SOUTH CAROLINA GENERAL ASSEMBLY
Legislative Audit Council

February 2022

# A REVIEW OF THE S.C. DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL CERTIFICATE OF NEED PROGRAM

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SOUTH CAROLINA GENERAL ASSEMBLY

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# A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program

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# Introduction and Background

## Audit Objectives

Members of the S.C. General Assembly asked the Legislative Audit Council (LAC) to conduct an audit of the S.C. Department of Health and Environmental Control (DHEC) Certificate of Need (CON) program. Our objectives for this audit were:

- Examine potential areas for reform of the certificate of need program.
- Review the certificate of need process.
- Review the role of staff in administering the certificate of need program.
- Review COVID-19 pandemic related issue pertaining to the certificate of need program.
- Review the role providers play in the certificate of need process.

## Scope and Methodology

The period of our review was generally 2018 to 2021 with consideration for earlier periods when relevant. We used the following sources:

- Interviews and correspondence with DHEC employees, hospital officials, physicians, and other interested parties.
- State laws and regulations.
- DHEC's CON policies and procedures.
- CON application files.
- Information regarding other states' CON programs.
- External studies of CON programs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those generally accepted government auditing standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives.

S.C. Code §2-15-50(b)(2) requires us to review the effectiveness of an agency to determine if it should be continued, revised, or eliminated. We did not conclude from this review that the CON program should be eliminated; however, our audit includes recommendations for improvement in several areas.

## Background

This report evaluates the certificate of need (CON) program administered by the S.C. Department of Health and Environmental Control (DHEC). South Carolina established its CON program in 1971, with the passage of the State Certification of Need and Health Facility Licensure Act (CON Act). The CON program has four stated goals:

- Cost containment.
- Prevention of unnecessary duplication of health care facilities and services.
- Establishment of health facilities and services to best serve public needs.
- High-quality services in health facilities.

The CON Act requires healthcare providers to apply for and obtain a CON before beginning a range of projects. Covered projects include:

- Construction or establishment of healthcare facilities.
- Changes to or expansions in services offered at healthcare facilities.
- Capital expenditures or acquisitions of medical equipment over a certain cost threshold.

Certain providers, including private practitioners, may obtain a written CON exemption determination from DHEC for certain projects. Providers may also seek a written non-applicability determination from DHEC if a question exists as to whether a particular project falls under the CON requirements.

DHEC employs a team of three staff who administer the CON program and related duties. Additionally, lawyers from DHEC's office of general counsel including general counsel who represents the agency in CON-related litigation.

## State Health Plan

The CON Act also requires the preparation and publication of a state health plan (SHP) at least every two years to facilitate the CON program. The SHP includes:

- An inventory and projection of health care facilities and services.
- Standards for distribution of health care, including types of services, utilization/occupancy rates, and travel time.
- A list of the most important criteria to be considered in reviewing CON applications for each type of facility or service, and a statement of whether duplication of that facility or service is justified by the benefits of increased accessibility.

The SHP is developed by DHEC's CON staff, with the advice and approval of a health planning committee composed of several interested groups. The SHP is then formally adopted by DHEC's Board.

## Issue for Further Study

Due to time constraints, we did not fully examine the methodology of the findings in the State Health Plan that speak to whether the benefits of improved accessibility for each facility, service, and equipment type outweigh the adverse affects of duplication. This may deserve further study in a subsequent review.

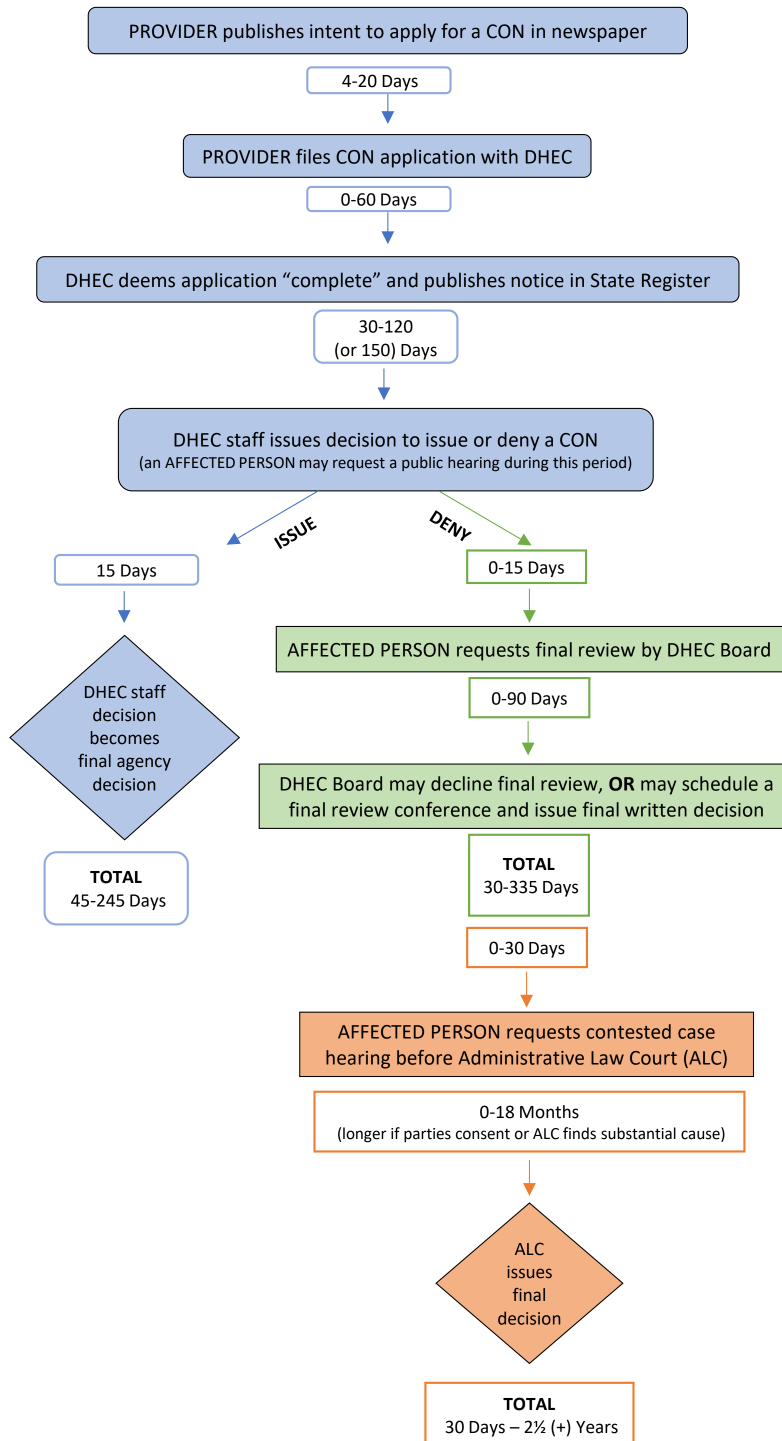
## Licensure

The CON Act also authorizes DHEC to establish safety and quality standards for healthcare as a complement to the CON program. Licensure must be obtained on a regular basis, typically annually.

## CON Application Review Process

The process for issuance of a CON is defined by both the CON Act and DHEC regulations. The exact procedure varies depending on the facts of each case and is especially impacted by how much the applicant or "affected" third parties contest DHEC's decisions. An uncontested application could receive a CON decision in under less than two months after filing. A contested application could take over 2½ years to receive a CON decision.

## Figure 1.1: Certificate of Need Procedure



## Appeals

Additionally, parties to an Administrative Law Court (ALC) decision may then appeal that decision to the S.C. Court of Appeals. There is no time limit to cases pending before the S.C. Court of Appeals. However, parties seeking to reverse the issuance of a CON to an applicant must post a bond of 5% of the total project cost or $100,000, whichever is greater, up to a maximum of $1,500,000. This bond is awarded to the applicant along with attorney's fees if the appeal is not successful.

## CON Application Review Factors Criteria

In reviewing a completed CON application, DHEC staff must analyze and consider three basic elements:

- Compliance with the SHP currently in effect (if the facility or service is included in the SHP).
- Overall compliance with multiple project review criteria.
- Compliance with other CON regulations issued by DHEC.

Staff must deny a CON application if the project does not satisfy all three criteria.

S.C. Reg. §61-15-802 establishes 33 different project review criteria, many of which contain multiple sub-criteria. DHEC groups the criteria into five categories:

- Need for the proposed project.
- Economic consideration.
- Health system resources.
- Site suitability.
- Special consideration.

In analyzing compliance with project review criteria, staff must identify and appropriately weigh the criteria that is most important to each application. Projects that do not comply with every criterion can still be approved at DHEC's discretion. DHEC staff must also make certain findings before issuing a CON, mostly regarding impacts to costs and accessibility.

## Project Implementation After Issuance of a CON

After receiving a CON, the provider must complete the project within one year, or other expanded timeline unless approved for an extension by DHEC. Providers with active CONs must submit quarterly progress reports to the agency, which the agency uses to verify progress and implementation status. Projects that do not make substantial progress may have their CONs invalidated. Projects with an active CON may not be sold or otherwise transferred.

After a project for which DHEC issued a CON is implemented, the process ends and does not need to be re-approved unless a facility or service is being relocated. Acquisitions and other changes in ownership are permissible at this point, although DHEC must be notified of the change in ownership.

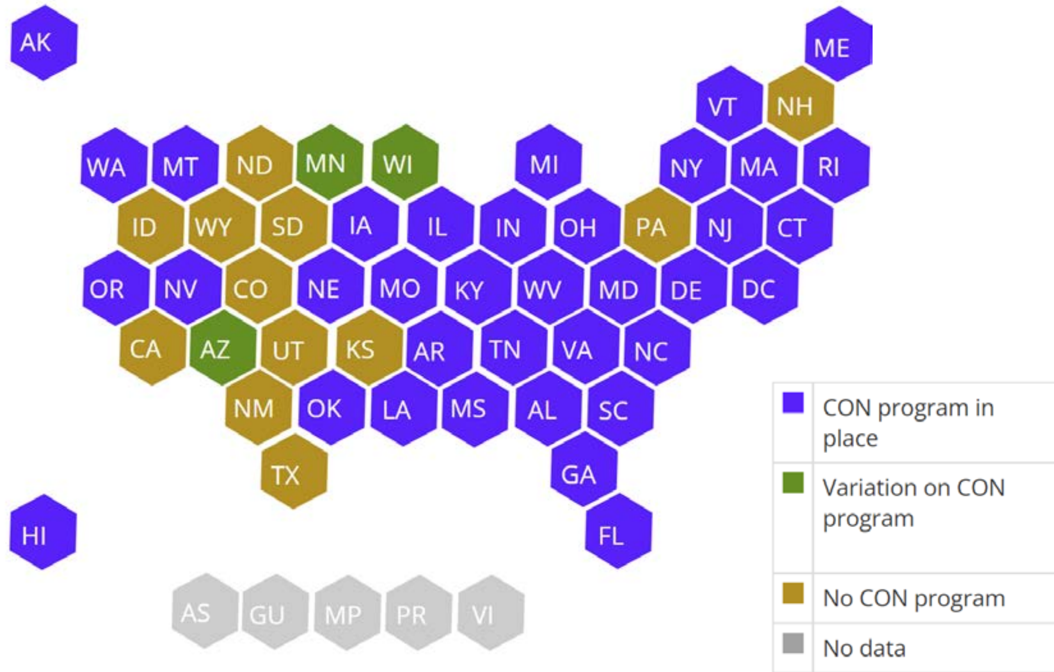
## History and Current Status of CON Laws Nationally

States first began adopting CON laws in 1964, generally as a way to control healthcare costs and incentives created by a cost-based reimbursement system.

In 1974, Congress passed a federal law that increased funding for state and local health planning regulations, resulting in all but one state adopting some form of CON laws by 1982. The federal funding was repealed in 1987. Several states have since repealed or modified their CON laws.

According to the National Conference of State Legislatures, 35 states and the District of Columbia operated some form of a CON program as of December 2021. Three other states operated programs that function similarly to CON. Only 12 states had fully repealed their CON laws.

## Figure 1.2: Certificate of Need State Laws Nationally




Source: National Conference of State Legislatures

## DHEC Staff

The CON program is administered by a small staff at DHEC. A staff of three currently reviews the initial applications in the Bureau of Health Planning and Construction. Additionally, three staff attorneys work on appeals related to CON determinations. We found that neither DHEC's CON program staff nor attorneys currently have a conflict of interest policy directly relating to CON. DHEC's attorneys who work on CON appeals do not have a conflict of interest policy directly relating to CON appeals, but the attorneys are subject to the S.C. Rules of Professional Conduct.

## CON Program Staff

CON applications are reviewed and determinations are currently made by a staff of three. Staff are not appointed but hired pursuant to state job postings. As of December 2021, the CON staff consisted of:

- SENIOR CONSULTANT
- PROJECT COORDINATOR
- ADMINISTRATIVE COORDINATOR

Additionally, there is a vacant project coordinator position.
In December 2021, the director of the CON program left DHEC.

There are currently no minimum qualifications or guidance in state law and regulations for CON program staff. We asked DHEC if the there is a policy addressing conflicts of interest regarding applications CON program staff review. In response, we received a State Ethics Commission opinion noting that members of DHEC's State Health Planning Committee are required to recuse themselves from all discussions, deliberations, votes, and other matters related to the economic interest of the public member's affiliated entity. Although this opinion dealt with conflicts of interest relating to planning committee members, it did not address CON program staff.

However, DHEC does have a general code of conduct for all staff. The code of conduct states, "Employees should always act in a manner that instills public confidence and should avoid participating in any matter where a real or perceived conflict of interest exists."

Additionally, DHEC policy prohibits employees from accepting outside work or compensation that could reasonably be construed as a conflict of interest. DHEC employees are also subject to the State Ethics Act, which prohibits employees from soliciting or accepting anything of value from entities regulated by DHEC.

## Office of General Counsel

Appeals of initial determinations of the CON staff are handled by DHEC's Office of General Counsel (OGC). Three attorneys in OGC spend a portion of their time on CON appeals. Like the CON staff, the attorneys who handle appeals are not appointed, but are directly hired by DHEC.

Like the CON program staff, we did not find an example of a conflict of interest relating to the OGC's handling of CON appeals. The OGC attorneys are subject to DHEC policies regarding conflicts of interest discussed earlier. Additionally, attorneys working for OGC are subject to the conflict of interest provisions of the S.C. Rules of Professional Conduct.

We reviewed who conducts agency determinations in other states. In Georgia and North Carolina, CONs are reviewed by agency staff, who are not appointed. In Tennessee, CONs are reviewed by an 11-member board. These board members represent ambulatory surgical treatment centers, consumers, home care, hospitals, nursing homes, physicians, and state agencies. The three consumer representatives in Tennessee are appointed by the Governor, Speaker of the House, and Speaker of the Senate, respectively.

## CON Program Funding and Fees

The CON program is funded by the state general fund. Table 1.3 shows the total program costs since FY 18-19.

### Table 1.3: CON Program Costs

| Fiscal Year | Staff Salaries | | Other Costs | TOTAL CON Program Cost |
|---|---|---|---|---|
| | CON | Office of General Counsel | | |
| 18-19 | $399,855 | $166,539 | $151,653 | $718,047 |
| 19-20 | $392,096 | $173,710 | $65,916 | $631,722 |
| 20-21 | $384,028 | $178,606 | $36,379 | $599,013 |

Source: S.C. DHEC

The CON program charges the following fees pursuant to S.C. Reg. §61-15-103:

- An initial filing fee of $500.
- An application fee, which is one-half of 1% of the total project cost, not to exceed $7,000.
- An issuance fee of $7,500 payable upon the granting of a CON whose total project cost is greater than $1,400,000.

S.C. Code §44-7-150(5) requires that the first $750,000 in fees collected by the CON program must be returned to the general fund. Fees collected in excess of $750,000 may be retained by the CON program. Table 1.4 shows the fees collected by the CON program and returned to the general fund for FY 18-19–FY 20-21.

**Table 1.4: CON Fee Collections**

| Fiscal Year | CON Fees Collected and Returned to the General Fund |
|---|---|
| 18-19 | $526,202 |
| 19-20 | $662,972 |
| 20-21 | $633,297 |

Source: S.C. DHEC

Table 1.4 shows the CON program has collected less than $750,000 in fees for the last three fiscal years. Thus, all fees have been returned to the general fund, and none of those fees funded the CON program.

# Impact of CON Program on Availability and Access to Healthcare Services

We reviewed CON's impact on the availability and access to healthcare services and found mixed results. We found that the CON program may be eliminated for services relating to home health and drug rehabilitation programs. We also found that the CON program's regulations have outdated thresholds relating to spending on capital expenditures and equipment and should be updated.

## Overall Impact of CON Laws on Healthcare

Evidence on CON laws' impact on healthcare is generally mixed and often not conclusive. There is rough evidence suggesting that nationally, costs imposed by various states' CON laws may exceed the benefits that such laws create. However, there is also evidence suggesting that nationally, states with CON laws have more competitive inpatient healthcare markets than states without such laws, and that most states with more competitive inpatient healthcare markets than South Carolina have more stringent CON laws. Additionally, South Carolina's CON program may improve key outcomes for certain healthcare services and markets but worsen other specific services and markets.

### Current Healthcare Access in South Carolina

"Access" is perhaps the primary concern of healthcare and public health professionals and policymakers. Negative impacts of lack of access include delays in receiving appropriate medical care, inability to access preventative care, unreasonable financial burdens, and preventable hospitalizations. One recognized definition of healthcare access is the "fit between characteristics and expectations of the providers and clients." This definition includes several interrelated factors, including affordability, availability (including personnel and technology), and geographical accessibility.

The U.S. Agency for Healthcare Research and Quality, part of the federal Department of Health and Human Services, collects, analyzes, and publishes national healthcare data in annual reports. The data is also published at the state level, including analyses of state performance compared to a national "benchmark" of top-performing states and the national average. For South Carolina, the report identifies five measures of structural access to healthcare that were measured most recently in 2018.

Four measures relate to the percentage of adults' ability to get routine or emergent care as soon as wanted, and one measure relates to the percentage adult home health patients' ability to get same-day help or advice. Compared to achievable benchmarks of top-performing states:

- Measures of routine health care access achieved and were close to the benchmark;
- Measures of emergent health care access were close to and far from the benchmark, and;
- The measure of home health access was close to the benchmark.

Similarly, compared to the national average, four measures related to routine and emergent health care were average in the most recent year reviewed and one measure related to home health providers was below average. Graphic representations of these analyses are in Figures 2.1 and 2.2.

**Figure 2.1: Structural Access Quality Measures for South Carolina, Compared to Achievable Benchmarks of Top-Performing States**

| Measure | Estimate | Benchmark | Distance to Benchmark |
|---|---|---|---|
| Achieved Benchmark or Better | | | |
| Adults who had an appointment for routine health care in the last 6 or 12 months who sometimes or never got an appointments for routine care as soon as wanted, Medicare fee-for-service | 10.0 | 9.5 | 4.8% |
| Close to Benchmark | | | |
| Adults who reported getting the help or advice they needed the same day they contacted their home health providers | 15.6 | 23.8 | 34.6% |
| Adults who had an appointment for routine health care in the last 6 or 12 months who sometimes or never got an appointments for routine care as soon as wanted, Medicare managed care | 11.2 | 8.2 | 35.8% |
| Adults who needed care right away for an illness, injury, or condition in the last 6 or 12 months who sometimes or never got care as soon as wanted, Medicare managed care | 6.5 | 4.3 | 49.9% |
| Far From Benchmark | | | |
| Adults who needed care right away for an illness, injury, or condition in the last 6 or 12 months who sometimes or never got care as soon as wanted, Medicare fee-for-service | 9.4 | 5.6 | 67.3% |

Source: Agency for Healthcare Research and Quality

**Figure 2.2: Structural Access Quality Measures for South Carolina, Compared to National Average**

| Measure | Recent | | | Baseline | | |
|---|---|---|---|---|---|---|
| | Year | Rate | Performance | Year | Rate | Performance |
| **Average in the Recent Year** | | | | | | |
| Adults who had an appointment for routine health care in the last 6 or 12 months who sometimes or never got an appointments for routine care as soon as wanted, Medicare managed care | 2018 | 11.2 | Average | 2010 | 16.3 | Worse than Average |
| Adults who had an appointment for routine health care in the last 6 or 12 months who sometimes or never got an appointments for routine care as soon as wanted, Medicare fee-for-service | 2018 | 10.0 | Average | 2010 | 11.9 | Average |
| Adults who needed care right away for an illness, injury, or condition in the last 6 or 12 months who sometimes or never got care as soon as wanted, Medicare managed care | 2018 | 6.5 | Average | 2010 | 14.0 | Worse than Average |
| Adults who needed care right away for an illness, injury, or condition in the last 6 or 12 months who sometimes or never got care as soon as wanted, Medicare fee-for-service | 2018 | 9.4 | Average | 2010 | 8.8 | Average |
| **Worse than Average in the Recent Year** | | | | | | |
| Adults who reported getting the help or advice they needed the same day they contacted their home health providers | 2018 | 15.6 | Worse than Average | 2012 | 19.6 | Worse than Average |

Note: Medicare fee-for service care typically covers fewer, but higher-cost patients.
Medicare managed care covers more patients, but these patients are typically lower-cost.

Source: Agency for Healthcare Research and Quality

Currently, South Carolina lacks acute care hospitals in eight counties. The location, utilization rates, and other information regarding many types of healthcare facilities and services in the state are documented in the State Health Plan.

## Likely Effects of CON on Healthcare Access

There is a substantial amount of literature regarding the various impacts of CON laws, but conclusions often conflict or find little effect in any direction. Furthermore, the scope and rigor varies, limiting its usefulness in determining what specific measures will best improve access to healthcare in South Carolina. Healthcare markets are extremely complex, and even the most carefully designed studies cannot be certain they control for every factor.

Studies are useful to inform CON policy decisions despite their limitations, especially studies on specific outcomes for particular types of services or facilities, or when multiple studies with different approaches achieve similar results. Researchers from Duke University, Providence College, and colleagues performed an extensive review of CON-related literature published through 2010. Findings of their review pertaining to access are summarized in Figure 2.3. One major issue with studies regarding access is that "access" has been defined differently in nearly every study. We also reviewed literature published after 2010 and included relevant findings in this report.

## Figure 2.3: Summary of Studies on the Effect of CON on Access Using Retrospective Cohort Design, Published Through 2010.

| Study | States | Years | Key Findings |
|---|---|---|---|
| **National Studies** | | | |
| Fric-Shamji and Shamji | 26 | 2004–2005 | CON has 0% effect on procedure rates, but may shift care to non-profit hospitals |
| | | 2004–2005 | CON has 0% effect on procedure rates |
| | | 2004–2006 | CON has 0% effect on procedure rates, but may shift care to teaching hospitals |
| Popescu | 50 | 2000–2003 | CON reduces that chance that a patient with AMI is admitted for revascularization by 18% |
| Ho | 50 | 1989–2002 | CON results in 19.2% fewer PCIs being performed |
| Ho et al. | 50 | 1989–2002 | Removing CON increases PCIs and CABGs by 0% |
| Short et al. | 50 | 1989–2002 | CON has 0% effect on cancer resection procedures |
| Ho, Ross et al. | 50 | 1989–2002 | CON increases CABGs by 0% |
| **Case Studies** | | | |
| DeLia et al. | NJ | 1995–2004 | Removing CON decreases racial disparity in cardiac angiography by 3% |
| Robinson et al. | PA | 1994–1999 | Removing CON increases CABGs by 0% |
| Kolstad | PA | 1994–2003 | Removing CON decreases travel distance for CAGB by 2.3 miles (9%) |

AMI = Acute Myocardial Infarction
PCI = Percutaneous Coronary Intervention
CABG = Coronary Artery Bypass Grafting

Source: Conover and Bailey study (bibliography).

The authors of the comprehensive literature review also used the information to perform a rough cost-benefit analysis to quantify the overall impacts of CON nationally. The analysis advised that its results were considerably uncertain and the implications for South Carolina's CON program specifically are unclear. However, researchers concluded that nationally, costs of CON laws probably outweigh the benefits by 8%. Counterintuitively, the analysis also found that there was a probability of 54% that CON laws' benefits outweigh the costs—in other words, that CON laws are a net positive. This is because the researchers used a range of estimates for costs and benefits; the range of possible benefits is moderate, but the range of potential costs is larger. This larger range of potential costs skewed the researchers' conclusion towards the final 8% figure.

We also reviewed the results of studies that focus on important, individual factors of access. These factors include cost, quality, geographic availability of health care services, and finances of safety net hospitals.

## Cost/Health Expenditures

Table 2.4 illustrates a summary of the findings of literature regarding healthcare costs or expenditures published through 2010.

**Table 2.4: Cost/Health Expenditures**

| Facility Type | Impact on Healthcare Costs/Expenditures |
|---|---|
| Hospitals | Evidence is generally mixed. CON laws applicable to hospitals have no overall impact on expenditures. |
| Nursing Homes | Recent evidence is limited, results in mixed conclusions, and impacts are statistically insignificant in two of three relevant studies. |
| Home Health | Weak and dated evidence that CON has either no impact or increases costs. |
| Hospice Care | One study suggests that CON states had fewer hospices, costing a roughly estimated $850,000 in unrealized annual savings. |
| Kidney Dialysis | One dated study found CON laws applicable to dialysis result in higher costs. |

Source: LAC literature review; Conover and Bailey study (bibliography).

One common limitation of studies that examine costs and healthcare expenditures is lack of good data. Although data on what providers charge on invoices is readily available, the final amount paid by a consumer after insurance or self-pay reductions is not.

One recent study examined per-capita spending from hospitals, hospital physicians, and nursing homes. It found there was no statistically significant estimate of CON laws reducing spending, but it did find increased spending by 3%–4% overall.

A recent study comparing nursing home and home health spending for Medicare and Medicaid patients found higher spending on nursing homes, but lower spending on home health in states with CON laws, compared to states without. However, there was no difference in overall spending on both types of care combined between states with different CON laws.

Another, more recent, study on a broad range of healthcare prices used insurer data that better reflects final costs. That study also found no statistically significant effect of CON laws on prices. A study on reimbursement for a spinal surgery found that states with CON laws generally had higher utilization and lower reimbursement rates.

### Competition

Proponents of eliminating CON laws point to a body of literature that largely shows increased healthcare competition results in lower costs and better quality, and assume that CON laws result in less competition. However, a recent study from researchers at Kennesaw State University in Georgia that reviewed data from years 2000–2009 found that CON laws increase competition in the inpatient healthcare market by an overall 33%. The researchers concluded that the pro-competitive effects of limiting incumbent expansion may dominate the anti-competitive effects of restricting new entry into the market. The researchers stated that their data revealed some insights specific to South Carolina's CON program and healthcare competitiveness.

- During this period, among the 36 states that have any CON law, 25 states had a higher inpatient care competition than South Carolina.
- Among the 25 states that were more competitive, 18 were actually more stringent than South Carolina, and 7 were less stringent.
- Among the 10 states that had CON Law in some capacity but were less competitive than South Carolina, 4 were less stringent and 6 were more stringent.

Patient outcomes are better if a provider maintains a high volume of services only for certain, high-risk health care services.

### Quality

Advocates for the continued use of CON laws cite "volume-outcome" effects that demonstrate a positive relationship between how often a hospital provides a service and the likelihood of good patient outcomes. Therefore, restricting the number of facilities or providers may increase healthcare quality. Opponents of CON laws infer that reduced competition may cause providers to be less likely to adopt better techniques, or that CON laws slow the adoption of innovative technology. Research indicates that both positive and negative "volume-outcome" effects exist for certain, relatively high-risk procedures and services. A systematic review found "consistent and striking" differences in mortality rates for conditions and procedures such as certain cancers, aneurysms, and pediatric cardiac problems. The review attributed low volume to 3.3 to 13 excess deaths among the conditions and procedures with the strongest associations between volume and quality. The review also found statistically significant but smaller associations between volume and quality for more routine procedures.

There is little evidence that CON laws currently are associated with differences in mortality, broadly. Neonatal mortality may be better in certain states with CON laws. Historically, adoption of CON laws was associated with worse heart attack mortality.

One measure of quality is mortality rates. One recent study examining all-cause mortality and its relationship with CON laws found no statistically significant association between the two. Another recent study concluded that states with CON laws, especially small states, were associated with lower numbers of intensive neonatal intensive care unit facilities, and that CON states with at least one large metropolitan area had better infant mortality outcomes. Research on heart surgery deaths, the focus of most research on mortality, is mixed, but the plurality of studies found no effect. A recent study focusing on deaths from heart attacks found that the adoption of CON laws from 1968–1982 was generally associated with 6%–10% higher mortality in the years immediately following adoption. The study attributed the cause of the increase in mortality to the slower establishment of hospitals and services that could timely respond to acute issues like a heart attack.

CON law repeal in Pennsylvania improved the fit of cardiac care between patients and providers. CON laws may reduce unnecessary heart attack intervention procedures.

Another measure is the "fit" or appropriateness of care delivered by the provider to the patient. One study that focused on heart attack interventions suggested that CON laws reduced medically unnecessary procedures but did not increase the rate of intervention when it was appropriate. Other studies regarding cardiac procedures following the repeal of CON laws in Pennsylvania found that the repeal "directed more volume to better doctors" and improved the "match between underlying medical risk and treatment intensity."

CON laws may cause higher cost but higher quality nursing home care. CON laws may worsen kidney dialysis care.

Quality of nursing home care also has mixed results. More recent studies suggest that higher Medicaid payments (in other words, higher cost) caused by CON laws resulted in higher nursing home quality. Another study suggests that CON laws worsened the quality of kidney dialysis care.

### Number and Geographic/Demographic Distribution of Facilities

A case study focused on Pennsylvania, which repealed its CON program, found that several new coronary bypass programs could be attributed to the repeal, reducing patient travel distance by an average of 9%. However, these facilities mostly opened in suburban areas and accepted Medicaid patients at a lower rate than incumbent facilities. A case study in New Jersey, which reformed its CON program to expand cardiac angiography services, found that although new entrants focused on white suburban areas, the reform reduced racial disparities by a modest 3% because incumbent urban hospitals utilized their capacity to serve more local black patients.

One study from 2018, regarding the establishment of substance abuse facilities, found that a state's adoption of either CON laws or Medicaid expansion (but not both) were associated with fewer facilities in that state compared to non-adopting states. However, states that adopted both CON laws and Medicaid expansion were associated with an increase in the number of facilities, illustrating the complexity of interaction between many factors in healthcare markets.

### Financial Viability of Safety-Net Hospitals

Perhaps the most common reason cited in defense of CON laws generally, and in South Carolina, is that it helps ensure financial viability of "safety net" hospitals that are obligated to treat patients regardless of their ability to pay, or hospitals that operate in low- or no-profit areas. By limiting the entry of facilities, safety-net or nonprofit providers may serve more patients with insurance and/or a higher ability to pay, or provide more high-margin services and use those profits to "cross-subsidize" losses from providing care to patients who cannot pay as much. Theoretically, cross-subsidization could result in overall increased access, though it could drive up prices for low or middle income patients with insurance.

The South Carolina Hospital Association and multiple regional medical systems in South Carolina assert that they depend on cross-subsidization effects from CON to continue to provide care, especially in rural and underserved areas. One medical system that operates across seven counties estimated that it would provide over $40 million in charity care in 2021.

One study that reviewed coronary surgery after Pennsylvania's CON repeal in 1996 found that incumbent hospitals providing the service experienced several years of negative margins after CON repeal, but eventually returned to profitability. Another study, not focused specifically on CON, found no association between increased market concentration and the provision of charity care by private hospitals.

## Necessity of CON Laws on Low-Cost Facilities and Services

DHEC's CON program intends to promote cost containment, yet there are some low-cost facilities and services, such as home health agencies and substance abuse treatment programs, that are required to obtain CON approval.

We found that CON laws may not be necessary for home health agencies because:

- The CON program is overwhelmed by the volume of applications received, and home health applications comprise approximately 50% from January 1, 2018 through September 30, 2021. Removing home health from CON laws in South Carolina would significantly reduce the number of CON applications received by the program and may improve the efficiency of the application process.
- The average cost of home health projects is less than 1% of the average of all other projected costs.
- There are mechanisms outside of the CON application process to ensure healthcare quality of the home health agencies.
- States with home health CON laws have a lower of number of home health agencies than states without CON laws. According to the SHP, the benefit of improved accessibility outweighs the adverse effects caused by the duplication of any existing home health service, and South Carolina has the 8th lowest rate of home health agencies per 100,000 people in the nation.

We found that CON laws may not be necessary for substance abuse treatment programs because:

- CON laws are associated with a decrease in the number of substance abuse facilities within a state.
- Accessibility is particularly important for these types of services.

## Home Health Agencies Overview

S.C. Code §44-69-20 defines a home health agency as a public, nonprofit, or proprietary organization providing services on a visiting basis and usually within the patient's residence. These services include:

- Part-time or intermittent skilled nursing care.
- Physical, occupational, or speech therapy.
- Medical social services, home health aide services and other therapeutic services.
- Medical supplies and the use of medical appliances.

S.C. Code §44-69-75 states that these agencies are required to obtain CON approval prior to receiving licensure.

## Volume and Cost of Home Health Applications

Overall, home health applications are a significant portion of the applications received by the program with the overwhelming majority of those receiving approval, but the average cost of home health projects is less than 1% of the average of all other projected costs. A DHEC official explained that the biggest challenge to the CON program meeting its goals is the high volume of applications received by the program.

From January 1, 2018 through September 30, 2021, 390 CON applications were published in the State Register as accepted for filing. Of those 390 applications, 198 applications were for home health agencies making up approximately half of the applications received by DHEC during that period. Of the 198 home health applications:

- 185 were approved.
- 2 were denied.
- 6 were withdrawn.
- 5 had not yet received a decision, as of November 10, 2021.

The average cost of the proposed home health projects for applications accepted for filing from January 1, 2018 through September 30, 2021 was approximately $27,000, while the average of all the proposed projects was $6.5 million. Because of the sheer volume of home health agency applications that account for such a low average project cost, when removed, the average cost of applicant projects would be $13.3 million, which is a 103% increase.

Table 2.5 shows the count, percentage of total applications, and average cost of CON applications by facility type from January 1, 2018 through September 30, 2021. Table 2.6 shows the difference in the average of projected costs by including and excluding home health applications.

**Table 2.5: CON Applications by Facility Type and Average Cost Per Facility January 1, 2018–September 30, 2021**

| Facility Type | Count | Percentage | Average Cost Per Facility |
|---|---|---|---|
| Home Health | 198 | 50.77% | $26,747.00 |
| Hospital | 107 | 27.44% | $15,969,671.34 |
| Ambulatory Surgery Facility | 26 | 6.67% | $9,781,277.60 |
| Nursing Home | 10 | 2.56% | $18,213,136.30 |
| Diagnostic Imaging | 8 | 2.05% | $3,639,540.75 |
| Opioid Treatment Program | 7 | 1.79% | $327,239.45 |
| Rehabilitation Facility | 7 | 1.79% | $28,656,523.86 |
| Emergency Department | 6 | 1.54% | $15,150,042.00 |
| Cancer Center | 5 | 1.28% | $5,724,326.62 |
| Residential Treatment Facility | 5 | 1.28% | $1,278,049.88 |
| Narcotic Treatment Program | 3 | 0.77% | $135,000.00 |
| Hospice | 2 | 0.51% | $3,355,015.00 |
| Radiation Therapy | 2 | 0.51% | $9,289,414.00 |
| No Facility Type* | 2 | 0.51% | $2,022,509.00 |
| Psychiatric Facility | 1 | 0.26% | $2,364,837.00 |
| Radiation Oncology | 1 | 0.26% | $12,014,596.00 |

* There was no service type listed for a project in DHEC's CON application data.

Source: LAC Analysis of DHEC Data

**Table 2.6: Average Projected Costs Including and Excluding Home Health, January 1, 2018–September 30, 2021**

| Average Cost of All Facilities | |
|---|---|
| Including Home Health | $6,544,944.70 |
| Excluding Home Health | $13,266,836.08 |

Source: LAC Analysis of DHEC Data

## Impact of CON Laws on Home Health Costs and Quality

### Home Health CON Laws and Cost Containment

The results are mixed on the impact of CON laws on cost containment. A 2020 study published in *Home Health Care Services Quarterly* shows that the presence of home health CON laws is associated with larger agency caseloads and lower per-patient costs per facility. Although, a 2016 study published in *Medical Care Research and Review* showed that spending on home health care by both Medicare and Medicaid increased at a much faster rate in states without CON laws.

### Home Health CON Laws and Quality of Service

Despite the potential impact of CON laws on home health care quality, quality may not be a concern in South Carolina. Although, the removal of CON laws for home health agencies may further improve home health agency service quality.

CON laws may adversely impact quality of home health agency services. Although the 2020 study referenced earlier describes that the presence of home health CON laws is associated with lower per-patient costs, the study also finds that the laws are associated with lower home health agency quality ratings. By preventing the entry of new home health agencies and increasing the market power of existing agencies, existing agencies may be less incentivized to compete on quality.

South Carolina ranks above national average in health care quality of home health agencies. Centers for Medicare & Medicaid Services (CMS) publish "Quality of Patient Care Star Rating," which include critical quality measures of home health agencies using a 1–5 star rating system. The system is used to summarize home health agencies' performance based on the quality of care provided across nine areas using seven measurements of quality. The rating system focuses on process and timeliness of care and patient outcome measures. According to CMS, a 3-star rating is considered good quality of care, and a rating higher than 3 means the agency performed "better than average." Table 2.7 shows the most recent publication of these ratings of South Carolina home health agencies are 0.5 star rating above the national average for the overall rating across all nine areas.

**Table 2.7: South Carolina's CMS Quality of Patient Care Star Rating Compared to the National Average, Released July 2021**

| Average Quality of Patient Care Star Rating | | | |
|---|---|---|---|
| Star Rating | National | South Carolina | Difference From National Average |
| 1–5 | 3.00 | 3.50 | +0.50 |

Source: LAC Analysis of CMS Data

## Established Statutory and Regulatory Mechanisms to Ensure Home Health Care Quality

There are mechanisms, outside of the CON program, in state law and regulations to ensure the quality of home health agency services. DHEC's licensing department, which is separate from the CON program, oversees home health care quality as established by laws and regulations. S.C. Code §44-69-75 requires each home health agency for which a license has been issued to be inspected by an authorized representative of the DHEC at least once a year. The inspection is to ensure that the licensee is providing quality care to its patients. S.C. Reg. §61-77, Standards for Licensing Home Health Agencies, outlines methods of enforcing home health regulations to include inspections, investigations, and consultations. The regulation also enables the department to take enforcement action on agencies that are in violation of specified classifications and allows for the DHEC to impose monetary penalties for certain violations.

## Need for Additional Home Health Agencies

The current number of home health agencies in South Carolina may not be adequate to serve the population. States with home health CON laws have a lower of number of home health agencies than states without CON laws. The previously mentioned 2016 *Medical Care Research and Review* and 2020 *Home Health Care Services Quarterly* studies both reached this conclusion.

Multiple officials stated that there is a need for more home health agencies in South Carolina. According to the SHP, the benefit of improved accessibility outweighs the adverse effects caused by the service duplication of any existing home health services. A DHEC official stated that the adverse effects of duplication are less for services like home health agencies and there is a need for home health agencies across the state. A representative from a major healthcare system in South Carolina is quoted saying "everyone agrees we need more home health services."

An influx of home health agency licensures following Governor Nikki Haley's veto of the CON program in 2013 may provide evidence that the CON program acts as a deterrent to open and operate a home health agency. A representative from the South Carolina Hospital Association and a DHEC official both explained that there was an influx of home health agency licensures during the period that Governor Nikki Haley vetoed the funding for the CON program in 2013.

By comparing the number of home health agencies registered to Medicare in each state to the population estimate, South Carolina has the 8th lowest rate of home health agencies per 100,000 people. This analysis shows that South Carolina's home health agency per capita rate is 1.48 per 100,000, and the national average is more than double that number at 3.35 per 100,000 people.

Table 2.8 compares S.C.'s home health agency per capita rates to states of similar populations and shows that S.C.'s rate is noticeably lower than the other states of similar population size.

**Table 2.8: Home Health Agencies Per Capita of South Carolina and States of Similar Population Estimates, 2021**

| State | Count of Home Health Agencies | 2021 Population Estimate in Millions | Home Health Agencies Per 100,000 |
|---|---|---|---|
| LA | 186 | 4.62 | 4.02 |
| AL | 121 | 5.04 | 2.40 |
| SC | 77 | 5.19 | 1.48 |
| MN | 171 | 5.71 | 3.00 |
| CO | 195 | 5.81 | 3.36 |

Source: LAC Analysis of U.S. Census Bureau Data & CMS Data

Table 2.9 compares South Carolina's home health agency per capita rates to surrounding states and shows that South Carolina has a more comparable rate to those surrounding states. Although, South Carolina's per capita rate is significantly lower than Florida.

**Table 2.9: Home Health Agencies Per Capita of South Carolina and Surrounding States, 2021**

| State | Count of Home Health Agencies | 2021 Population Estimate in Millions | Home Health Agencies Per 100,000 |
|---|---|---|---|
| FL | 930 | 21.78 | 4.27 |
| GA | 103 | 10.8 | 0.95 |
| NC | 173 | 10.6 | 1.64 |
| SC | 77 | 5.19 | 1.48 |
| TN | 129 | 6.98 | 1.85 |

Source: LAC Analysis of U.S. Census Bureau Data & CMS Data

## CON Laws Hinder Access to Substance Abuse Treatment Facilities

As the opioid epidemic continues to be a public health crisis in the United States, the removal of narcotic treatment programs and opioid treatment programs from CON requirements may improve accessibility to these services. There is a lack of evidence to support the requirement for a CON for substance use treatment facilities. A 2018 study published by De Gruyter found that the presence of CON laws on substance use treatment facilities reduces the number of facilities. A DHEC official explained that these types of services are low-cost, hugely effective, and require everyday access to treatment. Furthermore, the official mentioned that the types of patients using these services usually have unreliable transportation, and the patients need to receive the services daily. The SHP explains that clients using opioid treatment programs typically attend a center six days per week to receive medication. The Plan explains that the centers should be located throughout the state with one in each county to improve accessibility.

It is detrimental to healthcare outcomes for a patient to miss services from a substance abuse treatment facility. Furthermore, as seen in Table 2.5, opioid treatment programs (OTP) and narcotic treatment programs (NTP) are the second and third lowest cost services following home health agencies.

Of the 390 applications accepted for filing from January 1, 2018 through September 30, 2021, there were only 7 OTP applications and 3 NTP applications.

# Recommendations

1. The S.C. General Assembly should consider eliminating the requirement for a certificate of need for home health agencies.

2. The S.C. General Assembly should consider eliminating the requirement for a certificate of need for narcotic treatment programs and opioid treatment programs.

## Thresholds for Equipment and Capital Expenditures

The dollar thresholds for equipment and capital expenditures subject to review by the CON program are outdated. S.C. Reg. §61-15-102 requires that a CON be obtained when there is:

- A capital expenditure by or on behalf of a health care facility in excess of $2 million.
- The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of $600,000.

Since the original threshold amounts were enacted in 2001, healthcare costs have increased, making the $600,000 and $2 million thresholds obsolete. Interested parties, including physicians and hospital administrators, as well as DHEC officials agree that the current thresholds for capital expenditures are too low and need to be updated.

Neighboring states have either updated or eliminated such thresholds. For example:

TENNESSEE eliminated equipment and capital expenditure thresholds in 2016.

NORTH CAROLINA changed its law in 2021 to increase its thresholds:

- Diagnostic equipment from $500,000 to $1.5 million.
- "Major medical equipment" from $750,000 to $2 million.
- Capital expenditures from $2 million to $4 million.

GEORGIA changed its law in 2019 to increase its thresholds:

- Diagnostic equipment from $1 million to $3 million.
- Capital expenditures from $2.5 million to $10 million.

If South Carolina increases its thresholds for capital expenditures and diagnostic equipment, it will reduce the number of projects that require an application. This would allow CON staff to focus on other projects and reduce the number of appeals. For example, 42 decision certificates were issued by CON staff in 2019 for capital expenditures and equipment. If the thresholds for capital expenditures and medical equipment were increased to $5,000,000 and $2 million, respectively, approximately 19 of those applications would not have been necessary. Additionally, providing for the adjustment of these thresholds to the Medical Care Index component of the Consumer Price Index could prevent the thresholds from becoming outdated in the future.

## Recommendation

3. The S.C. General Assembly should increase the thresholds for equipment and capital expenditures for the certificate of need program and provide for the adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

## COVID-19 Response

We reviewed the impact of the 2019 Novel Coronavirus (COVID-19) on the CON program. According to DHEC officials and other members of the healthcare community, COVID-19 had little impact on the administration of the CON program. We found, however, that DHEC did not keep track of the number of times health providers attempted to obtain a waiver pursuant to the Governor's executive orders, which loosened certain CON regulations in response to COVID-19.

### Impact of Executive Orders

On March 19, 2020, Governor Henry McMaster issued Executive Order No. 2020-11, which authorized temporary changes to the CON program in response to COVID-19. The executive order authorized and directed DHEC to suspend regulations which restricted the use of:

- Unlicensed beds or space.
- Conversion of single and double occupancy patient rooms to account for higher patient capacity.
- Establishment of wards, dormitories, or other spaces not designated as patient rooms.

Additionally, the Governor's executive order suspended the monetary thresholds for items requiring CON review "….to the extent necessary and applicable, so as to permit healthcare facilities to make those capital expenditures and acquire medical equipment necessary to prevent, diagnose, treat, or monitor the progression of COVID-19."

Finally, the order directed DHEC to suspend certain sections of the SHP addressing health services requiring CON review to allow a healthcare facility to provide temporary health services to adequately care for patients who may be affected by COVID-19.

We spoke with DHEC officials and other members of the medical community regarding the executive order. All individuals we spoke with stated that the loosening of restrictions in the executive order did not have a material effect on the day-to-day operations of the CON program. DHEC officials noted that, although the executive order allowed for the relaxation of regulations and the SHP, there were other statutory requirements that could not be waived. For example, an official noted that the requirement for a CON for the addition of beds could not be waived by the executive order, but that other statutes allowed for the addition of beds, such as the Emergency Health Powers Act.

## Waiver Request Tracking and Communication

Although COVID-19 did not appear to significantly impact the CON program's operations, DHEC could not provide us with information on the number of waivers requested and the total number of waivers approved pursuant to the executive order. Additionally, one medical practice attempted to receive a waiver but, according to an administrator with that practice, never received a response from DHEC. Keeping track of waivers relating to executive orders and responding to waiver requests is necessary in order to ensure that such orders are followed and properly implemented.

# Recommendations

4. The S.C. Department of Health and Environmental Control should ensure that certificate of need waivers relating to the Governor's executive orders are properly tracked.

5. The S.C. Department of Health and Environmental Control should ensure that it adequately responds to requests for certificate of need waivers pursuant to the Governor's executive orders.

# CON Application Criteria

We reviewed the CON application criteria. We found that DHEC generally does not use quantitative metrics to gauge the quality of services provided by a CON applicant. Additionally, we found that most projects were completed within the approved cost limits, but the cost reported to DHEC likely does not account for the total amount spent by providers on CON projects.

## Quality Standards Used by CON Staff

The SHP contains qualitative standards that DHEC uses to assess the quality of services provided by a CON applicant. However, we found:

- The SHP contains few quantitative metrics to gauge quality.
- DHEC generally does not use quantitative metrics to gauge the quality of services provided by a CON applicant.

Quantitative metrics can help DHEC make better informed decisions on whether CON applicants provide quality services. This can be especially helpful in the instances of competing CON applications where providers in the same area are looking to add or expand the same service.

### Quantitative Metrics Not Widely Used

One of the stated purposes of the CON program is to ensure that high-quality services are provided in health facilities in South Carolina. While DHEC's Bureau of Health Facilities Licensing is responsible for enforcing standards, conducting inspections, and issuing licenses for many different types of healthcare facilities, CON staff have a few different ways to gauge whether an applicant will provide quality services.

According to CON staff, there is not a list of metrics or set of procedures to gauge quality issues for every application. Gauging quality is very project specific. Sometimes, metrics are brought up by an applicant or an opposing party, but, in general, quality metrics are not used unless outlined in state code, state regulations, or the SHP. As noted below, quality standards in state regulation and the SHP are nearly all qualitative in nature, which can result in subjectivity in the evaluation process.

The SHP contains standards specific to each type of facility or service. Within the standards for the various facility and service types are project review criteria, which CON staff are required to use when reviewing all CON applications. One of the 33 project review criteria is "Record of the Applicant." The SHP lists this criterion as one of the most important when reviewing applications for many different types of facilities and services, such as general hospitals, neonatal services, and opioid treatment programs.

As stated in S.C. Reg. §61-15.802(13), the "Record of the Applicant" criterion includes the following standards:

- The applicant's record should be one of successful operation with adequate management experience.
- The applicant should have a demonstrated ability to obtain necessary capital financing.
- If the applicant has no prior experience, sources of assistance should be specified (i.e. technical assistance from specific individuals or organizations).
- The applicant's record or his representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.

In addition to project review criteria, the SHP lists specific quality standards for various facilities and services. Some examples include:

**HOME HEALTH AGENCIES**

The applicant should have a track record that demonstrates a commitment to quality services. There should be no history of prosecution, consent order, abandonment of patients in other business operations, or loss of license.

**GENERAL HOSPITALS**

Factors to be considered regarding modernization of facilities include the ability to update medical technology within the existing plant and existence of accreditation body deficiencies or "grandfathered" licensure deficiencies, among other things.

**RESIDENTIAL TREATMENT FACILITY FOR CHILDREN AND ADOLESCENTS**

Each facility shall have a written plan for cooperation with other public and private organizations, such as schools, social service agencies, etc., to ensure that each child under its care will receive comprehensive treatment.

The only quantitative quality metrics that we identified in the SHP are volume requirements (e.g. minimum number of open heart procedure requirements) and utilization requirements (e.g. radiotherapy service utilization). However, additional quantitative metrics, such as those captured by the Center for Medicare & Medicaid Services (CMS), can help DHEC make better informed decisions on whether CON applicants provide quality services.

These quantitative metrics include, but are not limited to:

- *Percent of High-Risk Residents with Pressure Ulcers*, which can be used to gauge the quality of care for nursing homes.
- *Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures*, which can be used to gauge the quality of care at ambulatory surgical centers.
- *Improvement in Management of Oral Medications*, which can be used to gauge the quality of care for home health agencies.

Nothing currently prevents DHEC from utilizing CMS quantitative metrics during the CON application review process. In fact, the CON application asks applicants to "provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable." However, as previously stated, DHEC staff generally do not use quantitative quality metrics.

## Recommendation

6. The S.C. Department of Health and Environmental Control should add appropriate, quantitative quality metrics from the Center for Medicare & Medicaid Services to the State Health Plan.

## Evaluation of CON Project Costs

The first stated goal of the CON program in S.C. Code §44-7-120 is to promote cost containment. As part of this goal, DHEC staff evaluate the cost of a CON project from the time of application through the project's completion. Upon review of DHEC's evaluation methods, we found:

- The determination of what is a "reasonable cost" is subjective.
- Most projects' total costs were at or below the amounts approved when the CONs were issued.
- There were substantial differences in the approved cost amount for projects of the same facility and service type.
- The total project cost reported to DHEC likely does not account for the total amount spent by providers in obtaining and ultimately completing CON-approved projects.

In a CON application, providers are required to submit information on a project's total cost. Total project cost is defined by S.C. Reg. §61-15.103(24) as "the estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect's fee, financing cost, and other capital costs properly charged under generally accepted accounting principles as a capital cost." Providers are also required to document that a proposed project is economically feasible, and, in the case of existing facilities, "indicate what impact the proposed project will have on patient charges and cost per unit of service."

Before a CON can be issued for a new institutional health service, DHEC must determine whether a proposed project complies with the SHP, which includes evaluating whether "the capital and operating costs of the proposal and their potential impact on patient charges are reasonable," among other things. DHEC staff said that they compare a proposed project's cost to similar projects to decide whether the costs are reasonable. Likewise, staff review cost information from other providers' websites, the American Hospital Association, and Medicare to determine whether the proposed patient charges are reasonable. However, without any standards to help DHEC staff determine the "reasonableness" of a project's proposed cost and the potential impact on patient charges, the evaluation process lends itself to subjectivity.

When DHEC issues a CON, the agency is required to specify the approved total project cost. If a project's cost overruns the approved amount, DHEC reviews the overrun on an individual basis. We analyzed all CONs issued since January 1, 2018 to determine how many projects exceeded the approved project cost amounts. The results of the analysis are found in Table 3.1.

**Table 3.1: Number of CON Projects With and Without Cost Overruns, 2018 – 2021**

| Year | Number of Projects | | Total |
|---|---|---|---|
| | *Without* A Cost Overrun | *With* A Cost Overrun | |
| 2018 | 12 | 6 | 18 |
| 2019 | 14 | 4 | 18 |
| 2020 | 9 | 2 | 11 |
| 2021 | 2 | 0 | 2 |
| TOTAL | 37 | 12 | 49 |

Source: LAC Analysis of DHEC Data

As shown in Table 3.1, 12 of the 49 projects' costs exceeded the original approved amount. The amount of cost overruns for the 12 projects ranged from $1,729 to $677,622, with the median coming in at $50,073.
Table 3.2 shows the total approved project costs for all projects in 2018 through 2021, and the final costs for completed projects that were approved during the same time period.

**Table 3.2: Project Costs for All Approved and Completed Projects, 2018 – 2021**

| Year | All Projects | Completed Projects | |
|---|---|---|---|
| | Approved Cost | Approved Cost | Final Cost |
| 2018 | $292,524,765 | $81,000,356 | $76,946,453 |
| 2019 | $484,928,854 | $23,536,277 | $21,934,337 |
| 2020 | $322,746,738 | $11,598,956 | $10,281,471 |
| 2021 | $225,945,844 | $1,923,844 | $1,784,423 |
| TOTAL | $1,326,146,201 | $118,059,432 | $110,946,684 |

Source: LAC Analysis of DHEC Data

We found substantial differences in the approved cost amounts when we analyzed the projects by facility and service type. For example, hospitals that wanted to add beds were approved for projects ranging from $333,810 to $22,656,000 in cost; a more than $22 million difference. Similarly, ambulatory surgery facilities that wanted to add square feet were approved for projects ranging from $450,573 to $19,894,166 in cost; a difference of more than $19 million.

See Appendix A for a comparison of all facility and service types. While the cost of projects is expected to vary, the substantial differences between projects of the same facility and service type underscore the subjectivity in DHEC's evaluation process.

Determining the reasonableness of patient charges is similarly difficult. In CON applications, applicants are asked to provide a list of proposed charges for the project. S.C. Reg. §61-15.202(2)(b)(17) states that the "charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b."

In a sample of CON applications, we found that applicants provided inconsistent data. For example, one applicant provided the revenue per case for the proposed service, while other applicants provided the per day charge for an inpatient bed or bassinet at a hospital. Another applicant provided its chargemaster sheets, and others provided the average gross charges for each type of service. In addition to inconsistent data, providing only the gross charge prevents DHEC from properly assessing the effect the proposed project will have on patient charges. Most patients are insured and do not pay hospitals the gross charge. By requiring consistent information on patient charges and information on net patient charges, DHEC staff would be better equipped to determine the potential impact of a potential project, and further its goal of cost containment.

Another issue that affects DHEC's ability to promote cost containment is the fact that the total project cost reported by CON applicants does not always contain the actual amount spent by providers in obtaining and ultimately completing CON-approved projects. As previously stated, the definition of total project cost only includes capital costs. Other costs that providers can incur to implement a CON project include, but are not limited to, staff time, consultant fees, and legal/litigation costs. Providers sometimes hire consultants to help them navigate the CON process and providers can incur litigation costs when a DHEC decision is appealed. As we note in Chapter 4, some CON applications can spend years in litigation, which can significantly increase the amount providers spend on a project.

Since non-capital costs are not included in a project's total cost, it is impossible to know exactly how much providers in South Carolina have spent on them. However, through anecdotal evidence and surveys from other states, it is evident that non-capital costs can be substantial. For example, the Regional Medical Center in Orangeburg reported being $312,000 over budget due to professional expenses involved with the hospital's challenge of a DHEC decision to award a CON to a competing surgery center.

Further, a 2013 survey from Washington state found the estimated cost to submit a CON application may range anywhere from $10,000 to $200,000, excluding the application fee itself. Reducing the amount of time that a CON application can spend in litigation, as recommended in Chapter 4, and reducing the number of projects that need a CON, as recommended in Chapter 2, can reduce the amount that healthcare providers spend on non-capital costs.

## Recommendations

7. The S.C. Department of Health and Environmental Control should further standardize the information required of certificate of need applicants to ensure consistency in its evaluation process.

8. The S.C. Department of Health and Environmental Control should require certificate of need applicants to provide information on net patient charges when project impact on patient charges is a factor in the evaluation process.

9. The S.C. Department of Health and Environmental Control should amend S.C. Reg. §61-15.607(3) to require certificate of need applicants to report on non-capital expenses related to a project upon its completion.

## Prioritizing Competing Goals

To prioritize the statutory goals of the CON program, we found that DHEC staff uses project review criteria listed in the SHP and state regulations. However, we also found that DHEC staff have discretion to add additional review criteria not listed for each project, service, or equipment in the SHP. In addition, DHEC staff can reorder the importance of the criteria when reviewing a CON application.

S.C. Code §44-7-120 provides the following goals for the CON program:

- Promote cost containment.
- Prevent unnecessary duplication of health care facilities and services.
- Guide the establishment of health facilities and services which will best serve the public need.
- Ensure that high-quality services are provided in health facilities.

While some goals, such as cost containment and ensuring high-quality services, appear to be incompatible with one another, DHEC staff stated that the prioritization of the four goals depends on the type of service and facility. Prioritization guidance comes from project review criteria listed in the SHP. Specifically, DHEC is required by S.C. Code §44-7-190(A) to adopt project review criteria to "provide for the determination of need for health care facilities, beds, services and equipment," and S.C. Code §44-7-190(B) requires the project review criteria to "be used in reviewing all projects under the Certificate of Need process." S.C. Reg. §61-15.802 lists 33 criteria that are to be used when reviewing CON projects, but not all criteria are used to evaluate every project.

The SHP only lists project review criteria considered to be the most important in reviewing CON applications for each type of facility, service, and equipment. For example, the plan includes the following project review criteria for long-term acute care hospitals:

1. Compliance with the need outlined in long-term acute care hospital section of the SHP.
2. Common need documentation.
3. Distribution (accessibility).
4. Record of the applicant.

In addition to the project review criteria listed in the SHP as the most important for each type of facility, service, and equipment, DHEC can add additional review criteria from regulations when reviewing an application. When a type of facility, service, or equipment does not have a list of the most important project review criteria listed in the SHP, DHEC staff stated that they analyze the project review criteria and determine which are the most important. We were informed that a need component and distribution component were almost always included in reviews. Likewise, for cost-based projects, there is usually cost criteria (e.g. financial feasibility and cost containment) included.

Once a CON application is complete, DHEC is required by S.C. Reg. §61-15-304 to "notify the applicant…of the relative importance of the project review criteria to be used in reviewing the application." If DHEC gives more weight to the importance of some criteria over other criteria, it cannot reorder the criteria more than once after a project review meeting, per S.C. Code §44-7-190(B). In the past, DHEC believed it had the discretion to not utilize all the criteria listed in the SHP when evaluating a CON application. The issue was raised in an Administrative Law Court case in 2019. Ultimately, the Administrative Law Court held that DHEC did not have the discretion to choose whether to include criteria listed in the SHP when considering an application, although additional criteria could be considered.

## Duplication of Health Care Facilities or Services

One of the goals of the CON program as required by S.C. Code §44-7-120 is to "prevent unnecessary duplication of health care facilities and services." We found that DHEC has multiple tools to help determine whether an additional health care facility or service is "unnecessary," including:

- The SHP.
- CON applications.
- Public input.

In the SHP, DHEC is required by S.C. Code §44-7-180(B)(4) to include:

> …a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications…including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse effects caused by the duplication of any existing facility, service, or equipment.

Our review of the 2020 SHP found 19 facility and service types that included a "finding" about the need for accessibility versus the effects of duplication. Table 3.3 shows the 19 facility/service types by finding, as listed in the 2020 plan.

**Table 3.3: Facility/Service Types by Finding in 2020 South Carolina Health Plan**

| Facilities and services where improved accessibility will not/do not outweigh the adverse effects of duplication: |
|---|
| 1. Open heart surgery services<br>2. Nursing facilities<br>3. Institutional nursing facility |
| Facilities and services where improved accessibility will be equally weighed with the adverse effects of duplication: |
| 4. General hospital beds<br>5. Long-term acute care hospital beds<br>6. Obstetrical services<br>7. Neonatal services<br>8. Psychiatric beds<br>9. Rehabilitation facilities<br>10. Inpatient treatment facilities<br>11. Residential treatment facility beds for children and adolescents<br>12. Catheterization services<br>13. Stereotactic radiosurgery<br>14. Ambulatory surgical services<br>15. Hospice services |
| Facilities and services where improved accessibility may outweigh the adverse effects of duplication: |
| 16. Radiotherapy services |
| Facilities and services where improved accessibility will outweigh the adverse effects of duplication: |
| 17. Opioid treatment programs<br>18. Freestanding emergency services<br>19. Home health services |

Source: LAC Analysis of SHP

As shown in Table 3.3, for three services/facilities, it has been determined that improved accessibility will not or does not outweigh the adverse effects of duplication. In essence, duplication in these service/facility areas is unnecessary, unless a provider can present justification for additional facilities/services. The SHP provides varying reasons for these findings. For open heart surgeries, the SHP notes that physicians and staff should maintain a certain volume of procedures per year to develop and maintain competency in performing the procedures. It also states that "most of the open heart surgery providers are currently utilizing less than the functional capability… of their existing surgical suites," and "the number of open heart surgery cases is decreasing." For nursing facilities, the current accessibility of the facilities, and for institutional nursing facilities (also referred to as retirement community nursing facilities), the lack of need for additional facilities/beds provide insight on the SHP's findings.

When a provider applies for a CON, the provider is required to "[d]emonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public…and [provide] justification that the proposed project will not unnecessarily duplicate existing entities," per S.C. Reg. §61-15.202(2)(b)(11). If DHEC staff determines an application needs additional information to make it complete, DHEC staff will request additional information. The applicant, in return, is required to submit the requested information within 30 days or the application will be considered withdrawn.

However, before an application can be submitted, a provider is required to notify the public of its intention to submit a CON application to DHEC by publishing notification in the legal section of a daily newspaper in the local project area for three consecutive days. According to DHEC staff, this is typically how the agency gets information from the public.

The public can also be notified about a CON application when DHEC publishes notice in the State Register that an application has been accepted for filing or when the review cycle for the application has begun. Besides submitting documents in support or opposition to an application, members of the public who meet the "affected persons" criteria as defined in S.C. Reg. §61-15.103, can request a public hearing during the CON review period. At public hearings, any person can present information relevant to a CON application. While the public can participate in the CON review process, DHEC staff stated that almost all input is from competing organizations.

Another way DHEC can receive input from the public is through the SHP process. Before a Health Plan is adopted, DHEC is required by S.C. Code §44-7-180(C) to allow time for public comments and to host regional public hearings. According to DHEC staff, each comment is discussed by the SHP committee, and the committee responds to each comment that requires a response.

## Justification for Limiting Supply of Specialty Services

The CON program regulates many different types of facilities and services by requiring providers to obtain a CON before undertaking certain facility or service-related projects. By doing this, the CON program limits the supply of specialty services like perinatal, cardiovascular, and radiotherapy services. In general, we found that the SHP limits the supply of some specialty services because these services have a limited need and require highly skilled staff and specialized equipment. However, studies on these services provided mixed results.

Specialty services where supply is limited include perinatal services, cardiovascular services, and radiotherapy services. The 2020 SHP provides the following justification for limiting the supply of perinatal services:

> Because the cost of high-risk obstetrical and neonatal services is so great, it is not desirable or cost-effective for all hospitals in the State to provide the higher levels of care. Over the years, a regionalized approach to perinatal care has been implemented in South Carolina to address the need for high quality, risk-appropriate, cost-effective perinatal health care. Regionalization provides a coordinated system of perinatal care for a well-defined population group.

Other issues cited by the 2020 SHP include the limited need for the services and limited availability of skilled personnel. For cardiovascular services, the 2020 SHP contains the following justification:

> Both cardiac catheterization and open heart surgery programs require highly skilled staffs and expensive equipment. Appropriately equipped and staffed programs serving larger populations are preferable to multiple, minimum population programs. Underutilized programs may reflect unnecessary duplication of services in an area, which may seriously compromise quality and safety of procedures and increase the cost of care. Optimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff.

To maintain the skills of the staff, the 2020 SHP requires applicants to maintain a certain number of cardiovascular services per year by the end of the first three years of operation or risk losing a CON for those services. Similarly, for radiotherapy services, applicants must project that the proposed service will perform a minimum number of treatments annually within three years of initiation of services without reducing the utilization of existing machines in the service area below a certain threshold before the service will be approved.

Two separate studies that were published in peer-reviewed medical journals in 2010 and 2015 found associations with low volume perinatal/neonatal care units and higher risk of death for very low birth weight infants, suggesting that limiting the supply of neonatal intensive care units to keep volumes high at CON-approved hospitals would help reduce the risk of mortality for these infants.

Two other studies that were published in peer-reviewed medical journals in 2006 and 2009 made similar conclusions about the effect of CON regulations on the quality of care for coronary artery bypass graft (CABG) surgeries, which is an open-heart surgery. The 2006 study concluded that "CON states have significantly higher hospital CABG surgery volumes but similar mortality compared with non-CON states." The 2009 study found "no evidence that CON regulations are associated with higher quality CABG…"

A 2014 study on the effect of CON laws' ability to limit overtreatment of low-risk cancers concluded that:

> …there is more [radiotherapy] use in CON states for elderly patients who may not need this treatment for Stage 0-1 breast cancer and low-risk prostate cancer. This suggests that CON programs may not be effective in reducing overtreatment, an important quality of care issue in oncology.

However, a 2021 study found that CON laws decreased the travel time for patients in rural areas who needed radiation oncology services.

## Approval of New Facilities That Would Provide Duplicative Services

We were asked to determine whether DHEC has ever approved a CON for a new facility that would provide duplicative services to an existing facility to improve the quality of care. We found that DHEC has done this multiple times across multiple types of facilities. However, these decisions are often appealed to the Administrative Law Court (ALC).

### Example #1: Ambulatory Surgical Centers

In June 2021 and August 2021, DHEC approved the CON applications for the construction of four new ambulatory surgical centers (ASC) in Greenville County. Two of the applications stated that the ASCs would each have six operating rooms. Two applications also said that the ASCs would have endoscopy rooms. In September 2021, requests for a contested case were filed with the ALC for two of the four applications. Both cases are opposed by existing healthcare providers and were dismissed after the petitioners in each case filed a stipulation of dismissal in October 2021.

### Example #2: Diagnostic Imaging Centers

In February 2020, DHEC approved CON applications for American Health Imaging of South Carolina, LLC to establish three new freestanding imaging centers, two in Lexington County and one in Richland County. DHEC's approval of the three centers was appealed to the ALC by affiliates of MedQuest, Inc. which had existing imaging centers in the same towns where American Health Imaging proposed its new facilities. All three applications were appealed to the ALC where a settlement agreement was eventually reached in which MedQuest agreed to dismiss the contested case if American Health Imaging agreed to drop two of its three applications.

### Example #3: Acute Care Hospitals

In March 2021 and July 2021, DHEC approved CON applications for the construction of three new acute care hospitals and the renovation and expansion of another acute care hospital in Horry County, despite all four applications having opposition, mostly from other hospitals. In October 2021, requests for a contested case were filed with the ALC for three of the four applications. All three cases were opposed by existing healthcare providers and were still pending as of December 13, 2021.

# CON Program Process

We reviewed the CON program's process. We found that the CON process is greatly lengthened due to appeals to the Administrative Law Court (ALC) and courts of appeal. Additionally, we found that the CON process has deterred some providers from expanding services.

## Length of CON Application Process

S.C. Reg. §61-15 outlines the timeframes for DHEC's review of CON applications. We calculated the length of time that CON applications take from receipt to decision and found that it takes applications for some facility types significantly longer than it does for other facility types.

### CON Application Process

Step 1

When an application is first received by DHEC, the agency must verify that the applicant submitted proof of publication in a local newspaper, notifying the public of the application's submission. The applicant must also submit a $500 non-refundable filing fee. There is no time limit on this step.

Step 2

When DHEC provides notice that an application has been accepted for filing in the State Register, the agency has 30 days to request any additional information pertinent to the project. If additional information is requested, the applicant has 30 days to submit the requested information. If the applicant submits incomplete information, DHEC has 30 days to request additional information, and the applicant has another 30 days to respond.

Once an application is determined to be complete, DHEC invoices the applicant for the CON application fee. The applicant has 15 days to pay the fee. DHEC must also notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. The applicant is given 30 days to submit additional information. If DHEC determines that the relative importance of the review criteria has changed, the agency must notify the applicant and give them 30 days to submit additional information.

Step 3

Once an application is deemed complete and the application fee paid, DHEC must publish notice in the State Register that the review cycle for the project has begun. DHEC can make a decision no earlier than 30 days and no later than 120 days, unless a public hearing is held. A public hearing must be requested by an "affected person" within 30 days of notification of the beginning of the review process.

In practice, we found that applications take, on average:

- Step 1: 29 days
- Step 2: 36 days
- Step 3: 103 days
- Total: 168 days

However, there are significant differences among projects of different facility types. Narcotic treatment programs, for example, took 124 days, on average, from receipt to decision while rehab facilities took nearly twice as long, 223 days, on average. Table 4.1 shows the average number of days between application acceptance and CON decision for all applications accepted from January 1, 2018 through September 30, 2021.

## Table 4.1: Average Number of Days Between Application Acceptance and CON Decision, January 2018 – September 2021

| Facility Type | Average Number of Days | | | |
|---|---|---|---|---|
| | Between Receipt of Application and Official Acceptance | Between Official Acceptance and Application Deemed Complete | Between Application Deemed Complete and CON Decision | Between Receipt of Application and CON Decision |
| Ambulatory Surgery Facility | 24 | 57 | 120 | 201 |
| Cancer Center | 34 | 30 | 100 | 165 |
| Diagnostic Imaging | 22 | 25 | 121 | 168 |
| Emergency Department | 21 | 61 | 122 | 203 |
| Home Health | 30 | 31 | 96 | 158 |
| Hospice | 21 | 60 | 86 | 166 |
| Hospital | 29 | 37 | 109 | 176 |
| Narcotic Treatment Program | 29 | 12 | 84 | 124 |
| No Facility Type | 33 | 32 | 120 | 185 |
| Nursing Home | 28 | 46 | 109 | 183 |
| Opioid Treatment Program | 31 | 27 | 84 | 142 |
| Psychiatric Facility | 42 | 0 | 102 | 144 |
| Radiation Oncology | 50 | 28 | 81 | 159 |
| Radiation Therapy | 30 | 42 | 122 | 194 |
| Rehab Facility | 33 | 48 | 142 | 223 |
| Residential Treatment Facility | 27 | 46 | 99 | 172 |
| Overall Average | 29 | 36 | 103 | 168 |

Source: LAC Analysis of DHEC Data

## CON Application Appeals to the Administrative Law Court

Decisions made to approve or deny a CON application are appealable to the ALC. We calculated the length of time that applications take from CON decision to ALC decision for all applications that were appealed to the ALC. We found that appeals can extend the length of time of the CON application process by more than a year.

ALC APPEALS PROCESS

Step 1

When DHEC staff decide to grant or deny an application for a CON, they must notify the applicant and affected persons who requested notification. The staff's decision becomes the agency's final decision 15 days after notification unless the applicant or affected person submits a request for a final review by the Board of Health and Environmental Control and a filing fee. The Board, or its appointees, must conduct a final review within 60 days or the staff's decision becomes the agency's final decision. If a final review is held, DHEC must give at least ten days written notice to the applicant and affected person.

Step 2

Applicants and affected persons can file a request with the ALC for a contested case hearing within 30 days after:

- Notice that the Board declined to hold a final review conference.
- The 60-day deadline to hold a final review lapses and no final review conference is held.
- A final review conference decision is received by the applicant or affected person.

Step 3

The ALC must file a decision within 18 months after the contested case is filed with the clerk of the ALC, unless all parties in the case consent to an extension or the court finds substantial cause otherwise.

When we calculated the number of days that applications spend in the ALC appeals process, we found that few requests for final board reviews are made and even fewer applications are actually filed with the ALC. Of the 360 applications that were submitted between January 1, 2018 and September 30, 2021 and received a CON decision, only 41 had requests for a final board review. Of the 41, 18 were filed with the ALC, and 13 of those have a final ALC decision to date.

Table 4.2 shows the average number of days between a CON decision and an ALC final decision for applications submitted between January 1, 2018 and September 30, 2021, by facility type.

**Table 4.2: Average Number of Days Between a CON Decision and an ALC Final Decision for Applications Submitted January 2018 – September 2021**

| Facility Type | Average Number of Days | | | |
|---|---|---|---|---|
| | Between CON Decision and Request for Board Review | Between Request for Board Review and ALC Filing | Between ALC Filing and ALC Decision Date | Between CON Decision and ALC Decision |
| Ambulatory Surgery Facility | 14 | 70 | 313 | 396 |
| Diagnostic Imaging | 10 | 47 | 252 | 309 |
| Emergency Department | 13 | 55 | 607 | 675 |
| Home Health | 41 | N/A | N/A | *N/A |
| Hospital | 14 | 67 | 256 | 337 |
| Nursing Home | 14 | N/A | N/A | *N/A |
| Radiation Therapy | 9 | 34 | N/A | *N/A |
| Overall Average | 14 | 60 | 331 | 405 |

*These figures are not applicable because no projects with these facility types were filed with the ALC.

Source: LAC Analysis of DHEC Data

While the number of applications that are appealed to the ALC is relatively small, Table 4.2 shows that the length of time applications spend in the ALC appeals process can be substantially longer than the CON application process. See *Opportunity Cost of CON-Related Litigation* for a discussion of the appeals process beyond the ALC.

## Opportunity Cost of CON-Related Litigation

Litigation arising from DHEC decisions on CON applications generally causes project delays and may increase costs, especially litigation beyond the Administrative Law Court (ALC). Litigation usually does not result in court decisions that reverse the DHEC decisions. Out of 51 unique cases identified in a search of ALC orders issued from 2018 to September 2021, the ALC issued a final opinion after full litigation in only 11 cases, and only 4 of those reversed the agency's decision.

### Litigation Causes Project Delays

S.C. Code §1-23-600(G)(2) places an automatic "stay" on granted CONs if an affected party files a request for a contested case hearing to the ALC for review of the agency decision. This essentially suspends the project. The ALC may lift the stay under certain circumstances. Of the CON-related decisions issued by the ALC that we reviewed from 2018 through September 2021, we identified only three projects for which it was actually lifted while litigation was pending.

DHEC's Office of General Counsel handles CON-related litigation. CON-related litigation is tracked in an internal spreadsheet. During our review, in October 2021, 12 CON-related cases were pending before the ALC, and 5 were pending before the South Carolina Court of Appeals. CON litigation before the ALC is subject to an 18-month time limit, per statute—longer than the typical 12-month time limit for ALC cases. However, the litigation can extend even beyond the 18-month limit if the parties agree to an extension, or if the ALC finds substantial cause for an extension. ALC final decisions regarding CON may be appealed to the Court of Appeals. In turn, a final decision from the Court of Appeals could seek a final appeal before the Supreme Court of South Carolina. Providing for direct appeal from the ALC's final decisions to the Supreme Court could reduce the amount of CON lititgation.

Cumulatively, these projects had been pending in litigation for over 25 years, including a cumulative 17 years before the ALC, and nearly 8 years before the Court of Appeals. Table 4.3 details our analysis of the average number of days cases had been pending, by each facility type. Additional analysis of the time CON cases spent pending before the ALC can be found in *Length of CON Application Process*.

## Table 4.3: Active Cases and Average Number of Days Pending in Litigation by Facility/Service/Equipment Type

| Facility/Service/Equipment Type | | ALC | CoA | Overall Average |
|---|---|---|---|---|
| Ambulatory Surgical Facility | Cases (Number) | 2 | - | 2 |
| | Days Pending (Avg) | 27 | - | 27 |
| Hospital/Cardiac Catheterization Services (Diagnostic cath lab) | Cases (Number) | 1 | 1 | 2 |
| | Days Pending (Avg) | 180 | 1,837 | 1,009 |
| Hospital/Cardiac Catheterization Services (Emergent and Elective PCI) | Cases (Number) | 1 | - | 1 |
| | Days Pending (Avg) | 217 | - | 217 |
| Hospital/Freestanding Emergency Service | Cases (Number) | 2 | 1 | 3 |
| | Days Pending (Avg) | 345 | 1,411 | 700 |
| Hospital/Imaging Services (MRI) | Cases (Number) | 1 | 1 | 2 |
| | Days Pending (Avg) | 1,107 | 406 | 757 |
| Hospital/Neonatal Services (Intensive Care Bassinets) | Cases (Number) | 1 | - | 1 |
| | Days Pending (Avg) | 169 | - | 169 |
| New Ambulatory Surgical Center | Cases (Number) | 1 | - | 1 |
| | Days Pending (Avg) | 218 | - | 218 |
| New Hospital | Cases (Number) | 2 | 1 | 3 |
| | Days Pending (Avg) | 182 | 1,107 | 490 |
| Radiation Therapy Services (Linear Accelerator) | Cases (Number) | 1 | 1 | 2 |
| | Days Pending (Avg) | 224 | 1,321 | 773 |
| TOTAL Number of Cases | | 12 | 5 | 17 |
| TOTAL Average of Days Pending | | 269 | 1,216 | 547 |

ALC = Administrative Law Court
CoA = Court of Appeals
PCI = Percutaneous Coronary Intervention
MRI = Magnetic Resonance Imaging

Source: LAC Analysis of DHEC Data

On average, projects appealed to the Court of Appeals had been pending over 2½ years longer than cases before the ALC. However, the Court of Appeals cases, as a group, had spent more time at the ALC level than before the Court of Appeals, indicating that the delay may be more attributable to the inherent complexity of certain cases than to simple legal bureaucracy.

In one case, providers contesting the construction of an acute care hospital in Fort Mill exhausted their appeals in February 2019—nearly 13 years after DHEC issued a decision on the CON applications in 2006. During that time, the populations of Fort Mill and nearby Tega Cay increased by 105%. The hospital is expected to open in September 2022.

## Litigation is Costly and Can Impact Project Costs

CON litigation itself can be costly. Annual expenditures for DHEC's Office of General Counsel attributable to the CON program averaged $172,952 in state FY 18-19, FY 19-20, and FY 20-21. The cost of litigation for providers is likely much higher. For example, a small hospital system recently exceeded its monthly budget for legal services by over $300,000 due to its ongoing litigation before the Administrative Law Court, contesting a CON that DHEC issued to a competitor for an ambulatory surgical center.

Delays from litigation can also lead to changing costs and design of the project itself. In the Fort Mill hospital project, the provider's initial 2010 cost estimate was $140 million; a 2017 news article noted a lower estimated cost of $120 million, and a 2021 article noted a higher estimated cost of $170 million. The design of the Fort Mill hospital project has also necessarily changed along with developments in the healthcare industry since the first applications were filed. A 2020 news article reported that the hospital's design had changed to reflect both present and expected future healthcare needs. And in at least one other case, a provider revised its project during litigation in a way that reduced the overall project cost. A detailed analysis of project cost estimates and actual final project costs can be found in *Evaluation of CON Project Costs*, although the analysis is not specific to project cost changes caused by litigation.

Our review of cases that were contested before the ALC further corroborated the perverse incentives to challenge competitors' projects under the current CON program. In one instance, providers in Horry County that had submitted separate, non-competing CON applications for different facilities each challenged the other's application. The providers then used their challenges as bargaining chips in agreeing to dismiss each other's cases, citing the delay and cost of CON challenges and appeals.

## Recommendation

10. The S.C. General Assembly should consider restricting the extent of judicial review of final Certificate of Need (CON) decisions issued by the S.C. Department of Health and Environmental Control, including:

    Eliminating the special 18-month time limit to the pendency of contested case hearings regarding CON decisions before the Administrative Law Court (ALC), or otherwise reducing the time limit;

    Eliminating the party consent and/or good substantial exceptions to the pendency of contested case hearings before the ALC;

    Requiring direct appeal of the ALC's final decision to the Supreme Court of South Carolina, bypassing Court of Appeals review.

## Overall Impact of Incumbent Providers on CON Program

An incumbent provider can be involved in various points of DHEC's CON process within the disposition of an application and the opportunity to appeal a department decision. South Carolina CON laws and regulations are intended to promote cost containment and prevent unnecessary duplication of health care facilities and services, yet opponents of CON laws argue that the programs shield incumbent healthcare providers from market competition. Studies provide mixed results on the effects of the association between incumbent providers and the presence of CON laws.

In South Carolina, most CON applications accepted for filing do not face opposition, competing applications, or legal challenges. However, DHEC officials explained that the length of the appeals timeline is one of the biggest complaints the CON program receives, and the majority of legal challenges stem from existing providers appealing an approved CON. Due to the complexity of the healthcare system, it is difficult to determine whether a reduction in services or facility closures are a direct result of a CON decision. Overall, statutory, regulatory, and programmatic mechanisms allow incumbent provider involvement in DHEC's CON process.

## Potential Effects of CON Program on Incumbent Providers

While some argue that CON laws reduce or remove the benefits of competition by limiting facilities and services and insulating incumbent providers, others maintain that CON laws allow for incumbent providers to cross-subsidize charity care to underserved areas.

Opponents of CON programs state the laws prevent new entrants from the healthcare market and protect incumbent provider market share. Opponents of CON programs state incumbent providers may exploit the CON process, which could:

- Exacerbate anticompetitive harm.
- Reduce the competitive pressures for incumbent providers to enhance existing services or launch new services.
- Reduce the pressure on incumbent providers to control costs.

The evidence on the association between CON laws and the reduction in competitive pressures for incumbent providers is mixed. A 2017 study authored by Kennesaw State University a relationship between CON laws and an increase in healthcare competition by restricting excessive expansion from incumbent providers. However, a 2020 study published in *BMC Health Services Research* journal found that a repeal of CON in Pennsylvania improved healthcare outcomes of a particular service as the volume shifted from incumbent providers to new entrants.

An argument for CON laws is that the programs allow for incumbent providers to act as safety-net providers by cross-subsidizing charity care. An official representing a healthcare system in South Carolina maintained that the CON program allows for the system to cross-subsidize its services to low-income areas and that a full repeal of CON would negatively impact those areas. That official alluded to the potential for low-income facility closures in response to a CON repeal. The 2006 Federal Trade Commission working paper, “Hospital Competition and Charity Care,” determined that incumbent providers do not use their market control to cross-subsidize charity care, but this analysis did not include public hospitals.

## Incumbent Providers in South Carolina

S.C. Code § 44-7-130 (1) states an "affected person" includes "persons located in the health service areas in which the project is to be located and who provide similar services to the proposed project." Therefore, incumbent providers are considered "affected persons." A DHEC official explained the role of incumbent providers can often be very helpful, because those providers relay pertinent information to DHEC about a service area. However, this official also claimed that incumbent providers, at times, want to protect their market share.

In South Carolina from January 1, 2018 through September 30, 2021, 83% of CON applications accepted for filing did not have affected persons nor competing applications. Approximately 10% of the applications during that same time were legally challenged, and DHEC officials explain the majority of legal challenges stemmed from existing providers challenging the decision to approve a new CON.

## Public Notifications and Hearings

Prior to making a department decision, DHEC must comply with all requirements for public notice, receipt of public comments, and public hearing, all of which allow for affected person involvement. Per S.C. Code §44-1-60 (D), department staff shall take into consideration all material comments received in response to the public notice in determining whether to issue, deny, or condition a certificate. According to a DHEC official, most of the feedback the program receives is from competing organizations in the marketplace and not the general public.

The public is notified of certain stages of CON applications through newspaper and State Register publications. A provider must publish their intent to apply for a CON in the local newspaper for 3 consecutive days within 20 days prior to the submission of the application. Once an application is accepted for filing, DHEC publishes a notice in the State Register. The review period begins once an application is deemed complete and affected persons have been notified. DHEC subsequently publishes in the State Register a notification of the beginning of the review period.

An affected person can request a public hearing within 30 days of the notification of the beginning of review. If a public hearing is requested, DHEC is allotted 150 calendar days from the date affected persons are notified to make a decision on a complete application. The intent of the public hearing is to provide an opportunity for any person to present information relevant to the application.

## Application Process—Department Review and Decision-Making

DHEC must consider incumbent providers during its application review and decision-making. DHEC must follow the SHP and relevant statutory and regulatory requirements during the decision-making process. A DHEC official explained that all information received by the department is reviewed and considered when deciding on an application.

For an application to be issued, it must be in compliance with the SHP and the project review criteria outlined in S.C. Reg. §61-15.802. As delineated in the project review criteria, the proposed project should have the support of "affected persons" and documented opposition to a proposed project will be considered along with the application. Additionally, a proposed project should not "unnecessarily duplicate existing services or facilities in the proposed service area," as unnecessary duplication will not be approved. Furthermore, the criteria consider potential adverse effects that the proposed project will have on existing facilities' occupancy rates and staffing.

In the case of competing applications, DHEC shall award the certification to the applicant that most fully complies with the requirements, goals, and purposes of the CON program, SHP, project review criteria, and any other departmental regulations.

S.C. Codes § 44-1-60 (D) requires the department decision be based off the administrative record including the application and supporting exhibits, all public comments and submissions, and other supporting documents.

## Contested Department Decisions—Request for Final Review and Appeals

A DHEC official explained the largest number of complaints about the CON program stem from the appeals' timeline, and that the extended timeline is often a result of providers seeking to delay or stymie competition. Another DHEC official clarified most appeals litigation involved an approved project that another provider is challenging, and that it is generally existing providers challenging the decision to approve a new CON. Incumbent providers can oppose DHEC's application decision at two points in the application process:

1) Prior to the final agency decision by requesting a final review conference.
2) After the final agency decision is made by requesting a contested hearing before the Administrative Law Court.

Both final review conferences and legal challenges can increase the amount of time required to finalize a CON application.

Prior to the final agency decision, an affected person can request a final review conference. The initial decision made on the issuance of a CON application is referred to as the "staff decision." The DHEC staff decision becomes the final agency decision unless there is a request for a final review. If a person provided a written notice to DHEC during staff review that he is an affected person, the affected person can file a request for final review in opposition to the staff decision of a CON application.

DHEC has the option to deny the request for final review. During a final review conference, the staff provides an explanation for their decision and the materials used to reach that decision. The applicant or affected party presents their reasoning for contesting the staff decision. A final agency decision is made no later than 30 days of the final review conference.

An affected party may request a contested case hearing before the Administrative Law Court. This request is made 30 days after either the request for final review was denied, the deadline to hold a final review lapsed, or the final agency decision from the final review was received by the parties.

Table 4.4 shows the CON applications accepted for filing from January 1, 2018 through September 30, 2021 by department decisions and the number of opposed and/or competing applications.

**Table 4.4: Number of Applications Approved, Denied, and Opposed/Competing, January 1, 2018–September 30, 2021**

| Department Decision | Application Count | Opposed/Competing Application Count | Percentage Opposed/ Competing |
|---|---|---|---|
| Approval | 345 | 54 | 16% |
| Denial | 9 | 7 | 78% |
| Approval/Denial | 1 | 1 | 100% |
| Approval/Withdrawal | 1 | 1 | 100% |
| Withdrawal | 14 | 2 | 14% |
| N/A | 20 | 2 | 10% |
| TOTAL | 390 | 67 | 17% |

Source: LAC Analysis of DHEC Data

From January 1, 2018 through September 30, 2021, DHEC's CON program received 390 CON applications. Of those 390 applications, 345 were approved. Approximately 16% of the approved applications during this timeframe faced opposition by affected persons and/or were competing with another application. Only nine applications were denied, and one application received partial denial. Of the nine applications that were denied, seven applications were either opposed by affected persons or competing with another application.

Table 4.5 shows the CON applications accepted for filing from January 1, 2018 through September 30, 2021 by department decisions and the number of legally challenged applications.

**Table 4.5: Number of Applications Approved, Denied, and Legally Challenged, January 1, 2018–September 30, 2021**

| Department Decision | Application Count | Legally Challenged Application Count | Percentage Legally Challenged |
|---|---|---|---|
| Approval | 345 | 34 | 10% |
| Denial | 9 | 6 | 67% |
| Partial Approval/ Partial Denial | 1 | 0 | 0% |
| Partial Approval/ Partial Withdrawal | 1 | 1 | 100% |
| Withdrawal | 14 | 0 | 0% |
| N/A | 20 | 0 | 0% |
| TOTAL | 390 | 41 | 11% |

Source: LAC Analysis of DHEC Data

Forty-one out of the 390, or 11%, of the applications were legally challenged. Of the 345 applications that were accepted, approximately 10% were legally challenged. Six of the nine denied applications were legally challenged, but all six of those challenges were filed by the denied applicants themselves.

## Closures or Reductions of Services Despite Incumbent Provider Objections

It is unclear whether South Carolina healthcare facilities have experienced closures or reductions in services despite objections from incumbent providers. According to an official from the South Carolina Hospital Association, it would be difficult to ascertain whether a CON approval directly resulted in closures or reduced services. A DHEC official explained he witnessed closures or reductions in services due to market changes, but he is not aware of any closures or reductions in services of an incumbent provider as a result of a CON decision. Overall, healthcare markets are complex and multifaceted with various reasons for provider entry and exit. While CON laws may play a role in facility closures and/or service reduction, it would be conjectural to claim that an approval of a CON application directly caused a facility closure or reduction of services of another healthcare provider.

It should be noted, despite the presence of a CON law in South Carolina, the following rural hospitals have closed since January 2005:

- Marlboro Park Hospital
- Southern Palmetto Hospital
- Bamberg County Memorial Hospital
- Fairfield Memorial Hospital

## Examples of CON Process Deterring Applicants for New or Expanded Facilities and Services

South Carolina's current CON program deters some healthcare providers from applying to open or expand new facilities and services, or acquire new equipment, across a range of practice types and sizes. We contacted major state medical industry and professional associations, as well as individual doctors. There was broad acknowledgement among the healthcare providers and medical professionals that we contacted in South Carolina that the current CON program acts as a deterrent for *some* providers or potential providers, or at the very least can cause frustration and reluctance. While the full extent of potential deterrence is not clear, we were told that CON acted as a deterrent in the following specific instances:

- Two instances of different cancer centers with multiple locations, based in the Pee Dee and Midlands, that delayed or have outright declined seeking MRI machines due to concerns about potential costly opposition in the CON application process from other providers; one of these providers also declined to pursue operating a radiation treatment center.
- An ear, nose, and throat practice in the Upstate declined to both acquire diagnostic equipment and build an ambulatory surgical center, also due to concerns about potential costly CON opposition and legal challenges.
- A gastroenterology practice in the Pee Dee that declined to apply for a CON to open an endoscopy center to avoid costly opposition from another provider and potential negative publicity.
- Finally, a cardiology practice in the Midlands applied for a CON, which was denied after review by DHEC. We were told the practice declined to pursue judicial review of the decision due to the anticipated cost of litigation from opposing providers.
- Additionally, a doctor certified in family medicine who is interested in opening an outpatient or ambulatory surgical center in the Lowcountry characterized the CON process to us as daunting and burdensome, and raised concerns about it taking time away from primary care work and family.

Many of these providers, associations, and medical professionals also identified other, non-CON issues that may also serve as deterrents to opening or expanding facilities and services, such as:

- Non-compete agreements between physicians and existing healthcare providers.
- Revoking or restricting hospital admitting privileges and credentials.
- Provider and third-party insurer referral patterns.
- Other competitive advantages enjoyed by larger and/or tax advantaged institutions.

## Recommendations

11. The S.C. General Assembly should reform or repeal the State Certification of Need and Planning Act to exclude any review of low-cost facilities and equipment such as MRI machines and ambulatory surgical centers.

12. The S.C. General Assembly should consider restricting or regulating other anti-competitive practices in the healthcare industry, such as non-compete agreements.

## Post-Issuance Procedure

We reviewed relevant law and agency practice, and found that the agency staff continue to monitor projects for which DHEC issues a CON until the project is completed, and holders of a CON must make regular progress reports to the agency. The agency also retains authority to revoke or void a CON during this period if the project fails to make timely progress. However, the agency's internal tracking spreadsheet does not indicate that most progress reports were actually reviewed for CONs issued since 2019. Also, there is no regular review of the tracking spreadsheet to ensure it is complete and accurate.

If DHEC revokes a project's CON, that provider is ineligible to apply for any CON for one year; all potential providers must re-apply for that project's CON according to the normal procedure. Staff familiarity with the project and any prior applications may result in the relatively speedy issuance of a new CON in this scenario.

A graphic representation of the post-issuance procedure is shown in Figure 4.6.

## CON Issuance to Final Project Completion

After considering a CON application and making a final decision, DHEC issues the certificate of need via letter. The letter includes a timetable for the project, as submitted by the applicant. There are two major milestones for each project that receives a CON—implementation and final completion. Any project valued at over $1.4 million must also pay a $7,500 issuance fee within 15 days of receiving its CON.

### Implementation

Implementation of a CON occurs when:

- A detailed contract for the construction of the actual structure is executed (if the project is construction),
- A purchase order, lease, or service agreement is executed (if the project is equipment acquisition), or
- A new service is licensed by DHEC (if the project is a new licensed service).

All projects must be implemented within 12 months of the issuance of the CON. However, this deadline may be extended indefinitely in 9-month increments if the CON holder timely requests an extension and DHEC determines that the provider is making "substantial progress" on the project. Substantial progress includes site acquisition, architectural development, and progress towards financing.

### Final Completion

Final completion occurs when the project is fully completed and serving its intended purpose as described in the CON. The provider must send a Final Completion Report to DHEC. Once DHEC determines that the Final Completion Report is adequate, it issues a Closeout Letter and the CON is closed.

### Quarterly Progress Reports

During the entire post-issuance period, providers must submit quarterly progress reports to DHEC. The schedule for the quarterly progress reports is noted on each project's issuance letter when the provider first receives the CON.

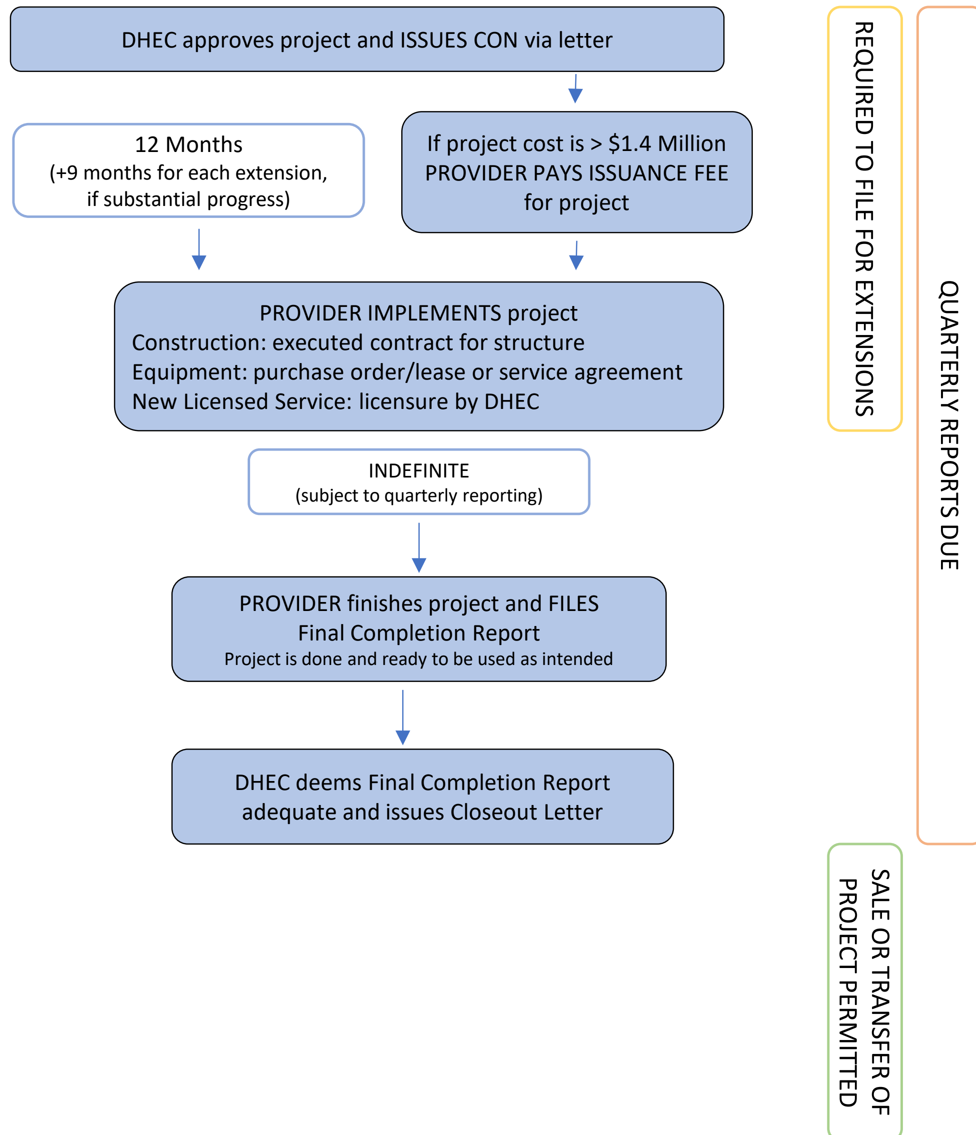
## Sale/Transfer of CON and Other Criteria to Revoke or Void

A CON may not be sold or transferred in any way during the post-issuance period. Once DHEC determines that the final completion report is adequate and closes the CON, the project may then be sold or otherwise transferred. An attempt to sell or transfer the CON, or the entity directly or indirectly holding it, results in the immediate voidance of the CON, and a one-year prohibition on applying for any new CON without approval from the DHEC Board.

If the CON's term expires before implementation without a proper extension, DHEC may void and revoke the CON. DHEC may also void and revoke a CON at any time for failure to meet the applicant's proposed timetables, or for failure to file quarterly progress reports. DHEC staff indicated that they generally advise providers of any outstanding items or deadlines rather than revoke CONs outright.

If DHEC revokes or voids a CON for any reason, all potential providers must re-apply for that project's CON according to the normal process and procedure. However, staff familiarity with the important review criteria and potential providers for the project could accelerate the timeline for review of any re-filed applications.

## Figure 4.6: Certificate of Need Procedure after Issuance




Source: S.C. Code of Laws, S.C. Code of Regulations 61-15, and DHEC Guidance

## Staff Review of Issued CONS

DHEC's CON staff regularly tracks issued CONs and essential deadlines on an internal agency spreadsheet. The spreadsheet notes whether quarterly progress reports have been received and reviewed by staff, and whether a CON holder has requested any extensions of the implementation deadline. Staff use of this tracking spreadsheet greatly reduces the risk of projects inappropriately lagging or being hoarded by providers.

DHEC's CON staff performed an audit of the status of CON holders' quarterly progress reports in 2017, but did not create any written findings of the results of the audit. Staff does not conduct regular audits of this spreadsheet, likely due to lack of staff time available to dedicate towards these types of projects. Our review of the quarterly progress reports tracking spreadsheet as of November 2021 found projects that were not marked as received. We also found that a minority of reports due for CONs issued from 2019 onward were actually marked as reviewed by DHEC staff.

## Recommendation

13. The S.C. Department of Health and Environmental Control should allocate additional staff to perform an annual review of the agency's tracking spreadsheet for issued Certificates of Need.

## Treatment of CONs After Purchase/Transfer of Existing Providers

CONs are valid for one year from the date of issuance, but DHEC can grant two extensions of up to nine months each if there is evidence of substantial progress. If, during the one-year period after issuance or subsequent extension period, the controlling interest or majority ownership of an existing provider who has an open CON is transferred, the CON for which the project was approved cannot be included in the transfer or the CON will become void. This is because CONs are nontransferable, per S.C. Code §44-7-230(E), which says that selling, transferring, or even attempting to transfer a CON would result in its immediate voidance. CONs that have been issued must be fulfilled prior to a change in ownership, otherwise the new owner must reapply for all CONs voided during the sale/transfer.

### Reduction or Closure of Services and Beds

If an existing provider wants to permanently reduce bed capacity or close a health care facility, it would be exempt from CON review. However, it would still need to obtain a written determination from DHEC prior to undertaking these actions. In addition, various sections of S.C. regulations require facilities to return their license to DHEC and provide information on the maintenance of records, identification of displaced patients, etc. if they plan to permanently close.

According to DHEC staff, this provides a way for the CON program to track facility closures and bed reductions for use when updating charts that contain inventories and projections of need in the Health Plan. However, the charts are not updated immediately following a facility closure or permanent bed reduction. Instead, the charts are updated with each revised Health Plan, which is required to be updated at least every two years. Nonetheless, DHEC staff stated that a reduction or closure would immediately impact how the agency counts inventory.

When asked if community impact is considered when a provider wants to permanently reduce beds or services, or permanently close a facility, DHEC staff stated that it is not considered. DHEC staff also do not use this information to review previously denied applications. According to DHEC staff, a provider whose previous application was denied would be required to file a new application and comply with the public notice requirements and other applicable requirements for CON review.

# Minimum and Maximum Amounts Approved for CON Projects by Facility and Service Type

| January 1, 2018 – November 1, 2021 | | | | |
|---|---|---|---|---|
| **Facility Type** | **Service Type** | **Minimum** | **Maximum** | **Range** |
| **Ambulatory Surgical Facility** | Add Square Feet | $450,573 | $19,894,166 | $19,443,593 |
| | Endoscopy | $1,964,000 | $4,399,413 | $2,435,413 |
| | Ear, Nose, and Throat | $10,428,069 | $10,428,069 | $0 |
| | No Service Type | $2,870,865 | $13,926,702 | $11,055,837 |
| | Ophthalmic | $3,984,230 | $3,984,230 | $0 |
| **Cancer Center** | Linear Accelerator | $3,926,310 | $3,926,310 | $0 |
| | Linear Accelerator/ Magnetic Resonance Imaging | $3,566,051 | $3,566,051 | $0 |
| **Diagnostic Imaging** | Magnetic Resonance Imaging & Computerized Tomography Scanner | $2,002,400 | $2,099,825 | $97,425 |
| | Magnetic Resonance Imaging | $1,907,721 | $1,907,721 | $0 |
| | No Service Type | $625,000 | $12,328,994 | $11,703,994 |
| **Emergency Department** | No Service Type | $8,924,000 | $15,298,187 | $6,374,187 |
| **Home Health** | Home Health | $1,500 | $78,834 | $77,334 |
| **Hospice** | Inpatient Hospice | $145,030 | $145,030 | $0 |
| | No Service Type | $6,565,000 | $6,565,000 | $0 |

| January 1, 2018 – November 1, 2021 | | | | |
|---|---|---|---|---|
| Facility Type | Service Type | Minimum | Maximum | Range |
| **Hospital** | Acute Care Beds | $14,964,996 | $14,964,996 | $0 |
| | Add Square Feet | $3,894,898 | $22,500,000 | $18,605,102 |
| | Bed Addition | $333,810 | $22,656,000 | $22,322,190 |
| | Bed Transfer | $65,000 | $65,000 | $0 |
| | Cardiac Catheterization | $0 | $2,961,659 | $2,961,659 |
| | Computerized Tomography Scanner | $1,803,793 | $1,803,793 | $0 |
| | Diagnostic Imaging | $1,528,768 | $1,955,726 | $426,958 |
| | Emergency Department | $12,400,000 | $37,583,218 | $25,183,218 |
| | Electrophysiology Lab | $2,650,525 | $7,062,274 | $4,411,749 |
| | Emergent/Elective Percutaneous Coronary Intervention | $0 | $5,008,938 | $5,008,938 |
| | Hospital | $2,200,000 | $39,000,000 | $36,800,000 |
| | Hybrid Operating Room | $4,269,096 | $20,759,624 | $16,490,528 |
| | Inpatient Psychiatric | $1,451,966 | $1,451,966 | $0 |
| | Magnetic Resonance Imaging | $2,654,407 | $3,038,620 | $384,213 |
| | Neonatal Intensive Care Unit | $503 | $1,969,293 | $1,968,790 |
| | No Service Type | $325,000 | $11,199,999 | $10,874,999 |
| | Psychiatric | $50,000 | $35,529,725 | $35,479,725 |
| | Psychiatric Beds | $0 | $34,700,000 | $34,700,000 |
| | Radiation | $2,400,000 | $8,853,649 | $6,453,649 |
| | Radiology | $3,737,048 | $8,500,000 | $4,762,952 |
| | Radiosurgery | $2,347,725 | $2,347,725 | $0 |
| | Radiotherapy | $11,608,014 | $11,608,014 | $0 |
| | Rehabilitation Beds | $1,225,540 | $3,988,056 | $2,762,516 |
| | Relocation | $3,224,054 | $3,224,054 | $0 |
| | Robotic Surgery | $1,132,250 | $9,660,000 | $8,527,750 |
| | Substance Abuse | $0 | $0 | $0 |
| **Linear Accelerator** | No Service Type | $5,259,629 | $5,259,629 | $0 |
| **Magnetic Resonance Imaging** | No Service Type | $1,950,114 | $1,950,114 | $0 |

| January 1, 2018 – November 1, 2021 | | | | |
|---|---|---|---|---|
| **Facility Type** | **Service Type** | **Minimum** | **Maximum** | **Range** |
| **No Facility Type** | Magnetic Resonance Imaging | $1,705,281 | $1,705,281 | $0 |
| | No Service Type | $2,074,992 | $119,808,964 | $117,733,972 |
| **Narcotic Treatment Program** | No Service Type | $114,400 | $156,500 | $42,100 |
| **Nursing Home** | Bed Conversion | $50,000 | $50,000 | $0 |
| | No Service Type | $15,397,458 | $56,457,735 | $41,060,277 |
| | Nursing Home | $944,540 | $35,813,632 | $34,869,092 |
| **Opioid Treatment Program** | Narcotic | $129,200 | $129,200 | $0 |
| | No Service Type | $107,357 | $696,457 | $589,100 |
| | Opioid Treatment Program | $111,200 | $111,200 | $0 |
| **Psychiatric Facility** | Substance Abuse | $2,364,837 | $2,364,837 | $0 |
| **Radiation Oncology** | Linear Accelerator | $10,836,005 | $12,014,596 | $1,178,591 |
| **Rehabilitation Beds** | No Service Type | $25,628 | $25,628 | $0 |
| **Rehabilitation Facility** | Rehabilitation | $36,659,910 | $36,661,437 | $1,527 |
| | Rehabilitation Beds | $6,254,842 | $39,997,285 | $33,742,443 |
| **Residential Treatment Facility** | No Service Type | $25,349 | $5,238,320 | $5,212,971 |
| | Residential Treatment Facility | $649,580 | $649,580 | $0 |

Note: "No Service Type" means that there was no service type listed for a project in DHEC's CON application data. Likewise, "No Facility Type" means that there was no facility type listed for a project in DHEC's CON application data.

Source: LAC Analysis of DHEC Data

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# Agency Comments

## Appendix C
## Agency Comments

Edward D. Simmer, MD, MPH, DFAPA
Director

February 4, 2022

K. Earle Powell, Director
Legislative Audit Council
1331 Elmwood Avenue, Suite 315
Columbia, SC 29201

Re: Agency Response to Legislative Audit Council's Report, *A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program*

Dear Director Powell:

Thank you for the Legislative Audit Council's staff efforts over the past months to thoroughly review the South Carolina Department of Health and Environmental Control's Certificate of Need Program. The Department appreciates the work undertaken by LAC and the detailed analysis and thoughtful recommendations presented in LAC's report. The Department will implement LAC's recommendations that are within the Department's authority to achieve.

In particular, the Department plans to implement LAC's recommendations as follows:

- Recommendation No. 4: The S.C. Department of Health and Environmental Control should ensure that certificate of need waivers relating to the Governor's executive orders are properly tracked.
  - The Department will ensure it properly tracks certificate of need waivers pursuant to any executive order or other authority allowing for such waivers in the future.
- Recommendation No. 5: The S.C. Department of Health and Environmental Control should ensure that it adequately responds to requests for certificate of need waivers pursuant to the Governor's executive orders.
  - The Department will ensure it adequately and timely responds to requests for certificate of need waivers pursuant to any executive order or other authority allowing for such waivers in the future.
- Recommendation No. 6: The S.C. Department of Health and Environmental Control should add appropriate, quantitative quality metrics from the Center for Medicare and Medicaid Services to the State Health Plan.
  - The Department will implement this recommendation by proposing the addition of appropriate quantitative quality metrics to the State Health Planning Committee during the next revision to the State Health Plan.

- Recommendation No. 7: The S.C. Department of Health and Environmental Control should further standardize the information required of certificate of need applicants to ensure consistency in its evaluation process.
    - The Department will implement this recommendation to the extent possible pursuant to existing authority through requests for additional information during the certificate of need application process. Additionally, the Department will pursue such changes as may be appropriate to the State Health Plan and to Regulation 61-15 during the next revision to each to further implement this recommendation.
- Recommendation No. 8: The S.C. Department of Health and Environmental Control should require certificate of need applicants to provide information on net patient charges when project impact on patient charges is a factor in the evaluation process.
    - The Department will implement this recommendation to the extent possible pursuant to existing authority through requests for additional information during the certificate of need application process. Additionally, the Department will pursue such changes as may appropriate to the State Health Plan and to Regulation 61-15 during the next revision to each to further implement this recommendation.
- Recommendation No. 9: The S.C. Department of Health and Environmental Control should amend S.C. Reg. §61-15.607(3) to require certificate of need applicants to report on non-capital expenses related to a project.
    - The Department will implement this recommendation by proposing an amendment to Section 607(3) during the next revision to Regulation 61-15.
- Recommendation No. 13: The S.C. Department of Health and Environmental Control should allocate additional staff to perform an annual review of the agency's tracking spreadsheet for issued Certificates of Need.
    - The Department will implement LAC's recommendation. The Department has allocated one additional agency administrative staff position to the Certificate of Need Program and is in the process of filling existing vacancies. The Department will continue to evaluate staffing needs and will ensure it has sufficient staff to review and track project implementation of final Certificate of Need decisions.

The Department also appreciates the recommendations LAC addresses to the General Assembly for its consideration. Of those, one recommendation could be implemented through a regulatory change:

- Recommendation No. 3: The S.C. General Assembly should increase the thresholds for equipment and capital expenditures for the certificate of need program and provide for the adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

- The Department will propose increases to the regulatory thresholds for equipment and capital expenditures and provide for the adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index during its next regulatory revision process for Regulation 61-15, in the event the General Assembly has not addressed this recommendation or made other applicable legislative changes to the Certificate of Need laws in the meantime.

We are aware the Legislature is discussing pending bills related to Certificate of Need, the outcome of which may provide direction to the Department. As such, we plan to publish a Notice of Drafting soon, and move forward with regulatory revisions as discussed above later this year. Our goal is to submit revisions to the regulation to our Board in the Fall and, if approved, to the Legislature for consideration in 2023.

We appreciate the opportunity to present this response to LAC's draft report concerning the CON program. Should you have any questions concerning this important issue, please do not hesitate to contact my office.

Sincerely,

Edward D. Simmer

cc: Gwendolyn Thompson, Director, Healthcare Quality, DHEC

LAC/21-5

This report was published for a total cost of $118; 25 bound copies were printed at a cost of $4.72 per unit.