

CHANGES ARE COMING TO SOUTH CAROLINA'S CON PROGRAM: *Proposed Amendments to DHEC Regulation 61-15*

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In some ways not surprising given the amount of attention South Carolina's Certificate of Need ("CON") laws received during the last session of the General Assembly, but at the same time long overdue—the state agency responsible for administering the CON laws (the South Carolina Department of Health and Environmental Control (DHEC)) is in the final stages of the regulatory process necessary to amend the CON regulations found at Regulation 61-15 of the South Carolina Code of Regulations. The tailwinds surely driving these first changes to the regulations since 2012 also includes a relatively biting report issued by the Legislative Audit Council (LAC) in February 2022 (find the DHEC CON Review Report [here](#)), as well as the near repeal of the CON program. As we explained in an earlier post, the SC Senate passed repeal legislation that subsequently failed in the SC House of Representatives but only after an intense debate. Now, DHEC has proposed the first substantive amendments to Regulation 61-15 in over a decade, which have been approved by the DHEC Board and published for public comment through October 24, 2022.^[1] The proposed changes appear to track closely with a number of the LAC's recommendations and could go a long way in addressing many of the concerns held by critics of the program that underpinned the Senate's push for repeal.

This article offers an overview of the LAC report and recommendations. Perhaps most importantly, the LAC stated: "We did not conclude from this review that the CON program should be eliminated; however, our audit includes recommendations for improvement in several areas". In its report, the LAC provides specific recommendations for improvement, summarized below:

1. Narrowing the scope of regulated services by eliminating from CON review home health agencies and narcotic and opioid treatment

programs;

2. Increasing the dollar thresholds for equipment and capital expenditures, and providing for future indexing to inflation. The current thresholds were enacted in 2001 and have not accounted for inflation;
3. Encouraging DHEC to adequately respond to requests for CON waivers under the Governor's COVID Executive Orders and properly track the waivers that are issued;
4. Adopting quantitative quality metrics in the State Health Plan;
5. Providing for further standardization of information provided in CON applications to ensure consistency in DHEC's evaluation of applications;
6. Requiring greater detail from applicants on a proposed project's impact on net patient charges and include disclosure of non-capital expenses related to a project upon its completion;
7. Shortening the contested case process in the Administrative Law Court and requiring appeals from the ALC go directly to the S.C. Supreme Court, bypassing the S.C. Court of Appeals;
8. Suggesting the General Assembly reform CON laws to exclude low-cost facilities and equipment such as MR¹ [2] and ambulatory surgery centers^[3] from CON review;
9. Suggesting the General Assembly consider restricting the use of non-compete agreements in the healthcare industry; and
10. Allocating DHEC staff to annually review the agency's tracking spreadsheet for issued CONs.

Before the LAC report was issued in February 2022, the South Carolina Senate voted 35 to 6 on January 25, 2022 in favor of bill S.290, which fully repealed the CON program except as to nursing homes. The Senate debate was heavily focused on many of the issues subsequently highlighted by LAC, with particular focus on the lengthy and expensive CON appeal process and the impact of CON on competition in the healthcare market. Many of the most vocal proponents of repeal outside the Senate chamber during the debate were independent surgeons expressing a particular concern (objection) to the requirement of CON review for the addition or expansion of ambulatory surgery facilities. While there was generally consensus in the South Carolina Hospital industry to reform the CON program, such as raising the dollar thresholds for CON review on medical equipment and capital expenditures as well as to improve the appeal process to make less costly and more efficient, the proposed wholesale repeal was concerning primarily for the absence of any plan for the resulting unintended consequences. Upon arrival in the South Carolina House, S.290 was referred to the Ways and Means Committee and a public hearing was held on the bill at which the support for S.290 was promoted mostly by the independent surgeons, while hospital leadership largely encouraged the House to take a more measured approach by reforming the CON program. With no apparent compromise achievable within the healthcare industry, S.290 remained in the Ways and Means Committee when the 2022 Session ended, resulting in the bill's defeat.

The demise of S.290 set the table for DHEC's current efforts to amend CON Regulation 61-15. After an initial round of public comments earlier this year, the DHEC staff proposed a number of substantive amendments to 61-15 that the DHEC Board took up at its meeting on September 8, 2022. The Board approved the proposed amendments for publication and public comment. The amendments that the Board approved and presented for

public comment include:

- The definition of “affected person” now requires that a person “specifically states their grounds for opposition” (Section 401), which acts as a clarification to the present language that an affected person was only required to “specifically state their opposition.” It emphasizes the importance of including opposition points in a letter to DHEC during staff review.
- There is now a definition of “controlling interest,” which reads: “Ownership interest in a company (corporation, limited liability company, partnership, or other entity) with enough voting shares or other interests to prevail in any motion. A majority of voting shares or interests is always a controlling interest.” (Section 102(4)) In the CON statute, the sale or transfer of a controlling interest or majority ownership in a corporation, partnership, or other entity holding a Certificate of Need results in the transfer and voidance of a CON.
- In several places throughout the regulations, there is a new emphasis on “non-capital costs” which include consulting fees and legal fees. There seems to be a new focus on disclosure of these underlying costs related to CON, something suggested in the LAC report. In Section 607(3)(g), an applicant is now required to provide the Department with “a listing of non-capital costs” as part of the final completion report of the project.
- Section 104 (“Applicability”) proposes to change the threshold for a capital expenditure to in excess of \$5 million, a capital and the acquisition of medical equipment used for diagnosis or treatment if the total project cost is in excess of \$2 million.
- Section 105 (Determinations of Non-Applicability) now states that a determination of non-applicability is valid for 18 months, rather than 12 months, after the date of issuance. If evidence of implementation is not submitted within 18 months of issuance, a new non-applicability request must be submitted.
- The regulations with respect to the Application components (Section 202) have been stricken entirely. Instead, Section 301 now states “The application shall be submitted using the web-based application available on the Department’s website or by such other means the Department may provide.” It is unclear why these are being removed, and if the electronic application will contain the same requirements.
- Importantly, there will now be only one publication in the State Register when a project has been “deemed complete,” and there will no longer be an earlier publication of when a project is accepted for filing. This means that unless an affected person sees a public notice in the newspaper (or online), the first time the public will learn about DHEC’s review of a CON project is on the day it has been deemed complete, which is when the 15-day timer will start to run for submitting a competing application, and the 30-day timer will start to run for submitting comments. This is a fairly significant change, and it will be more important now to monitor public notices.
- The Project Review Criteria at Section 802 that DHEC staff is required to consider when reviewing a CON application have been materially condensed and cleaned up. Some of the lesser-considered criteria have been removed or consolidated. The specific findings under Section 501 DHEC was required to make for “new institutional health services” have also been removed. Of particular note is the addition of “Quality of Care” as a project review criterion.

The public comment period on the DHEC Board’s proposed amendments closed October 24, and we now await DHEC publishing comments received. It is expected that the DHEC Board will consider the public comments at its regularly scheduled meeting on December 8, 2022, at which time the DHEC Board will likely adopt final amendments to then be delivered to the South Carolina General Assembly for action. If the General Assembly neither votes to approve or reject the proposed amendments within 120 days after receipt, the amendments will take effect.

[1] The June 24, 2022 State Register is available on the South Carolina Legislature’s website: https://www.scstatehouse.gov/state_register.php.

[2] Notably, if the dollar thresholds are increased for equipment as proposed, it is unlikely that projects that include the purchase of Magnetic Resonance Imaging (MRI) equipment will be subject to review regardless. MRI is not a service for which there are standards in the South Carolina Health Plan, having been removed from the State Health Plan a number of years ago, and therefore purchases of MRI equipment have only been subject to CON review when the total project cost exceeded the dollar threshold for equipment (which has been \$600,000 since 2001).

[3] Ambulatory Surgery Facilities are a type of outpatient facility where same-day surgeries are performed. Magnetic Resonance Imaging (MRI) equipment at one time