

**SYNOPSIS**  
*Rule 111-2-2-.06*

**STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE**

The purpose of this proposed amendment is to modify an existing regulation to change the number of copies of CON-related documents and forms that must be submitted to the Division of Health Planning.

**DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES**

The existing regulation, 111-2-2-.06(5), is modified to require the submission of a signed original and only one copy for all CON-related documentation and forms submitted to the Division of Health Planning. The current rule requires the submission of a signed original and three copies.

**PROPOSED RULES  
OF  
DEPARTMENT OF COMMUNITY HEALTH**

**111-2  
HEALTH PLANNING**

**111-2-2  
Certificate of Need**

**111-2-2-.06 Application for Certificate of Need.**

**(1) Contents of Application.** Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

- (a) identification of the applicant;
- (b) ownership;
- (c) site identification;
- (d) compliance with State and local codes and ordinances, including flood hazards;
- (e) a detailed and complete description of proposed project;
- (f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;
- (g) staffing and operation;
- (h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender. Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;
- (i) cost containment and quality of care considerations;
- (j) project design and construction schedule including as applicable
  - 1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the

Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect's evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicant's program and schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicant's site for the Project based on the information provided by the Applicant of site conditions, and the Applicant's program, schedule and budget for the Cost of the Work, and an evaluation of the applicant's proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the 60 days immediately preceding submission of the application;

(l) documentation from the Office of Regulatory Services of the Department of Human Resources of no uncorrected licensure operational standards in the applicant's facility, if applicable.

**(2) Submittal of Applications.**

(a) Applicants should submit to the Department ~~one (1) signed copy~~ of the application plus the original. The original, signed by the applicant, must accompany the ~~copy~~. Failure to provide ~~a copy or an original signature of the legal representative of the applicant~~ will result in non-acceptance and return of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

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**(3) Filing Fee Required.**

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in 111-2-2-.06(3)(d) and 111-2-2-.06(3)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to \$1,000,000, the fee shall be \$1,000; and
2. for applications with a total project cost greater than \$1,000,000, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed \$50,000; and
3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a current (within six months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by certified check or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than \$500. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

**(4) Review for Completeness.**

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or, as may be specified in this Section, submitted previously to the Department:

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by 111-2-2-.06(1)(e);

- (ii) financial program to meet the requirements of 111-2-2-.06(1)(h);
- (iii) documentation of necessary financing for the project, such as a letter of credit, etc.;
- (iv) financial pro forma to meet the requirements of 111-2-2-.06(1)(h); and
- (v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);
- (vi) for projects invoking service-specific Rules, as outlined in Rules 111-2-2-.20 et seq., the appropriate service-specific review considerations;
- (vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by 111-2-2-.06(1)(k);
- (viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. appropriate number of copies of the application sent to the Department, pursuant to and in compliance with 111-2-2-.06(5);
3. signatures on all copies, with an original signature of the applicant on the application determined by the applicant as the original;
4. payment of the filing fee, as described in 111-2-2-.06(3);
5. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;
6. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessor's and lessee's commitment to participate in the lease once the CON is approved;

7. authorization to conduct business, including but not limited to, as appropriate:

- (i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;
- (ii) by-laws, articles of incorporation, or articles of organization; and
- (iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

8. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

9. all post-approval reporting requirements as mandated at 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

10. the written vendor lobbyist certification required by 111-1-2-.03(2);

11. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

12. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

(c) The Department shall notify the applicant within ten business days following receipt of the application that the application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is postmarked by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a nongrant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

(i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will be no less than three percent of the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous year's financial records, except the first year of operation following an acquisition the three percent will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department..

**(5) Submission of Information and Documents.** For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents either via the postal service or hand delivery, as the term hand delivery is commonly known and used. For the purposes of this rule, the use of a common carrier or a courier service shall meet the requirement of hand delivery. At all times, the interested party shall submit either the original document or a certified copy thereof. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in 111-2-2-.04, including, but not limited to,

applications, opposition letters, supplementary information, requests for determinations, challenges to determinations, and requests for letters of non-reviewability shall be submitted with a signed original and one (1) copy.

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**SYNOPSIS**  
*Rule 111-2-2-.10*

**STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE**

The purpose of this proposed amendment is to modify an existing regulation to indicate that the appropriate section within the Department of Community Health for the submission of challenges to CON determination and LNR requests is the Division of Health Planning and not the Office of General Counsel.

**DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES**

The existing regulation, 111-2-2-.10(6), is modified to reflect that the appropriate section of the Department to which individuals should submit challenges to determination requests and LNR requests is the Division of Health Planning.

**PROPOSED RULES  
OF  
DEPARTMENT OF COMMUNITY HEALTH**

**111-2  
HEALTH PLANNING**

**111-2-2  
Certificate of Need**

**111-2-2-10 Determinations and Letters of Non-Reviewability.**

**(1) General Provisions Relating to Determinations and Letters of Non-Reviewability**

(a) Determinations and Letters of Non-Reviewability are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination or letter of non-reviewability, as applicable. Therefore, the conclusions of a specific determination or letter of non-reviewability shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination or letter of non-reviewability shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the is to be granted by the Department.
2. the exact legal name of each person whose rights are affected and who is requesting a determination or letter of non-reviewability and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;
3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and
4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination or letter of non-reviewability shall address only one matter per request.

(e) Requests for determination or letter of non-reviewability shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Such requests shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

(f) Requests for determination or letter of non-reviewability shall include payment of a request fee. Payment of the fee shall be by certified check or money order made payable to the State of Georgia Department of Community Health and must be received by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the request.

1. The request fee for determination shall be \$250.00;
2. The request fee for letters of non-reviewability shall be \$500.00;
3. State-owned institutions shall be exempt from payment of these fees; and
4. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination.** Pursuant to O.C.G.A. § 31-6-47(c), if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

(a) No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party.; and

(b) In addition to the requirements of 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(3) **Requests for Letters of Non-Reviewability for Below Threshold Diagnostic or Therapeutic Equipment.** In addition to the requirements of 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at 111-2-2-.01(44), the Department applies the following rules as they concern requests for determinations that the value of certain diagnostic or therapeutic equipment does not exceed the Department's equipment threshold, pursuant to O.C.G.A. § 31-6-2(14)(F), (H), or (F) and (H) and therefore that such equipment is not subject to prior CON review and approval.

(a) The party who requests the letter of non-reviewability must submit a manufacturer's or vendor's price quotation or purchase order for the diagnostic or therapeutic equipment. This requirement applies even if the equipment is to be leased.

(b) The party who requests the letter of non-reviewability must submit a sworn affidavit affirmed by a person capable of making a binding commitment on behalf of the manufacturer or vendor of the diagnostic or therapeutic equipment for which a determination containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and
2. that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or
3. In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(c) A party requesting a letter of non-reviewability for the purchase of diagnostic or therapeutic equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the party;
2. that no acquisition of additional items not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic or therapeutic equipment at issue to include functionally related equipment, will be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic or therapeutic equipment or its operational configuration over the Department's equipment threshold;
3. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;
4. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;
5. that the Line Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Rule 111-2-2-.10(3), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

6. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

7. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(d) The request for a letter of non-reviewability must include a, Equipment Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic or therapeutic equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line Item Valuation Sheet and indicate the dollar amount as \$0. For each simultaneous and associated unit of equipment, as outlined at 111-2-2-.10(3)(j) below, a separate line item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;
2. Any expense incurred for the purchase of a first year's warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor;
3. Any expense incurred for operator training;
4. Any expense incurred for installation and assembly of the equipment;
5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;
6. Any expense incurred for functionally related diagnostic or therapeutic equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.
7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;
8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;
9. Any dollar amount attributable to service contracts for the initial year of operation;
10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of non-reviewability by the manufacturer or vendor of the equipment;
11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven items.

(e) 1. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Functional Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to build-out to make the equipment functional to include, but not to be limited to, electrical and plumbing work to be performed, masonry expenses to lay a concrete pad, and construction of modular buildings. Each item of build-out shall be delineated. If functional build-out will not be necessary, i.e. because equipment was previously used in the exact same space, the requesting party should include the Functional Build-Out/Finish Line Item Valuation Sheet and indicate that no functional build-out is required.

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2. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to finishing and build-out items, activities, and expenditures, if such items are associated and simultaneously developed or proposed, including, but not limited to, clinical office space, administrative areas, waiting rooms, etc. If there will be no associated and simultaneous build-out/finish, the requesting party should include the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet and indicate that no associated and simultaneous build-out/finish is required.

(f) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Furnishings Line Item Valuation Sheet, generated by the party requesting a letter. Pursuant to the definition of “associate with and simultaneously developed or proposed,” the Furnishings Line Item Valuation Sheet should include a description of each item of furniture, the quantity of each item, a price per item, and a total based on the quantity multiplied by the price. A grand total should be calculated at the bottom of the Sheet. If no associated with and simultaneously developed or proposed expenditures related to furnishings will be incurred within 6 months of the operation of the equipment, submit a sheet entitled “Furnishings Line Item Valuation Sheet” and indicate that no furnishings will be acquired;

- 1. if items of furnishings are to be leased, the current market value of the furnishings shall be listed;
- 2. submit price quotes as applicable; and
- 3. both moveable and fixed furnishings shall be included;

(g) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate New Construction Line Item Valuation Sheet, generated by the party requesting a letter, listing all costs attributable to associated with and simultaneously developed or proposed new construction, including, but not limited to vaults, office space and waiting rooms. If the facility under construction will be leased, the cost of the new construction for the share of the building to be occupied by the facility or service, inclusive of a share of any common spaces, shall be included. Also,

any costs associated with renovation of existing space shall be included. Each item of construction shall be delineated. If new construction will not be necessary or will not be associated with and simultaneously developed or proposed, the requesting party should include the New Construction Line Item Valuation Sheet and indicate that no construction is required;

(h) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include an Aggregate Valuation Sheet, generated by the party requesting a letter, listing the following items and totals:

1. The Total of each Equipment Line Item Valuation Sheet;
2. The Total of the Functional Build-Out/Finish Line Item Valuation Sheet;
3. The Total of the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet;
4. The Total of the Furnishings Line Item Valuation Sheet;
5. The Total of the New Construction Line Item Valuation Sheet; and
6. The grand total of the previous five items.

(i) A party adding an item, or incurring an expense of the types listed in 111-2-2-.10(3)(d) through (g), within a 6-month period following the date of installation of the equipment, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization. A party acquiring functionally related equipment or items, including those items and expenses listed in 111-2-2-.10(3)(d) within a 6-month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of need authorization;

(j) All simultaneously acquired and associated diagnostic and therapeutic equipment regardless of modality shall be aggregated. See the definition of “associated with and simultaneously developed or proposed.” If additional diagnostic and therapeutic equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic and therapeutic equipment;

(k) A letter of non-reviewability for the acquisition of diagnostic or therapeutic equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of non-reviewability change in any way, the letter is no longer valid;

(l) Upon completion of the acquisition of the equipment, the party requesting a LNR shall submit a final statement of the total costs of the equipment, including separate line item valuation sheets with the same detail and documentation as required in subsections 111-2-2-.10(3)(d) through (h) above. In addition, if the if the equipment and associated activities are not completed within 180 days of the issuance of the LNR, the party requesting a LNR shall submit an interim statement within two weeks of the end of that 180 day period and within two weeks of the end of each succeeding 90 day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a LNR. Failure to comply with the provisions of this subsection may result in the rescission of the LNR issued.

(4) **Reserved.**

(5) **Administrative Remedies for Adverse Determinations.** When the Department makes a determination or decision or declines to issue a letter of non-reviewability pursuant to Sections 111-2-2-.10(1) through (4) of this rule or any other determination or decision over which the Health Planning Review Board lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Department's determination or decision. Such request for a hearing must be made in writing and must be received by the Department within 30 days of the date of the Department's determination or decision. If such written request is not received by the Department within 30 days, the Department's determination or decision shall become final upon the 31st day.

(6) **Persons Challenging Determinations and Letters of Non-Reviewability.** Interested persons may challenge a request for a letter of determination or letter of non-reviewability, as applicable, either during the Department's consideration of the request or within 30 days of the Department's issuance of the determination or letter of non-reviewability, as applicable. Challenges must be in writing and mailed to the [Division of Health Planning at 2 Peachtree Street, 5<sup>th</sup> Floor, Atlanta, Georgia 30303](#). Upon receipt of a timely challenge, the following procedures will be in effect:

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(a) The Department will forward the written challenge to the requestor or holder, as applicable, of the letter of determination or letter of non-reviewability. The requestor or holder, as applicable, shall have 10 business days to respond to the Challenge, unless such time is extended in the Department's sole discretion for good cause.

(b) Upon receipt of the requestor's or holder's response, the Department will forward the response to the challenger. If the challenger wishes to respond, the challenger shall have 10 business days to respond to the requestor's or holder's response, unless such time is extended in the Department's sole discretion for good cause.

(c) Should the challenger respond to the requestor's or holder's response, the Department will forward the challenger's response to the requestor or holder, as

applicable. The requestor or holder shall have 10 business days to make a final response to the challenge.

(d) Upon receipt of the final response from the requestor or holder, the Department shall make a determination as to the merits of the challenge.

(e) Challenges shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Challenges shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

(f) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need. Furthermore, this challenge process shall not be construed as a proceeding meeting the definition of "contested case" under the Georgia Administrative Procedure Act.

(g) If a determination or letter of non-reviewability is revoked or cancelled by the Department pursuant to these challenge provisions, the requestor or holder shall have appeal rights pursuant to 111-2-2-.10(5).