intensive care beds have increased, from 456 intermediate and 338 intensive care beds in 2000, to 482 intermediate and 391 intensive care beds in 2004. Figure 7-4 below describes the number of beds at each level of perinatal service for the past five years.

**FIGURE 7-4: Number of Perinatal Beds (Basic, Intermediate and NICU), Georgia, 2000-04**

<b>Supply of Perinatal Beds 2000-04</b>			
<b>Year</b>	<b>Basic Perinatal Beds</b>	<b>Intermediate Beds</b>	<b>NICU Beds</b>
2000	1828	456	338
2001	1884	451	372
2002	1861	494	380
2003	1803	491	394
2004	1803	482	391

*Sources: Georgia Division of Health Planning's Perinatal Services Database; Recommended Guidelines for Perinatal Care in Georgia; Rules of the Department of Community Health.*



## Utilization

Over the past decade, the birth rate in Georgia has stayed fairly constant, between a low of 45.2 live births per 1,000 females in 1994 to a high of 47.4 per 1,000 females in 2000. Nationwide, after dropping steadily from 1990 to 1997, the nationwide birth rate has fluctuated only slightly, but is lower generally than in Georgia. Figure 7-5 below describes the number of births, birth rates, and fertility rates in Georgia from 1994 to 2004.

**FIGURE 7-5: Number of Births, Birth Rates, and Fertility Rates in Georgia, 2006**

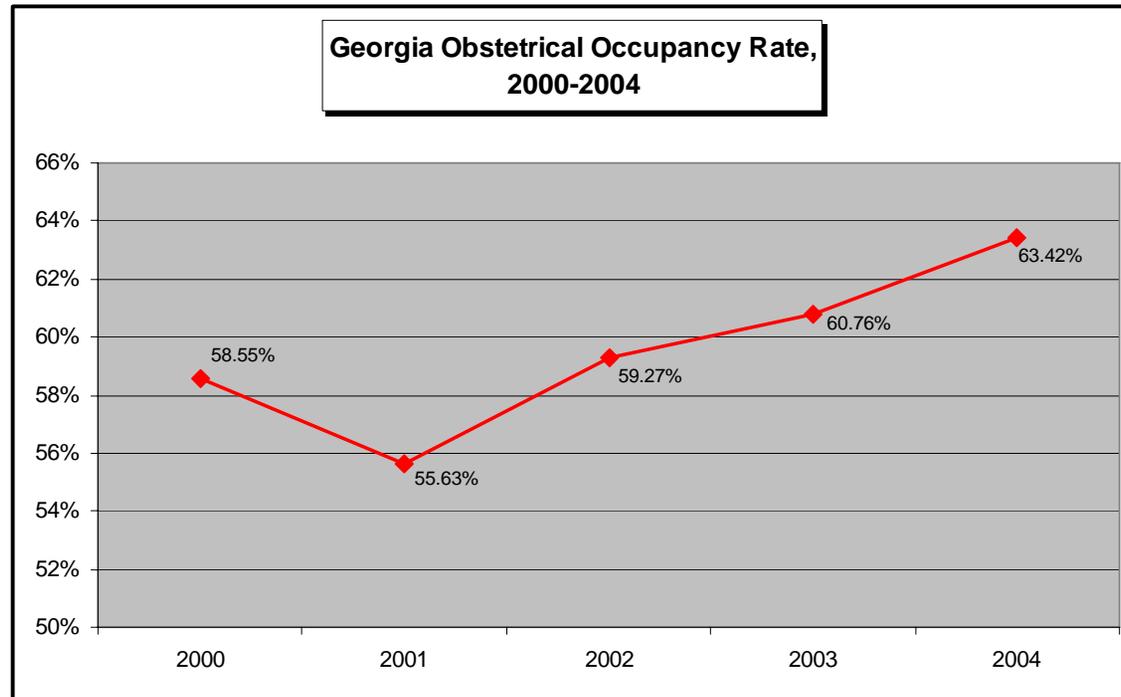
<b>Trends in Number of Births, Birth Rates, and Fertility Rates for Georgia Residents, 2001-04</b>			
<b>Year</b>	<b>Number of Births</b>	<b>Birth Rate</b>	<b>Fertility Rates</b>
1994	110,986	45.2	64.0
1995	112,246	44.7	63.6
1996	113,986	44.3	63.4
1997	118,167	44.8	64.6
1998	122,366	45.5	65.9
1999	126,494	46.1	67.3
2000	132,286	47.4	69.7
2001	133,468	46.7	69.3
2002	133,285	45.9	68.4
2003	135,831	46.3	69.2
2004	138,561	46.8	69.9

*Source: Georgia DHR, Division of Public Health*



In terms of obstetrical beds, the occupancy rate has generally increased from 2000 to 2004, from 58.55% in 2000 to 63.42 in 2004. Figure 7-6 below depicts the change in the obstetrical occupancy rates over the past five years.

**FIGURE 7-6: Trends in Obstetrical Occupancy Rates, Georgia, 2000-04**



Consistent with the increased number of live births and the increased occupancy rates for obstetrical services, the total number of admissions for all levels of perinatal services has also increased, as have the total number of days of care. Figure 7-7 below depicts the growth in admissions and perinatal days of care. As shown in Figure 7-8 below, however, the average length of stay

has decreased for neonatal intensive care services, fluctuated for intermediate services, and increased for basic neonatal services over the same time period. The average length of stay for obstetrical services has remained fairly constant over the past five years, fluctuating between 2.65 days in 2000 to a high of 2.73 days in 2004.



**FIGURE 7-7: Perinatal Services Admissions and Number of Days of Care, Georgia 2000-04**

<b>Trends in Perinatal Services Utilization 2000-04</b>						
<b>Year</b>	<b>Basic Admits</b>	<b>Intermediate Admits</b>	<b>Intensive Care Admits</b>	<b>Basic Days</b>	<b>Intermediate Days</b>	<b>Intensive Care Days</b>
2000	120,991	7,604	5,296	263,252	91,182	96,099
2001	121,840	6,137	7,094	272,740	86,033	103,132
2002	121,395	7,247	6,176	275,273	102,448	94,182
2003	123,867	8,009	6,565	279,646	103,404	99,992
2004	124,424	9,774	6,500	287,528	113,343	109,543

**FIGURE 7-8: Average Length of Stay for Newborns, Georgia 2000-04**

<b>Trends in Perinatal Services Average Length of Stay, 2000-04</b>			
<b>Year</b>	<b>ALOS (days) – Basic</b>	<b>ALOS (days) – Intermediate</b>	<b>ALOS (days) – NICU</b>
2000	2.18	11.99	18.15
2001	2.24	14.02	14.54
2002	2.27	14.14	15.24
2003	2.26	12.91	15.23
2004	2.31	11.59	16.85

*Source: Georgia, Division of Health Planning Perinatal and Obstetrical Services Database*

According to the Georgia Guidelines for Early Newborn Discharge, developed by the Council on Maternal Health, a 48- to 72-hour hospital stay for a newborn is typically necessary for appropriate postpartum medical care and observation of the newborn, although the Council did recognize some potential benefits of early newborn discharge (prior to 48 hours). The above average lengths of stay for newborns after uncomplicated deliveries in Georgia are within the Guidelines' recommendations. Moreover, while there is still some debate about the impact of short hospital

stays for obstetric patients, studies continue to reveal that early obstetric discharges after uncomplicated spontaneous vaginal deliveries are safe. However, there is minimal information regarding the consequences of early discharge following cesarean and assisted vaginal deliveries.

For Georgia hospitals, cesarean section rates averaged 29.2 percent in 2004, according to the National Vital Statistics Report 2004. This is an increase over the 3-year rate for 2002-2004 of



26.2% reported by the Georgia Department of Human Resources, Division of Public Health, and continues a trend of increasing delivery by cesarean section rate over the past decade in Georgia, which hovered in the 20<sup>th</sup> percentile throughout the 1990s. Georgia trends are consistent with increasing cesarean delivery rates nationwide. The national rate of cesarean delivery increased by 6 percent from 2003 to 29.1 percent of all births and is the highest rate ever reported in the United States. After falling between 1989 and 1996, the national cesarean rate has risen by 41 percent. The continued escalation in the cesarean delivery rate, and the risks, benefits and long-term consequences of cesarean delivery, are the subject of intense debate and will need to be considered in planning for perinatal programs.

In 2004, there were 145,214 deliveries in the State of Georgia. The average charge for uncomplicated deliveries was \$5,086 and the average charge for premature delivery was \$7,714. In 2003 there were 142,594 deliveries with an average charge of \$4,817 for uncomplicated deliveries and \$6,596 for premature deliveries. Figure 7-9 below depicts the trends in average hospital charges for premature and uncomplicated deliveries from 2000 to 2004 (data relating to premature delivery charges are available only since 2003).

### Cost

In 2004, pregnancy and newborn infant care were the second and third most expensive conditions treated in United States hospitals. Pregnancy complications require an average of 2 million hospital days of care per year at a cost of \$1 billion per year for hospital charges. The average cost of treatment in a neonatal intensive care unit is between \$20,000 and \$30,000. Some researchers estimate the cost of delivery and initial care of a baby with very low birth weight can exceed \$100,000 (in year 2000 dollars), and based on data from Georgia's Department of Medical Assistance, the cost of care for a very low birth weight baby can reach \$500,000.00.

Over the past several years, hospital costs associated with perinatal care have increased nationwide. Several factors contribute to this rise. Among them inflation, new technologies, including neonatal intensive care units; the rising cost of malpractice insurance; and the loss of revenue due to uncompensated medical care.



**Figure 7-9: Average Hospital Charges for Perinatal Services, Georgia 2000-04**

Average Hospital Charges For Premature and Uncomplicated Delivery		
Yearly Aggregate Totals		
Year	Premature Delivery Average Charge	Uncomplicated Delivery Average Charge
2000	*	\$3,807.00
2001	*	\$3,940.00
2002	*	\$4,401.00
2003	\$6,596.00	\$4,817.00
2004	\$7,717.00	\$5,086.00

\* = Question not asked during survey year.

Prepared by: Data Resources and Analysis Section, Division of Health Planning -- 11/6/2006

Source: Annual Hospital Questionnaire

From 2000 to 2004, the hospital with the lowest reported average charge for uncomplicated deliveries in the State was Minnie G. Boswell Memorial Hospital in Greene County. In November 2006, Minnie G. Boswell closed its maternity ward, citing shortfalls to their labor and delivery department due to changes in the Medicaid program. The hospitals reporting the highest average charges for uncomplicated deliveries during this time period were East Georgia Regional Medical Center in Bulloch County (2000-04), Atlanta Medical Center in Fulton County (2000-02), Miller County Hospital in Miller County (2001), South Georgia Medical Center in Lowndes County (2002), Mountainside Medical Center in Pickens County, (2003), North Fulton Regional Medical Center in Fulton County (2003), and Spalding Regional Medical Center in Spalding County (2003-04). The Department did not begin collecting data on the average costs of premature deliveries until 2003. In both 2003 and 2004, SSSR 3, encompassing metropolitan Atlanta had by far the highest average charge for premature deliveries -- \$12,414 and \$14,921, respectively – almost twice the State average. Grady Memorial Hospital in Fulton County (SSDR 3) had the highest average charges for premature deliveries in 2003 (\$47,893) and 2004 (\$57,674) and Minnie G. Boswell Memorial Hospital, Louis Smith Memorial

Hospital in Lanier County, and Meadows Regional Medical Center in Toombs County had the lowest.

**Quality**

The leading single cause of infant mortality in the United States, according to the Recommended Guidelines for Perinatal Care in Georgia, is birth defects. Because most birth defects occur early in pregnancy, often before recognition of pregnancy and the first prenatal visit, Georgia planners have recognized that to have a significant impact on the health of women and infants, policy makers must focus considerable attention and efforts on preconception and interconception. The Guidelines also recognize that access to prenatal care has long been associated with reduction in infant and maternal mortality and morbidity. These issues, although beyond the focus of the Certificate of Need program and this report, are some of the most important factors contributing to the quality outcomes of the State's perinatal health services.

Another quality issue facing perinatal health policymakers in Georgia and nationwide is the shortage of qualified personnel and



staff in an ever-changing and technologically advancing service. It is crucial that hospitals offering perinatal services be able to secure qualified physicians and nursing staff to provide an optimum level of care to the mother and the newborn. In addition, because perinatal services have become increasingly specialized, an important factor for health planners to consider is the need to sustain a sufficient number and variety of patients for specialized providers in order to maintain competency and proficiency.

## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

The Office of Regulatory Services of the Georgia Department of Human Resources regulates through licensure maternal and newborn services offered through hospitals at all three levels of care, as well as maternity homes, and birthing centers. ORS rules include requirements for the level of staffing, equipment and physical plant of facilities offering perinatal services.

#### *Department of Community Health.*

The Department regulates perinatal services through its Component Plan for Perinatal Services and attendant Certificate of Need service-specific rules for perinatal services and birthing centers. DCH determines the need for new or expanded perinatal hospital services through the application of a numerical need method and an assessment of the aggregate occupancy rate of existing services. The Department uses three separate need formulas to determine need for basic obstetric perinatal services, neonatal intermediate care, and neonatal intensive care, all of which are based on a calculation of the demand for such services in the horizon year (use rate for the services times the projected population in the horizon year) and the existing supply of beds. For basic obstetric service the current rules require existing

services be utilized at a rate of 75% for two years before a new or expanded service can be approved. For neonatal intermediate and intensive care, 80% utilization for two years is required.

In addition, the current rules have a very specific adverse impact requirement, protecting perinatal physician training programs, nurse midwifery training programs, and regional perinatal centers from new perinatal services that would adversely impact these existing programs and facilities by decreasing the number and type of patients accessing these services. An exception to the need methodology is permitted to assure geographic access in rural areas, to allow expansion for an existing service with consistently high utilization, or to remedy atypical barriers to service.

As shown in Figure 7-10 below, more applicants have proposed to offer basic obstetric services than neonatal intermediate or intensive care services since 1979. Of the 113 applications submitted to offer basic obstetric services since 1980, 80% were approved. These applications generated a fairly high percentage of appealed decisions, 31%, although the Department's decision was only reversed 3 times in the early 1990s. Of the 28 newborn/nursery and 29 NICU and intermediate care applications submitted since 1980, 75% and 86% were approved, respectively. These applications also generated a fairly high percentage of appeals, 21% and 30% respectively, although the Department's



decisions with respect to these services have not been reversed. The total dollar amount of the projects reviewed by the Department for obstetric services since 1980 is \$1,480,891,980. The total amount of newborn/nursery projects review is \$426,922,258 and the total amount of NICU and intermediate care services is \$899,543,831.

**FIGURE 7-10: Final Findings of Perinatal CON Applications Filed From 1979 to Present**

<b>Perinatal Applications, 1979 to Present, Final Findings</b>				
	<b>Approval</b>	<b>Denial</b>	<b>Withdrawal</b>	<b>Appeals</b>
<i>Obstetrics</i>	91	10	12	31
<i>Newborn/Nursery</i>	21	3	4	5
<i>NICU/Intermediate</i>	29	2	2	8

*Source: Georgia, Division of Health Planning; Department of Community Health Service-Specific Rules for Perinatal Services*

The current need projections for perinatal services indicate no numerical need for additional basic obstetric services in the current horizon year of 2011. Moreover, none of the SSDRs have aggregate utilization over 75% for basic services during either of the past two years as required by the Rule. With respect to Neonatal Intermediate Beds, the need projection indicates a deficit of intermediate beds in 2011 in SSDR 2 (deficit of 7 beds) and 3 (deficit of 8 beds), but only SSDR 2 has the requisite aggregate utilization (132.3% in 2003 and 145.9% in 2004). With respect to NICU beds, the 2011 need projection indicates a deficit of 25 beds in NICU Planning Area 4 and aggregate utilization in that area of over 80% for the past 2 years (166.7% in 2003 and 179.7% in 2004). The other 4 NICU planning areas have a surplus of NICU beds and aggregate utilization below 80%.

#### Comparison States

Unlike Georgia, not all states regulate perinatal services, even if they have Certificate of Need programs. 16 states regulate obstetrics services through CON and 23 states regulate NICUs. Of the comparison states used by the Georgia Health Policy Center, only Iowa, Maine and Washington join Georgia in regulating both services through CON. Florida, Massachusetts, and West Virginia cover NICUs, but not obstetric services by CON, and Colorado, Oregon, and Wisconsin do not cover either service. These results are depicted in Figure 7-11.



**FIGURE 7-11: Comparison States CON Regulation of Perinatal Services**

<b>Perinatal Services: CON Regulation</b>		
	<b>Obstetrics</b>	<b>NICU</b>
<i>Colorado</i>	No	No
<i>Florida</i>	No	Yes
<i>Georgia</i>	Yes	Yes
<i>Iowa</i>	Yes	Yes
<i>Maine</i>	Yes	Yes
<i>Massachusetts</i>	No	Yes
<i>Oregon</i>	No	No
<i>Utah</i>	No	No
<i>Washington</i>	Yes	Yes
<i>West Virginia</i>	No	Yes
<i>Wisconsin</i>	No	No

Source: American Health Planning Association, National Directory of State Certificate of Need Programs, 2006

Federal Oversight

*Medicare/Medicaid*

Medicaid is currently the primary payer source for about one-half of all births in the state (49% of all births were Medicaid births in 2002, ranking Georgia 11<sup>th</sup> in the nation for % of Medicaid births). Georgia ranks 6<sup>th</sup> in the nation for total number of Medicaid births in 2002, with 66,307 births covered by Medicaid.

*EMTALA*

Another federal law that impacts the delivery of perinatal care in Georgia is the Emergency Medical Treatment and Active Labor Act (“EMTALA”), passed as part of the Consolidated Omnibus Budget Reconciliation Act of 1986. The overall purpose of EMTALA, referred to as an “anti-dumping” measure, is to prevent hospitals from rejecting patients, refusing to treat them, or transferring them to “charity hospitals” because they are unable to pay or are covered under the Medicare or Medicaid programs. Essentially, EMTALA requires that any patient who comes into the



emergency department of a hospital must be provided with an “appropriate medical screening examination” to determine if she is suffering from an “emergency medical condition.” A pregnant woman who presents in active labor and is found to be in have emergency medical condition must be provided with treatment until she is stable or can be transferred to another hospital if appropriate under EMTALA regulations.

In May 2004, the Centers for Medicare and Medicaid (“CMS”) created an EMTALA Technical Advisory Group, which shall provide recommendations to the Administrator of CMS on EMTALA regulations and their application to hospitals and physicians. The EMTALA TAG had its fourth meeting on November 2-3, 2006.

## Strategic Options

### Option 7.0

*Maintain existing CON regulation of obstetrical and perinatal services.*

### Option 7.1

*Deregulate obstetrical and perinatal services from Certificate of Need.*

### Option 7.2

*Deregulate obstetrical and perinatal services and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for obstetrical and perinatal services; however, hospitals would still be required to report data on a regular basis.

### Option 7.3

*Deregulate obstetrical and perinatal services and create detailed licensure standards.*

Under this option, applicants would not need to obtain a CON for obstetrical and perinatal services; however, licensure would create more detailed standards for such services.

### Option 7.4

*Deregulate perinatal services by level.*

7.4A: Deregulate Level I

7.4B: Deregulate Level II

7.4C: Deregulate Level III



## Option 7.5

*Maintain existing CON regulation of freestanding birthing centers.*

## Option 7.6

*Deregulate freestanding birthing centers from Certificate of Need.*

## Recommendations

*NOTE: The Commission did not reach full consensus on the regulation of perinatal and obstetrical services.*

### Recommendation 7.0 *(6 Agree, 1 Disagrees, 3 Abstain)*

*Deregulate Level I perinatal services and continue regulation of Level II and Neonatal Intensive Care.*

Most members of the Commission recommend that Level I perinatal services be deregulated because these services are already provided by most hospitals in the state and do not require specialized labor. These members believe that access to perinatal and obstetrical care will be enhanced by their recommendation. The fact that federal law already requires a facility to treat a woman in active labor further supports this recommendation. The members who make this recommendation maintain that Level II and Level III services should continue to be regulated by CON because of the highly-skilled nature of these services and the workforce that is required to support them. One member of this group further believed that Level II should be deregulated in addition to Level I.

One member of the Commission made the recommendation to maintain existing CON regulation for this service. This member believes that maintaining Certificate of Need regulation of Level I perinatal services will address the problem of large fixed costs incurred by facilities that provide these services and the shortage of skilled workforce.

Several members of the Commission report that this recommendation should be limited to Level 1 perinatal services at hospitals and should not be construed as a recommendation regarding freestanding facilities.



## Mental Health Services

### An Analysis and Evaluation of Psychiatric and Substance Abuse Inpatient Programs in Georgia

#### Overview

##### Background

Approximately 26.2 percent of adults in the United States have symptomatic mental disorders, such as major depression, according to National Institute of Mental Health (NIMH) estimates. When applied to the 2004 U.S. Census residential population estimate for ages 18 and older, this figure translates to 57.7 million people. NIMH estimated that over 20 percent of adults requiring care do not seek it. In addition, an estimated 1 in 10 children and adolescents in the United States suffers from mental illness severe enough to cause some level of impairment. An estimated two thirds of all young people are not getting the help they need, according to the Center for Mental Health Services (CMHS).

Substance abuse disorders including alcohol and drugs are among the most common mental disorders found in 8.1 percent of Americans, according to the Substance Abuse and Mental Health Services Administration: 2005 National Survey on Drug Use and Health. Psychiatric catastrophic illnesses are among the top leading catastrophic illnesses comprising over 40 percent of the total costs of mental health per year. These costs can be expected to rise as our population ages

and the number of people with chronic disorder and organic syndrome increases. Additionally, the need for mental health services increases in areas where the level of environmental risk factors such as poverty increases. Both nationally and in Georgia recognition of mental illness and its costs to society have increased. Spending and insurance coverage for mental health services have dramatically increased, although the majority of funds are directed at hospitalization. It has been recognized that the provision of mental health services reduces the need for other health care services. In addition, untreated mental disorders result in other costs such as reduced productivity and lost employment. Due to the complex biological, social, and psychological etiologies of mental illness, and the range of disabilities, treatment approaches vary. Planning for mental health services should include a range of interrelated services that provide a continuum of care for individuals in a variety of settings. Ideally, clients may then be treated in the least restrictive setting appropriate for their treatment needs at different stages in time. Inpatient psychiatric and substance abuse hospital care is viewed as one important component of this health care system that is restrictive, highly-developed and resource-intensive. Outpatient therapy day or night treatment programs



community mental health centers, halfway houses, group homes, residential treatment centers, and part-time hospitalization are other components of the mental health system that are less costly and can be made available at the community level.

Statewide, hospitalization for mental health disorders constituted 44 percent of total mental health expenditures. Outpatient therapy residential treatment centers and other treatment settings provide appropriate levels of mental health care for many individuals and reduce the need for hospitalization. Preventive services and early treatment may reduce the need for hospital care while community-based follow up care limits the number of hospital readmissions.

When assessing the need for inpatient hospital care, the range of services provided by the mental health system in an area must be evaluated. If there is limited availability of one type of service other related services may be over-utilized. The availability and utilization of mental health services is also influenced by such factors as government funding, reimbursement, economic status, and unemployment. Fiscal policies at the national and state levels have, for example, limited the resources available for preventive mental health programs.

Utilization of state psychiatric hospitals has dramatically decreased due to policies of deinstitutionalization, funding limitations and the growth of the private sector, as well as increased possibilities for treatment of certain disorders. In Georgia, state programs are currently stressing a community oriented approach, which includes residential treatment facilities. For some individuals these facilities provide a less costly and a more efficacious form of treatment than inpatient hospital care.

Reimbursement issues often dictate what type of treatment an individual may receive and where that care may be provided.

Reimbursement can also determine what types of services are offered. Although reimbursement for mental health services has increased, the focus is still on inpatient hospital services. For example, short-term hospital stays are often covered by private insurance and there has been a growth in the number of private psychiatric facilities in Georgia. Residential treatment centers, which are often not covered by private insurance, are not being developed in Georgia.

The range of third-party coverage for mental health services includes no coverage (indigents and medically indigents), Medicaid-eligible, under-insured Medicare-eligible and fully insured. The availability of care for the uninsured or underinsured is limited and there are restrictions concerning Medicaid and Medicare coverage. The state regional hospitals provide inpatient services to the public sector in Georgia. These hospitals experience high occupancy rates, which limit the number of beds available for new admissions. Private free-standing psychiatric hospitals are not reimbursed by Medicaid in Georgia, limiting the availability of such care to Medicaid patients.

Historically, private insurance coverage for mental health services was limited when compared to coverage for other types of illness. The Mental Health Parity Act prohibits different dollar limits for mental health services and general health care.

Prepaid health plans, such as health maintenance organizations and preferred provider organizations, experience higher utilization rates for outpatient mental health services than traditional insurance plans. Such plans usually offer coverage for a range of services, while emphasizing and encouraging the use of less costly, preventive services that induce the use of early treatment and avoid hospitalization.



## Access, Supply and Distribution

Inpatient psychiatry is one of the medical services defined in the statute as requiring a Certificate of Need. Inpatient psychiatric care involves crisis intervention, diagnosis, and understanding the manifestations of mental disease in the patient, development of an ongoing plan of treatment designed to minimize critical episodes and the promotion of the patient's ability to live and function in the community.

There are three types of facilities providing inpatient psychiatric and substance abuse services in Georgia:

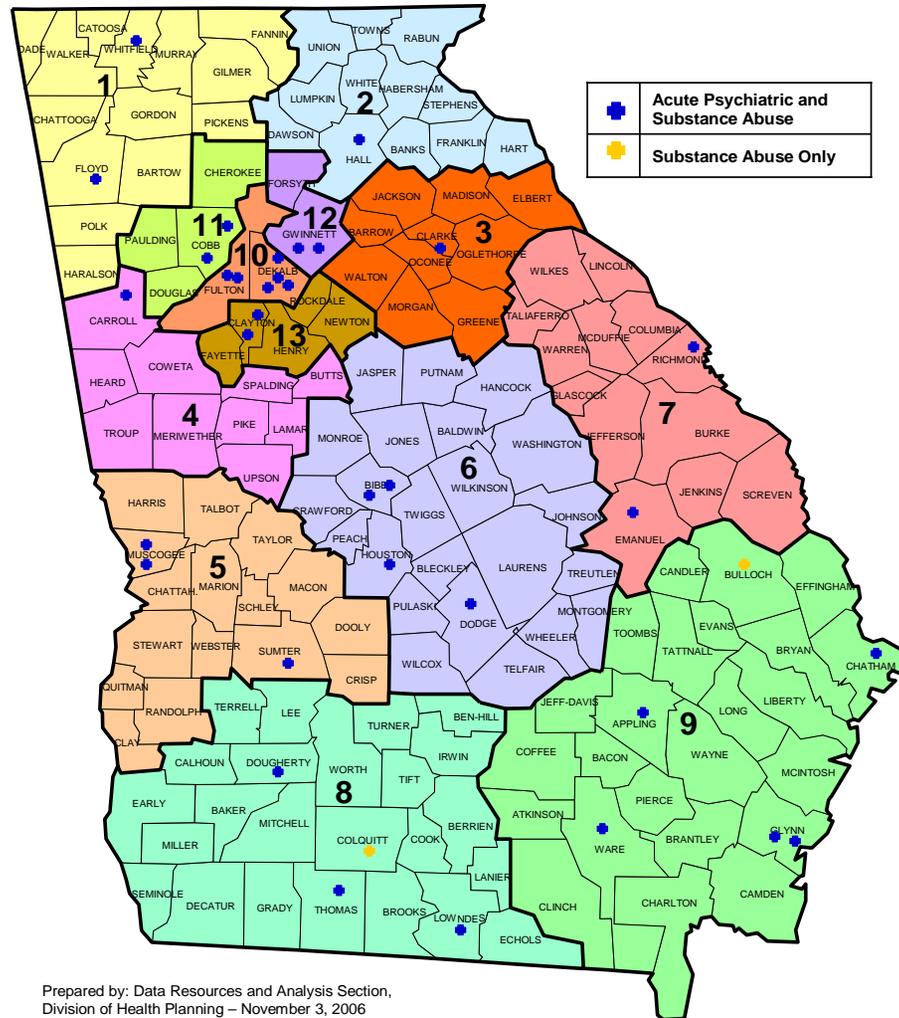
- Public freestanding hospitals (State's regional hospitals)
- Private freestanding hospitals
- General or other specialty hospitals with psychiatric and/or substance abuse programs

The locations and distribution of these facilities throughout Georgia are provided in Figures 8-1, 8-2, and 8-3.



FIGURE 8-1.

**Adult Acute Psychiatric and Substance Abuse  
Program Locations and Planning Areas  
(Private Sector)**

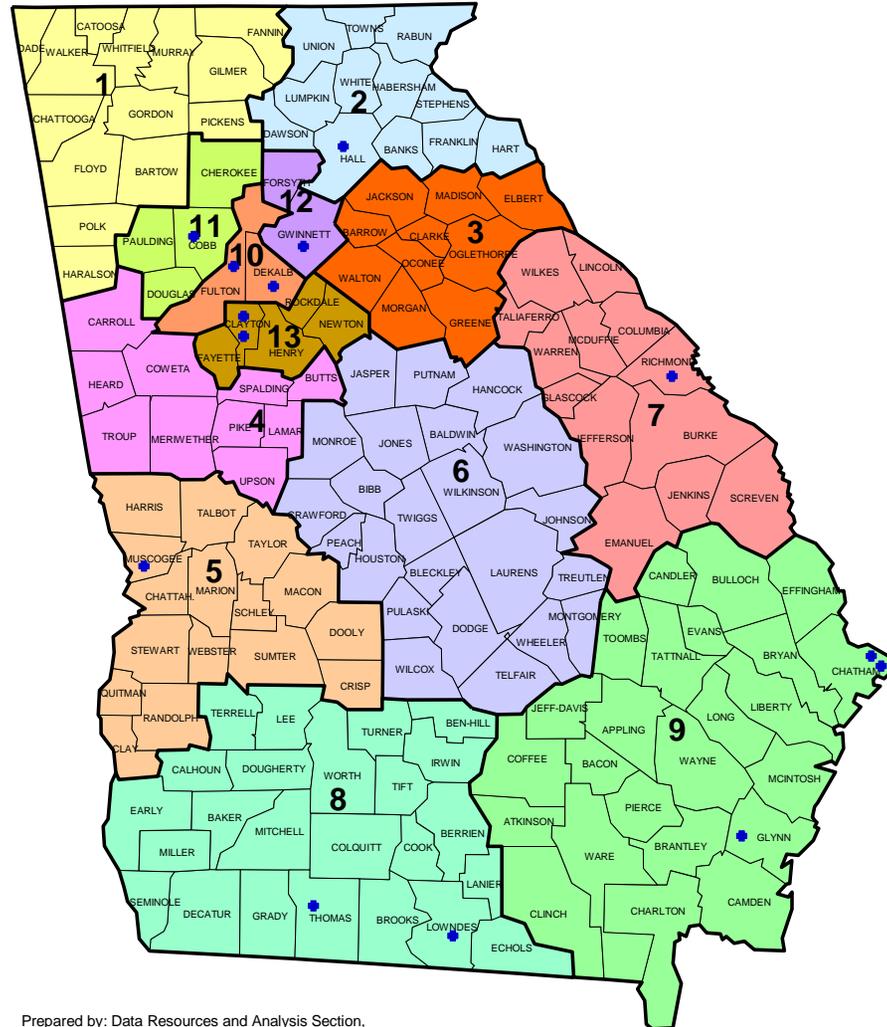


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 8-2.

**Private Sector  
Child and Adolescent Acute Psychiatric and Substance Abuse  
Program Locations and Planning Areas**

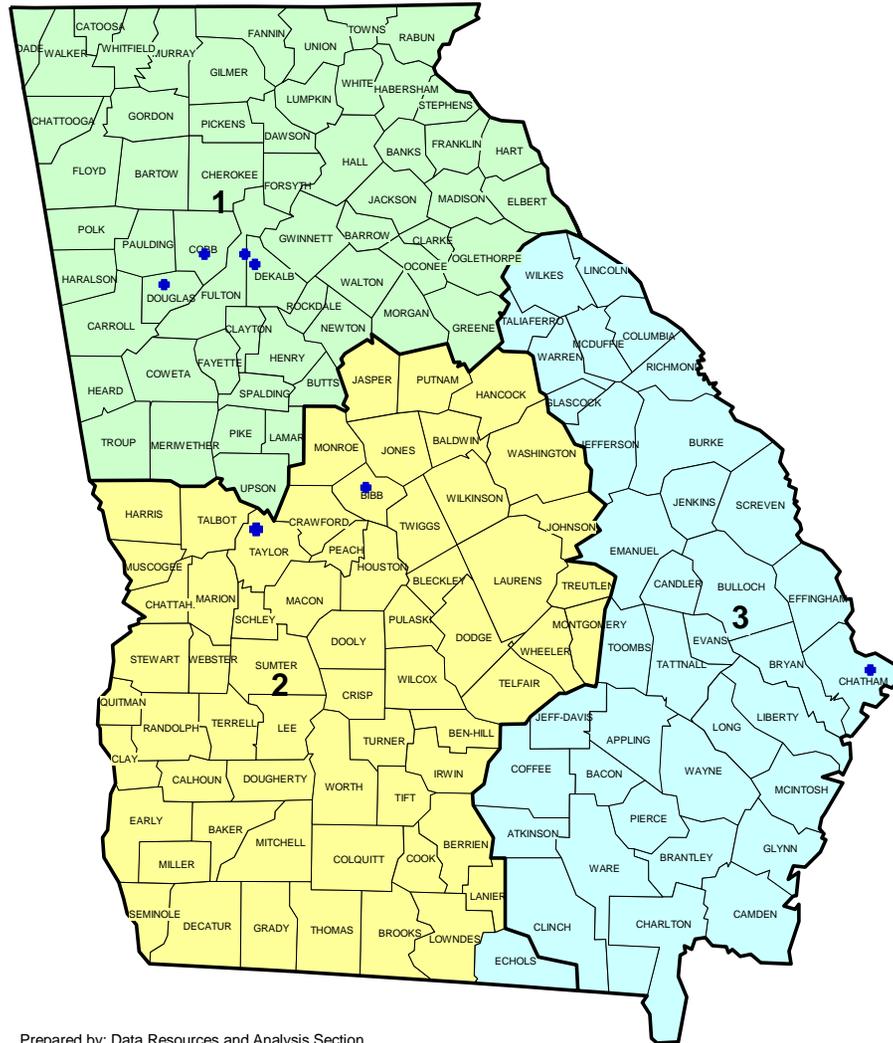


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 8-3.

**Child and Adolescent Extended Care Psychiatric  
Program Locations and Planning Areas  
(Private Sector)**



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



There are 50 facilities statewide providing psychiatric and substance abuse services, representing 1,691 beds; 1,464 for age 18 and over and 237 for 0-17. Figure 8-4 below presents a summary of the number of inpatient psychiatric and substance abuse bed capacity, by category.

**FIGURE 8-4.**

<b>Psychiatric and Substance Abuse Beds by Ownership</b>							
Hospital Type	Adult Psych	Adult SA	Total Facilities	Child Psych	Adolescent Psych	Adolescent SA	Total Facilities
Private	1,013	442	35	75	234	52	20
Public	884	8	7	38	116	0	7
Total	1,897	450	42	113	350	52	27



## Utilization

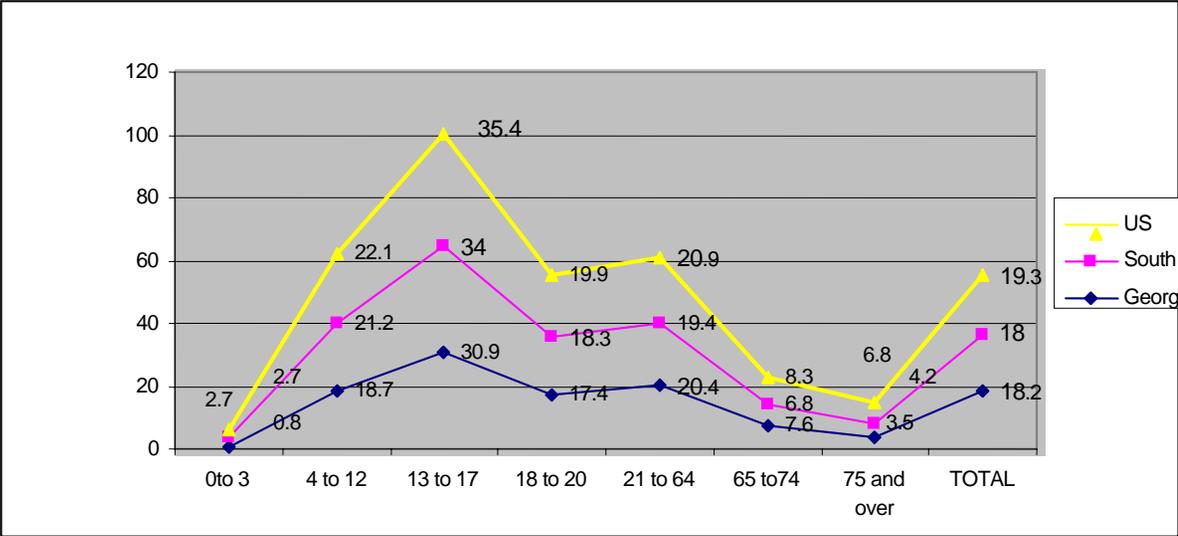
Figures 8-5 and 8-6 demonstrate the utilization of psychiatric and substance abuse programs in the state of Georgia, by planning area, and in comparison to regional and national trends.

**FIGURE 8-5.**

<b>Psychiatric Bed Occupancy Rates by Planning Area</b>					
Planning Area	Total Facilities	O/R Ages 0-12	O/R for Ages 13-17	O/R for Ages 18+	O/R for Total CON Beds
1	2	0%	0%	63%	63%
2	1	57%	99%	115%	106%
3	1	0%	0%	17%	17%
4	1	0%	0%	81%	81%
5	4	27%	15%	40%	33%
6	5	0%	0%	43%	39%
7	2	54%	67%	74%	69%
8	4	57%	36%	50%	48%
9	6	17%	17%	59%	41%
10	9	41%	48%	67%	65%
11	4	146%	68%	71%	71%
12	2	0%	37%	81%	73%
13	2	77%	75%	93%	89%



## 2004 Mental Health Service Utilization



Note: Total Utilization rate per 1,000 population

**FIGURE 8-6.**



## Cost

Total expenditures for psychiatric services in Georgia compared to national levels is illustrated in Figure 8-7.

**FIGURE 8-7.**

<b>State Expenditures for Mental Health Fiscal Year 2003</b>				
	State Expenditure	% State Mental Health Expenditures	U.S. Expenditures	% U.S. Mental Health Expenditures
State Hospitals- Inpatient	\$188,955,538	44%	\$7,529,415,330	29%
Other 24-Hour Care	\$38,646,153	9%	\$4,771,823,921	18%
Ambulatory/Community	\$187,897,364	44%	\$13,431,433,352	51%
<b>Total</b>	<b>\$415,499,055</b>		<b>\$25,732,672,603</b>	

## Quality

The quality of a psychiatric or substance abuse program is a function of many interrelated variables which include the program plan, admission policies and criteria, treatment protocols, discharge planning and the institutional or programmatic capacity to deliver services in an efficient and cost effective manner.

Outcome measures such as a patient's readjustment to society are also an important tool for determining the level of treatment delivered. Figure 8-8 below indicates the percentage of patients readmitted to state psychiatric hospitals within 30 to 180 days.



**FIGURE 8-8.**

<b>Outcome Measures</b>					
	<b>Georgia</b>		<b>U.S.</b>		
State Hospital Readmissions: Within 30 Days	2,388	12.5%	13,514	9.1%	40*
State Hospital Readmissions: Within 180 Days	5,048	26.3%	30,167	20.4%	41
Readmission to any psychiatric Hospital: 30 Days	N/A	-	27,625	14.6%	15

\*Represents the number of reporting states

In order to insure that the program quality is provided in an efficient and cost effective manner, the minimum size of one program is eight beds, the minimum size of a freestanding hospital is 50 beds, and a general hospital with psychiatric and/or substance abuse programs must have a minimum of 15 beds dedicated to these programs. The general hospital may have one program with a minimum of 15 beds or two or more programs that together have 15 or more beds designated for their use. Unit facilities below this level are usually too small to be able to provide specialized staff and services at a reasonable cost and maintain program integrity and quality.

## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

The Georgia Department of Human Resources currently does not regulate psychiatric or substance abuse inpatient programs. The Office of Regulatory Services of the Department of Human Resources monitors compliance with Georgia's licensure rules and regulations for psychiatric and substance abuse programs.

#### *Department of Community Health.*

The Georgia Department of Community Health currently has specific review requirements that address both acute and extended care psychiatric or substance abuse inpatient programs. Acute care psychiatric or substance abuse inpatient programs as defined in Rule 111-2-2-.26(1)(a), provides medically oriented evaluation, diagnosis, stabilization and short term treatment for an average of 45 days or less for adults and usually 120 days or less



for children and/or adolescents. Five programs are defined: adult psychiatric, adult substance abuse, adolescent psychiatric, adolescent substance abuse and child psychiatric. Substance abuse care for children is included in the child psychiatric program. There are currently 1,897 adult acute psychiatric and 52 adult substance abuse beds statewide. 350 acute psychiatric beds and 52 acute substance abuse beds exist for adolescents. There are 113 acute child psychiatric beds in the State.

Extended care psychiatric and substance abuse inpatient programs focus on self-help and basic living skills to enhance the patient's ability to perform successfully in society upon discharge. The program is designed to treat people who do not require acute care and who usually have at least one previous acute care admission. Two programs are defined: adult psychiatric and substance abuse and adolescent/child psychiatric and substance abuse. There are currently 489 adult extended beds over 42 facilities in Georgia and 980 adolescent/child extended beds dispersed between 27 providers.

For the public sector a Certificate of Need is not required for new or expanded psych/substance abuse programs as long as the proposed number of beds does not exceed the total number needed statewide as determined in the short-stay bed need methodology and as long as the capital costs do not exceed the CON threshold. All entities desiring to expand their services for the first time must apply under these considerations.

For the private sector, a Certificate of Need is required prior to the establishment of a new psychiatric or substance abuse program, when capital expenditures for an existing program exceed the CON threshold. A CON is also required for the increase of beds in an existing program except when the increase is exempt or will not result in an increase in the bed capacity of a facility. Figure 8-9 demonstrates the application volume for psychiatric and substance abuse services since CON began in Georgia.

**FIGURE 8-9.**

<b>Psychiatric and Substance Abuse Applications 1979 to Present</b>				
	Approved	Denied	Withdrawn	Appeals
Adult Inpatient Psych	63	25	39	52
Adult Substance Abuse	32	17	26	29
Child/Adolescent Psych	19	1	8	5
Child/Adolescent Substance Abuse	11	2	3	5
Extended Care Psych	11	2	2	3



## Comparison States

Of the 10 survey states, 5 currently regulate inpatient psychiatric and substance abuse services. These results are depicted in 8-10.

**FIGURE 8-10.**

<b>Psychiatric and Substance Abuse CON Regulation</b>	
Colorado	No
Florida	Yes
Georgia	Yes
Iowa	No
Maine	Yes
Massachusetts	Yes
Oregon	No
Utah	No
Washington	No
West Virginia	Yes
Wisconsin	No

## Federal Oversight

### *Medicare.*

A freestanding psychiatric hospital public or private which is JCAHO accredited is deemed to meet Medicare certification except for two Medicare special conditions which are evaluated each year by ORS or by the National Institute of Mental Health.



## Strategic Options

### Option 8.0

*Maintain existing CON regulation of inpatient psychiatric and substance abuse services.*

### Option 8.1

*Deregulate inpatient psychiatric and substance abuse services from Certificate of Need.*

### Option 8.2

*Deregulate inpatient psychiatric and substance abuse services and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for inpatient psychiatric and substance abuse services; however, hospitals would still be required to report data on a regular basis.

### Option 8.3

*Deregulate inpatient psychiatric and substance abuse services and create detailed licensure standards.*

Under this option, applicants would not need to obtain a CON for inpatient psychiatric and substance abuse services; however, licensure would create more detailed standards for such services.



## Recommendations

### Recommendation 8.0

*Maintain existing CON regulation of inpatient psychiatric and substance abuse services.*

The Commission members agree that inpatient psychiatric and substance abuse services should continue to be regulated by Certificate of Need.



## Skilled Nursing

### An Analysis and Evaluation of Nursing Home Services and Continuing Care Retirement Communities in Georgia

#### Overview

##### Background

Application of the CON process to the long-term care industry has a somewhat different rationale than for other, more specialized services. The extent to which public payers, particularly state Medicaid programs, pay for nursing home services and the budgetary impact of such expenditures for public payers has caused policy makers to look for ways to constrain the growth of these programs. Therefore, many states have retained CON programs to limit the supply of long-term care beds in order to constrain public expenditures. Furthermore, some states have implemented a moratorium on the licensing of new nursing home beds even in the absence of a CON program.

As Georgia's population ages and becomes more diverse, there is growing concern about long-term care and how to assure provision of needed long-term care services. Population projections for the year 2006, developed by the Governor's Office of Planning and Budget, indicate the state now has 1,004,115 citizens (civilian, non-institutional) aged 65 and older. By the year

2011, Georgia's population aged 65 and over is expected to reach over 1.2 million.

In addition, the last 100 years have brought with them a steady evolution and dramatic changes in science, medicine, technology, economics, sociology and a host of other environmental variables. A very important contribution to the market for retirement housing has been the vast improvement in the financial and economic condition of the elderly. In 1985, 75 percent of the elderly owned their own homes and 83 percent owned them mortgage free.

The improved economic condition of the elderly has spurred the development of a different model of nursing home services, those which are offered as part of a continuing care retirement community ("CCRC").

While there is no typical make-up of a CCRC, each offers some form of continuum of care that includes residential living arrangements and the availability of nursing facility services. A CCRC differs from other retirement options by providing a continuum of housing, services, and health care, centrally planned, located, and administered. For those communities providing



nursing care, two circumstances determine the fee for such care. Direct entry into a nursing facility bed from outside the CCRC typically requires payment of a daily rate commensurate with the market rate for the area. Those who transfer to a nursing facility bed from the residential portion of the CCRC pay either a specific monthly fee or a daily rate. For communities that include health care coverage in their monthly fee, residents are able to declare a certain portion of the medical fees on their annual income tax statements as medical deductions.

The independent living units (ILUs) of a CCRC could range from studio apartments to individual cottages. The assisted living or personal care units can be either individual apartments or rooms. The nursing care beds consist of either private or shared rooms. In addition to the residential units and nursing beds, CCRC facilities have common areas and amenities which can be used by all the residents. All of the CCRCs have dining facilities and lounges or meeting rooms on their premises. Other amenities could include salons, barber shops, game rooms, fitness centers, chapels, libraries, and a host of other services.

The variety of continuing care agreements (or contracts) offered by CCRCs has increased over the years largely due to the advent of Medicaid and Medicare, rising health care costs, shifting consumer preferences and government regulations which have precipitated a myriad of contractual arrangements with residents. The most significant variation relates to the amount of health care coverage included and the types of payment plans and refund options offered. Extensive agreements cover most long-term health care without additional charges beyond the entry fee and/or monthly fees paid by residents. Modified agreements usually cover some portion of long-term health care services. Fee-for-service agreements usually require residents to pay for the long-term health care services on an as-needed basis. While the majority of CCRCs provide lifetime care in exchange for an up-front entrance fee and ongoing monthly fee, as stated earlier, some CCRCs provide an agreement that may be for a shorter period with no up-front entrance fee required.

Monthly fees are charged by all facilities. Typically, the greater the endowment (entrance) fee at a facility, the greater the average monthly fee. The various types of CCRC resident agreements are:

- **Type A: All Inclusive** Guarantees resident fully paid nursing care at no extra cost beyond the resident's monthly fee.
- **Type B: Modified** Does not guarantee unlimited nursing care but provides a pre-specified number of days each year or during a resident's lifetime. Residents pay a daily charge for additional nursing care beyond the predetermined number of days.
- **Type C: Fee-For-Service** Guarantees residents access to their nursing wing, but usually charges for each day of care.
- **Type D: Equity Models** The condo/co-op model offers residents an equity opportunity to share in the ownership of the community and is an option for those looking for the benefits of owning real estate and the deduction of mortgage interest on taxes.

#### Access, Supply and Distribution

As of October 30, 2006, the Department's facility inventory shows that there are 379 nursing care facilities in Georgia with a total of 42,790 existing and/or approved nursing beds. This data is depicted in Figures 9-1 and 9-2. There are currently 9 CCRCs. These facilities are dispersed throughout the State, with the highest concentration in state service delivery region 3 (metro Atlanta). Information regarding CCRCs is depicted in Figure 9-3.



FIGURE 9-1.

<b>Number of Nursing Home Beds (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	3871	3889	3901	3889	3889	3889
2	2179	2263	2269	2256	2212	2202
3	10,865	10,875	10,802	10,758	10,658	10,668
4	2410	2396	2386	2442	2406	2406
5	2017	2013	2013	2013	2013	2013
6	4361	4401	4401	4436	4436	4436
7	3568	3568	3548	3597	3597	3597
8	2470	2470	2470	2470	2470	2470
9	3106	3106	3106	3106	3106	3106
10	2346	2506	2506	2506	2506	2506
11	2665	2695	2695	2695	2680	2680
12	2718	2866	2766	2760	2760	2760
<b>TOTAL</b>	<b>42,576</b>	<b>43,048</b>	<b>42,863</b>	<b>42,928</b>	<b>42,733</b>	<b>42,733</b>



FIGURE 9-2.

<b>Number of Nursing Home Facilities (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	40	39	40	39	39	39
2	21	23	22	21	20	19
3	82	84	81	79	78	77
4	23	22	21	23	22	22
5	24	24	23	23	23	23
6	39	40	40	39	39	39
7	31	31	30	30	30	30
8	20	20	20	20	20	20
9	33	33	33	33	33	33
10	25	25	25	25	25	25
11	25	27	27	27	26	26
12	29	30	29	28	28	28
<b>TOTAL</b>	<b>392</b>	<b>398</b>	<b>391</b>	<b>387</b>	<b>383</b>	<b>381</b>



FIGURE 9-3.

<b>Number of CCRC Facilities (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	0	0	0	0	0	0
2	1	1	1	1	1	1
3	2	2	2	2	3	3
4	0	1	1	1	1	1
5	0	0	0	0	0	0
6	1	1	1	1	1	1
7	0	0	0	0	0	0
8	0	0	0	1	1	1
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	0	0	0
12	0	1	1	2	2	2
<b>TOTAL</b>	<b>4</b>	<b>6</b>	<b>6</b>	<b>8</b>	<b>9</b>	<b>9</b>

Utilization

According to Department data, the State's 39,660 approved and existing nursing beds had an overall occupancy rate of 89 percent in 2005. There were no individual planning areas that reached the 95 percent threshold that would allow for new or expanded services. This information is further depicted in Figure 9-4.



FIGURE 9-4.

<b>Nursing Home Patient Days &amp; Occupancy Rates (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	1,337,900 94.69 %	1,308,626 92.19 %	1,344,351 94.42 %	1,261,251 88.85 %	1,268,682 89.38 %	1,281,622 90.29 %
2	747,871 94.03 %	760,306 92.05 %	761,786 91.98 %	755,617 91.76 %	736,764 91.25 %	760,542 94.63 %
3	3,298,003 83.16 %	3,280,196 82.64 %	3,324,546 84.32 %	3,336,265 84.96 %	3,292,289 84.63 %	3,510,320 90.15 %
4	843,175 95.85 %	833,403 95.3 %	817,300 93.85 %	821,365 92.15 %	810,772 92.32 %	819,187 93.28 %
5	683,846 92.89 %	649,788 88.44 %	689,637 93.86 %	671,987 91.46 %	682,954 92.95 %	635,241 86.46 %
6	1,212,725 76.19 %	1,228,204 76.46 %	1,153,885 71.83 %	1,246,096 76.96 %	1,226,949 75.78 %	1,228,045 75.85 %
7	1,018,564 78.21 %	999,761 76.77 %	958,492 74.01 %	1,096,952 83.55 %	1,040,818 79.28 %	1,076,392 81.99 %
8	850,193 94.3 %	845,715 93.81%	840,347 93.21 %	820,959 91.06 %	803,912 89.17 %	792,512 87.91 %
9	992,592 87.55 %	994,168 87.69 %	1,001,428 88.33 %	937,863 82.73 %	914,392 80.66 %	1,030,149 90.87 %
10	765,383 89.38 %	794,990 86.91 %	809,842 88.54 %	795,059 86.92 %	782,586 85.56 %	761,733 83.28 %
11	899,406 92.46 %	884,814 89.95 %	794,324 80.75 %	894,962 90.98 %	894,382 91.43 %	871,653 89.11 %
12	793,860 80.02 %	837,256 80.04 %	866,840 85.86 %	860,464 85.41 %	753,128 74.76 %	803,844 79.79 %
<b>TOTAL</b>	<b>13,443,518</b> <b>86.81 %</b>	<b>13,417,227</b> <b>85.39 %</b>	<b>13,362,778</b> <b>85.41 %</b>	<b>13,498,840</b> <b>86.15 %</b>	<b>13,207,628</b> <b>84.68 %</b>	<b>13,571,240</b> <b>87.01 %</b>



## Cost

According to Kiplinger's 2004 Retirement Report, the U.S. average cost for Nursing Home care is \$57,700 a year (\$158 a day). For Georgia, the average costs were \$43,200 a year (\$118 a day). According to the Georgia State University Report, Georgia has an average charge of \$129 per day for a private room in an urban area. This information, along with reimbursement information relating to other comparison states, is depicted in Figure 9-5.



**FIGURE 9-5.**

**Reimbursement per Bed Day, 2002<sup>5</sup>**

	Medicaid	Medicare	Private (Urban Average)
Total: USA	\$118	\$265	\$158
All Study States	\$119	\$265	\$162
Absolute Moratorium States			
Florida	\$134	\$262	\$149
Maine	\$132	\$252	\$187
Massachusetts	\$141	\$285	\$233
Utah	\$103	\$277	\$118
Washington	\$129	\$296	\$165
West Virginia	\$130	\$234	\$151
Wisconsin	\$110	\$259	\$168
Mean: Moratorium States	\$126	\$266	\$167
Limited Restriction States			
Colorado	\$123	\$266	\$140
Georgia	\$91	\$245	\$129
Iowa	\$95	\$239	\$195
Oregon	\$111	\$301	\$137
Mean: Limited Restriction States	\$105	\$263	\$150
Mean: CON States	\$120	\$264	\$168
Mean: Non-CON States	\$112	\$267	\$142



## Quality

Quality is accounted for in the accreditation and licensing process. In order to receive a CON for nursing home services, an applicant must demonstrate the following:

- An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Office of Regulatory Services of the Department of Human Resources; and
- An applicant shall provide evidence that there are no uncorrected operational standards in any existing Georgia nursing homes owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plant deficiencies in the applying facility must be included in the application; and
- An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction or Medicaid or Medicare fraud; and
- An applicant shall demonstrate the intent and ability to recruit, hire and retain qualified personnel to meet the current Medicaid certification requirements of the Department's Division of Medical Assistance for the services proposed to be provided and that such personnel are available in the proposed geographic service area; and

- An applicant shall provide a plan for a comprehensive quality improvement program that includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance accordingly.
- In competing applications, favorable consideration will be given to an applicant that provides evidence of the ability to meet accreditation requirements of appropriate accreditation agencies within two years after the facility becomes operational.

On the structural measures of quality, the long-term care facilities located in markets in the most restrictive states have significantly higher levels of licensed and total care hours per patient per day than facilities located in the less restrictive states. In addition, facilities located in CON states have significantly higher levels of licensed and total care hours per patient per day than facilities located in non-CON states.

One measure of quality is the number of licensed staff per resident per day. Figure 9-6 compares Georgia to the select group of comparison states.



FIGURE 9-6.

	Licensed Staff Hours per Resident per Day	Total Patient Care Staff Hours per Resident per Day
<b>ALL STUDY STATES</b>	<b>1.42</b>	<b>3.86</b>
Absolute Moratorium States		
Florida	1.57	4.4
Maine	1.37	4.42
Massachusetts	1.59	3.91
Utah	1.66	4.16
Washington	1.49	4
West Virginia	1.25	3.67
Wisconsin	1.67	3.79
<b>Mean: Moratorium States</b>	<b>1.51</b>	<b>4.065</b>
Limited Restriction States		
Colorado	1.51	3.76
Georgia	1.31	3.49
Iowa	1.14	3.26
Oregon	1.25	3.86
<b>Mean: Limited Restriction States</b>	<b>1.24</b>	<b>3.5</b>



## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

ORS regulates long-term care facilities, which include 378 nursing homes, 13 intermediate care facilities for people with mental retardation, 180 community living arrangements, and 1,701 personal care homes. The Long-Term Care Section is also responsible for the licensing and inspection of residential child care facilities, which include child caring institutions, therapeutic camps, and private adoption agencies.

The following facilities, programs and services are required to be licensed or registered by the Department of Human Resources (DHR), Office of Regulatory Services (ORS). Some of these facilities may also be certified for Medicare and Medicaid (federal programs). Federal certification is a voluntary program. The following long-term care residential services are licensed by ORS:

- Intermediate Care (Nursing) Homes
- Community Living Arrangements
- Skilled Nursing Homes
- Personal Care Homes

#### *Department of Community Health.*

In July 1996, the Department of Community Health changed its procedures for reviewing Certificate of Need (CON) applications for nursing home beds by adopting a batching review process. Under this process, all applications for nursing

home beds are reviewed simultaneously, at six-month intervals. (CCRC applications may be submitted at any time). The Department will only accept and review applications in counties within planning areas where an identified need for nursing home beds exists. On January 9, 1997, the Health Strategies Council adopted a new Nursing Facilities Component Plan. In light of the Council's commitment to revisit the plan as significant changes occur in the long-term care industry, the Health Strategies Council appointed the Technical Advisory Committee to begin work in May 1999, specifically to reexamine the Nursing Home Bed Need Methodology. The TAC examined the Nursing Home Bed Need Methodology of several states, as well as changing demographics and use patterns in Georgia. After much discussion and several data runs, utilizing Georgia data, the TAC felt that the approach that stratified the population into four age categories (specifically 0-64, 65-74, 75-84, and 85+ age groups) would be best suited for the state of Georgia. This methodology places higher weights on the 75-84 and 85+ age groups, those population groups with the highest nursing home utilization. The TAC felt that this methodology was most reflective of community needs, service experience and state policy expectations. Furthermore, they agreed to maintain the following standards, as outlined in the Skilled Nursing and Intermediate Care Facilities Rules that were adopted and/or reissued in 1997:

- Three-year Planning Horizon;
- Urban/Rural/Retirement Bed Size Requirements;
- Favorable Consideration Standard; and
- Exceptions to Need Standard



The Department of Community Health, Division of Health Planning regulates health care services in the state through the Certificate of Need program. For nursing home services and CCRC services, a CON is required before a provider can offer services. A CON is required for the expansion of existing services and/or the establishment of a new service.

Figure 9-7 summarizes the number of CON applications that the Department has received since the beginning of the CON Program. For CCRC, the Department has approved every application that has been submitted under the CCRC sheltered-bed rule.

:

**FIGURE 9-7.**

<b>CON Applications for Skilled Nursing (1979 – Present)</b>	
Approved	243
Denied	96
Pending	2
Withdrawn	119
<b>Total</b>	<b>460</b>

### Comparison States

Nin comparison states (Florida Georgia, Iowa, Massachusetts, Maine, Oregon, West Virginia, Washington, and Wisconsin) have a CON process that applies to Nursing Homes, while Colorado and Utah do not. In Iowa and Oregon, the expansion possibilities through the CON process apply to specific beds. In Colorado, only Medicare or private-pay beds may be built. No additional Medicaid beds are being approved.



## Federal Oversight

### *Medicare.*

Skilled nursing facilities (SNFs) and nursing facilities (NFs) are required to be in compliance with the requirements in 42 CFR Part 483, Subpart B, to receive payment under the Medicare or Medicaid programs. To certify a SNF or NF, a state surveyor completes at least a Life Safety Code (LSC) survey, and a Standard Survey.

The State has the responsibility for certifying a skilled nursing facility's or nursing facility's compliance or noncompliance,

except in the case of State-operated facilities. However, the State's certification for a skilled nursing facility is subject to CMS' approval. "Certification of compliance" means that a facility's compliance with Federal participation requirements is ascertained. In addition to certifying a facility's compliance or noncompliance, the State recommends appropriate enforcement actions to the State Medicaid agency for Medicaid and to the regional office for Medicare.

The CMS regional office determines a facility's eligibility to participate in the Medicare program based on the State's certification of compliance and a facility's compliance with civil rights requirements.

## Strategic Options

### Option 9.0

*Maintain existing CON regulation of skilled nursing facilities.*

### Option 9.1

*Maintain existing CON regulation of skilled nursing facilities and issue a moratorium on new beds.*

### Option 9.2

*Deregulate from CON but issue a moratorium on new skilled nursing beds.*

### Option 9.3

*Deregulate skilled nursing facilities from Certificate of Need.*

### Option 9.4

*Deregulate skilled nursing facilities and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for the establishment or expansion of a skilled nursing facility; however, skilled nursing facilities would still be required to report data on a regular basis.

### Option 9.5

*Deregulate skilled nursing facilities in general and only require a CON for Medicaid-Certified Beds.*

### Option 9.6

*Maintain existing CON regulation of CCRCs.*



## Option 9.7

*Deregulate CCRCs as long as the nursing beds remain sheltered.*

Under this option, sheltered skilled nursing components of CCRCs would be exempt from having to obtain a CON.

## Recommendations

### Recommendation 9.0

*(Unanimous)*

*Maintain existing CON regulation of skilled nursing facilities.*

The members of the Commission unanimously recommend maintaining CON regulation of skilled nursing facilities. As the state's population of elderly citizens grows, there will be an increased need for skilled nursing services. CON works to ensure that there will be an adequate number of services to meet that need. CON also serves as a gatekeeper to ensure the quality of skilled nursing service market entrants.

### Recommendation 9.1

*(Unanimous)*

*Deregulate CCRCs as long as the nursing beds remain sheltered.*

Commission members agreed unanimously to exempt Continuing Care Retirement Communities (CCRC) from Certificate of Need regulation because these facilities have been routinely approved by the Department in large part because they have already been approved by the Department of Insurance before applying for a Certificate of Need. The Commission recommends that CCRCs continue to comply with Department rules that their skilled nursing beds remain sheltered to prevent any inaccuracies in projecting need for other skilled nursing beds throughout the State. Therefore, the Commission recommends that only CCRCs that maintain sheltered nursing beds be added to the list of statutorily-exempt services and facilities.



## Home Health Care

### An Analysis and Evaluation of Home Health Services in Georgia

#### Overview

##### Background

The continuum for long-term care services consists of a wide range of service options for seniors, persons with disabilities and others in need of transitional living and support services. Skilled and intermediate care nursing facilities provide services at the most restrictive and intensive end of the long-term care continuum. These facilities provide health care support and maintenance within a residential setting, ideally for individuals who could not otherwise be served in their own home or another community setting.

A wide range of home and community-based services also are available in the continuum, starting with residential services such as assisted living (known in Georgia as personal care homes) and ending with minimally restrictive programs such as adult day health care and home delivered meals. Many of these services are available to citizens through several waiver programs offered by the Department of Community Health through its Medicaid programs. Persons served through these home and community-based waiver programs must meet the potential criteria for nursing home or institutional care.

Home health service is one component of the long-term care continuum. It is a health care service that allows patients to receive services in their own homes or the home of a family member. Home health services also fill an important role in providing nursing services and therapeutic care for individuals transitioning out of an acute care setting. Home health is a very specific, specialized type of home care, requiring skilled nursing care, ordered by a physician. Visits are part-time or intermittent, and treatment plans have to be reviewed and updated at least every two months. Medicare generally defines "intermittent" services as those provided or needed less than 7 days each week or less than 8 hours each day for period of 21 days or less. (Medicare Advisory: October 1998). Medicare and Medicaid reimburse most costs associated with the provision of home health services to qualified enrollees.

There are other services available through home and community-based programs. Personal support and private home provider services are other types of home care services. Many of these services and programs do require state licensure, but do not require a certificate-of-need for operation. Since these services are not provided as physician-directed health care, they are not reimbursable by Medicare. Many



home and community-based services are reimbursed by Medicaid through their waiver programs. Because of the medically directed, costly nature of home health care, it is one of the few long term care services which require a Certificate of Need.

### Access, Supply and Distribution

Home health care in the United States is a diverse and dynamic service industry. Approximately 20,000 providers deliver home care services to 7.6 million individuals who require services because of acute illness, long-term conditions, permanent disability, or terminal illness. Annual expenditures for home care were projected at \$38.3 billion in 2003, according to the National Association for Home Care & Hospice.

Several historic and demographic factors have influenced the provision of home care services over past years and continue to shape the industry. Some of these factors are discussed below:

- Changing demographics, especially the aging of the population: Since age and functional disability are likely predictors of the need for home health services, the aging of Georgia's population will impact the need for these services.
- Impact of Medicare's Prospective Payment System (PPS): Shorter hospital stays for Medicare beneficiaries, as a result of the PPS, have resulted in more people discharged quicker and in frailer conditions. Also, more diagnostic and treatment procedures are being done on an ambulatory basis. During the 1980's, Medicare's annual home care benefit increased significantly and the number of home care agencies had risen to over 10,000. More recently, the number of Medicare-certified home health

agencies declined to 7,747, the direct result of changes in Medicare home health reimbursement enacted as part of the Balanced Budget Act of 1997. (National Association of Home Care, 2004)

- Changes in technology: Advances in complex medical care now allow many people to survive traumatic events and to live longer than ever before with serious health conditions. In recent years, technology has allowed home care to become increasingly high-tech, including intravenous infusions, parenteral nutrition, supplemental oxygen, monitoring devices, and respirators.
- Increased Consumer Demand: There continues to be a growing interest in finding ways to keep patients out of institutions treating patients in home or community settings. Home care supporters are quick to point out that care delivered in a patient's home should cost far less than similar care in a hospital or nursing home.

Data from the Annual Home Health Services Survey indicates that in 2000 there were 104 home health agencies licensed statewide, down from 117 agencies in 1999. By 2005 the number of agencies statewide decreased by only one, to 103.

One of the major concerns in planning for statewide services is the provision of home health services for Georgia's rural communities. Access to healthcare services is particularly problematic, given historical problems in recruitment and retention of health care personnel. Staffing vacancies and their impact on home health agencies vary across the state. Figure 10-1 below demonstrates the vacancy rates for registered nurses, licensed practical nurses and nurse aides by SDDR. In 2005, skilled nursing (RNs and LPNS) and home health aides accounted for 67 percent of all home health visits in the state of Georgia. The vacancy rates for the home health workforce are provided below in Figure 10-1.



FIGURE 10-1.

2005 Home Health Workforce: Vacancy Rate by Planning Area										
	Total Facilities	FT RN	Vacant RN	Vacancy Rate	FT LPN	Vacant LPN	Vacancy Rate	FT Aides/ Assistants	Vacant Aides/ Assistant	Vacancy Rate
Georgia	103	43,123	109.47	0.25%	316.56	41.00	12.95%	505.34	20.45	4.05%
SSDR 1	7	93.79	12.00	12.79%	41.00	3.00	7.32%	30.89	0.00	0.00%
SSDR 2	8	67.5	5.00	7.41%	24.00	6.00	25.00%	20.00	1.00	5.00%
SSDR 3	22	42,356.3	45.60	0.11%	91.84	16.00	17.42%	82.33	4.50	5.47%
SSDR 4	6	61.5	3.80	6.18%	14.18	0.00	0.00%	25.50	0.25	0.98%
SSDR 5	7	66.57	7.30	10.97%	23.15	2.00	8.64%	17.56	0.50	2.85%
SSDR 6	5	52.5	3.00	5.71%	16.00	2.00	12.50%	21.50	1.00	4.65%
SSDR 7	7	70.15	10.85	15.47%	16.50	1.00	6.06%	28.00	3.00	10.71%
SSDR 8	8	50.5	4.00	7.92%	9.50	2.00	21.05%	37.60	3.50	9.31%
SSDR 9	7	105.17	3.00	2.85%	42.00	1.00	2.38%	161.48	2.00	1.24%
SSDR 10	7	84.7	8.70	10.27%	20.88	6.00	28.74%	46.25	3.00	6.49%
SSDR 11	11	66.11	1.21	1.83%	11.50	1.00	8.70%	24.28	1.00	4.12%
SSDR 12	8	48.92	5.01	10.24%	6.01	1.00	16.64%	9.95	0.70	7.04%

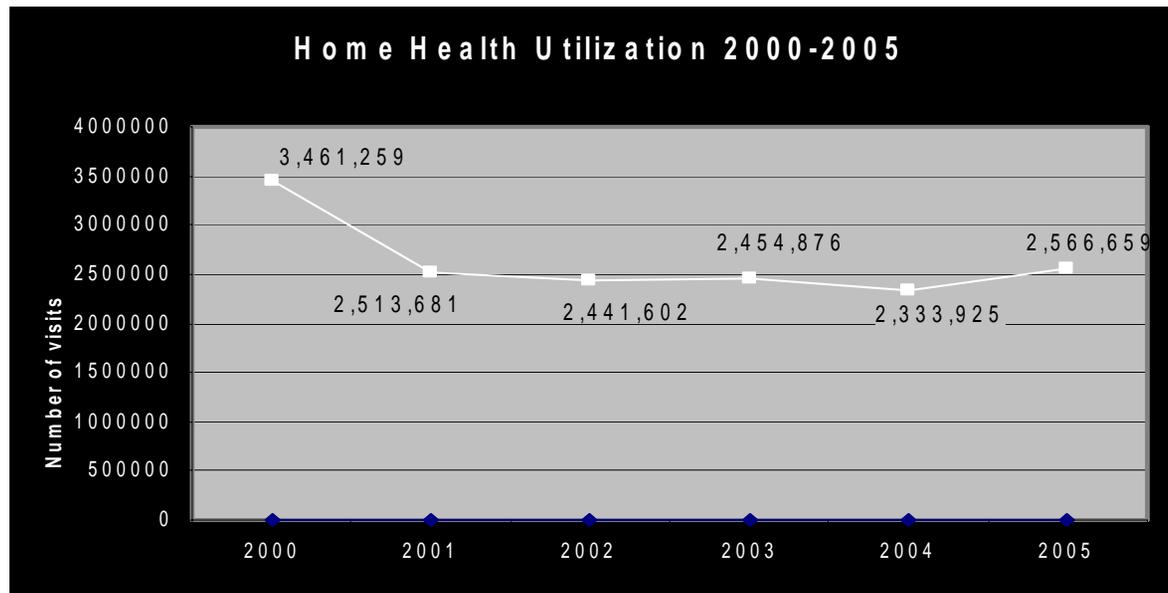


## Utilization

Between 2000 and 2005 the number of home health patients decreased from 113,232 to 125,463, or by 10.8 percent, and the number of patient visits declined 25.8 percent. Decreasing reimbursement rates for this service has led to decreases in the number of providers. Limits on the frequency and duration of home care services as set by the PPS have significantly decreased patient visits.

The utilization of home health agencies is provided in Figure 10-2.

**FIGURE 10-2.**



Cost

Most third-party payers, including HMOs and other private carriers, reimburse for home health agency and other home care services. Private insurers will generally cover home health agency care for their beneficiaries when this care substitutes for hospitalization or other institutional care. However, the services provided by home health agencies, in Georgia and across the nation, are primarily a Medicare benefit. In Georgia in 2005, Medicare accounted for 69 percent of home health agency patients and approximately 90.2 percent of net patient revenues for the service. Because Medicare is the dominant payer for home health services, changes in payment policies have ceased the rapid growth in spending for the service.

**FIGURE 10-3.**

<b>Home Health Average Charge Per Visit</b>			
<b>SSDR</b>	<b>2000</b>	<b>2003</b>	<b>2005</b>
Georgia	\$104.15	\$130.17	\$142.10
1	\$113.62	\$127.94	\$144.54
2	\$105.42	\$142.09	\$160.90
3	\$112.19	\$138.09	\$148.03
4	\$102.19	\$126.96	\$130.31
5	\$109.58	\$137.97	\$157.90
6	\$112.19	\$156.86	\$167.56
7	\$112.19	\$136.75	\$136.48
8	\$101.26	\$127.15	\$141.44
9	\$86.92	\$105.82	\$118.59
10	\$87.02	\$118.56	\$121.81
11	\$102.67	\$104.23	\$109.99
12	\$96.08	\$138.36	\$152.15



## Quality

The quality of care provided by home health agencies may be examined through the measurement of the outcome of treatment. Home Health Quality Measures are depicted in Figure 10-4, as compiled by the Commission's Georgia State consultants.



FIGURE 10-4.

Home Health Agency Measures										
State	% of Patients who get better at walking or moving around	% of patients who get better at getting in and out of bed	% of patients whose bladder control improves	% of patients who have less pain when moving around	% of patients who get better at bathing	% of patients who get better at taking medicines	% patients who are short of breath less often	% of patients who had to be admitted to the hospital*	% Patients who need urgent, unplanned medical care	% patients who stay at home after an episode of home care
All Study States	37	51	46	60	60	37	56	28	22	68
CON States	37	52	44	59	59	38	56	30	25	65
Georgia	40	54	51	63	61	40	60	29	21	67
Iowa	38	49	40	56	59	37	54	30	24	65
Washington	37	52	50	58	63	38	61	21	18	76
West Virginia	43	56	46	59	59	36	56	28	25	70
Non-CON States	37	51	47	61	60	37	56	27	21	69
Colorado	35	49	48	56	62	36	59	23	21	72
Florida	38	51	49	62	63	41	57	24	18	71
Maine	38	55	48	58	59	39	58	27	22	70
Massachusetts	39	50	51	63	60	41	59	32	23	65
Oregon	35	53	50	58	62	37	62	21	20	76
Utah	41	57	52	58	67	40	63	23	20	71
Wisconsin	38	51	47	59	58	36	58	26	22	71



## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

Georgia's licensure rules and regulations for Home Health Agencies were established to provide some basic minimum requirements pertaining to the operation and management of home health agencies. The Office of Regulatory Services of the Department of Human Resources monitors compliance to state guidelines.

#### *Department of Community Health.*

A wide variety of home health agencies have emerged serving individuals in many different settings. The Certificate of Need (CON) Program covers only licensed home health agencies which are defined as: private organizations, which are primarily engaged in providing care to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' home, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

- physical therapy;
- occupational therapy;
- speech therapy;
- medical-social services under the direction of a physician; or

- part-time or intermittent services of a home health aide.

A Certificate of Need for a home health agency is required prior to the establishment of a new home health agency or the expansion of the geographic service area of an existing agency.

The need for a new or expanded home health agency is determined through application of a numerical need methodology and an assessment of the projected number of patients to be served by existing agencies. Home health applications are accepted semi-annually and undergo a competitive review. Figure 10-5 demonstrates the number of CON applications that have been received by the Department since the beginning of the CON program.



FIGURE 10-5.

Home Health Applications 1979 to Present, Final Findings				
BATCHED REVIEW	Approved	Denied	Withdrawn	Appeals
383 TOTAL APPLICATIONS	133	182	68	180

*JCAHO, CHAP.*

Two major accreditation bodies for these services are the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the Community Health Accreditation Program, Inc. (CHAP). Accreditation by these organizations is recognized nationwide as a "seal of approval." Such an approval indicates that an organization meets certain performance standards. Because these standards reflect state-of-the-art performance expectations, organizations that meet these standards improve their ability to provide quality patient care. Both of these organizations perform on-site visits and establish standards for many aspects of home health agencies including, but not limited to, patient advocacy, governance, administration, quality of care, quality assurance and medical records. Home Health Agencies that are surveyed and certified by CHAP and/or JCAHO have deemed status with Medicare and the Department of Human Resources/Office of Regulatory Services. Accreditation may also be a condition of reimbursement for certain insurers and other payers.



## Comparison States

Among the states that have a CON program, home health services are not always covered. Nationwide only 17 states include home health care as a reviewable service.

**FIGURE 10-6.**

HOME HEALTH AGENCY CON Regulation	
Colorado	No
Florida	No
Georgia	Yes
Iowa	Yes
Maine	No
Massachusetts	No
Oregon	No
Utah	No
Washington	Yes
West Virginia	Yes
Wisconsin	No

As depicted in Figure 10-6, among our eight study states with CON, only Georgia, Iowa, Washington and West Virginia include home health as a reviewable service.

## Federal Oversight

### *Medicare.*

As the federal agency with authority over Medicare's administrative, clinical, and reimbursement policies, CMS effectively shapes the home health agency environment, and determines its direction as a covered benefit. CMS established, and periodically updates, the Medicare Conditions

of Participation, standards by which CMS's contracting agency in each state – in Georgia, the Department of Human Resources/Office of Regulatory Services – evaluates home health agencies and certifies them for participation in, and reimbursement by, Medicare. The Conditions of Participation are also used by many state Medicaid programs, to determine eligibility for participation in and payment by that federal-state entitlement program.

As part of a broad quality improvement initiative, the federal government began requiring that every Medicare-certified home health agency complete and submit health assessment information for their clients. The instrument/data collection tool used to collect and report performance data by home health agencies is called the Outcome and Assessment Information Set (OASIS). Since fall 2003, CMS has posted on the Medicare website a subset of OASIS-based quality performance information showing how well home health agencies assist their patients in regaining or maintaining their ability to function. Measures of how well people can get along in their homes performing activities of daily living (ADLs) form a core of the measures, but these are supplemented with questions about physical status and two use-of-service measures (hospitalization and emergent care).

In 2004-05, a private non-profit organization, the National Quality Forum (NQF), convened technical experts representing varying perspectives to review quality measures for home health care. Following a long review and consensus development process, the group endorsed measures for use in public reporting. The ten measures CMS includes in Home Health Compare (as of September 2005) reflect those recommendations.

The measures (all collected via the OASIS data set) are:

- Improvement in Ambulation/Locomotion



- Improvement in Bathing
- Improvement in Transferring
- Improvement in Management of Oral Medication
- Improvement in Pain Interring with Activity
- Acute Care Hospitalization
- Emergent Care
- Discharge to Community
- Improvement in Dyspnea (Shortness of Breath)
- Improvement in Urinary Incontinence

Another part of the HHS/CMS quality initiative includes Quality Improvement Organizations (QIOs). QIOs exist in each state and are private organizations that contract with CMS to help improve the quality of care provided to Medicare patients. In addition to assisting beneficiaries with complaints about the quality of care they receive, physicians and other health care experts work with home health agencies to encourage the adoption, use, and monitoring of best practices and quality measures.



## Strategic Options

### Option 10.0

*Maintain existing CON regulation of home health.*

### Option 10.1

*Maintain existing CON regulation of home health and issue a moratorium on new agencies.*

### Option 10.2

*Deregulate from CON but issue a moratorium on new home health agencies.*

### Option 10.3

*Deregulate home health from Certificate of Need.*

### Option 10.4

*Deregulate home health and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for the establishment or expansion of a home health agency; however, home health agencies would still be required to report data on a regular basis.

### Option 10.5

*Deregulate home health agencies in general and only require a CON for Medicaid-Certified Agencies.*



## Recommendations

### Recommendation 10.0 *(Unanimous)*

*Maintain existing CON regulation of home health services.*

The Commission unanimously recommends that home health services continue to be regulated by CON. Members of the Commission believe that CON regulation adequately determines need and assesses quality in this area. Committee members considered the concerns expressed by home health agency stakeholders regarding indigent and charity care commitment stated in the service-specific rules. They decided to leave the issue of determining the proper indigent and charity care requirement to the Department and its rule-making authority.



## Assisted Living

### An Analysis and Evaluation of Personal Care Home Services in Georgia

#### Overview

#### Background

Personal care homes are residential care settings for persons who can no longer live independently and who require some supervision but do not require clinical care or support. They provide housing, meals, supervision, and some assistance with activities of daily living (ADL) to residents who may not need the level of skilled care provided in nursing homes. There is no uniform personal care home model. They vary in the types of services they provide and the types of residents they serve. Personal care homes range from small, freestanding, independently owned homes with a few residents to large, corporately owned facilities that offer meals, housekeeping, and limited personal assistance. Some services may be provided by the facility's staff or by staff under contract to the facility. In other instances, the facility may arrange with an outside provider to deliver some services, with residents paying the provider directly, or residents may arrange and pay for services on their own. Residents come to personal care homes from their own residences, family referrals or referrals from healthcare facilities. States have the primary responsibility for overseeing the care that personal care home facilities provide to their residents. The terms "personal care home" and "assisted living" are synonymous. The

number of states that use the term "assisted living" has increased significantly in the past two years, and there is wide variation among the states in how the term is defined. The State of Georgia uses the term "personal care homes."

- Personal care homes represent a consumer-focused model of resident housing which organizes the setting and delivery of services around the resident rather than the facility. The personal care home model is continuing to evolve and is offering a level of care that is considered to be appropriate for seniors wishing to maintain independent lifestyles. Whereas personal care homes were previously developed as a "between" level of care from a retirement community to a nursing home, today, personal care homes are now being developed as core resident models. This is evident with the increasing number of freestanding facilities.

There are several factors which are expected to impact the demand for personal care homes in the future, including the aging of the American population and the increase in life expectancy, the increase in the number of persons aged 85 and over and the increase in the number of people who live alone. Forecasters predict that the 85+ age cohort will increase 33.2 percent between



2000-2010. Another factor is the increasing numbers of persons 80-years and older with incomes sufficient to afford assisted living. Moreover, the National Academy for State Health Policy suggests that among the long term care trends that have been evident over the past five to ten years has been the endorsement by providers of the “aging in place” concept. This concept would allow providers to retain residents with higher levels of impairment and allow limited health related services to be provided onsite. Other trends include the provision of specialized resources for residents with Alzheimer’s disease or related dementia. The rapid growth of the frail elderly is expected to impact the demand for this resident model. Demographically, this population increase reflects an aging population in which women outlive men. This growth in the number of elderly living alone has resulted in the increasing demand for services that historically have been provided by a spouse, other family members or live-in caretakers. Other changes including the rising rates of divorce have increased the number of people living alone.

#### Access, Supply and Distribution

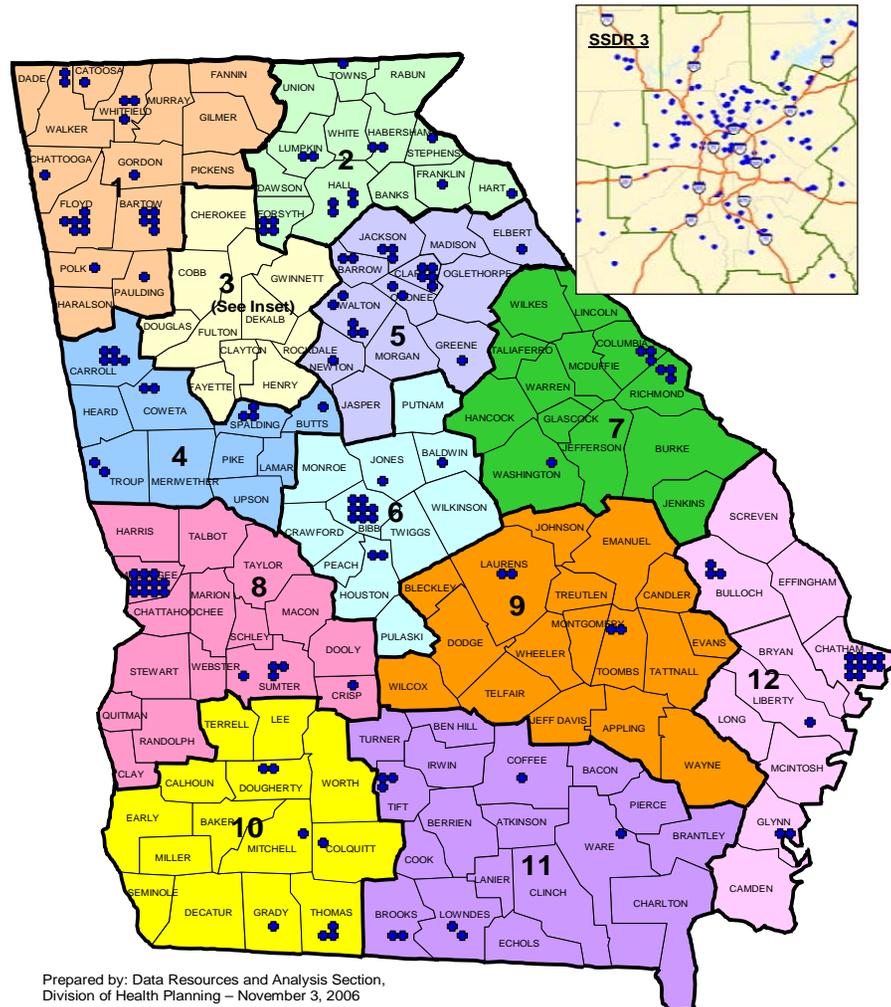
As of June 2001, the Georgia Department of Human Resources, Office of Regulatory Services reported licensing 1,611 personal care homes with a bed capacity of 25,234 beds. While 85% (1,366) of all personal care homes in Georgia are those that have 24 beds or less, these facilities maintain only 40% of all beds. Facilities with 25 beds or greater (245) represent fifteen percent (15%) of all facilities and maintain 60% of personal care home beds. Only facilities with 25 beds or greater are currently regulated by the state’s Certificate of Need process. In 2005, 255 facilities with 25 beds or greater existed in Georgia.

Figure 11-1 depicts the current distribution of personal care homes in the state.



FIGURE 11-1.

Personal Care Homes Over 24 Beds  
by State Service Delivery Region



## Utilization

In Georgia, the average occupancy rate for personal care homes with 25 beds or greater was 87.50% in 2005, based on 12,573 rentable beds in 255 facilities.

A 2000 Price Waterhouse Coopers/ALFA study and an ad hoc survey conducted by Georgia-ALFA indicated that personal care homes serve mostly residents with an average age of about 83 years old. The Georgia – ALFA survey focused only on facilities with 25 or more beds. The Price WaterHouse Coopers survey indicated that over half of the residents in this age cohort have some level of Alzheimer or dementia impairment and require help with three ADL's, typically bathing, dressing and medication administration. A typical resident in a personal care home is female and is either widowed or single.

## Cost

Most residents of personal care homes pay for care out-of-pocket, through other private funding, health insurance, or long term care policies. Costs vary depending on the size of the resident's room and the types of services required by residents. Nationally, the average daily cost in 1999 was \$76.60, equating to approximately \$2,247/month, or \$28,000 annually. In 2005, the average monthly room and board charge in Georgia was \$3,242. Figure 11-2 tracks the number of facilities and average monthly charge for Georgia's personal care homes.



FIGURE 11-2.

<b>Georgia Personal Care Homes</b>			
<b>Year</b>	<b>Number of Facilities</b>	<b>Number of Residents</b>	<b>Average Charge/Month</b>
2001	273	9,057	\$2,022
2002	282	9,875	\$2,069
2003	267	10,709	\$2,498
2004	253	10,831	\$2,263
2005	255	11,001	\$3,242

### Quality

A CON applicant for a new or expanded personal care home is required to provide evidence of intent to comply with all appropriate licensure requirements, resident life safety standards, and operational procedures required by the Georgia Department of Human Resources.



## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources*

DHR licenses a personal care home as any dwelling that provides or arranges for the provision of housing, food service, and one or more personal services for two or more adults who are not related to the owner or administrator by blood or marriage. (Personal services include but are not limited to individual assistance with and supervision of self-administered medications and essential activities or daily living such as eating, bathing, grooming, dressing, and toileting.)

The following facilities are exempt from this licensure requirement:

- Boarding homes or rooming houses that provide no personal services other than lodging and meals.
- Facilities offering temporary shelter such as those for the homeless and victims of family violence.
- Treatment facilities that provide medical nursing services and that are approved by the state and regulated under more specific authorities.
- Facilities providing residential services for correctional institutions.
- Hospices.
- Therapeutic substance abuse treatment facilities.
- Group residences organized by or for persons who choose to live independently or who manage their own

care and share the cost of services including but not limited to attendant care, transportation, rent, utilities and food preparation.

- Charitable organizations providing shelter and other services without charging any fee to the residents.
- Any personal care home operated by the federal government.

All personal care homes shall be licensed as provided for in Code Section 31-7-3, except that, in lieu of licensure, the department may require persons who operate personal care homes with two or three beds for non-family adults to comply with registration requirements designed to protect the health, safety, and welfare of the occupants of such personal care homes.

#### *Department of Community Health*

The 2001 Personal Care Home Technical Advisory Committee (TAC) recommended that need for Personal Care Homes be determined through the application of a numeric formula. This three-tiered stratification formula is similar to the methodology that is used for nursing home and home health services. Need is projected on a three-year planning horizon.

The numeric need for a new or expanded personal care home facility in any planning area in the horizon year is determined by a population-based formula which is the sum of the following:

- A ratio of 18 beds per 1,000 projected horizon year civilian noninstitutional (CNI) population age 65-74



- A ratio of 40 beds per 1,000 projected horizon year civilian noninstitutional (CNI) population age 75-84;
- A ratio of 60 beds per 1,000 projected horizon year civilian noninstitutional (CNI) population age 85+.

The net numerical unmet need for personal care home beds in each health planning area is determined by subtracting the number of existing and approved personal care home beds in the health planning area from the projected number of personal care home beds needed in the horizon year; provided however, that if the net numerical unmet need exceeds fifty percent (50%) of the current existing and approved beds in the planning area, the net numerical unmet need is limited to fifty percent (50%) of the existing and approved beds at the time the calculation is made.

In addition to the numerical need standard, the Department, through the Division of Health Planning and the CON process, uses a number of other standards in determining whether to grant a personal home operating certificate. Among these standards are:

- physical plant design
- continuity of care
- quality of care
- personnel
- quality improvement program
- financial accessibility
- data reporting

## Comparison States

Many states do not regulate personal care homes through a CON program. Specifically, of the ten comparison states, only two regulate personal care homes through a certificate of need process. Figure 11-3 is a listing of the comparison states.



FIGURE 11-3.

Personal Care Homes	
CON Regulation	
Colorado	No
Florida	No
Georgia	Yes
Iowa	No
Maine	No
Massachusetts	Yes
Oregon	No
Utah	No
Washington	Yes
West Virginia	No

### Federal Oversight

By law, Medicare does not pay for personal care home expenses.



## Strategic Options

### Option 11.0

*Maintain existing CON regulation of personal care homes with greater than 24 beds.*

### Option 11.1

*Maintain existing CON regulation of personal care homes but also require a CON for those homes with fewer than 25 beds.*

### Option 11.2

*Maintain existing CON regulation of personal care homes but increase the bed threshold to a higher limit.*

### Option 11.3

*Deregulate personal care homes from Certificate of Need entirely.*

### Option 11.4

*Deregulate personal care homes and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for the establishment or expansion of a personal care home; however, personal care homes would still be required to report data on a regular basis.

### Option 11.5

*Deregulate personal care homes except for Medicaid-Certified Personal Care Homes*

Under this option all personal care homes that are to be Medicaid-Certified would require a CON regardless of size.



## Recommendations

### Recommendation 11.0 *(Unanimous)*

*Deregulate personal care homes except for Medicaid-Certified personal care homes.*

The Commission unanimously recommends that CON regulation of personal care homes be discontinued except for those personal care homes that seek Medicaid certification. This recommendation requires that all Medicare-certified personal care homes, including those with 24 or fewer beds, be regulated by CON because they receive reimbursement from the State. In order to encourage personal care homes as an alternative to skilled nursing facilities, the Commission recommends that all non-Medicaid personal care homes be exempt from the Certificate of Need process and regulation.



## Rehabilitation Services

### An Analysis and Evaluation of Comprehensive Inpatient Physical Rehabilitation Services in Georgia

#### Overview

##### Background

A Comprehensive Inpatient Physical Rehabilitation (CIPR) Program is generally defined as a facility that provides medical and rehabilitation services for twenty-four hours a day. The Department of Community Health rule that governs this service defines CIPR Programs as “rehabilitation services which have been classified by Medicare as an inpatient rehabilitation facility as per 42 C.F.R. §412.23(b)(2), provided to a patient who requires hospitalization, which provides coordinated and integrated services that include evaluation and treatment, and emphasizes education and training of those served. The program is applicable to those individuals who require an intensity of services which includes, as a minimum, physician coverage 24 hours per day, seven days per week, with daily (at least five days per week) medical supervision, complete medical support services including consultation, 24-hour-per-day nursing, and daily (at least five days per week) multidisciplinary rehabilitation programming for a minimum of three hours per day.”

A key indicator of increased demand for inpatient services is population growth. Georgia’s growing population is expected to

result in higher inpatient utilization and as this growing population ages, the demand for inpatient services also will increase.

More importantly, another substantial gain in population is anticipated in the 75 & over age group. This is attributed to both medical advances and lifestyle improvements that have increased life expectancy. As a direct result of this aging of the population, there will be an increased demand for health care services.

Inpatient Rehabilitation Facilities are intended to serve patients recovering from medical conditions that typically require an intensive level of rehabilitation in an inpatient setting. The number of inpatient rehabilitation facilities (IRF) has grown steadily over the past decade as have Medicare payments made to these facilities. According to a recent GAO Report, the number of IRFs grew from 907 in 1992 to 1,256 in 2003. The aging of the population will continue to add to the demographic shift in the population. Additionally, the longer life span of patients with chronic diseases and disability should also increase the need and demand for rehabilitation services. Because of the ongoing challenges to industry providers, planning for the development of inpatient rehabilitation services remains a difficult process.



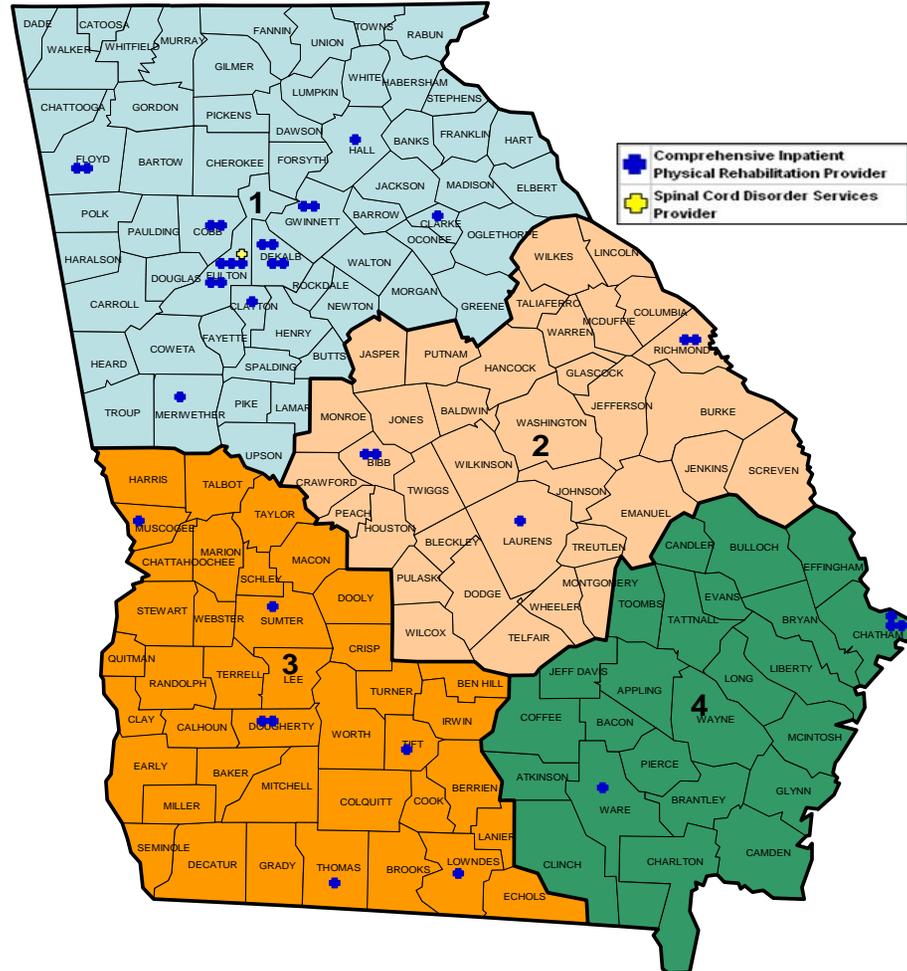
## Access, Supply and Distribution

The rules for Comprehensive Inpatient Physical Rehabilitation Services delineate four planning areas called Rehabilitation Regions. Figure 12-1 is a map of the service regions including the existing facilities.



FIGURE 12-1.

**Comprehensive Inpatient Physical Rehabilitation Services Providers by CIPR Planning Areas**



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



Figure 12-2 shows the number of CIPR beds, Average Length of Stay (ALOS), and the occupancy rates of each CIPR facility by Rehabilitation Region. In 2005, there were twenty-seven facilities that reported data regarding their CIPR programs. These facilities reported a total of 704 beds throughout the state. The average occupancy rate for facilities in Area 1 is 56.74%, 67.74% in Area 2, 49.00% in Area 3, and in Area 4 it is 59.40%. The largest concentration of facilities and beds in is Area 1 which includes the metropolitan Atlanta area. Children’s Healthcare of Atlanta – Scottish Rite has the highest average length of stay and the highest occupancy rate in the state, as it has the greatest number of pediatric inpatient rehabilitation beds. Currently, the Roosevelt Warm Springs Institute for Rehabilitation has the highest number of set-up and staffed CIPR beds, its occupancy rate is 71.13%, and the ALOS for the facility is 26.9 days.

**FIGURE 12-2.**

**Number of Beds, Percent Occupancy, & Average Length of Stay by Planning Area, 2005**

<b>CIPR Area</b>	<b>Facility</b>	<b>Total No. of Beds</b>	<b>Percent Occupancy</b>	<b>Average Length of Stay</b>
<b>1</b>	St. Mary's Hospital	20	75.73%	15.4
	Southern Regional Medical Center	20	23.75%	15.5
	DeKalb Medical Center	25	46.71%	14.5
	Emory University Hospital	46	69.63%	14.3
	Wesley Woods Geriatric Hospital	16	54.59%	10.1
	Floyd Medical Center	17	65.72%	13.6
	Redmond Regional Medical Center	20	49.10%	10.1
	Atlanta Medical Center	17	54.17%	13.5
	CHOA - Scottish Rite	23	83.00%	29.8



**Number of Beds, Percent Occupancy, & Average Length of Stay by  
Planning Area, 2005**

<b>CIPR Area</b>	<b>Facility</b>	<b>Total No. of Beds</b>	<b>Percent Occupancy</b>	<b>Average Length of Stay</b>
	North Fulton Regional Hospital	33	64.87%	15.1
	Piedmont Hospital	15	75.34%	12.9
	South Fulton Medical Center	20	46.23%	13.7
	Emory Eastside Medical Center	20	14.42%	12.1
	Roosevelt Warm Springs Institute	64	71.13%	26.9
<b>2</b>	Coliseum Medical Centers	29	73.29%	11.6
	HealthSouth Central GA Rehab	58	81.79%	15.0
	Fairview Park Hospital	15	60.11%	12.6
	Doctor's Hospital of Augusta	28	55.78%	12.2
<b>3</b>	Palmyra Medical Centers	48	27.49%	11.6
	Phoebe Putney Memorial Hospital	18	61.22%	10.8
	South Georgia Medical Center	24	35.90%	11.6
	Hughston Orthopedic Hospital	28	49.13%	13.4
	Archbold Memorial Hospital	20	78.73%	13.8
	Tift Regional Medical Center	15	41.61%	7.5
<b>4</b>	Candler Hospital	23	71.22%	14.5
	St. Joseph's Hospital	22	68.95%	12.5
	Satilla Regional Medical Center	20	37.97%	11.9



FIGURE 12-3.

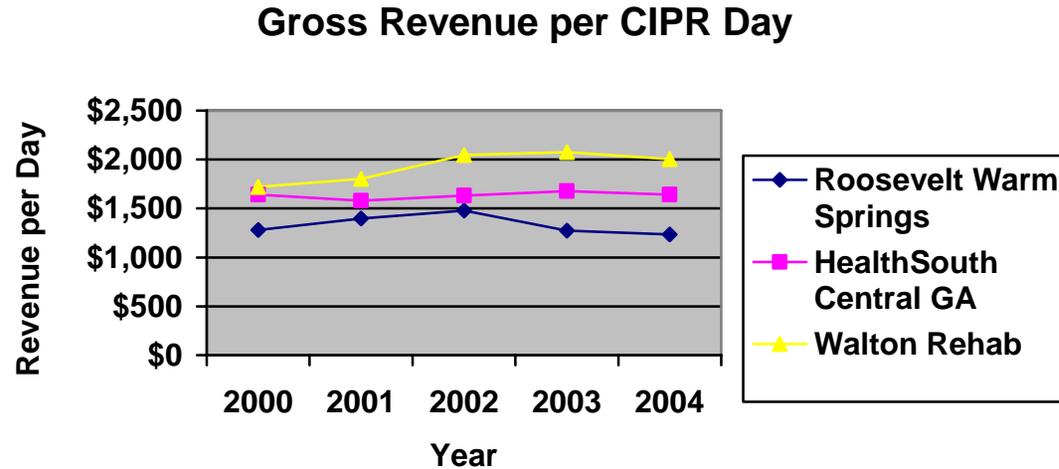


Figure 12-3 shows the gross revenue per CIPR day from 2000-2004 for the three rehabilitation specialty hospitals in the state. Those facilities are: Roosevelt Warm Springs Institute for Rehabilitation, HealthSouth Central Georgia Rehabilitation Hospital, and Walton Rehabilitation Hospital. Gross revenues per CIPR day remained fairly steady for each facility over this time period. Since 2002, Roosevelt Warm Springs has seen a slight decline in gross revenue, while the number of CIPR days

increased. Both the gross revenues and number of patient days remained consistent for HealthSouth Central Georgia. Walton Rehabilitation Hospital saw a peak in gross revenue per CIPR day in 2002. During that year, the facility saw its highest gross revenue to date, however the number of patient days declined eleven percent (11%) from the previous year. The following year, both gross revenue and CIPR days declined, however, the trend reversed in 2004.



## Quality

The Commission on Accreditation of Rehabilitation Facilities (CARF) is a private, not-for-profit third party accreditation body that accredits over 30,000 programs across the human health services continuum. Purchasers and providers of medical rehabilitation care choose CARF accreditation as a blueprint for rehabilitation services that demonstrate that their organizations' programs meet internationally recognized standards.

CARF requires organizations to demonstrate to a survey team conformance to standards highlighting the organization's values and approaches in the following areas: core values and mission; input from persons served and other stakeholders; individual-centered planning; design, and delivery; rights of the persons served; continuity of care; quality and appropriateness of services; leadership, ethics, and advocacy; planning and financial management; human resources; accessibility; health and safety; infrastructure management; outcomes management and performance improvement.

A quality organization, according to CARF, illustrates the following:

- Service design and delivery that is focused on the needs of the persons served and the organization's other stakeholders.
- Involvement of the persons served as partners in the individual planning process.

- An outcomes management system that is used to continuously improve the quality of individual programs and organizational practices.

The mission of CARF is to promote the quality, value, and optimal outcomes of services through a consultative accreditation process that centers on enhancing the lives of the persons served. Since assuring access to high quality health care services has always been a staple of Georgia's CON standards, the Georgia CON rules & standards for comprehensive inpatient physical rehabilitation services require facilities to be CARF accredited.



## Current Regulatory Scheme

### Georgia

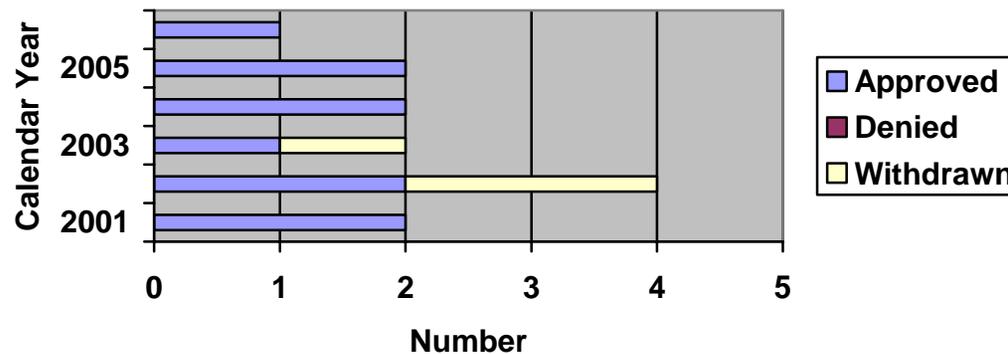
#### *Department of Community Health*

In Georgia, Comprehensive Inpatient Physical Rehabilitation (CIPR) is a covered service under the CON program. The rules governing this service were recently revised in mid-2006. The revised rules require that CIPR programs be classified by Medicare as an inpatient facility within twenty-four months of accepting its first patient. The rules also establish standards for minimum bed sizes, licensure and expansion, and data collection.

Figure 12-4 is a summary of the CON applications submitted to the Department for Inpatient Rehabilitation Services from 2001 to 2006. An average of two applications per year was submitted over this period. None of the fourteen applications submitted were denied. Four of the applications were withdrawn prior to a final decision. Only three applications have been appealed over this time period.

FIGURE 12-4.

### CON Applications Submitted Requesting Rehabilitation Services



## Comparison States

Of the comparison states, Maine, Massachusetts, Washington, and West Virginia also regulate rehabilitation services under their individual CON programs. Colorado, Florida, Iowa, Oregon, Utah, and Wisconsin do not regulate these services by Certificate of Need. Of the thirty-six (36) states with Certificate of Need programs, twenty-six regulate rehabilitation services. Figure 12-5 represents the study states and whether they regulate rehabilitation services.

**FIGURE 12-5.**

<b>Rehab Services Regulated by CON</b>	
Colorado	N
Florida	N
Georgia	Y
Iowa	N
Maine	Y
Massachusetts	Y
Oregon	N
Utah	N
Washington	Y
West Virginia	Y
Wisconsin	N

## Federal Oversight

During the 1990s, the rehabilitation industry experienced considerable changes due to shifting market forces. The driving forces of change were threefold and included a shift in payer type, from indemnity, fee-for-service insurers to managed care organizations (MCOs); changes in Medicare reimbursement methodologies mandated by the Balanced Budget Act of 1997

(BBA); and the Centers for Medicare & Medicaid Services' Seventy-five Percent Rule.

### *Balanced Budget Act*

Passed in August 1997, the main objective of the Balanced Budget Act (BBA) was to reduce Medicare outlays. A component of the BBA, the prospective payment system (PPS), has had significant implications for the rehabilitation industry. The PPS for



rehabilitation was intended to reduce the significant amount of money paid by Medicare to rehabilitation hospitals.

The BBA also instituted the PPS for rehabilitation facilities, an action the government took in an attempt to reduce some of the unnecessary shifting of patients between PPS facilities to the more favorable TEFRA-based reimbursement facilities. The conversion of acute rehabilitation from a cost-based reimbursement system to PPS was phased-in over a three-year period that was intended to begin on October 1, 2000, but was postponed until 2002. During that time, acute rehabilitation facilities were reimbursed under a blended rate schedule combining rates established under TEFRA and the PPS.

#### *Seventy-five Percent Rule*

One of the most challenging issues facing the inpatient physical rehabilitation services industry is the implementation of the 75% Rule. Originally issued in 1983, the 75% Rule serves as a method for the Centers for Medicare & Medicaid Services (CMS) to be able to distinguish IRFs from other settings for payment purposes. The Rule also ensures that Medicare patients who may need less intensive services are not placed in IRFs.

The 75% Rule was most recently revised in 2004 and is being implemented over a three-year period that started in July, 2005. The revised Rule states that in order for a facility to be classified as an IRF, it must show that during a 12-month period at least 75 percent of all its patients, including its Medicare patients, required intensive rehabilitation services for the treatment of at least one of the thirteen conditions listed in the rule. The Rule allows the remaining 25 percent of patients to have other conditions not listed in the rule. If an IRF does not comply with the requirements of the

75 percent rule, it may lose its classification as an IRF and would no longer be eligible for reimbursement at a higher rate. The 2004 final Rule also laid out a 3-year transition period during which enforcement of the rule was resumed, with the threshold percentage of patients meeting the condition requirements being lowered to 50 percent for the first year and subsequently rising in stages to reach 75 percent for the IRF's cost reporting period starting on or after July 2007. Effective July 1, 2007, the close of the transition period, IRFs will be expected to meet full compliance with the 75% Rule.

#### *Medicare Reimbursement*

Medicare payments to IRFs grew from \$2.8 billion in 1992 to an estimated \$5.7 billion in 2003. Payments are projected to grow to almost \$9 billion per year by 2015. Because patients treated at IRFs require more intensive rehabilitation than is provided in other settings, such as an acute care hospital or a skilled nursing facility, Medicare pays for treatment at an IRF at a higher rate than it pays for treatment in other settings. With the increase in total payments, CMS also projects significant savings during the first full year after implementation of the Seventy-five percent Rule.



## Strategic Options

### Option 12.0

*Maintain existing CON regulation of comprehensive inpatient physical rehabilitation services.*

### Option 12.1

*Deregulate comprehensive inpatient physical rehabilitation services from Certificate of Need.*

### Option 12.2

*Deregulate comprehensive inpatient physical rehabilitation services and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for the establishment or expansion of comprehensive inpatient physical rehabilitation services; however, existing entities would still be required to report data on a regular basis.

### Option 12.3

*Deregulate comprehensive inpatient physical rehabilitation services from CON but increase licensure standards.*



## Recommendations

### Recommendation 12.0 *(6 Agree, 1 Disagrees, 3 Abstain)*

*Maintain existing CON regulation of Comprehensive Inpatient Physical Rehabilitation.*

A majority of the Commission recommends that comprehensive inpatient physical rehabilitation (CIPR) services continue to be regulated by CON. In addition, these members of the Commission recommend that the need methodology for CIPR services be based on set-up-and-staffed beds and not on authorized beds. Such members agreed that this change to the need methodology will allow the Department to accurately project need and allow new providers to enter the market, increasing access to CIPR services. Such members did not recommend the deregulation of this service because they felt that the service required a highly-skilled workforce and that deregulation may drain the workforce from existing facilities, thereby lowering quality of care.

One member of the Commission disagreed with this recommendation. This member supports the deregulation of CIPR services to promote access and competition.



## Traumatic Brain Injury

### An Analysis and Evaluation of Traumatic Brain Injury Services in Georgia

#### Overview

##### Background

The CON rules define traumatic brain injury as "a traumatic insult to the brain and its related parts resulting in organic damage thereto that may cause physical, intellectual, emotional, social, or vocational changes in a person. It shall also be recognized that a person having a traumatic brain injury may have organic damage or physical or social disorders, but shall not be considered mentally ill." According to the National Center for Injury Prevention and Control, the severity of a TBI may range from "mild," i.e., a brief change in mental status or consciousness to "severe," i.e., an extended period of unconsciousness or amnesia after the injury. The severity of a TBI can range in severity from "mild" (a brief change in mental status or consciousness) to "severe" (an extended period of unconsciousness or amnesia).

There are three stages of treatment for TBI: acute, sub-acute, and chronic. The goal of acute treatment is to stabilize the patient immediately after injury; once the patient is stabilized, the focus turns to maintaining body fluid levels and preventing or treating other complications. During acute treatment, particular attention is paid to monitoring and treating swelling in the brain as it could lead to intracranial pressure (ICP). ICP can prevent blood from

circulating properly in the brain tissue causing excessive damage to brain cells. A brief period of excessive ICP could cause permanent damage. Other concerns of acute TBI treatment are preventing the buildup of fluid in the brain and preventing the onset of other medical problems (e.g. seizures, pneumonia, sinusitis, etc.).

Sub-acute treatment is provided after stabilization, and can range from maintaining medical stability to returning a patient to the community to admitting a patient to a chronic care facility. During sub-acute treatment, patients are generally admitted to acute rehabilitation hospitals that are equipped to manage TBI and its complications. The main goals of sub-acute treatment are early detection of complications, facilitation of neurological and functional recovery, and prevention of additional injury. Neurological function improvement is often fragmented, so rehabilitation professionals that specialize in TBI (e.g. physical and occupational therapists, neurologists, and others) help patients and their caregivers understand neurological improvements. Some patients have to re-learn basic and routine tasks such as buttoning a shirt or tying shoelaces. When some patients are admitted to acute rehabilitation hospitals following a TBI, they may experience post-traumatic amnesia (PTA). During PTA, patients



may experience poor balance, poor coordination, or weakness. They may be unaware of the extent of their injuries and their physical limitations, and may try to walk or climb out of bed by themselves, which may cause them further harm. Generally, once patients and their caregivers can demonstrate that the patient will be safe at home, the patient is discharged from the acute rehabilitation facility.

There are two categories of chronic treatment, community-based rehabilitation and return to work or school, and treatment of long-term effects of TBI. In order for a patient to experience the full benefits of rehabilitation, it must take place in their communities and outside of a controlled environment. Depending on the complexity of their cases, some patients do best with individual therapy at an outpatient facility or in their own homes while others benefit from case-management programs. Both settings involve working with specialists, but the case-management approach also involves a case manager, and can also include social workers and/or vocational specialists. Some TBI patients may experience residual symptoms that require skilled management by qualified neurologists, physiatrists, and neuron-psychologists.

The key component of treatment of and ultimately recovery from TBI is social support. A patient's care network consisting of family, friends, and professionals becomes essential to his recovery. Once a patient plateaus, his care network must work together to provide the physical, mental, and emotional treatment necessary to help the patient achieve his recovery goals.



## Access, Supply and Distribution

There are eight designated TBI facilities in the state of Georgia. Figure 13-1 below lists the facilities along with the location and official bed count of each.

**FIGURE 13-1.**

<b>SSDR</b>	<b>County</b>	<b>Facility Name</b>	<b>Total Beds</b>
1	Walker	Safehaven	12
3	Cobb	Transitions Atlanta	14
3	DeKalb	Shepherd Pathways	27
3	Fulton	Atlanta Rehabilitation Institute	10
3	Fulton	Restore Neurobehavioral Center	24
3	Gwinnett	Learning Services Corporation- Peachtree Campus	18
3	Gwinnett	Palm Creek Farm	6
7	Richmond	Walton Transitional Living Center	20

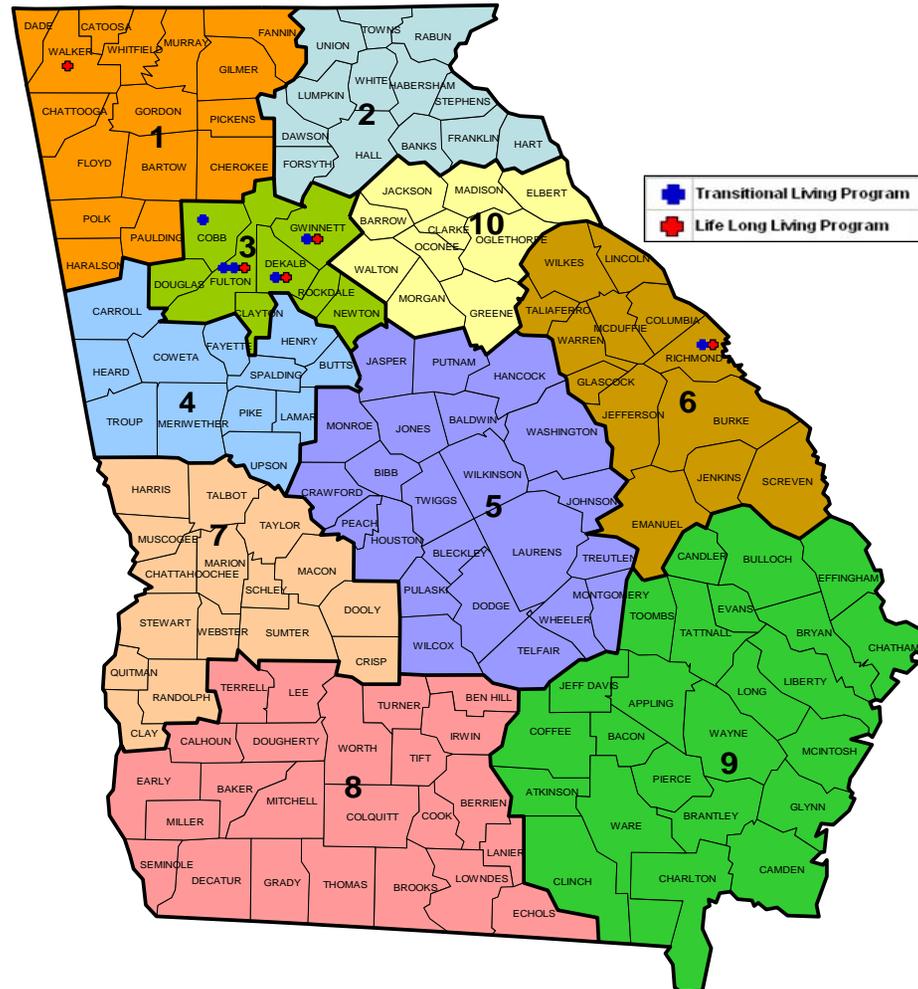
For purposes of the administration and implementation of the CON program, need for Traumatic Brain Injury services is based on the need method described in the State Health Component Plan for Traumatic Brain Injury Facilities. Need is determined by a demand-based forecasting model which takes into account patient projections for both Transitional Living and Life Long Living Programs.

The services and facilities are distributed throughout Georgia as depicted on Figure 13-2.



FIGURE 13-2.

**Traumatic Brain Injury Services Providers  
by TBI Planning Areas**



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006

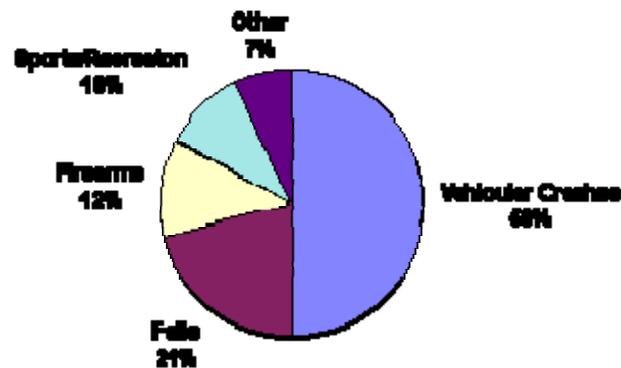


## Utilization

The most common causes of TBI are falls, motor vehicle accidents, struck by/against events, and assaults. More than half of all TBIs are the results of falls and motor vehicle accidents. In the United States, 1.4 million people sustain a TBI each year. Of that number, 235,000 are hospitalized and survive, and 50,000 die. In addition, 80,000 to 90,000 people experience the onset of long-term or lifelong disability associated with TBI. At least 2% of the US population currently lives with disabilities associated with TBI. Approximately 75% of TBIs that occur each year are concussions or other forms of mild TBI.

FIGURE 13-3.

### Causes of Brain Injury



SOURCE: *Brain Injury Association of Oklahoma*



There are some segments of the population that are at high risk for TBI. They include:

- Young people
- Low-income individuals
- Unmarried individuals
- Members of ethnic minority groups
- Residents of inner cities
- Men
- Individuals with previous history of substance abuse
- Individuals with previous TBI

Men are twice as likely to sustain a TBI as women and are more than three times as likely to die from a TBI. The age groups at highest risk for TBI are 0-4 and 15-19. Among children ages 0-14, TBI results in an estimated 435,000 emergency department visits and 37,000 hospitalizations. The highest mortality rate occurs in the 15-24 age group. TBI hospitalization rates are highest among African Americans and American Indians/Alaska Natives. African Americans have the highest death rate.

## Cost

The CDC estimates that the direct medical and indirect costs of TBI totaled \$60 billion in the United States in 2000. Indirect costs include the loss of productivity, which occurs when an individual sustains a TBI and is unable to return to his former occupation. The total cost of acute care and rehabilitation is estimated to be \$9 billion - \$10 billion alone. It is estimated that the care for a survivor of severe TBI costs \$600,000 to \$1,875,000 over a lifetime.

In 2002, a study was conducted at Craig Hospital in Denver, Colorado to examine the service utilization, payor source and costs associated with TBI one year after discharge from initial rehabilitation. The study followed 60 participants who had sustained a TBI and had been hospitalized in an inpatient rehabilitation setting. During the one year after inpatient discharge, the average charges per person were \$40,348. The services included in that time frame were therapy, medical services, psychological services, personal assistance, equipment, and other services. Therapy comprised the largest percentage of charges. Personal assistance was the most expensive service on a per person basis; however, only 20% of the study group received this service. At Craig Hospital, the payors of outpatient services include auto insurance, commercial insurance, Medicaid, and Worker's Compensation. Auto and commercial insurance tended to pay more for these services.

## Quality

Under CON rules, an applicant for or an owner of a TBI facility must meet the standards of the Commission on Accreditation of Rehabilitation Facilities. Also, the applicant/owner must meet the licensure rules of the Georgia Department of Human Resources for Traumatic Brain Injury Facilities.



## Current Regulatory Scheme

Georgia

*Department of Human Resources*

As stated previously, an applicant/owner must meet the licensure Rules of the Georgia Department of Human Resources for Traumatic Brain Injury Facilities.

*Department of Community Health.*

The Georgia Department of Community Health uses a component plan and specific review considerations in regulating TBI facilities. The component plan was last updated in 1990, but is currently being revised by the Department and the Health Strategies Council.

## Strategic Options

Option 13.0

*Maintain existing CON regulation of traumatic brain injury facilities.*

Option 13.1

*Deregulate traumatic brain injury facilities from Certificate of Need.*

Option 13.2

*Deregulate traumatic brain injury facilities and create a data reporting model.*

Under this option, applicants would not need to obtain a CON for the establishment or expansion of traumatic brain injury facilities; however, existing entities would still be required to report data on a regular basis.

## Recommendations

Recommendation 13.0

*(Unanimous)*

*Deregulate traumatic brain injury facilities as long as detailed licensure standards are developed.*

The Commission unanimously supports the deregulation from Certificate of Need of Traumatic Brain Injury facilities. Evidence demonstrates that there have been no applications for new or expanded facilities in recent years. In addition

Licensure already has detailed licensure standards for such services as Traumatic Brain Injury Facility is a specific licensure classification. Therefore, as long as these service-specific licensure standards are maintained, the Commission supports the deregulation of these facilities.



## Ambulatory Surgery

### An Analysis and Evaluation of Ambulatory Surgery Services in Georgia

#### Overview

##### Background

Ambulatory surgery is best characterized as any surgical procedure performed on patients who are admitted to a facility that does not admit patients for treatment which would normally require a stay exceeding 24 hours and that does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

The growth in ambulatory surgery services and transition from inpatient to outpatient surgery services continues to be rapid. Research indicates that the number of ambulatory surgery centers in Georgia has increased by 254% from 1994. Several factors have contributed to this rapid growth in outpatient surgery. These factors include:

- Consumer demand - Outpatient surgery is perceived as more convenient and less threatening than inpatient surgery and has proven to be less costly than inpatient surgery because it eliminates costly hospital inpatient stays.
- Third Party Payers - because ambulatory surgery services are a low cost alternative to inpatient surgery services, outpatient surgery services are more attractive to health insurance carriers who bear most of the costs of surgery. Therefore, these carriers offer their members financial incentives to have surgery performed on an outpatient rather than inpatient basis.
- Medicare Reimbursement – Medicare has continued to add numerous procedures covered by Medicare when performed by an ambulatory surgery center certified by Medicare.
- Managed Care Environment – Today's managed care environment is creating a healthcare market place that encourages the development of outpatient surgery services. Managed care companies and other third party payers recognize that quality care can be provided on an outpatient basis in a more cost effective manner.



- **New Surgical Techniques** – New surgical techniques that require no hospital stay or greatly reduce lengths of stay are boosting the number of outpatient surgical procedures in both hospitals and surgery centers. Technological breakthroughs have contributed greatly to the growth and success of ambulatory surgery services.
- **Physician Reimbursement** – Increased overhead and declining reimbursement for professional services have encouraged physicians to seek ways to expand office capacity and to make their practices more efficient. Performing outpatient surgery in freestanding facilities or in their own offices is more convenient and cost-effective for physicians because performing surgery in these facilities rather than in hospitals allow physicians to schedule surgeries more easily and to do more surgeries in a significantly shorter time.
- **Competition** – The growth of non-hospital affiliated freestanding surgery centers is causing hospitals to position themselves to protect their market share. Hospitals have reacted by offering their own outpatient surgery centers.

Currently under Georgia regulations, ambulatory surgery services are characterized as either multi-specialty or limited purpose. A multi-specialty ambulatory surgery service offers general surgery; or, general surgery and surgery in one or more of, but not limited, to the following specialties; or, surgery in two or ore of, but not limited, to the following specialties: dentistry/oral surgery, gastroenterology, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology. A limited purpose ambulatory surgery services offers surgery in only one of the above-mentioned specialty areas.

Under current regulations, the following categories of ambulatory surgery facilities fall under Certificate of Need (CON) review:

- Hospital-based, multi-specialty facilities

These facilities are part of a hospital and offer surgical services to patients who do not require inpatient hospitalization, and only fall under CON regulation if they incur expenses in excess of the current CON threshold.

- Freestanding, multi-specialty facilities:

These are freestanding surgical facilities that offer surgical services to patients in at least two specialty areas. These facilities can be owned by hospitals, physicians, or any other business entity and fall under CON regulation in three ways: (1) as a new healthcare facility; (2) if an existing ambulatory surgery facility incurs expenditures in excess of the current CON threshold; or (3) as a diagnostic, treatment, or rehabilitation center.

- Freestanding, limited purpose facilities:

These are freestanding facilities that are owned by hospitals or any other business entity and offer surgical services to patients within a single specialty. These facilities fall under CON regulation in three ways: (1) as a new healthcare facility; (2) if an existing ambulatory surgery facility incurs expenditures in excess of the current CON threshold; or (3) as a diagnostic, treatment, or rehabilitation center.

- Physician-owned, single specialty freestanding facilities, over the threshold:

These are freestanding surgical facilities that are owned by physicians and that incur development costs over the threshold amount, which is currently set at \$1.61 million. These facilities offer surgical services to patients within a single specialty. These facilities fall under CON regulation as a new institutional health



services in or through a diagnostic, treatment, or rehabilitation center.

Currently, physician-owned, single-specialty freestanding facilities that are developed for under the threshold amount are **EXEMPT** from CON review. Figure 14-1 is a table indicating the number of freestanding facilities that are either CON-approved or exempt as physician-owned. (There is no reliable data available regarding the number of operating rooms in the exempt facilities because these entities are not required to report data to the Department.)

**FIGURE 14-1.**

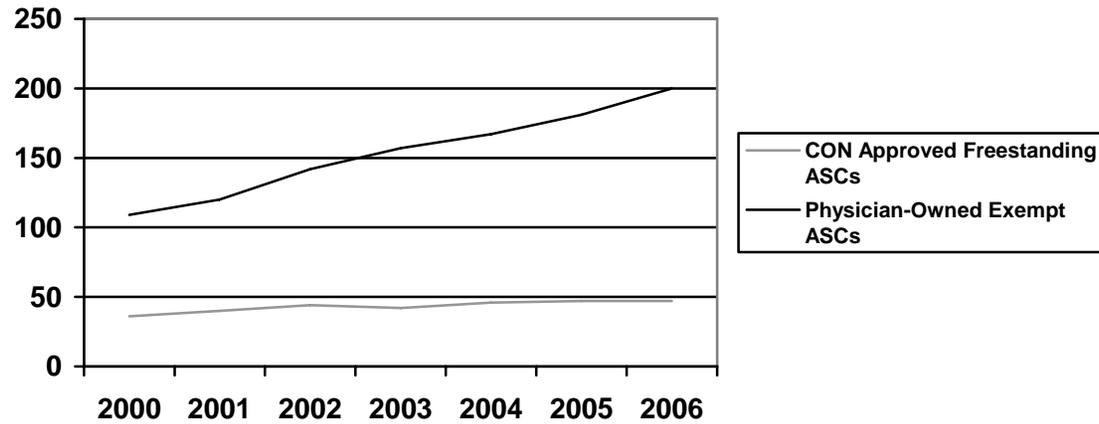
<b>Ambulatory Surgery Facilities and ORs Georgia, CY2006</b>		
<b>Type</b>	<b>Facilities</b>	<b>ORs</b>
<i>Freestanding CON-Approved ASCs</i>	47	132
<i>Physician-Owned Exempt ASCs</i>	200	N/A

As indicated by Figure 14-2, the number of freestanding ASCs that have received CON approval since 2000 has increased moderately, from 36 to 47, but the number of exempt facilities

has almost doubled during that same period, from 109 facilities to 200 facilities in 2006.



FIGURE 14-2.



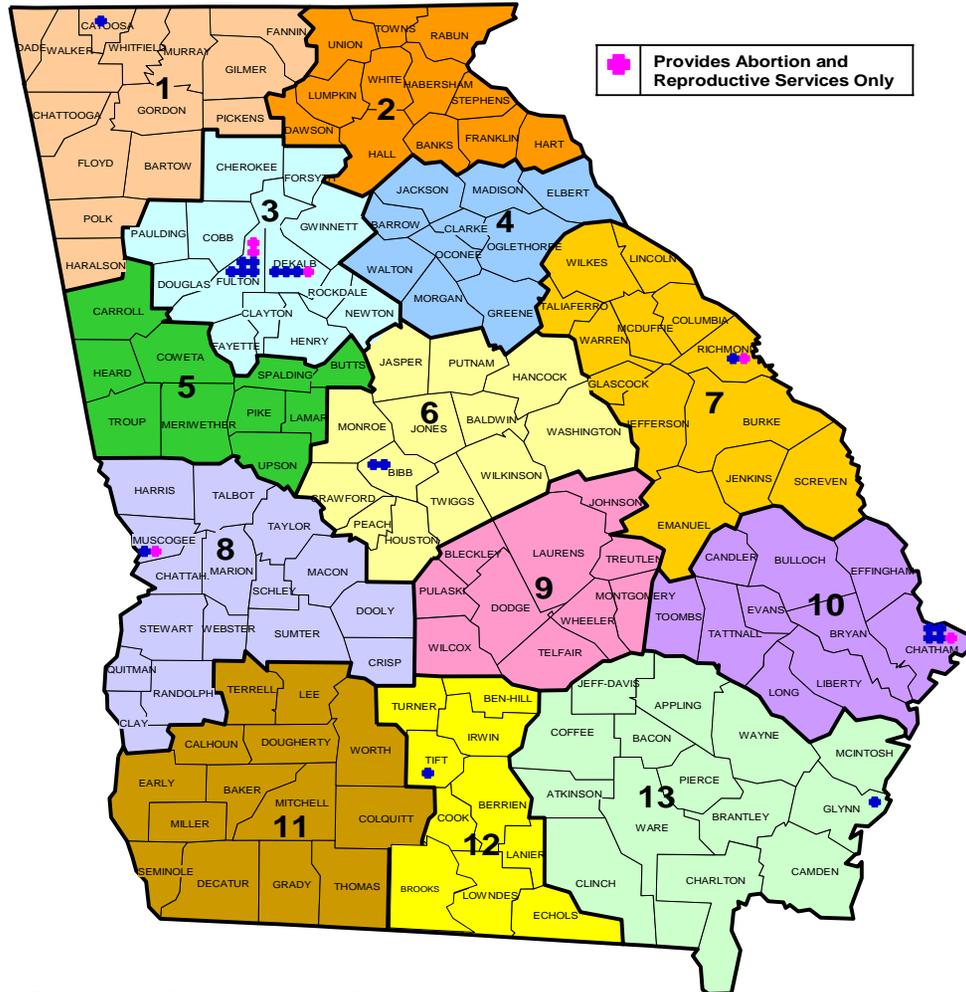
### Access, Supply and Distribution

In 2006, there were 25 limited-purpose CON-approved ambulatory surgery centers with 54 existing and approved operating rooms (many of these provide abortion and reproductive services only). There were 52 multi-specialty ambulatory surgery centers during this period, with 95 existing and approved ORs. The following two maps, Figures 14-3 and 14-4, indicate the distribution of these centers throughout the state.



FIGURE 14-3.

Limited Purpose Freestanding Ambulatory Surgery Centers  
By Health Planning Areas



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



FIGURE 14-4.

Multi-Specialty Freestanding Ambulatory Surgery Centers  
By Health Planning Areas



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006

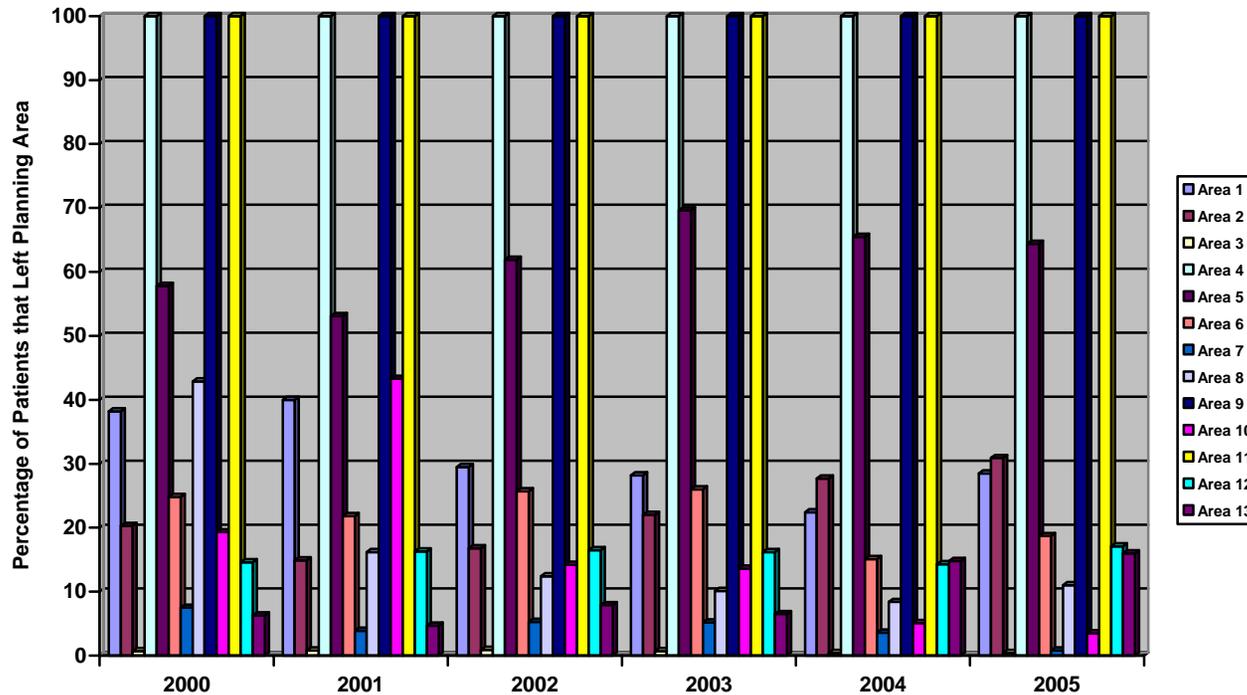


As depicted in the Figures 14-3 and 14-4 above and the Figure 14-5 below, patients residing in Health Planning Areas 4, 9, and 11 do not have ambulatory surgery services within their HPA and must leave their planning area in order to access these services. Less

than 1% of residents of HPAs 3 and 7, encompassing metropolitan Atlanta and Augusta respectively, leave their planning areas for ambulatory surgery.

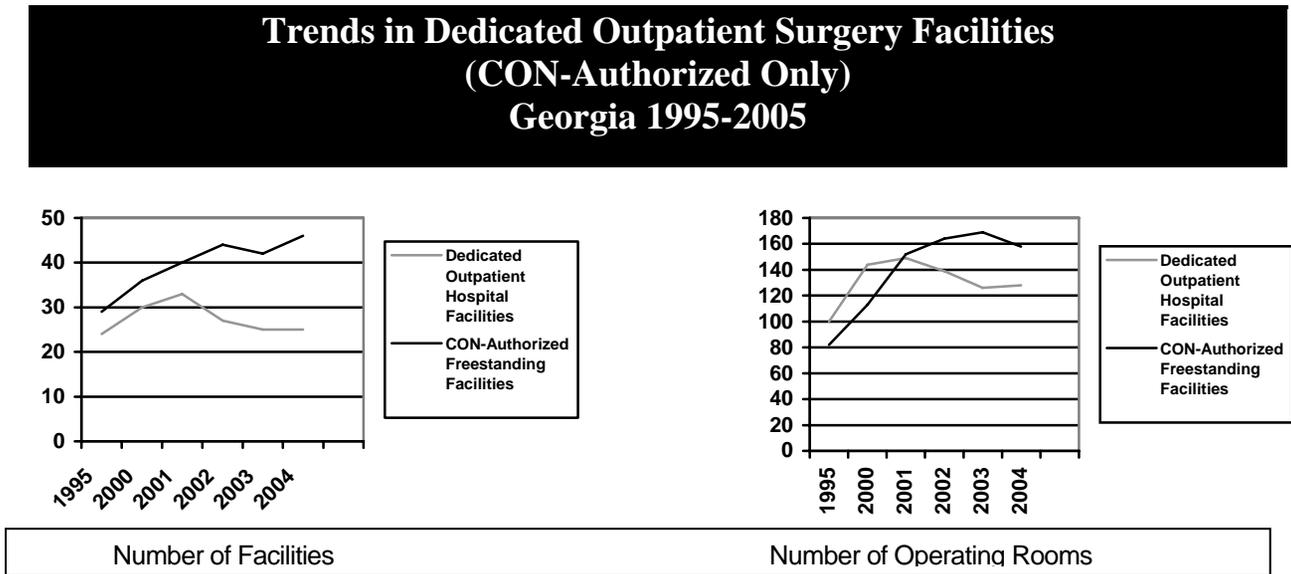
FIGURE 14-5.

**Percent of Residents Leaving the Planning Area  
Georgia 2000-2005**



In terms of the supply of dedicated outpatient surgery facilities state-wide, the number of hospitals offering dedicated outpatient facilities has fluctuated over the last decade, peaking in 2001 and declining to 25 facilities in 2004. The number of dedicated outpatient operating rooms in hospitals have followed similar trends. CON-authorized free-standing facilities have increased in the past decade, as have the number of operating rooms in these facilities. This information is depicted in Figure 14-6.

FIGURE 14-6.



In 2001, Georgia had a total of 154 ASCs throughout the state, with a per capita rate of 1.88. As reflected in Figure 14-7, Georgia is above the national average among Medicare-certified ASCs in terms of per capita rates, but well below the top five states, which range from 5.53 in Maryland to 2.63 in Idaho.

FIGURE 14-7.

<b>Medicare-Certified ASCs and Number per Population</b>			
	<b>Number of ASCs 2001</b>	<b>2000 Population</b>	<b>Per Capita</b>
<b>Georgia</b>	154	8,186,453	1.88
<b>TOP FIVE</b>			
<i>Maryland</i>	293	5,296,486	5.53
<i>Washington</i>	157	5,894,121	2.66
<i>North Dakota</i>	17	642,200	2.65
<i>Wyoming</i>	13	493,782	2.63
<i>Idaho</i>	34	1,293,953	2.63
<b>BOTTOM FIVE</b>			
<i>Iowa</i>	12	2,926,324	0.41
<i>Michigan</i>	33	9,938,444	0.33
<i>Virginia</i>	20	7,078,515	0.28
<i>New York</i>	51	18,976,457	0.27
<i>Vermont</i>	1	608,827	0.16
<b>US</b>	3,202	285,230,516	1.12

Source: Health Care Financing Administration; U.S. Census of Population, 2000



## Utilization

The number of procedures performed at CON-authorized ambulatory surgery centers has steadily increased over the last decade. The growth in the number of procedures has outpaced the patient volumes at these facilities, as indicated in the Figures 14-8, 14-9, and 14-10. In addition, the procedure volume per freestanding operating room has increased dramatically in the past few years. The patient volume in dedicated outpatient operating rooms has been in general decline in the past five years, consistent with the decline in the number of dedicated outpatient operating rooms available in Georgia hospitals.

**FIGURE 14-8: Volume of CON-Authorized Freestanding ASCs in Georgia, 1995-2004**

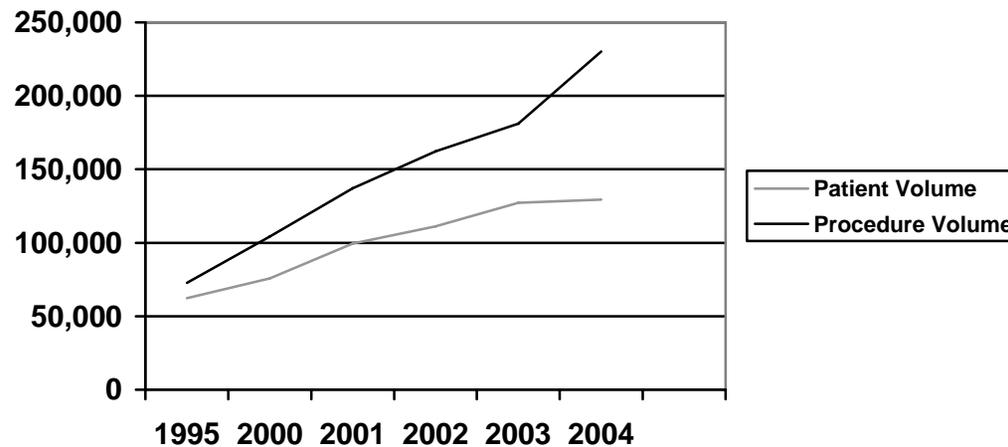


FIGURE 14-9: Freestanding Procedures per Operating Room

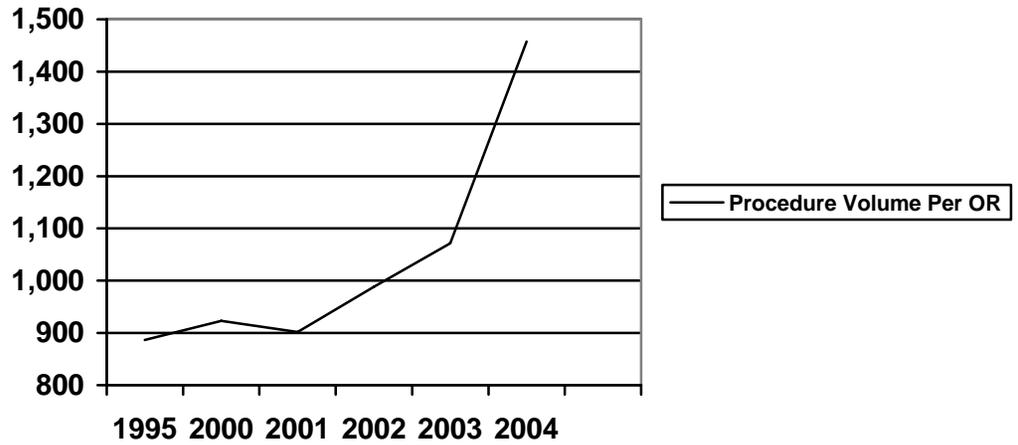
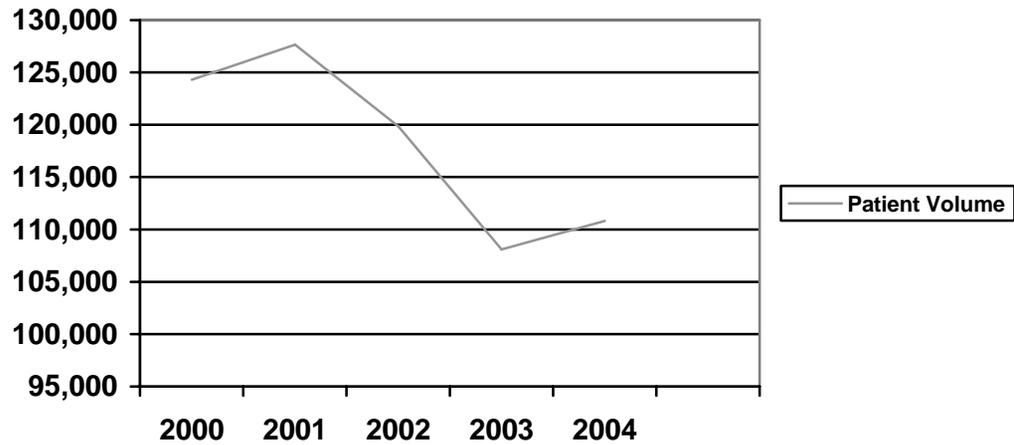


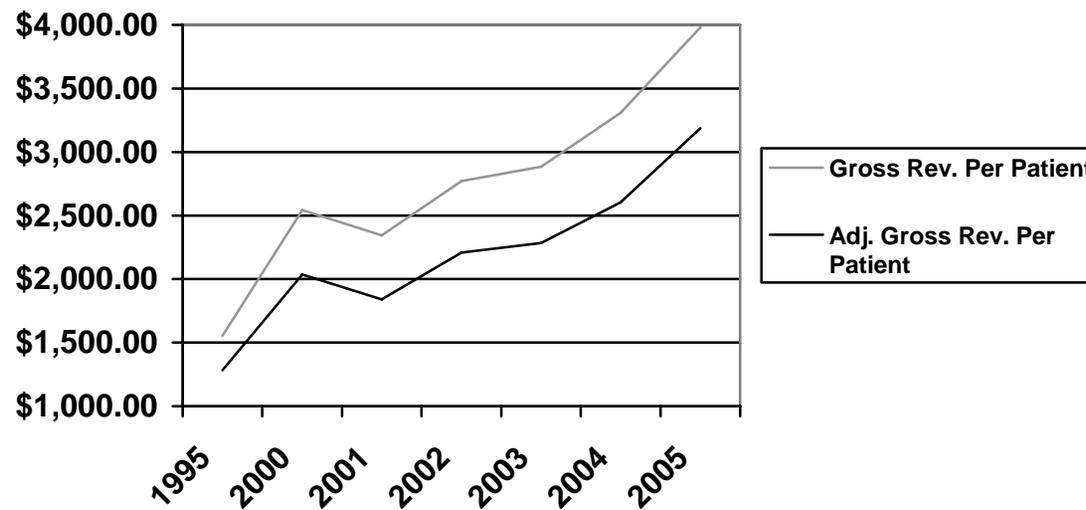
FIGURE 14-10: Patient Volume in dedicated outpatient hospital ORs



## Cost

Because exempt ambulatory surgery facilities do not provide data to the Department of Community Health, it is difficult to get a complete picture relating to the costs of ambulatory surgery services in Georgia. DCH does collect data from those ASCs that have CONs. As reflected in Figure 14-11 below, both gross revenue and adjusted gross revenue per patient in these CON-authorized facilities consistently increased between 2000 and 2005, with the exception of a dip in 2001. In 2005, the gross revenue per patient for CON-authorized ASCs was \$3979 and adjusted gross revenue was \$3186.

**FIGURE 14-11.**

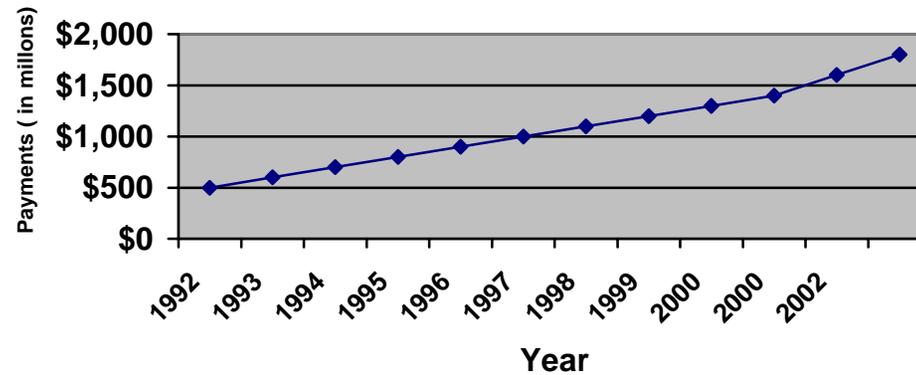


On a national level, Medicare collects data for the payments and costs associated with ASCs that provide services to Medicare beneficiaries. Essentially, Medicare uses a fee schedule to pay for a bundle of facility services provided in an ambulatory surgery center. In 2002, ambulatory surgery centers furnished almost 3.5

million surgical procedures to Medicare beneficiaries and received almost \$1.9 billion in related payments. Medicare payments to ambulatory surgery centers increased by 17% in 2002 and have nearly tripled since 1992, as reflected in Figure 14-12.

FIGURE 14-12.

### Medicare payments to ASCs more than tripled, 1992-2004



Note: ASC (ambulatory surgical center). Medicare payments include program spending and beneficiary cost sharing. Average annual growth of payments (1992-2002) equals 14 percent. Source: CMS, Office of the Actuary

As of April 2004, the national average of Medicare payment rates for high-volume ambulatory surgical services varied depending on

whether the procedures occurred in a hospital outpatient, ASC, or physician's office setting, as reflected in the Figure 14-13 below.



FIGURE 14-13.

<b>Hospital outpatient, ASC, and physician practice expense payment rates vary for high-volume ambulatory surgical services, 2004</b>					
<b>Procedure code</b>	<b>Description</b>	<b>Share of Medicare payments to ASCs, 2002</b>	<b>2004 payment rates</b>		
			<b>Hospital outpatient</b>	<b>ASC</b>	<b>Physician practice expense</b>
66984	Cataract removal and lens insertion	46%	\$1,254	\$973	\$285
66821	After-cataract laser surgery	6%	\$270	\$446	\$149
45378	Colonoscopy, diagnostic	6%	\$453	\$446	\$226
43239	Upper gastrointestinal endoscopy, biopsy	5%	\$427	\$446	\$208
45385	Colonoscopy with removal of lesion by snare	4%	\$453	\$446	\$287
62311	Epidural injection, lumbar or sacral	3%	\$288	\$333	\$183
45380	Colonoscopy with biopsy	3%	\$453	\$446	\$264
45384	Colonoscopy with removal of lesion by forceps	2%	\$453	\$446	\$250
52000	Cystoscopy	1%	\$375	\$333	\$126
G0121	Colonoscopy, cancer screening	1%	\$405	\$446	\$226

Note: ASC (ambulatory surgical center). Procedures are arranged by share of Medicare payments to ASCs in 2002, from highest to lowest. Payment rates shown here are the national averages for each procedure. Physician practice expense rates are for services provided in the office setting. ASC rates are as of April 1, 2004, when rates will be reduced to fiscal year 2003 levels, as required by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). Physician practice expense rates reflect the 1.5% increase for 2004 required by the MMA.  
Source: CMS 2004, CMS 2003a, CMS 2003b



## Quality

Various organizations play a role in ensuring the quality of care during at medical facilities. These organizations include the Joint Commission for Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, and the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

These organizations ensure that accreditation requirements are met and qualified personnel deliver the various services. Health care facilities are also required to provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted

privileges to perform these procedures by the organization's governing body.

Additionally, facilities are required to submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

The purpose of these procedures is to improve the quality of care provided by ambulatory surgery centers. This process not only ensures that high quality services are being provided by qualified personnel, but the review procedure allows facilities to monitor and measure the quality of those services and perhaps develop new methods to improve the quality of care.

## Current Regulatory Scheme

### Georgia

#### *Department of Community Health.*

The Department of Community Health is responsible for reviewing Certificate of Need applications for ambulatory surgery services in a variety of circumstances. As summarized above, hospital-based ambulatory surgery services are regulated by CON only if they incur expenses in excess of the current threshold. Freestanding ambulatory surgery facilities, both multi-specialty and limited purpose facilities, are regulated by CON if they are developing a new health care facility or diagnostic, treatment or rehabilitation center, or if they are an existing facility that incurs expenses over the threshold. Finally, single-specialty ambulatory surgery services that are located in physician's offices are regulated by CON only if they incur expenses over the current statutory threshold.

### Comparison States

Of the 37 states with some form of Certificate of Need regulation, 27 states regulate ambulatory surgery services. Of the 8 comparison states studied by the Georgia State University consultants, 5 other states besides Georgia review ambulatory surgery centers. Among the comparison states with active CON programs, Florida and Oregon do not include ASCs under CON review. Two other states that regulate ASCs indicate that ASCs are not a significant regulatory issue because there is either a lack of need in the state for those services (Massachusetts) or because of a dearth of applicants and hospital acquisition of independent ASCs (Maine). Figure 14-14 details the CON regulation of ASCs in the comparison states.



FIGURE 14-14.

Ambulatory Surgery Centers and Freestanding Imaging Centers									
State	FL	GA	IA	ME	MA	OR	WA	WV	WI
<b>Threshold</b>	Not review-able	Capital: 1,483,083; Equip: 823,934, Physician Owned ASC: 1,610,823	Any amount except PET Scanners: \$1,500,000	Capital: \$510,000; Equip: \$1,333,098, New Svc: \$121,880	Capital: \$12,516,300; Equip: \$1,335,272	Not reviewable	Capital:1,200,000; Any new service	Capital: \$200,000; Equip: \$200,000; New Svc or Facility: None	Not reviewable
<b>New Freestanding Imaging Centers (FSIC)</b>		Yes – for equipment over threshold	Yes	Yes	Yes – except MRL also must be considered innovative		Yes	Yes	
<b>New Ambulatory Surgery Centers (ASC)</b>		Yes – ASC and equipments	Yes	Yes	Yes – except MS-ASC, no need for SS – ASC		Yes	Yes	
<b>Existing FSIC, ASC</b>		Yes, including hospitals exceeding threshold	Yes	Yes	Yes		Yes	Yes	
<b>Sale or Transfer</b>		Yes-if new owner is not a CON holder	Yes-if it would be a new service	Yes	No		No	Yes	
<b>Renovation</b>		Yes	No	Yes	Yes		Yes	Yes	
<b>Relocation</b>		Yes	No	Yes	Not available		Yes	Yes	
<b>Licensure, Regulation</b>		Must meet appropriate accreditation requirements of the JCAHO, AAAHC, (ASF) and/or other accrediting agency		Must be licensed	Must be licensed		State Incentives	Not available	
<b>Moratoria, Caps</b>					No need for MRI and MS-ASC				



Among the comparison states, Georgia experienced the most rapid growth in the numbers of ambulatory surgery centers, as reflected in the chart below. Florida has the greatest number of ambulatory surgery centers and Washington has the most per-capita. Figure 14-15 below also reflects the assessment of the

“rigor” of the CON program in each state, as determined by the Georgia State University consultants. The consultants concluded that there is not a statistically significant relationship between CON rigor and the number or growth of ASCs in a state.

**FIGURE 14-15.**

<b>Ambulatory Surgery Centers by State and Measures of CON Rigor</b>						
<b>State</b>	<b>ASCs 2004</b>	<b>ASCs 1994</b>	<b>Change</b>	<b>ASC per 100,000</b>	<b>Hospital Rigor</b>	<b>Free Standing Centers Rigor</b>
<b>Washington</b>	195	85	129%	3.2	108	108
<b>Georgia</b>	198	56	254%	2.3	122	110
<b>Florida</b>	319	169	89%	1.9	105	30
<b>Colorado</b>	38	14	171%	1.7	0	0
<b>Utah</b>	38	14	171%	1.6	0	0
<b>Oregon</b>	55	18	206%	1.5	94	19
<b>Maine</b>	18	8	125%	1.4	143	146
<b>Wisconsin</b>	39	21	86%	0.7	0	0
<b>West Virginia</b>	11	8	38%	0.6	117	117
<b>Iowa</b>	17	7	143%	0.6	117	117
<b>Massachusetts</b>	37	17	118%	0.6	118	124

Finally, as reported in the 2006 National Directory of State CON Programs, of the 27 states that regulate ambulatory surgery services, the nature and criteria for regulation varies, as reflected in Figure 14-16, which follows.



FIGURE 14-16.

<i>States with CON Program</i>	<i>Ambulatory Surgery Centers</i>	<i>Review Thresholds</i>		
		<i>Capital</i>	<i>Med. Equip.</i>	<i>New Svc.</i>
Alabama	<input checked="" type="checkbox"/>	4,251,780	2,125,890	Any Amount
Alaska	<input checked="" type="checkbox"/>	1,050,000	1,050,000	1,050,000
Arkansas		500,000	N/A	N/A
Connecticut	<input checked="" type="checkbox"/>	1,000,000	400,000	0
Delaware	<input checked="" type="checkbox"/>	5,000,000	5,000,000	N/A
Dist. of Columbia	<input checked="" type="checkbox"/>	2,500,000	1,500,000	600,000
Florida		N/A	N/A	N/A
Georgia	<input checked="" type="checkbox"/>	1,483,083	823,934	Any Amount
Hawaii	<input checked="" type="checkbox"/>	4,000,000	1,000,000	Any Amount
Illinois	<input checked="" type="checkbox"/>	7,167,063	6,575,036	Any Amount
Iowa	<input checked="" type="checkbox"/>	1,500,000	1,500,000	500,000
Kentucky	<input checked="" type="checkbox"/>	1,951,612	1,951,612	N/A
Louisiana		N/A	N/A	Any LTC/
Maine	<input checked="" type="checkbox"/>	2,666,198	1,333,099	112,800
Maryland	<input checked="" type="checkbox"/>	10,000,000	N/A	5,000,000
Massachusetts	<input checked="" type="checkbox"/>	12,516,300	1,335,072	Any Amount
Michigan	<input checked="" type="checkbox"/>	2,715,000	Any Amount	Any Clinical
Mississippi	<input checked="" type="checkbox"/>	2,000,000	1,500,000	Any Amount
Missouri		1,000,000	1,000,000	1,000,000
Montana	<input checked="" type="checkbox"/>	1,500,000	N/A	150,000
Nebraska		Any LTC	N/A	N/A
Nevada	<input checked="" type="checkbox"/>	2,000,000	N/A	N/A
New Hampshire	<input checked="" type="checkbox"/>	2,150,000	400,000	Any Amount
New Jersey		1,000,000	1,000,000	Any Amount
New York	<input checked="" type="checkbox"/>	3,000,000	3,000,000	Any Amount
North Carolina	<input checked="" type="checkbox"/>	2,000,000	750,000	0



Ohio		2,000,000	N/A	N/A
Oklahoma		500,000	N/A	Any W/Beds
Oregon		Any LTC/Hosp	N/A	Any LTC/Hosp
Rhode Island	<input checked="" type="checkbox"/>	2,000,000	1,000,000	750,000
South Carolina	<input checked="" type="checkbox"/>	2,000,000	600,000	1,000,000
Tennessee	<input checked="" type="checkbox"/>	2,000,000	1,500,000	Any W/Beds
Vermont	<input checked="" type="checkbox"/>	3,000,000	1,000,000	500,000
Virginia	<input checked="" type="checkbox"/>	5,000,000	Any Listed Equip	Any Listed Service
Washington	<input checked="" type="checkbox"/>	Varies by Svc	N/A	Any Amount
West Virginia	<input checked="" type="checkbox"/>	2,000,000	2,000,000	Any Amount
Wisconsin		1,000,000	600,000	Any LTC
<b>NO. OF STATES</b>	<b>27</b>			
This graph was put together using the 2006 National Directory of State CON Programs.				

## Federal Oversight

### *Medicare.*

Over the years, Medicare has paid a facility fee for certain surgical procedures provided in ambulatory surgery centers. However, to receive payments from Medicare, ambulatory surgery centers must meet Medicare's conditions, which specify minimum standards for administration of anesthesia, quality evaluation, operating and recovery rooms, medical staff, nursing services, and other areas. Between 1997 and 2003, the number of Medicare-certified ASCs increased over 50%, as reflected in Figures 14-17, 14-18, and 14-19. Moreover, the volume of surgical services provided to Medicare beneficiaries grew faster in ASCs than in hospitals outpatient departments. Notwithstanding this trend, over half of the most common ambulatory surgical procedures were still performed in hospital outpatient departments in 2001.



FIGURE 14-17.

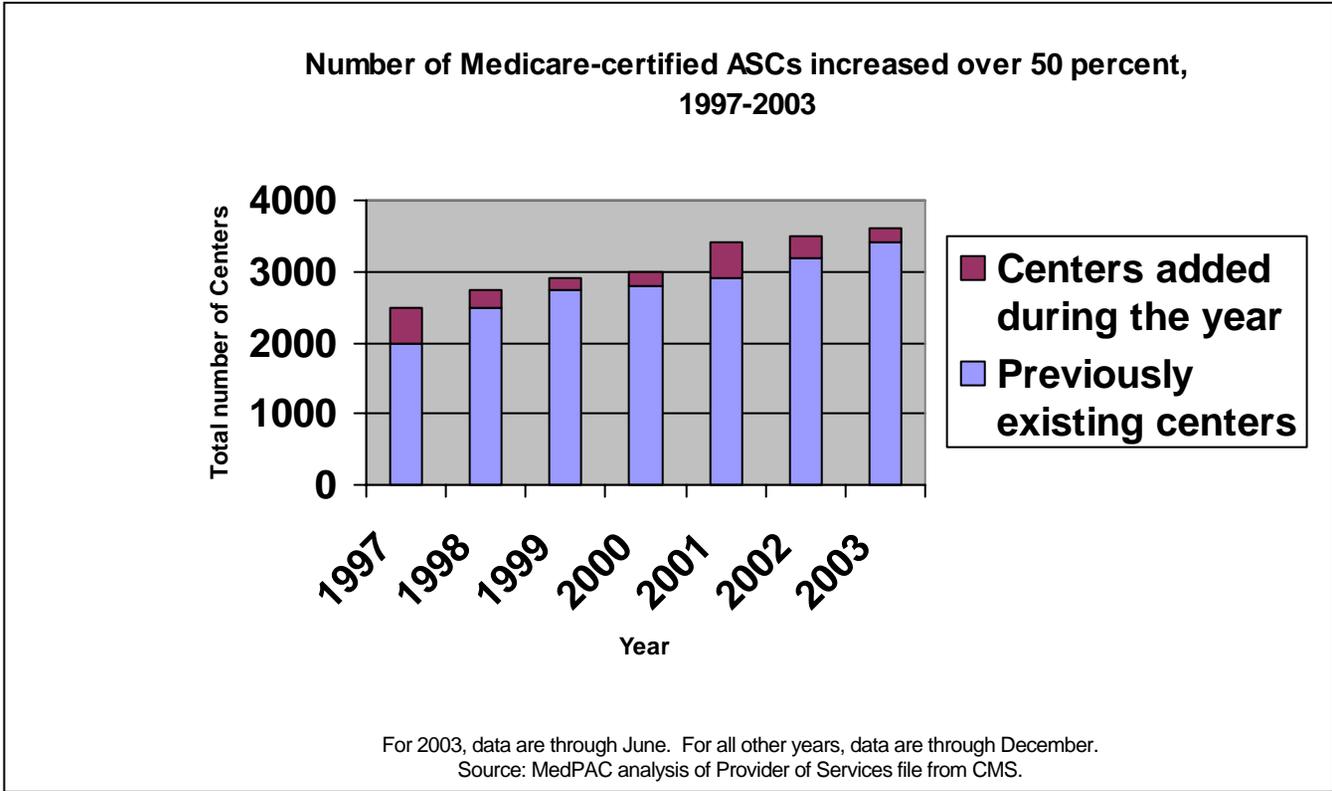


FIGURE 14-18.

<b>The volume of surgical services grew faster in ASCs than in hospital outpatient departments</b>		
<b>Measure</b>	<b>Average annual change, 1998-2002</b>	
	<b>ASCs</b>	<b>Outpatient departments</b>
<b>Number of services provided to Medicare beneficiaries</b>	15.09%	1.7%
<b>Number of beneficiaries served</b>	14.5	4.8
<b>Services per beneficiary</b>	0.4	-3.0

Note: ASC (ambulatory surgical center). To ensure comparability, we analyzed the volume of the same set of ambulatory surgical services in each setting by selecting only those services that are payable by Medicare when provided in an ASC. Services per beneficiary is the change in the total number of ambulatory surgical services provided in each setting divided by the number of beneficiaries who received surgical services in each setting  
 Source: MedPAC analysis of the 5 percent Standard Analytic files of ASC and hospital outpatient department claims from CMS.



FIGURE 14-19.

Over half of the most common ambulatory surgical procedures were performed in hospital outpatient departments, 2001				
Procedure category	Share of ambulatory surgical volume, all settings (%)	Share of volume, by setting		
		Outpatient departments (%)	Physician offices (%)	ASCs (%)
Colonoscopy	16.0	70.8	4.3	24.9
Cataract removal and lens insertion	12.5	47.7	0.5	51.8
Minor procedures – musculoskeletal	10.7	48.1	31.1	20.8
Upper gastrointestinal endoscopy	9.5	72.0	4.5	23.5
Cystoscopy	9.0	28.7	63.8	7.5
Ambulatory procedures-skin	7.9	42.4	52.6	5.0
Other ambulatory procedures	7.3	69.8	16.5	13.8
Other eye procedures	6.9	27.5	33.6	39.0
Other minor procedures	5.0	30.1	63.3	6.5
Ambulatory procedures-musculoskeletal	3.4	59.8	17.4	22.9
<b>Total</b>	<b>88.1</b>	<b>53.1</b>	<b>24.1</b>	<b>22.8</b>

Note: ASC (ambulatory surgical center). Table only includes ambulatory surgical procedures that are on the list of services payable by Medicare when performed in an ASC. Procedure categories are arranged by their share of ambulatory surgical procedure volume across all settings, from highest to lowest. Minor procedures – musculoskeletal includes interventional pain management procedures (such as epidural injection and facet joint block), soft tissue biopsy, and tumor excision. Ambulatory procedures-skin includes skin debridement, excision of lesion, wound repair, and skin graft. Other ambulatory procedures include breast biopsy, nasal polyp excision, abscess drainage, and nerve graft. Other eye procedures includes after-cataract laser surgery. Other minor procedures include nasal, oral, urological, and nerve procedures. Ambulatory procedures-musculoskeletal includes hammertoe operation, anthrotomy, tenotomy, and tendon repair.  
Source: MedPAC and RAND analysis of the 5 percent Standard Analytic files of physician, outpatient department, and ASC claims from CMS, and the Berenson-Eggers Type of Service classification scheme from CMS.



Most ASCs that provide services to Medicare beneficiaries are for profit, freestanding and urban, as reflected in Figure 14-20.

**FIGURE 14-20.**

<b>ASC type</b>	<b>1998</b>	<b>2000</b>	<b>2002</b>
<b>For profit</b>	94%	94%	95%
<b>Nonprofit</b>	6%	6%	5%
<b>Freestanding</b>	99%	99%	99%
<b>Hospital owned and operated</b>	1%	1%	1%
<b>Urban</b>	89%	88%	87%
<b>Rural</b>	11%	12%	13%
Note: ASC (ambulatory surgical center). Source: MedPAC analysis of the Provider of Services file from CMS.			

**STARK.**

Section 1877 of the Social Security Act, known as the Stark law, prohibits physicians from making referrals for certain types of services to entities with which they have financial relationships. Stark applies to several types of services, such as clinical laboratory, radiology, physical therapy, and home health. However, the Stark law does not apply to surgical procedures provided in an ASC. Stark does prohibit health care providers from receiving or paying anything of value to influence the referral of services covered by federal health programs. Federal oversight authorities have developed “safe harbor” regulations that protect physician investors in ASCs

from prosecution under Stark if certain conditions are met. Among other requirements, these regulations provide protection to physicians who invest in ASCs if the ASC is an extension of their office practice, if the physicians’ share of the ASC’s profits is tied to their overall investment, rather than their volume of referrals.



## Strategic Options

### Option 14.0

*Maintain existing CON regulation of freestanding ambulatory surgery services.*

### Option 14.1

*Deregulate freestanding ambulatory surgery services from CON.*

### Option 14.2

*Deregulate freestanding ambulatory surgery services from CON but require data reporting.*

Under this option, applicants would not need to obtain a CON for freestanding ambulatory surgery centers; however, these centers would still be required to report data on a regular basis.

### Option 14.3

*Maintain existing regulations but require both hospital and freestanding centers to address same need standards.*

### Option 14.4

*Abolish entirely the exemption for freestanding single specialty office based physician-owned ambulatory surgery centers.*

### Option 14.5

*Amend the statutory exemption for freestanding single specialty office based physician-owned ambulatory surgery centers.*

14.5A: Remove the dollar threshold cap and add a cap on the number of ORs that can be built out.

14.5B: Increase the dollar threshold

14.5C: Decrease the dollar threshold

14.5D: Add general surgery to the statutory definition of single specialty

### Option 14.6

*Require statutorily exempt ambulatory surgery centers to provide a commitment to indigent and charity care as a condition on the exemption.*

### Option 14.7

*Require statutorily exempt ambulatory surgery centers to provide data to the Department as a condition on the exemption.*

### Option 14.8

*Require doctors performing procedures at statutorily exempt surgery centers to be a member of a hospital staff as a condition on the exemption.*



## Recommendations

*NOTE: The Commission did not reach full consensus on the regulation of ambulatory surgery, except for the current regulation of freestanding multi-specialty centers.*

### Recommendation 14.0 *(Unanimous)*

*Maintain existing CON regulation of freestanding multi-specialty ambulatory surgery services.*

The Commission recommends that the existing regulation of freestanding multi-specialty ambulatory surgery services should be maintained.

### Recommendation 14.1 *(5 Agree, 1 Disagrees, 4 Abstain)*

*Treat General Surgery in a consistent manner as all other single specialties.*

The majority of the Commission recommends that General Surgery be treated in a manner consistent with all other single specialties, regardless of the regulatory requirement for single specialty facilities.

One member disagrees and maintains that general surgery should be treated as a multi-specialty because of the complex nature of the cases that a general surgeon may perform.

### Recommendation 14.2 *(5 Agree, 3 Disagree, 2 Abstain)*

*Abolish entirely the exemption for freestanding single specialty, office-based, physician-owned ambulatory surgery centers and require physician-owned limited purpose ambulatory surgery*

*centers to obtain a Certificate from the Department. Upon application, such applicants would not be required to address need criteria but would be required to make indigent and charity care commitments, to accept Medicaid, to supply data to the Department of Community Health, and to verify that all its physicians are members of a hospital staff and are willing to accept emergency room coverage.*

The membership of the Commission was sharply divided on the issue of physician-owned single specialty ambulatory surgery centers, which are currently exempt from Certificate of Need if the center can be established for a dollar amount less than approximately \$1.6 million. One contingent of the Commission agrees with the recommendation that the current exemption be abolished and that limited-purpose, physician-owned ambulatory surgery centers (“ASC”) obtain a Certificate, although such centers would be free from an objective need methodology. Such ASCs would be required to commit to the provision of indigent and charity care at a level of 3 percent of adjusted gross revenues. In addition, this contingent recommends that these ASCs agree to accept Medicaid, if at all possible, and provide services as a minimum community standard, that such facilities agree to provide annual data to the Department, and that all physicians who perform procedures at the facility be required to hold hospital staff privileges, if possible, and to accept ER coverage. The members who agree with this recommendation do so because freestanding single-specialty ambulatory surgery centers have been shown to be high quality and low cost alternatives. These members who argue for less regulatory control contend that to artificially restrain these services raises costs reduces efficiency, and prevents physicians from billing facility fees.



Other members disagreed with this recommendation and maintain that the exemption for physician-owned ambulatory surgery centers should be abolished and that such centers should be required to obtain a Certificate of Need addressing all applicable review criteria including a determination of need. These members are concerned that if ambulatory surgery centers are allowed to proliferate significantly, hospitals will not have a financially sustainable business model. Mainly, these members maintain that ambulatory surgery centers take low acuity, paying patients, and leave hospitals to treat the complex cases and individuals without the ability to pay.

The CON Commission has been unable to reach consensus with regard to the best policy to address this difficult issue because its root causes involve complex factors relating to reimbursement and costs that are beyond the CON program's purview. A real and sustainable solution to this dilemma will require a health policy approach that corrects the cost and payment problems for both professional services and hospital-based services, particularly with respect to the under-insured and uninsured.

Recommendation 14.3 *(3 Agree, 3 Disagree, 4 Abstain)*

*Abolish the exemption for physician-owned, office-based, single specialty ambulatory surgery centers and require such facilities to obtain a Certificate of Need under the exact same standards as all other ambulatory surgery centers.*

The original recommendation of the Specialized Services Subcommittee was to abolish the current ASC exemption and require all ASCs to obtain a Certificate of Need without exception. The full Commission discussed this recommendation, but was sharply divided and no final conclusion was reached on the recommendation.

Recommendation 14.4 *(Unanimous)*

*Require all providers of ambulatory surgical services to make indigent and charity care commitments, to accept Medicaid patients, and to supply data to the Department (even if some remain exempt).*

The Commission recommends unanimously that all providers of ambulatory surgical services share the burden of caring for those who have the inability to pay for services. The Commission further recommends that it is in the best interest of the state's health planning efforts to have complete data regarding ambulatory surgical services, regardless of the level of CON regulation.



## Radiation Therapy

### An Analysis and Evaluation of Radiation Therapy Services in Georgia

#### Overview

##### Background

Data from the United States Department of Health and Human Services (HHS) indicates that cancer is commonly treated by surgery, radiation, chemotherapy, hormones, and immunotherapy, or a combination of two or more of these methods. Radiation therapy is a clinical specialty in which ionizing radiation is used to treat cancer. The predominant form of radiation therapy uses an external force of radiation, which is focused on the diseased area. Radiation therapy is an effective way to treat many kinds of cancer in almost any part of the body. For many cancer patients, it may be the only treatment needed. For others, radiation therapy may be used in combination with other cancer treatments like chemotherapy and surgery.

In Georgia, cancer is the second leading cause of death, exceeded only by heart disease. In Georgia, cancer causes one in every four deaths. In 2005, the American Cancer Society estimates that more than 35,000 Georgians will develop cancer and almost 15,000 Georgians will die from their cancer.

Both in Georgia and the nation as a whole, disparities in both incidence and mortality rates exist between rural and metropolitan

residents and between African Americans and white residents. For example, there are numerous counties in rural south and east Georgia where mortality rates are significantly higher than the state average. Counties in the metropolitan area of Atlanta, with the exception of Fulton County, have significantly lower cancer mortality rates than the state average. Moreover, African Americans in Georgia were 27% more likely to die of cancer than whites. Nationwide, African Americans have a higher mortality rate than whites for each of the major cancer sites, colorectal, male lung, female breast, and prostates, as well as a higher incidence rate for all of these cancers except female breast.

##### Access, Supply and Distribution

The Department's facility inventory shows that there are 57 radiation therapy facilities in Georgia with a total of 78 existing and/or approved linear accelerators and 3 cobalt machines. These facilities are dispersed throughout the State, with the highest concentration in state service delivery region 3 (metro Atlanta). The inventory is reflected in Figures 15-1 and 15-2.



FIGURE 15-1.

<b>Number of Radiation Therapy Facilities (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	2	4	4	4	4	4
2	2	3	4	4	4	4
3	23	24	24	23	23	23
4	4	4	4	4	4	4
5	3	3	3	3	3	3
6	3	5	5	5	5	5
7	3	2	2	2	2	2
8	2	2	2	2	2	2
9	1	1	1	1	1	1
10	2	2	2	2	2	2
11	3	3	3	3	3	3
12	3	4	4	4	4	4
<b>TOTAL</b>	<b>51</b>	<b>57</b>	<b>58</b>	<b>57</b>	<b>57</b>	<b>57</b>



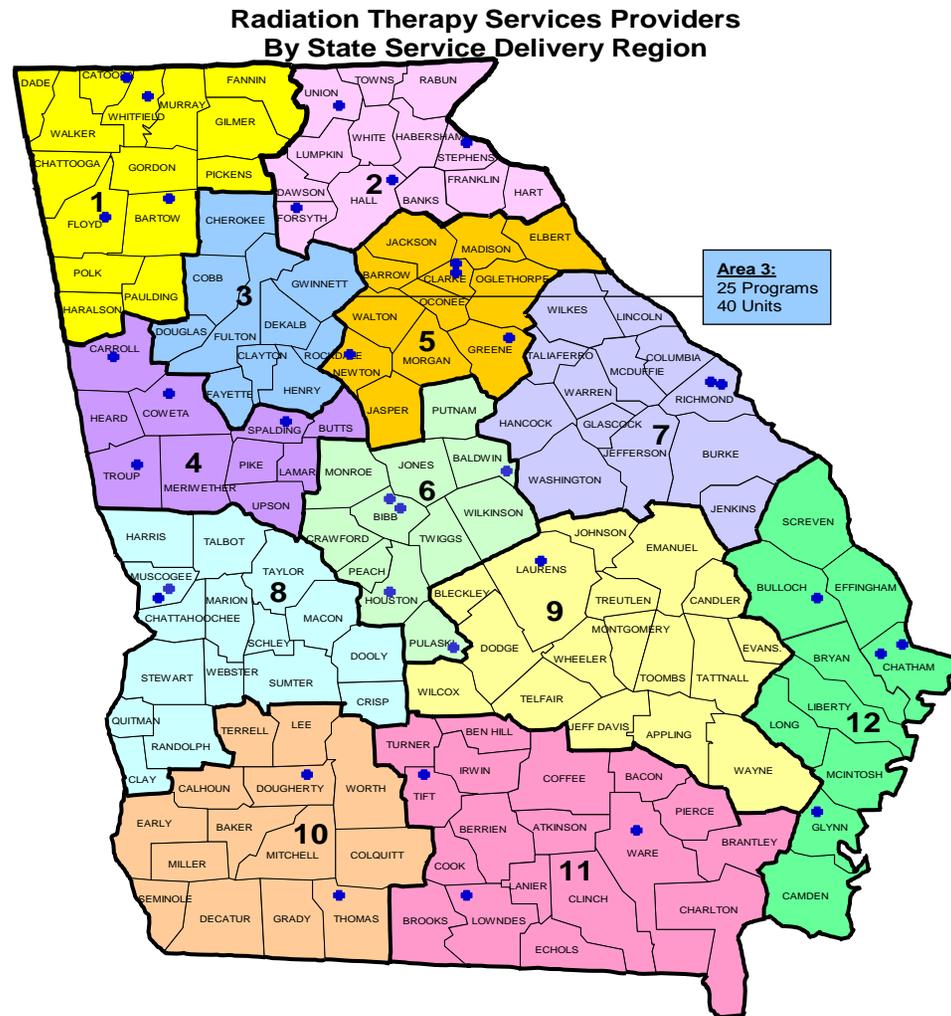
FIGURE 15-2.

<b>Number of Linear Accelerators (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	3	3	3	2	6	6
2	2	3	3	4	5	2
3	34	33	34	30	36	36
4	5	5	5	5	5	5
5	2	3	3	2	2	3
6	2	4	3	3	2	3
7	4	4	4	5	5	5
8	5	3	3	3	5	2
9	1	1	1	1	2	2
10	3	3	3	4	4	4
11	4	4	4	4	4	3
12	7	7	7	7	7	7
<b>TOTAL</b>	<b>72</b>	<b>73</b>	<b>73</b>	<b>70</b>	<b>83</b>	<b>78</b>

These services are distributed throughout the state according to the following map in Figure 15-3.



FIGURE 15-3.



Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



## Utilization

According to Department data, the state's 83 approved and existing linear accelerators had an overall utilization rate of 83 percent for 2004. This information is depicted in Figure 15-4.



FIGURE 15-4.

<b>Radiation Therapy Visits &amp; Utilization Rates (2000 – 2005)</b>						
<b>SSDR</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
1	22,260 123.66 %	20,397 113.31 %	20,444 113.57 %	7,393 61.6 %	24,767 58.96 %	34,416 95.6 %
2	14,733 122.77 %	15,722 87.34 %	14,594 81.07 %	20,940 87.25 %	20,654 68.84 %	9,650 80.41 %
3	189,651 92.96 %	206,100 104.09 %	195,670 95.91 %	183,829 102.12 %	185,173 85.72 %	170,707 78.75 %
4	23,887 79.62 %	23,868 79.56 %	25,085 83.61 %	23,087 76.96 %	24,813 82.71 %	19,088 63.62 %
5	17,531 146.09 %	19,049 105.82 %	26,364 146.46 %	17,990 149.91 %	17,579 146.49 %	22,301 123.89 %
6	11,700 97.5 %	26,466 110.27 %	11,812 65.62 %	11,534 64.07 %	7,667 63.89 %	12,246 68.03 %
7	25,990 108.29 %	27,083 112.84 %	30,090 125.37 %	33,291 110.97 %	31,947 106.49 %	30,841 102.8 %
8	17,607 58.69 %	13,401 74.45 %	12,585 69.91 %	11,802 65.56 %	20,055 66.85 %	8,790 73.25 %
9	12,250 204.16 %	6,875 114.58 %	6,183 103.05 %	5,302 88.36 %	4,966 41.38 %	5,854 48.78 %
10	23,585 131.02 %	21,714 120.63 %	23,948 133.04 %	25,041 104.33 %	28,199 117.49 %	26,417 110.07 %
11	24,376 101.56 %	11,091 46.21 %	19,136 79.73 %	16,198 67.49 %	19,038 79.32 %	13,753 76.4 %
12	31,331 74.59 %	33,684 80.2 %	36,440 86.76 %	40,857 97.27 %	33,888 80.68 %	36,111 85.97 %
<b>TOTAL</b>	<b>414,901</b> <b>96.04 %</b>	<b>425,450</b> <b>97.13 %</b>	<b>422,351</b> <b>96.42 %</b>	<b>397,264</b> <b>94.58 %</b>	<b>418,746</b> <b>84.08 %</b>	<b>390,174</b> <b>83.37 %</b>



## Cost

Figure 15-5 reflects the average charge per radiation therapy visit from 2000 to 2005 derived from Department radiation therapy survey data. The average charges per visit have increased dramatically over the past five years, in part due to the increasing use of intensity-modulated radiation therapy and other more specialized and expensive forms of radiation therapy.

**FIGURE 15-5.**

Year	Average Charge per Radiation Therapy Visit
2000	\$618
2001	\$764
2002	\$923
2003	\$1,110
2004	\$1,281
2005	\$1,524



## Quality

Radiation therapy centers must be licensed by the Department of Natural Resources for use of radioactive emissions. In addition, CON rules require applicants to document a plan whereby the facility and its medical staff agree to provide or, in the case of a free-standing facility, agree to participate in a full array of cancer services to the community, including, but not limited to, community education and outreach, prevention, screening, diagnosis, and treatment. In addition applicants must document current and ongoing participation in the State Cancer Registry Program.

## Current Regulatory Scheme

### Georgia

*Department of Community Health.*

The Department of Community Health, Division of Health Planning regulates health care services in the state through the Certificate of Need program. For radiation therapy services, a Certificate of Need (CON) is required before a provider can offer services. A CON is required for the expansion of existing services and/or the establishment of a new service. Radiation therapy services are governed by a need methodology for each state service delivery region, with criteria to allow for exceptions to add services when there is no numeric need or utilization is below the required threshold. Radiation therapy services can currently be applied for at any time.

Figure 15-6 represents the CON application volume for radiation therapy since 1979.



FIGURE 15-6.

<b>CON Applications for Radiation Therapy Services (Including Gamma Knife/Cyber Knife)</b>	
Approved	93
Denied	19
Pending	1
Withdrawn	26
<b>Total</b>	<b>139</b>

*Department of Natural Resources*

The Environmental Protection Division (EPD) of the Georgia Department of Natural Resources is a state agency charged with protecting Georgia's air, land, and water resources through the authority of state and federal environmental statutes. These laws regulate public and private facilities in the areas of air quality, water quality, hazardous waste, water supply, solid waste, surface mining, underground storage tanks, and others. EPD issues and enforces all state permits in these areas and has full delegation for federal environmental permits except Section 404 (wetland) permits.



## Comparison States

Four of the 11 study states (Georgia, Iowa, Massachusetts, West Virginia,) have a CON process that applies to Radiation Therapy/Linear Accelerators, while Colorado, Florida, Maine, Oregon, Utah, Washington, and Wisconsin do not. The comparison states are depicted in Figure 15-7.

**FIGURE 15-7.**

Comparison State	CON Regulation for Radiation Therapy
Colorado	NO
Florida	NO
Georgia	YES
Iowa	YES
Maine	NO
Massachusetts	YES
Oregon	NO
Utah	NO
Washington	NO
West Virginia	YES
Wisconsin	NO

## Federal Oversight

Radiation therapy services have federal oversight from the U.S. Department of Health and Human Services. There are standards to be recognized as a Medicare-approved facility, which must be met in order for a facility to receive reimbursement. The Food and Drug Administration regulates the research and use of cancer treatment drugs and pharmaceuticals.



## Strategic Options

### Option 15.0

*Maintain existing CON regulation of radiation therapy services.*

### Option 15.1

*Deregulate radiation therapy services from CON.*

### Option 15.2

*Deregulate radiation therapy services from CON but require data reporting.*

Under this option, applicants would not need to obtain a CON for radiation therapy; however, providers of these services would still be required to report data on a regular basis.

### Option 15.3

*Deregulate radiation therapy services from CON but increase licensure standards.*

Under this option, applicants would not need to obtain a CON for radiation therapy; however, licensure would increase its licensing standards for such services.

## Recommendations

### Recommendation 15.0

*(Unanimous)*

*Maintain existing CON regulation of radiation therapy services.*

All Commission members agree that the existing regulation of radiation therapy services is sufficient and should be maintained because of the cost of the equipment used to deliver the services and the complex nature and highly-skilled workforce required to deliver radiation therapy.



## CT, MRI, and PET Imaging Services

### An Analysis and Evaluation of Specialized Diagnostic Imaging Services in Georgia

#### Overview

##### Background

The Department of Community Health partially regulates diagnostic imaging services; this regulation is dependant upon the specific type of service and the cost of the equipment and related capital expenditures. Acquisition of computed tomography (CT) scanners and magnetic resonance imaging (MRI) units are not currently regulated by any specific rules, unlike positron emission tomography (PET) machines, for which a component plan and service-specific rules exist. A CT scanner utilizes radiation (x-rays) and detectors to provide a cross-section of various organs and body tissues. The scanner is able to analyze bone, tissue, and blood vessels in a very detailed manner, and thus is a useful tool in the diagnosis of musculoskeletal conditions, cancer, trauma, and cardiovascular disease, among other disorders. An MRI unit utilizes radiofrequency waves and a magnetic field to provide detailed and clear pictures of internal organs and tissues. The machine is a useful tool in the diagnosis of sports-related injuries, coronary heart disease, abdominal cavity conditions, tumors, and other diseases that are difficult to detect without detailed images. A PET machine detects the emission of positrons, which are particles emitted from a radioactive substance administered to the patient undergoing the procedure; it provides

images of areas of the body based on physiological functions. PET scans are most commonly utilized in the detection of cancer, but are also used to examine the physiology of the heart and the brain.

The American College of Radiology (ACR) produces guidelines to address the full range of standards and criteria recommended by experts for the provision and interpretation of quality imaging studies, including CT, MRI, and PET procedures. These documents outline specific qualifications and responsibilities of personnel performing scans, scanning techniques and indications, and possible contraindications; the guidelines are intended to assist medical practitioners in providing appropriate medical care for patients. The current component plan for positron emission tomography in Georgia contains aspects of the guidelines released by the ACR. As no specific component plan currently exists for CT or MRI services, standards for the provision of those services are not regulated in the state. A component plan for magnetic resonance imaging was created in 1985, and was utilized until 2001; this plan did describe for the provision of MRI studies based on then-current guidelines set by the American College of Radiology.



As MRI and CT technology is now widely utilized for obtaining cardiac images, a clinical competence statement on this particular type of cardiovascular diagnostic tool was jointly released by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the American College of Physicians (ACP) Task Force on Clinical Competence and Training in 2005. The recommendations included in the report aim to assess the expertise of providers of cardiovascular health in interpreting and applying CT and MRI technology.

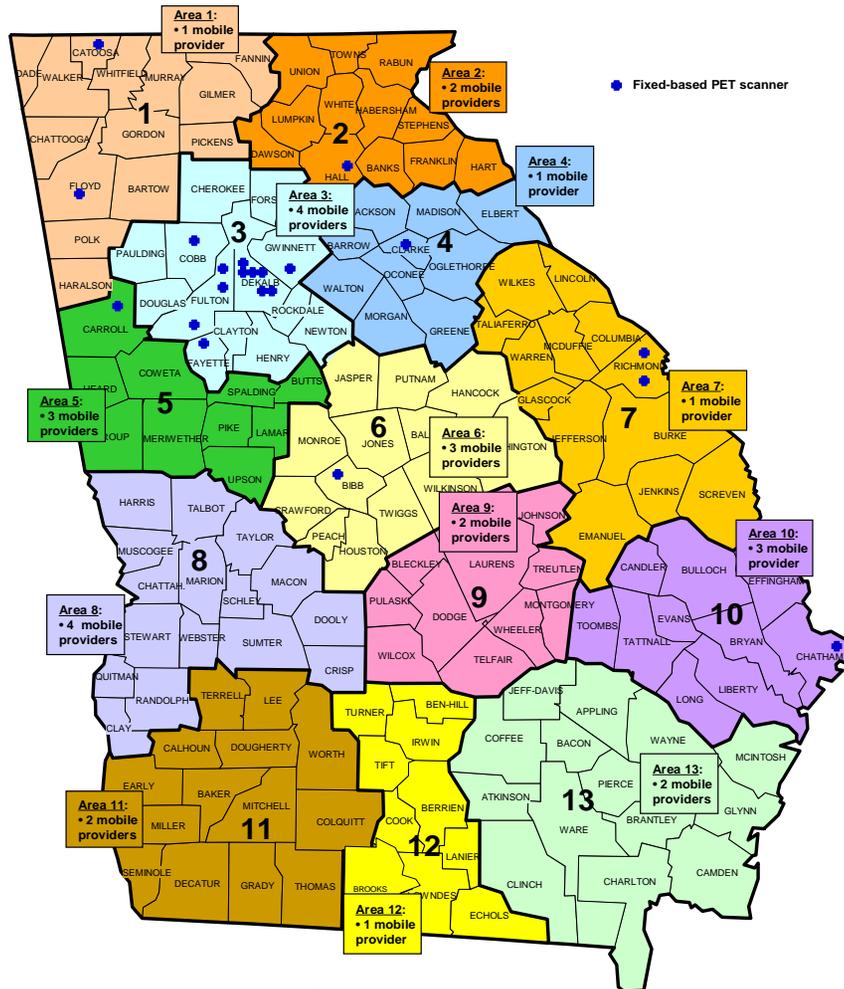
### Access, Supply and Distribution

There is no region of the state that lacks a PET provider as evidenced by the following map. However, 5 regions of the state rely solely on mobile PET providers, mainly in Southern Georgia. A map of the distribution of services throughout the state is depicted in Figure 16-1.



FIGURE 16-1.

Positron Emission Tomography (PET) Services Providers  
By Health Planning Areas

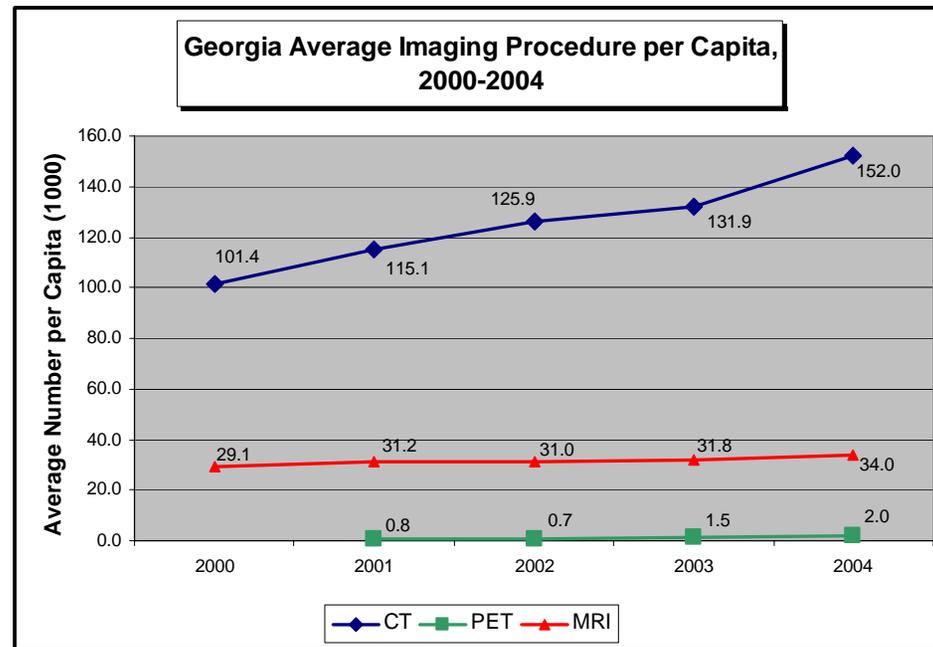


Prepared by: Data Resources and Analysis Section,  
Division of Health Planning – November 3, 2006



The objective need methodology for positron emission tomography services established by the PET Component Plan allows the need for services in an area to be calculated based on aggregate utilization data, demand for services, population projections, and cancer incidence rates. Since 2001, the number of PET studies performed per capita (1000) has increased, along with the number of MRI and CT procedures, as shown in the chart below. 2.0 persons per 1000 underwent a PET scan in 2004, an increase of 150 percent from 2001. The CT use rate has grown 49.9 percent during the period from 2000 to 2004; during the same time period, MRI utilization also grew, but at a much smaller amount of 16.84 percent. Per capita use rates are depicted in Figure 16-2.

FIGURE 16-2.



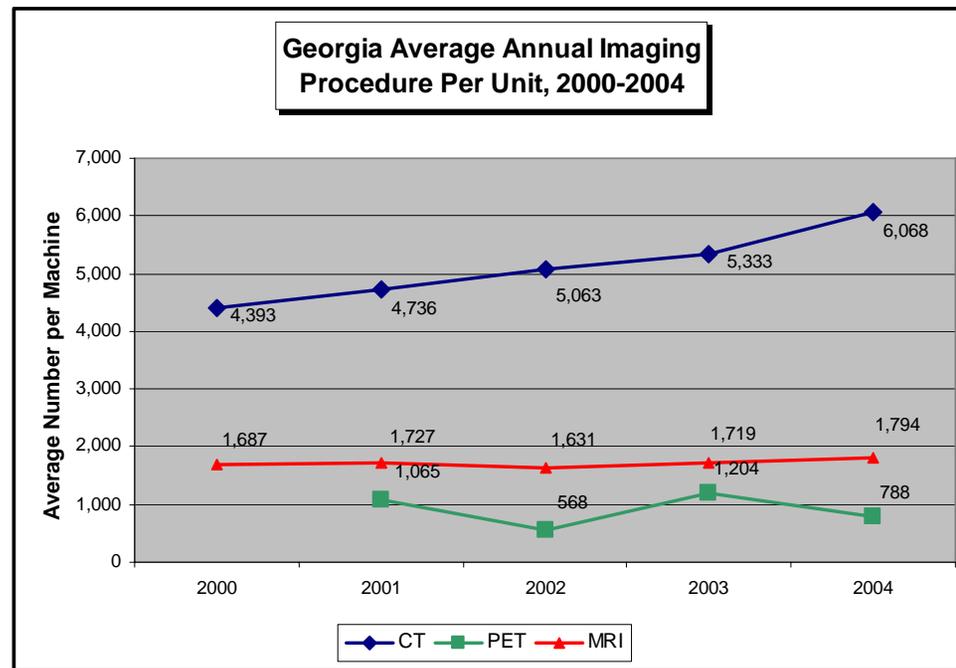
Sources: Hospital Survey (Annual Hospital Questionnaire) & PET Services Survey, Georgia Department of Community Health, Division of Health Planning



The number of PET providers in the state of Georgia has grown steadily since 2001; 23 units currently are operating in the state. The number of hospitals that offer MRI and CT services has also increased, growing 18.18 percent from 2000, for a 2004 total of 390 hospital-based MRI and CT units. However, many facilities operate more than 1 specialized imaging machine on site, and due to increasing demand, often utilize multiple MRI and multiple CT units each. These numbers also do not take into account freestanding imaging facilities, or those CT and MRI machines that individual physician practices may operate, as those facilities and

practices are not required to report data to the state. Similar to the per capita rates, the average number CT and MRI studies performed per machine has increased from the year 2000. MRI procedures per unit grew 6.34 percent, while the average number of CTs performed by unit increased 38.13 percent. State Service Delivery Region 3, in which much of the Atlanta metropolitan area resides, contained 42.33 percent of Georgia's total population in 2004; 41.52 percent of CT scans, 44.17 percent of MRI studies, and 59.83 percent of PET scans took place in this area. Imaging procedure per unit volumes are shown in Figure 16-3.

**FIGURE 16-3.**



Sources: Hospital Survey (Annual Hospital Questionnaire) & PET Services Survey, Georgia Department of Community Health, Division of Health Planning

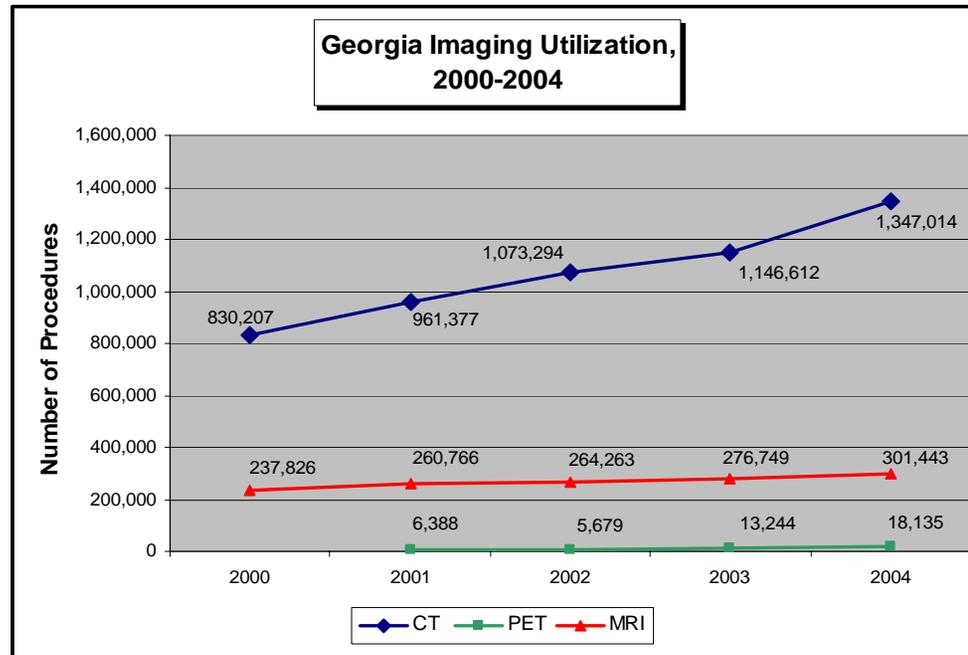


## Utilization

As was discussed in the previous section, and shown in the graphs below, the total number of CT and MRI procedures performed statewide has increased 54.35 percent during the 2000 to 2004 time period. The growth in CT scanning utilization has been much greater than for MRI; the number of CT studies performed grew

62.75 percent over the past 5 years, while MRI has only increased by 26.75 percent. From 2001 to 2004, PET utilization increased the most, growing 183.89 percent. In 2004, CT studies accounted for 80.82 percent of the specialized imaging procedures in Georgia. Total utilization volumes are depicted in Figure 16-4.

**FIGURE 16-4.**



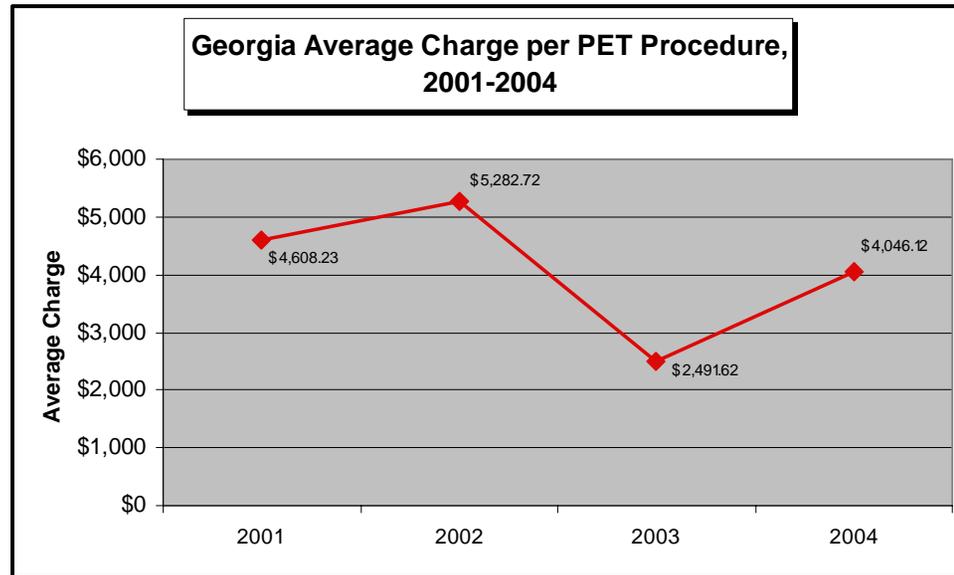
Sources: Hospital Survey (Annual Hospital Questionnaire) & PET Services Survey, Georgia Department of Community Health, Division of Health Planning



## Cost

Currently, data is not collected by the state regarding actual charges of hospital-based CT and MRI studies. However, PET data is compiled, and in 2004, the average charge in Georgia for a PET scan was \$4,046.12. It is difficult to determine if procedural charges have decreased; the average charges per scan have fluctuated since data was first collected in 2001. Average charge per procedure for PET is depicted in Figure 16-5.

**FIGURE 16-5.**



Source: PET Services Survey, Georgia Department of Community Health, Division of Health Planning

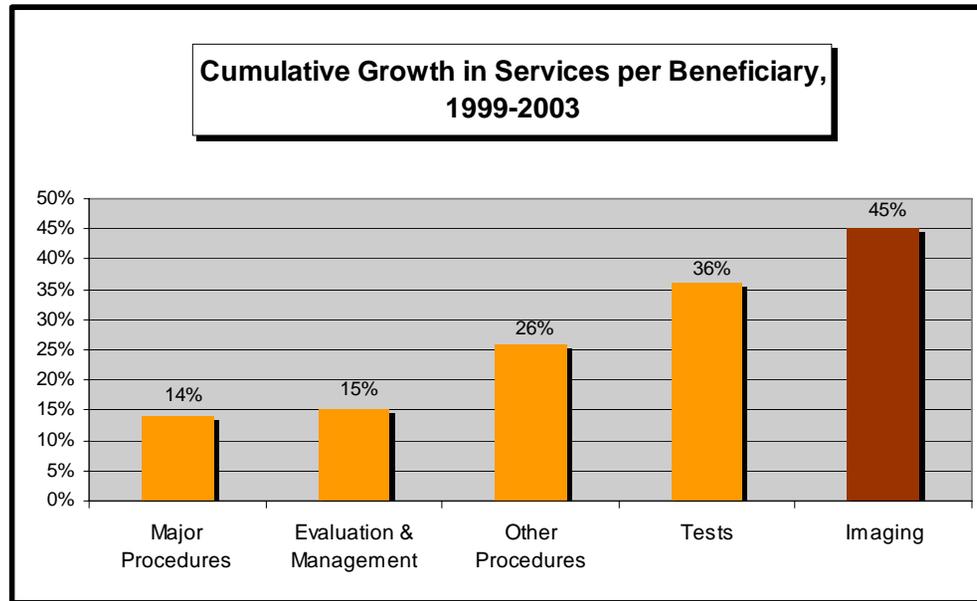
It is difficult to decipher if the costs for specialized diagnostic imaging services in the state of Georgia have been growing, based on currently available data. However, the federal government, through data analysis, concluded that the imaging services that are paid

under Medicare's physician fee schedule have increased more than any other type of physician service, at a rate twice as fast of all physician services, as shown in Figure 16-6. This study, conducted by the Medicare Payment Advisory Commission, also found that in



2003, Medicare spent \$9.3 billion for imaging services, an increase of over 63 percent since 1999. This payment growth is not entirely attributable to the trend of performing the tests in physician offices rather than an outpatient hospital setting.

**FIGURE 16-6.**



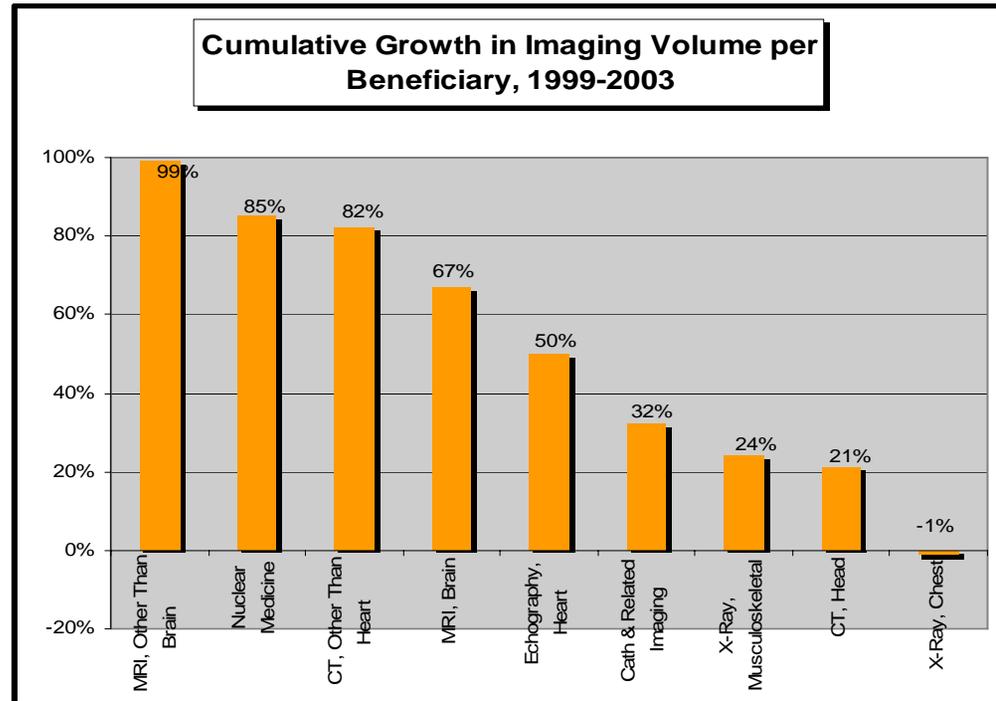
Source: MedPac recommendations on imaging services

Figure 16-7 shows that the Medicare Payment Advisory Commission also studied the growth of specific types of advanced imaging tests. Nationally, from 1999 to 2003, MRI studies conducted on the body, other than the brain, increased 99 percent. Similarly, CT scans performed on parts of the body besides the head grew 82 percent. This increased utilization of diagnostic tests could be fueled in part by the innovations in technology that allow more detailed images to

be produced in shorter amounts of times. Improved technology could allow the machines to be used to detect an even wider array of conditions, thereby allowing practitioners to recommend their use more frequently. Additionally, many physicians are able to provide these tests in a freestanding setting, or in their own office, thereby increasing access to the technology.



FIGURE 16-7.



Source: MedPac recommendations on imaging services

### Quality

*ACR Guidelines* The American College of Radiology publishes specific guidelines for many types of advanced imaging modalities, including CT, MRI, and PET; the most recent editions were released in 2006. These guidelines provide a framework for practitioners to provide appropriate radiologic care. Qualifications

of personnel, possible contraindications, techniques, examination and equipment specifications, safety guidelines, and quality control and improvement for CT, MRI, and PET are all addressed in their respective specific reports. The guidelines conclude that quality, patient education, infection control, and safety should be created and implemented based on standards set by ACR.



*ACCF/AHA/ACP Guidelines* The cardiac imaging competence statement, published in 2005, includes factors related to knowledge and training of clinician, facility requirements, and standards of cardiovascular computed tomography (CCT) and cardiovascular magnetic resonance (CMR). The recommendations stress the need for physicians performing cardiac imaging procedures to be competent in CCT and CMR, which includes specific training, mentoring, and image interpretation skills.

In terms of quality, the Positron Emission Tomography Component Plan and rules do not specifically recognize the guidelines recommended by the ACR. However, similar standards related to quality are included in the rules. Currently, an applicant wishing to offer or expand CT or MRI services is not

required to demonstrate that they will meet any standards set by the American College of Radiology, in terms of both facility and practitioner quality and competence.

## Current Regulatory Scheme

### Georgia

#### *Department of Human Resources.*

The Georgia Office of Regulatory Services licenses and inspects hospitals that provide specialized diagnostic imaging services. The Office also inspects facilities that provide x-ray services, such as freestanding imaging centers and physician's offices.

#### *Department of Community Health.*

The Georgia Department of Community Health currently has a component plan and specific review requirements and considerations that address PET services; the most recent

component plan for this service was issued in May, 2002. In terms of setting standards for establishing or expanding PET services at a facility, the component plan utilizes standards set by another state and the Georgia Cancer Coalition. All entities that desire to expand their PET services, or a facility that wishes to offer these services for the first time, must apply under these considerations, and address all of the rules.

As shown in Figure 16-8, applicants that propose to offer or expand CT and MRI services are very successful at being granted a CON; over 92 percent of CON applications for each of the services were granted. Fewer applicants have applied to offer PET services in the state, and of those who have since 2001, over 68 percent were granted a CON. CT applicants had the highest rate of appeal by an opposing party, with 28.22 percent.



FIGURE 16-8.

<b>Imaging CON Applications, 1979 to Present, Final Findings</b>				
	<b>Approval</b>	<b>Denial</b>	<b>Withdrawal</b>	<b>Appeals</b>
<i>CT</i>	187	5	10	57
<i>MRI</i>	220	7	11	28
<i>PET</i>	28	4	9	9

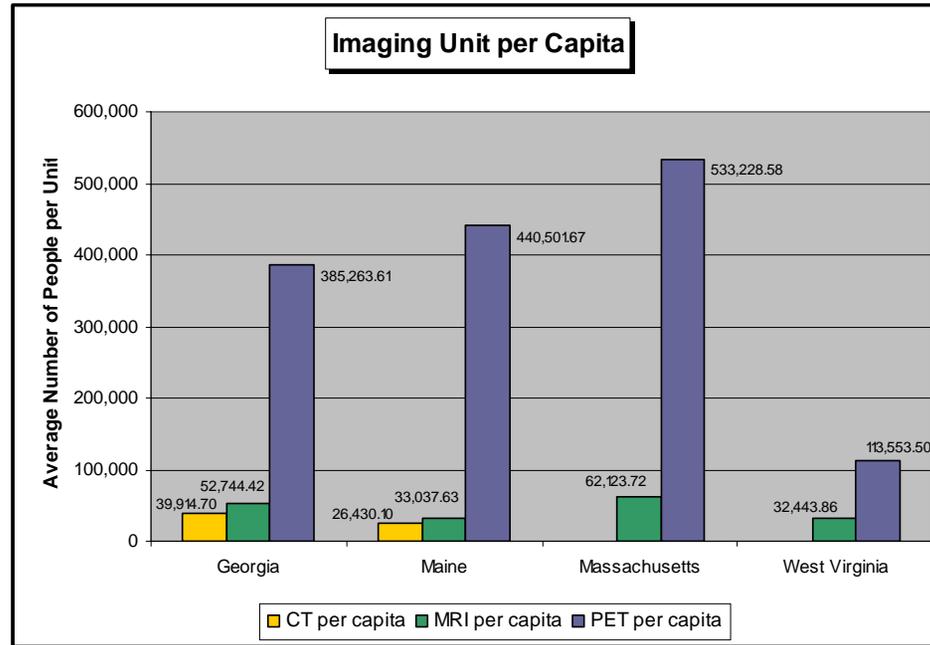
Sources: *Hospital Survey (Annual Hospital Questionnaire) & PET Services Survey, Georgia Department of Community Health, Division of Health Planning*

### Comparison States

Like Georgia, many states do not regulate the provider and the number of facilities that provide specialized diagnostic imaging services such as CT, MRI, and PET services via a Certificate of Need Program. Currently, of the states included in the CON study, Iowa, Massachusetts, Maine, and West Virginia have provisions for the procurement of PET scanners. Additionally, Massachusetts, Maine, and West Virginia govern MRI services, and Maine also controls CT unit expansion. From currently available data, it is evident that Georgia has a higher number of people per CT and MRI unit than Maine. Georgia's PET rate is lower than other comparison states. West Virginia had the least number of people per MRI and PET unit when compared to the other states included. This information is depicted in Figure 16-9.



FIGURE 16-9.



Sources: Hospital Survey (Annual Hospital Questionnaire) & PET Services Survey, Georgia Department of Community Health, Division of Health Planning

Freestanding imaging centers are not specifically regulated in Georgia currently, although many come under CON review due to the total cost exceeding the capital expenditure threshold. Iowa, Maine, Massachusetts, Washington, and West Virginia have more specific governance over the creation of these facilities, as shown in Figure 16-10.



FIGURE 16-10.

Freestanding Imaging Centers									
	FL	GA	IA	ME	MA	OR	WA	WV	WI
<i>Threshold</i>	Not Reviewable	Capital:\$1,483,083; Equip: \$823,934	Any Amount Except PET Scanners: \$1,500,000	Capital:\$510,000; Equip: \$1,333,098; New Svc: \$121,880	Capital:\$12,516,300; Equip: \$1,335,272	Not Reviewable	Capital:\$1,200,000; Any New Svc	Capital:\$2,000,000; Equip: \$2,000,000; New Svc or Facility: None	Not Reviewable
<i>New Freestanding Imaging Centers (FSIC)</i>		Yes, for equip over threshold	Yes	Yes	Yes-except MRI, also must be considered innovative		Yes	Yes	
<i>Existing FSIC</i>		Yes- including hospitals exceeding threshold	Yes	Yes	Yes		Yes	Yes	
<i>Sale or Transfer</i>		Yes- if new owner is not a CON holder	Yes- if it would be a new service	Yes	No		No	Yes	
<i>Renovation</i>		Yes	No	Yes	Yes		Yes	Yes	
<i>Relocation</i>		Yes	No	Yes	Not available		Yes	Yes	
<i>Licensure, Regulation</i>		Must meet appropriate accreditation requirements of the JCAHO, and/or other accrediting agency		Must be licensed	Must be licensed		State licenses	Not available	
<i>Moratoria, Caps</i>					No need for MRI				

Source: Report of Data Analyses to the Georgia Commission on the Efficacy of the CON Program



## Federal Oversight

### *Medicare.*

Diagnostic specialized imaging studies are currently reimbursable services. However, in 2005, due to the proliferation of office-based available machines, and thus increasing utilization of MRI and CT, the Medicare Payment Advisory Commission recommended that standards should be set regarding quality of services, bundling of diagnostic imaging services, and payment for the services.

### *Medicaid.*

In Georgia, Medicaid currently does not reimburse for services provided by freestanding imaging facilities.

## Strategic Options

### Option 16.0

*Maintain existing CON regulation of PET.*

### Option 16.1

*Deregulate PET from CON.*

### Option 16.2

*Deregulate PET from CON but require data reporting.*

Under this option, applicants would not need to obtain a CON for PET; however, providers of PET services would still be required to report data on a regular basis.

### Option 16.3

*Deregulate PET from CON but increase licensure standards.*

Under this option, applicants would not need to obtain a CON for PET; however, licensure would increase its licensing standards regarding PET.

### Option 16.4

*Abolish entirely the exemption for diagnostic or therapeutic equipment that can be obtained below threshold.*



## Option 16.5

*Amend the statutory exemption for diagnostic or therapeutic equipment that can be obtained below threshold.*

16.5A: Remove the dollar threshold cap and

1. Require all freestanding imaging centers to obtain a CON
2. Require all imaging within physician practices to obtain a CON
3. Exempt imaging within physician practices
4. Exempt hospital-based imaging

16.5B: Increase the dollar threshold

16.5C: Decrease the dollar threshold

## Option 16.6

*Require statutorily exempt providers of diagnostic or therapeutic equipment to make a commitment to indigent and charity care as a condition on the exemption.*

## Option 16.7

*Require statutorily exempt providers of diagnostic or therapeutic equipment to provide data to the Department as a condition on the exemption.*



## Recommendations

*NOTE: The Commission did not reach full consensus on the regulation of imaging services. The equipment expenditure threshold is addressed in Recommendation 3.2.*

### Recommendation 16.0 (4 Agree, 3 Disagree, 3 Abstain)

*Maintain existing CON regulation of Positron Emission Tomography.*

A majority of the Commission recommends that Certificate of Need regulation of Positron Emission Tomography (PET) services be maintained. These members maintain that the high cost of PET equipment necessitates a higher degree of regulation. PET also requires a trained workforce such as dosimetrists, physicists, etc.

Another portion of the Commission maintains that PET services should be deregulated. These members maintain that PET services have great potential in saving lives and that the deregulation of the service would improve access to the citizens of the state. In addition, these members have concern about the perceived accessibility problems in Georgia associated with PET. In relation to other neighboring states, Georgia has fewer PET scanners per capita.

### Recommendation 16.1 (Unanimous)

*Require statutorily-exempt providers of diagnostic or therapeutic equipment to make a commitment to indigent and charity care as a condition of the exemption.*

Members of the Commission unanimously recommend that freestanding providers of diagnostic imaging should provide indigent and charity care. Therefore, the Commission recommends that the statutory exemption be modified to

specifically require providers to make an indigent and charity care commitment as a condition of the exemption.

### Recommendation 16.2 (Unanimous)

*Require statutorily exempt providers of diagnostic or therapeutic equipment to provide data to the Department as a condition of the exemption.*

The lack of data from all providers of healthcare in the state adversely impacts the state's health planning functions. Therefore, the Commission unanimously recommends that all exempt providers of diagnostic imaging services commit to provide data to the Department annually as a condition of being exempt.

### Recommendation 16.3 (5 Agree, 1 Disagree, 4 Abstain)

*Modify the exemption for equipment below threshold to require all freestanding diagnostic imaging centers to obtain a Certificate of Need for equipment regardless of costs, except for de minimis x-ray equipment. Physician offices and hospitals and other health care facilities would still be able to obtain equipment under threshold, but freestanding imaging centers would require a Certificate of Need.*

A majority of the Commission recommends that the exemption for equipment below threshold should not apply to Freestanding Imaging Centers. Under this recommendation, Freestanding Imaging Centers would need to obtain a Certificate of Need regardless of the cost of the equipment being acquired and used in the facility, except that such facilities would be permitted to obtain *de minimis* x-ray equipment without obtaining a Certificate of Need. The members who make this recommendation do so because of concerns over the quality of freestanding imaging centers and the potential for over-utilization of imaging services at



freestanding imaging centers, which has been substantially documented.

Those who oppose this recommendation maintain that the equipment threshold should be applicable to freestanding imaging centers as for all other providers of imaging services because the cost of freestanding imaging centers to the patient and to insurers is substantially less than the cost of hospital-based imaging.

