



Certificate of Need: Maintaining Regulatory Compliance Following Issuance of a CON



Changes During the Review Period

- Often, changes to a project can be more easily made during the review period.
- These changes should be communicated to your reviewer and an open dialogue should continue.
- The Department will determine if the changes constitute a new project.

Section 310. Project Changes During Review Period:

If an applicant amends his application during the review process, the Department will determine whether or not the amendment is substantial and constitutes a new application. If the change results in an increase in cost, the fees will be adjusted accordingly.



Issuance Letters

- New issuance letter format began this year.
- Additional information to assist you in maintaining compliance is now included in the letter itself.
- It is very important to review and understand this information.

As required by Regulation No. 61-15, Section 607, you must submit quarterly progress reports from the date of issuance of this Certificate of Need documenting compliance with the timetable, which you submitted in your application. You must report on, if applicable:

- a. Costs incurred on the project;
- b. Construction activity;
- c. Program or service activity; and
- d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

- 1st Quarterly Report: 10/18/2017
- 2nd Quarterly Report: 01/16/2018
- 3rd Quarterly Report: 04/16/2018
- 4th Quarterly Report: 07/15/2018

Should the length of your project exceed the initial 12-month period of the Certificate of Need being issued, you are required to file an extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for this extension request, if one is needed, is **June 20, 2018**. Extension requests received after this date will not receive consideration from the Department.



Payment

- Payment of any issuance fee is critical to the continued success of your project.
- Ensure that someone at the receiving address will immediately forward the issuance letter, CON, and invoice to the appropriate staff in your organization.
- Failure to pay results in invalidation.

Section 309. Certificate of Need Issuance Fee:

Projects with a total project cost greater than one million four hundred thousand dollars (\$1,400,000) will require payment of a Certificate of Need issuance fee of seven thousand five hundred dollars (\$7,500) upon the granting of the certificate of need. An invoice will be enclosed with the certificate which will be sent by certified mail. **The Department must receive payment within fifteen (15) calendar days from receipt of the certificate by the applicant for the certificate of need to remain valid.**

Enclosed please find our invoice for the required Certificate of Need issuance fee of \$7,500. The invoice may be paid by check made payable to the S.C. Department of Health and Environmental Control or by electronic check through the Department's website (www.scdhec.gov) using the "Pay Invoices" hyperlink at the bottom of each webpage. This is a secure website. **Payment must be made within fifteen (15) calendar days of your receipt of this letter for the Certificate of Need to remain valid.** Should this deadline fall on a weekend or State holiday, it will be extended to the next calendar day that is neither weekend nor holiday pursuant to Regulation No. 61-15, Section 303.



Quarterly Progress Reports

- QPRs should be separate for each project if you have more than one current CON.
- Always trend towards more info rather than less.
- Describe **all** deviations from the approved application.
- Send to CONinfo@dhec.sc.gov and via traditional carrier.

Section 607. Periodic Reporting of Certificate of Need Implementation:

1. The applicant is required to submit a quarterly progress report that corresponds with the timetable included in the Certificate of Need application beginning ninety (90) calendar days after receipt of the Certificate of Need. Failure to meet the timetable results in the revocation of the Certificate of Need by the Department unless a determination is made by the Department that circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay.
2. The applicant shall report on, if applicable: (1) costs incurred on the project; (2) construction activity; (3) program or service activity; and (4) any deviations from the submitted application with supporting documentation.



Quarterly Progress Reports

Failure to timely report, as laid out in the issuance letter, may result in Department sanctions including, but not limited to: monetary penalties, voidance, or denial of extension requests.

The Department will be performing an audit of open files over the next 60 days to determine compliance with this regulatory requirement. Letters detailing non-compliance will be sent to Certificate holders as necessary.



Excerpts From a Sufficient Report

History Previously Reported:

1. The [REDACTED] has submitted SC DHEC License application for preliminary filing to DHEC's Health Facility Licensing on [REDACTED]
2. Signed a general contractor's agreement with [REDACTED] of [REDACTED] on [REDACTED], included in documentation in the August 2017 Quarterly Report.
3. [REDACTED] is the Project Manager and [REDACTED] is the Project Superintendent.
4. [REDACTED] became the architect of record on November 24, 2015, documentation was included in the August 2017 Quarterly Report. [REDACTED] revised the design/plans of the facility, completed the construction documents, passed through the DHEC Health Facility Construction Review process and oversees construction.
5. The project received a site work permit on November 7, 2016, included documentation in the August 2017 Quarterly Report.
6. Finalized financing for construction with [REDACTED].
7. Owners authorized the general contractor to proceed with the project in September of 2016.

construction has taken place. The roof decking is installed, exterior and interior studs are being hung. HVAC ductwork, plumbing and electrical are completed.

4. Unforeseen Storm Water Drainage issues have also caused 2 additional revisions to the site plan. These adjustments and changes will also add \$60,818 to the total project cost.
5. All these additional costs will be shared with [REDACTED] who will also be a tenant in the building alongside [REDACTED]. At the end of the project, these additional costs will be allocated accordingly between the two entities.
6. A Clinical Administrator has been identified and was engaged in April 2017 to manage the details of development and ASF operations including regulatory issues, policy and procedures, financial management and staffing. The Clinical Administrator will also be supported by an outside consultant.

Resolved Problems/Past Progress:

1. A significant delay in this project was caused by the dissatisfaction and ultimate termination of the owner's original design/build relationship with [REDACTED]. New contractors and architectural firms were vetted and a new general contractor [REDACTED] and architectural firm [REDACTED] were formally engaged on the project.
2. The effects of Hurricane Matthew during October 2016 caused delays in the design and planning process.
3. Several unforeseen delays were encountered during the initial site work in November 2016 when 1) a Soils Report came back labeling a large portion of the site as unsuitable. 2) After protracted study and the engagement of a second Environmental Engineering firm to engineer a mitigation plan and 3) implement actions to resolve the soils issue. This process has delayed the project several months and resulted in a change order that increased the cost of the project by \$92,665. Successful soil mitigation has resulted in the foundation being installed and vertical

Update, Realized and Expected Progress:

1. The surgery center has incurred change orders totaling \$52,085.55 this past quarter. Changes include but are not limited to Card Reader Access Doors, Electrical X-Ray Changes, Deductive CR and IT System Conduit, and Conduit for Lighting Changes and Data for OR Rooms. Please see the attached comprehensive change order list for August 2017 through November 2017.
2. The project has progress nicely this past quarter. Per the revised construction schedule, (see attached) anticipated completion date is [REDACTED]



Excerpts From Insufficient Reports

This correspondence represents a progress report on the above-listed project. The project is on schedule. Design work and all necessary permitting have been completed. Site cleaning will begin this month, and the project is scheduled to be completed in the second quarter of 2018.

This correspondence represents a progress report on the above-listed project. [REDACTED] caused a delay in the installation of the steel framing that may extend the project completion date to early in the third quarter of 2018. Installation of interior block, roof decking, and exterior and interior framing are now underway.

(1) The monthly and final progress report is depicted below:

Budgeted Costs: 0

Actual costs: 0

Project is deemed complete by [REDACTED] as of August 14, 2017.

- Architectural and engineering drawings in progress

[REDACTED]				
Construction	1,863,686			
Admin., Fees, Inspections	168,402	71,899		
FF&E, I.T. Equip	249,973	6,822		
Construction Contingencies	127,908			
Total	2,409,969	78,721	[REDACTED]	2,331,248

Implementation

- **What does it mean?**
 - It means that no extension is needed for the CON to remain valid.
- **What doesn't it mean?**
 - It doesn't mean that quarterly reporting ends.
 - It doesn't mean that the CON is fulfilled and closed out.

Section 601. Voidance and Extension Procedures:

1. The Certificate of Need shall become void twelve months (one year) from the date of issuance. The Department may void a Certificate of Need if requested by the applicant, or if the Department determines that the Certificate of Need has not fully implemented within one year from the date issued. **Implementation may be evidenced by, but not limited to, a properly negotiated valid construction contract or appropriate purchase order for service projects.**

The Department is providing a handout to demonstrate implementation for a variety of project types.

Extension Requests

- **1st and 2nd extensions**
 - Issued by staff based on a written request for extension by the applicant
 - Up to nine months each
 - 30 days before expiration
- **3rd and subsequent**
 - Granted by the DHEC Board
 - Up to nine months each
 - 90 days before expiration

Section 602. Extension Request:

1. A Certificate of Need extension shall be requested by the applicant at least thirty (30) days before the expiration date and shall contain such information as the Department may reasonably require.
2. This information shall include at least the following
 - a. A detailed description of any changes in the configuration, costs, services, or scope of the project.
 - b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.
 - c. An estimated timetable for commencement and completion of all remaining components of the project.
 - d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance beyond the control of the applicant if the timetable was not met.

Extension Requests

- Substantial progress must be demonstrated in order for the Department to approve an extension.
- Guidance is offered in the Regulation concerning this substantial progress.
- It is important to address all of these criteria in your request.

Section 603. Criteria for Extension:

The following criteria shall be used to determine whether substantial progress has been made by the applicant:

1. Site procurement: The applicant should have made definitive progress toward permanent acquisition of the intended site. Such progress may include purchase of property previously under option or consummation of long-term lease agreements.
2. Architectural Progress: The facility architect should have been employed and definitive progress should be made toward development of final drawings.
3. Financial Status: The applicant should document definitive progress toward finalizing any necessary loans or lease-purchase arrangements.
4. The applicant should provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.



Final Completion Reports

- **Welcome to the finish line!**
- Once the project is complete and serving its intended purpose or function, the focus must turn to the final mandated report laid out in Regulation 61-15.
- Lack of a Final Completion Report leaves your case open and subject to reporting and timetable requirements.

Section 607. Periodic Reporting of Certificate of Need Implementation:

3. After the project has been fully implemented, the applicant shall provide the Department with a final completion report that contains, at a minimum:
- a. An audited cost report that shows all expenditures on the approved project;
 - b. A list of average charges and costs for the services approved in the application and documented by affidavit, certification or other proof;
 - c. A registered architect's or engineer's signed statement of final construction costs;
 - d. An equipment listing and inventory for the project;
 - e. A program and/or service narrative describing the final project configuration; and
 - f. An explanation of any deviation from the approved application with justification, or a signed statement from the applicant that the project was implemented as outlined in the application.



Final Completion Reports

- Depending on the type of project, not all of the aforementioned criteria may be applicable.
- Final Completion Reports should be as thorough as possible in order for the Department to issue a closeout letter.
- When in doubt, contact the Department with questions regarding Final Completion Reports.
- Submit to CONinfo@dhec.sc.gov and via traditional carrier.

Substantial Changes After Issuance

- To assist the Department in analyzing a substantial change request, you should submit the following information:
 - New project schematics
 - Updated timetables
 - Updated itemized cost reports
 - Narrative describing how the change continues to comply with the original Project Review Criteria
- Submit to CONinfo@dhec.sc.gov and via traditional carrier.

Section 605. Project Changes After Receipt of Certificate of Need:

If an applicant amends or alters his project after receipt of a Certificate of Need, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.

Transfer/Conveyance

- A CON cannot be transferred.
- Certificate holders must take care not to attempt to make a transfer of an open CON through a subsequent application.
- If any doubt exists as to the Department's interpretation of a transfer or attempted transfer, contact us.

Section 604. Non-Transferability of Certificate of Need:

A Certificate of Need is nontransferable. A Certificate of Need or rights there under may not be sold, assigned, leased, transferred, mortgaged, pledged, or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in the immediate voidance of the Certificate of Need. Any of the aforementioned transactions involving an entity directly or indirectly holding a Certificate of Need before fulfillment of the Certificate of Need results in the transfer and the subsequent voidance of the Certificate of Need. Fulfillment of the Certificate of Need occurs, although not limited to, the submission of an adequate final completion report as determined by the Department. Anyone having their Certificate of Need voided shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval.



Overlap

- Guidance regarding multiple application submissions to the Department:
 - Whenever possible, avoid submitting an application which is, in any way, dependent on the outcome of another pending application or project which is subject to a contested case.



Contact Us

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