

Brian P. Kemp, Governor

Frank W. Berry, Commissioner

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Certificate of Need Batching Review Cycle Notification for MegaVoltage Radiation Therapy Services/Units December 18, 2020

Please Note New Filing Procedures Below. This notice is issued in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.08(1) of the Batching Review Process and in accordance with O.C.G.A. § 31-6-43(e).

Non-Special MegaVoltage Radiation Therapy Services/Units

The Department of Community Health, Office of Health Planning, will not accept or review Certificate of Need applications filed pursuant to the need referenced in Ga. Comp. R. & Regs. r. 111-2-2-.42(3)(a) for new or expanded Non-Special MegaVoltage Radiation Therapy Services/Units during the current batching review cycle.

The Department **will** accept applications for new or expanded Non-Special MegaVoltage Radiation Therapy Services/Units filed pursuant to the exceptions to the need methodology referenced in Ga. Comp. R. & Regs. r. 111-2-2-.42(3)(b).

The Department's next assessment of need for new or expanded Non-Special MegaVoltage Radiation Therapy Services/Units will occur on or around **June 30, 2021**.

Special Purpose MegaVoltage Radiation Therapy Services/Units

The Department **will** accept applications for new or expanded Special Purpose MegaVoltage Radiation Therapy Services/Units filed pursuant to the need and exceptions to the need methodology referenced in Ga. Comp. R. & Regs. r. 111-2-2-.42(4)(a) and (b).

The Department's next assessment of need for new or expanded Special Purpose MegaVoltage Radiation Therapy Services/Units will occur on or around **June 30, 2021.**

<u>All</u> applications must be submitted in accordance with all provisions of Ga. Comp. R. & Regs. r. 111-2-2-.06(1), 111-2-2-.08(1), and 111-2-2-.42, pursuant to O.C.G.A. § 31-6-43.

Notices of Intent

Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(1) and 111-2-2-.08(1), all parties interested in applying under the Rule must notify the Department in writing of that party's intent to apply using the Letter of Intent Form found on the Department's website at www.dch.georgia.gov/con-applications-and-forms. The Department will not accept any notices of intent submitted by either telephone, facsimile or e-mail pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(c)1. Notices of intent must be submitted electronically at https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. In-person filings are no longer accepted. Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(c)2, the notice of intent is due by Sunday, January 17, 2021 and must be received by the Department no later than the close of business (5:00 P.M.) on Tuesday, January 19, 2021 (rollover date).

In the event that the Department fails to receive the notice of intent with the required information by the stated deadline, the interested party is automatically disqualified from applying during this batching cycle in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(c)4.

Submitting the Certificate of Need Application

Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(d), to participate in this review cycle, any interested party must have, in the Department's office, subject to a properly submitted notice of intent to apply, a properly submitted application. The application is due and must be received by the Department no later than 12:00 P.M. on Tuesday, February 16, 2021. No exceptions to this requirement will be made. Any application received after the deadline is precluded from participating in the current batching cycle and will be returned. For purposes of batching only and pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(e), an application will be deemed properly submitted if the following requirements are met:

- A signed original application, one (1) signed copy of the original application, and the correct filing fee are submitted in the proper form pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(3)(a).
- The application must include (at Appendix A) a documented statement from the Office of Health Planning certifying that all required data surveys have been submitted to the Department and are complete.
- All of the items and information addressed in the Completeness Checklist are provided, as certified, in the "Application Certification" on page 39 of the original application. Please include a current **Certificate of Existence** in addition to any other required authorizing documents.
- Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(5)(b)8, the applicant must file an additional copy of the Certificate of Need 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, in Appendix A, an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission.

Filing Fees

Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(4), payment of a filing fee is required at the time the Certificate of Need application and one (1) copy are submitted to the Department. The amount of the filing fee is determined by the cost of a proposed project according to the following schedule.

- \$1,000 for projects with total costs of zero to \$1,000,000;
- One-tenth of one percent (0.001) of the total project costs for projects costing more than \$1,000,000; provided that,
- No filing fee shall exceed \$50,000.

In accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(c), the Department will accept **only certified checks or money orders** made payable to the State of Georgia.

Application Forms

All applications must be submitted electronically through the Department's website at https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0. https://dch.georgia.gov/office-health-planning-applications-and-requests-forms-0.

The Certificate of Need Application Form and the MegaVoltage Radiation Therapy Services/Units Rules can be accessed from the Certificate of Need Section of the Department's website at www.dch.georgia.gov.

The Department will not accept any information or documents by telephone or facsimile in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6).

Batching Cycle Review Procedures

Pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(g), the batching review cycle will last 120 days. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the 120th day. The first day of the batching review cycle is the day upon which all properly submitted applications are deemed to be received.

On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle.

The deadline for interested parties to submit notices of opposition shall be the sixtieth (60th) day of the batching review cycle. Any notices of opposition that are received after the sixtieth (60th) day of the batching review cycle shall not be considered by the Department in its review of the pertinent application(s) and the notice(s) shall not become part of the master file compiled for the pertinent application(s). Such notice must be submitted pursuant to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(g)4. No earlier than the ninetieth (90th) day of the batching review cycle, those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices.

Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6), and can be submitted no later than the one hundredth (100th) day of the batching review cycle.

The last day for the applicant(s) to submit final amendments and responses to the opposition comments made orally and submitted in writing at the opposition meeting is the 110th day of the batching review cycle pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(g)5.

No later than the 120th day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s), pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(g)6 and in accordance with the review considerations in Ga. Comp. R. & Regs. r. 111-2-2-.42.

STATE SERVICE DELIVERY REGIONS

Amended Effective July 1, 2005

