AMERICANS FOR PROSPERITY FOUNDATION

Permission to Care:

How North Carolina's Certificate of Need Law Harms Patients and Stifles Health Care Innovation

About Americans for Prosperity Foundation

Americans for Prosperity Foundation is a 501(c)(3) nonprofit organization committed to educating and training Americans to be courageous advocates for the ideas, principles, and policies of a free and open society.

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Executive Summary

Certificate of need ("CON") laws in North Carolina harm patients who need medical care while deterring new jobs and health care investment in the state. American for Prosperity Foundation's ("AFPF") analysis of CON applications submitted from 2012 to 2022 found the Department of Health and Human Services ("DHHS") denied almost **$1.5 billion** in health care investment.

Accounting for prohibitive application costs, competitor opposition, and industry gatekeeping, the true value of health care investment foreclosed over the last decade is assuredly much greater than the $1.5 billion in denied CON applications. The result of so much lost health care investment is that North Carolinians pay higher prices for less access and lower quality health care.

Health care entrepreneurs in North Carolina face severe barriers to entry. AFPF estimates applicants paid an average fee of around $13,000 per CON application. The application fee does not include the cost of legal representation or outside consultants to prepare applications and fend off opposition, which can balloon up to hundreds of thousands of dollars.

The CON statute allows competing providers to challenge others' CON applications. DHHS makes appeal data available for petitions filed since January 2020. During that time, applicants appealed DHHS' decisions on CON applications for nearly $1 billion in proposed capital expenditures. Approximately half of the appeals are from competing providers contesting CON approvals, tying up roughly $423 million in approved capital expenditures in litigation. These appeals unnecessarily prevent and delay the development of new health care provisions.

North Carolina's CON regime empowers the State Health Coordinating Council to determine the state's health care needs. AFPF's analysis of current Council members found that at least 15 of the 25 current members are employed or affiliated with health care providers regulated by the Council. The Council members act as gatekeepers protecting the incumbent care providers with which they are affiliated from competition.

In the last decade, state bureaucrats have denied over $1 billion in new investment, and potentially deterred just as much, in one of North Carolina's most vital industries: health care. Specifically, North Carolina's certificate of need ("CON") laws and regulations empower these bureaucrats, rather than patient demand, to decide whether new health care services are needed.

The CON laws require health care providers to obtain approval from the Department of Health and Human Services ("DHHS") before acquiring, replacing, or adding facilities, services, or equipment. DHHS states, "[t]he fundamental premise of the CON law is that increasing health care costs may be controlled by governmental restrictions on the unnecessary duplication of medical facilities."[1]

Fifty years ago, lawmakers believed they could control rising health care costs by preventing providers from offering the same services in the same proximate area. In 1974, Congress mandated states establish CON laws to receive federal health care funds. Congress lifted the mandate in 1987 after CON laws proved ineffective at controlling costs. At least a dozen states have since repealed their CON laws.

However, North Carolina's CON scheme persists to protect incumbent care providers from competition by limiting the supply of health care in the state at the patients' expense. Indeed, DHHS does not even claim the CON law reduces health care costs; instead, the agency suggests that CON *may* control increasing health care costs [emphasis added].[2] Americans for Prosperity Foundation's ("AFPF") review of North Carolina's CON program finds otherwise.

CON Creates a Prohibitive and Stagnant Health Care Market

CON precludes a tremendous amount of new health care investment in North Carolina. AFPF's analysis of CON applications from January 2012–June 2022 finds DHHS denied approximately $1.5 billion in proposed health care investment. But this just scratches the surface: the mere existence of the prohibitive CON program actively prevents an untold number of health care entrepreneurs from even trying to apply and enter the market.

North Carolina has one of the nation's most expansive CON laws.[3] Only one state regulates more services.[4] In total, the Tar Heel State has an eye-popping 61 different types of CON regulating beds, services, equipment, facilities, and emergency medical transport.[5]

$1.5 BILLION

health care investment denied in the last decade

Obtaining a CON is an expensive and arduous process that takes months to years to complete. CON applications have a non-refundable minimum fee of $5,000 and a maximum of $50,000. The fee is based on the dollar amount of the proposed capital expenditure for the project. **AFPF's analysis of CON applications submitted since 2012 estimates that health care providers paid an average fee of $13,000 per application.**

But the application fee is just the money required to get DHHS to accept the CON application; it does not include the costs of attorneys and consultants necessary to navigate all the red tape to gain approval. The Civitas Institute estimated in 2011 that health care providers, "on average, pay a minimum of $32,000 per Certificate of Need (CON) application."[6] For basic applications, these costs include application preparation consulting fees ranging from $25,000–$35,000 and public hearing consulting fees from $2,000–$15,000, on top of the DHHS application fee.[7] The costs for attorneys to appeal DHHS's decision to approve/disapprove a CON application can cost up to $300,000.[8]

The Institute for Justice reported in 2018 that "[p]utting together an MRI CON application can cost about $40,000—unless the case is contested, which almost always happens with MRI scanners. Then, the costs can top $400,000."[9]

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[1] *Certificate of Need*, N.C. Dep't of Health & Human Servs., https://info.ncdhhs.gov/dhsr/coneed/index.html (last visited Sept. 21, 2022).
[2] *Id.*
[3] *North Carolina and Certificate-of-Need Programs 2020*, Mercatus Ctr. at George Mason Univ. (Mar. 26, 2021), https://www.mercatus.org/publications/certificate-need-laws/north-carolina-and-certificate-need-programs-2020.
[4] *Id.*
[5] Inst. for Justice, CONNING the Competition: A Nationwide Survey of Certificate of Need Laws at 143 (Aug. 2020), *available at* https://ij.org/wp-content/uploads/2020/08/Conning-the-Competition-WEB-08.11.2020.pdf.
[6] Regina Conley, *Certificate of Need: The Cost of the Process*, Civitas Institute, Sept. 16, 2011, https://www.nccivitas.org/2011/certificate-of-need-the-cost-of-the-process.
[7] *Id.*
[8] *Id.*
[9] *North Carolina CON*, Inst. for Justice, https://ij.org/case/north-carolina-con/ (last visited Sept. 21, 2022).

Attorneys are necessary because health care entrepreneurs looking to provide services in the Tar Heel State must overcome opposition from other care providers. North Carolina allows competing providers to intervene in the CON process. First, they can submit public comments to DHHS opposing other providers' applications. Then, after DHHS has issued a decision, an affected party—*i.e.*, the applicant or competing providers—can appeal the decision, embroiling the parties in discovery and litigation that can delay new health care provisions for years.

DHHS makes appeal data available for petitions filed since January 2020. During that time, applicants appealed DHHS' decisions on applications for nearly $1 billion in proposed capital expenditures. Competing providers contesting CON approvals comprise more than half of the appeals, delaying approximately $423 million in already-approved health care investment.

$423 MILLION

in approved health care investment delayed in appeals from competing providers

For example, in 2018, the state identified a need for one mobile PET scanner, a device used to detect conditions such as cancer, heart disease, and brain disorders.[10] Early detection of these diseases is vital to patient outcomes, and PET scanners can detect them before other imaging devices. After receiving applications from four providers, DHHS awarded one the CON. One of the providers whose application was disapproved filed multiple appeals, delaying the deployment of the PET scanner for more than two years until the Court of Appeals of North Carolina ultimately affirmed DHHS' decision in July 2021.[11]

Under North Carolina's CON law, the State Health Coordinating Council ("SHCC") determines the state's need for health care facilities and services. Each year, the SHCC prepares the State Medical Facilities Plan ("SMFP") for the governor's approval. The SMFP includes the need-determination methodologies for most facilities and services regulated under CON for the upcoming year.

Where the SHCC has determined there is no need, DHHS will not accept CON applications for those facilities and services. This scheme prevents many health care entrepreneurs from ever applying to provide new or additional services in the state.

The SHCC board is comprised of members appointed by the governor. AFPF's analysis of current Council members found that at least 15 of the 25 current members are employed or affiliated with health care providers regulated by the Council. These members are incentivized to protect their employers and affiliates from competition through restrictive need methodologies that prevent new entrants into the health care market.

Thus—accounting for prohibitive applications costs, competitor opposition, and industry gatekeeping—it is clear the true value of health care investment foreclosed over the last decade is likely much greater than the $1.5 billion in denied CON applications.

CON regulations further stifle innovation by limiting the implementation of emerging technologies. In states without CON, providers can replace aging and obsolete equipment with new state-of-the-art technology. This is not the case in North Carolina. For example, suppose a provider in the Tar Heel State replaces an outdated specialized MRI machine with a new general-purpose MRI machine that can perform the specialized function AND far more. Under the state's CON law, they are forced to continue providing MRIs for only the specialized purpose for which DHHS initially granted their CON.

One provider subject to this limitation wrote to the SHCC:

> *"This does not enhance services to patients and is inconsistent with the basic principles of safety, quality, access and value governing development of the SMFP and the purpose of the CON Law...it does not make economic sense or serve the best interests of patients to spend approximately $2 million on a general purpose MRI scanner that can only be used for a limited subset of patient needs.*[12]

Patients Pay the Price

Billions of dollars in foregone health care investment means patients in North Carolina have less access to care. The Mercatus Center finds that states with CON have fewer hospitals and ambulatory surgical centers per 100,000 residents.[13] Mercatus estimates that without CON North

[10] N.C. Dep't of Health & Hum. Servs., North Carolina 2018 State Medical Facilities Plan at 140 (2017), *available at* https://info.ncdhhs.gov/dhsr/ncsmfp/2018/2018smfp.pdf.
[11] *Mobile Imaging Partners of N.C. v. N.C. Dep't of Health & Human Servs.*, 862 S.E.2d 217, 2021 NCCOA 302 (N.C. Ct. App. 2021) *available at* https://appellate.nccourts.org/opinions/?c=2&pdf=40407.
[12] Novant Health, Inc., Petition Regarding Existing and Approved Specialized Breast MRI Scanners, Excluded From Planning Inventory at 6 (Mar. 3, 2021) *available at* https://info.ncdhhs.gov/dhsr/mfp/pets/2021/NovantMedQuestBreastMRIPetition.pdf.
[13] Thomas Stratmann & Christopher Koopman, *Entry Regulation and Rural Healthcare: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals*, (Mercatus Ctr. At George Mason Univ. Working Paper, 2016), *available at* https://www.mercatus.org/system/files/Stratmann-Rural-Health-Care-v1.pdf.

"CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved communities or in underserved areas... the evidence suggests CON laws are ineffective. There is no compelling evidence suggesting that CON laws improve quality or access, inefficiently or otherwise... Evidence also fails to support the claim that CON programs would increase access to care for the indigent, or in medically underserved areas."

– Reforming America's Healthcare System Through Choice and Competition. A joint report by the U.S. Department of Health and Human Services, U.S. Department of the Treasury, and U.S. Department of Labor (December 3, 2018)

Carolina would have 55 additional hospitals, 24 of which would serve rural areas.[14]

Rather than control costs, research indicates that CON is associated with higher health care spending.[15] Mercatus estimates North Carolinians would spend $213 less on health care annually per capita if the state did not have a CON program.

CON is also associated with lower quality care. If the state did not have CON, patients in North Carolina could expect higher quality hospitals, lower readmission and mortality rates from heart attacks and heart failure, as well as fewer deaths from post-surgery complications.[16] Ultimately, with CON, North Carolinians are paying more for less access and lower quality care.

CON is Monopolistic and Inefficient

North Carolina's original CON law was struck down by the state's supreme court in 1973. The court ruled the CON "requirement establishes a monopoly in the existing hospitals contrary to the provisions of Article I, § 34 of the Constitution of North Carolina and is a grant to them of exclusive privileges forbidden by Article I, § 32."[17]

Subsequently, the state legislature passed a new CON law that is currently being challenged in the courts. The Institute for Justice is representing an ophthalmologist who is suing DHHS so he can perform surgeries at his private practice in Craven County.[18] The SHCC has determined there is no need for more surgery centers in his community. So, Dr. Singleton, the petitioner, is forced to perform surgeries at a nearby hospital where such surgeries are significantly more expensive for his patients.[19]

The COVID-19 pandemic further exposed CON's shortcomings as a public health policy. Early in the public health emergency, Governor Roy Cooper recognized the CON program would prevent health care providers from ramping up services to respond properly to the crisis. Like many other states with CON laws, the governor issued an order on April 8, 2020,[20] authorizing DHHS to "accept requests to temporarily: (1) relocate beds; (2) add or relocate dialysis stations; (3) acquire medical imaging equipment and (4) operate ambulatory surgical facilities as temporary hospitals."[21]

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[14] *Id.*

[15] James Bailey, *Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws* (Mercatus Ctr. at George Mason Univ. Working Paper, 2016), *available at* https://www.mercatus.org/system/files/Bailey-CON-v1.pdf.

[16] Matthew D. Mitchell, *North Carolina's Certificate-of-Need Program: Three Numbers Everyone Should Know About CON Laws* (Mercatus Ctr. at George Mason Univ. Policy Brief, 2022), *available at* https://www.mercatus.org/system/files/mitchell_-_policy_brief_-_con_laws_in_north_carolina_-_v1.pdf.

[17] *In re Certificate of Need for Aston Park Hosp., Inc.*, 282 N.C. 542 (1973).

[18] *Singleton v. N.C. Dep't of Health & Human Servs.*, 2022 NCCOA 412 (N.C. Ct. App. 2022).

[19] *North Carolina Ophthalmologist Challenges Outdated Certificate of Need ("CON") Law*, Inst. for Justice, https://ij.org/case/north-carolina-con-ii/ (last visited Sept. 21, 2022).

[20] Office of Governor Roy Cooper, Executive Order No. 130 (Apr. 8, 2020), https://governor.nc.gov/media/1793/open.

[21] *Supra* note 5.

The following year, the governor took additional steps to circumvent the state's restrictive CON requirements. In 2021, Governor Cooper unilaterally added "70 adult substance use disorder inpatient/residential treatment beds in the Eastern Region" to the SMFP before approving it.[22] In the wake of the ongoing COVID-19 pandemic, there was a spike in mental health issues.[23] The governor's signing statement indicated that he felt the proposed SMFP underestimated the actual need for mental health beds.[24]

But CON laws always restrict the supply of health care, not just during pandemics, and they hinder preparedness for the next public health emergency. One working paper even found higher mortality rates from COVID in states with CON laws compared to those without them.[25]

The state legislature also recently made changes to CON.[26] Last year, the legislature passed a bill to raise the capital expenditure threshold at which providers must apply for a CON. The threshold for facilities with major medical equipment increased from $750,000 to $2 million. Diagnostic and treatment centers outside of hospitals must apply for a CON if their equipment costs exceed $1.5 million, up from $500,000. And the threshold for other new services doubled to $4 million.

The SHCC, too, administratively eased CON regulations by removing the need determination methodologies for psychiatric and chemical dependency beds from the 2022 SMFP.[27] While providers must still apply for a CON, the change allows them to apply to offer these services anywhere in the state; that is, they are no longer restricted to applying only where the SHCC had determined there is a need for those services.

These piecemeal changes highlight the inefficiencies inherent to North Carolina's CON regime. While these changes will allow patients and providers more health care access at the margins, the CON scheme still artificially limits the supply of health care to protect politically proficient providers from competition.

Unilateral Adjustments to SMFP Highlight Arbitrary Nature of Need Determinations Under CON

The governor's power over the SMFP goes far beyond just appointing the members of the SHCC. AFPF's review of annual SMFPs from 2007–2022 found six years in which the presiding governor unilaterally made changes to need determinations. One change included modifying existing service area designations. While the CON statute does not explicitly reference the governor's authority to modify the SMFP, it does require the SMFP to be "approved by the governor." The ability of the governor to unilaterally alter need determinations or make other changes to the SMFP does not appear to have any functional limitations.

- 2007 Plan: Governor Michael Easley added a need determination for a second linear accelerator for Wake, Harnett, and Franklin counties.
- 2009 Plan: Governor Michael Easley adjusted a "need determination for 10 inpatient rehabilitation facility beds in Rowan County to be awarded to an existing acute care hospital in Rowan County."
- 2011 Plan: Governor Beverly Eaves Perdue originally approved the plan on December 21, 2010. The SHCC recommended changes after the plan was in place, and Governor Perdue approved those changes on March 8, 2011. The change "eliminates all projected need for additional Medicare-certified Home Health Agencies or Offices in the state."
- 2013 Plan: Governor Beverly Eaves Perdue approved with two changes:
    - "The determination of need in the 2013 State Medical Facilities Plan (SMFP), and subsequent plans for Hoke County and Cumberland County, will reflect no need for acute care bed, operating room, MRI, and cardiac catheterization services until one of the two approved hospitals in Hoke County is licensed, in order that a more accurate determination can be made regarding the needs of Hoke County residents."
    - "In addition, I determine that the 2013 SMFP, and subsequent plans, should eliminate all references to the Moore-Hoke and Cumberland-Hoke Multi-County Service Areas, and designate that Hoke County shall be a single-county service area for acute care bed, operating room, MRI, and cardiac catheterization need methodologies."
- 2016 Plan: Governor Pat McCrory originally approved with one sentence but also approved an amendment on April 26, 2016, eliminating "the projected need for one operating room in Rowan County."
- 2021 Plan: In the 2021 plan, Governor Roy Cooper added "70 adult substance use disorder inpatient/residential treatment beds in the Eastern Region." He admits the adjustment of the SMFP is "extraordinary" and that "it is preferable that requests for adjustments to need determinations go through the regular process."

[22] N.C. Dep't of Health & Hum. Servs., North Carolina 2021 State Medical Facilities Plan (2020), *available at* https://info.ncdhhs.gov/dhsr/ncsmfp/2021/2021-F-SMFP-assembled-num-bookmarks.pdf#page=6.
[23] Anne Blythe and Elizabeth Thompson, *State health leaders discuss COVID exit strategy, mental health need*, NC Health News (Feb. 16, 2020), https://www.northcarolinahealthnews.org/2022/02/16/state-health-leaders-discuss-covid-exit-strategy-mental-health-need/.
[24] *Supra* note 22.
[25] Sriparna Ghosh, et al., *Certificate-of-Need Laws and Healthcare Utilization During COVID-19 Pandemic* (working paper, July 29, 2020), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3663547.
[26] N.C. Gen. Stat. § 131E.
[27] N.C. Dep't of Health & Hum. Servs., North Carolina 2022 State Medical Facilities Plan 289 (2021), https://info.ncdhhs.gov/dhsr/ncsmfp/2022/2022-SMFP.pdf#page=329.

Conclusion

In 1974, Congress mandated states establish CON laws to receive federal health care funds. Along with 48 other states, North Carolina complied. Congress later repealed the federal mandate in 1986 after CON laws proved ineffective at achieving their goals. Since then, at least a dozen states have revoked their CON laws completely. Recently, in the face of mounting evidence against CON, multiple states have made changes to deregulate or eliminate CON programs:

- Tennessee exempted several services from CON in a reform bill signed in 2021.
- Montana reformed its CON law in 2021 to only cover long-term care facilities.
- Florida eliminated CON requirements for numerous services in 2019.
- New Hampshire legislation from 2012 phased out the state's CON program in 2016.

North Carolina's CON regime has directly denied $1.5 billion in health care investment over the last decade—and deterred much more. CON laws harm patients and health care providers. Health care entrepreneurs face serious barriers to entry: thousands of dollars in application fees, political and legal opposition from competitors, and miles of red tape. The result of so much lost health care investment is that North Carolinians pay higher prices for less access and lower quality health care. CON is not only costing North Carolina jobs, it may also be costing lives.

"[C]ounsel for Defendants clearly and correctly admitted the CON statutes are restrictive, anti-competitive, and create monopolistic policies and powers to the holder, and Plaintiffs correctly assert the CON process is costly and fraught with gross delays, and service needs are not kept current."

– Opinion from the Court of Appeals of North Carolina in Singleton v. N.C. Dep't of Health & Hum. Servs. (June 21, 2022)

Fact-Checking DHHS and the North Carolina Hospital Association on Certificate of Need

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North Carolina Hospital Association: "Modifying the current CON law would hurt the stability of rural hospitals[.]"

FALSE. According to the University of North Carolina Sheps Center for Health Services Research, the number of rural hospitals in North Carolina declined by 11 since January 2005 despite the CON law being in place.[1] No scholarly research indicates that CON laws protect rural hospitals, and the few studies that examine the issue conclude CON is associated with fewer rural hospitals and medical facilities.[2]

States are beginning to acknowledge that CON laws harm rural areas and are moving to exempt them from CON requirements. According to the National Conference of State Legislatures: "Maine and Oregon exempted rural hospitals from their CON laws, and Georgia waived the requirement that rural hospitals pay a fee when applying for CON approval. Washington enacted legislation in 2020 removing rural health clinics from the list of facilities under CON purview."[3]

DHHS: "increasing health care costs may be controlled by governmental restrictions on the unnecessary duplication of medical facilities."

FALSE. According to a joint study from the Federal Trade Commission ("FTC") and the Antitrust Division of the Justice Department: "The evidence to date, however, suggests that CON laws are frequently costly barriers to entry for healthcare providers rather than successful tools for controlling costs or improving healthcare quality. Based on that evidence and their enforcement experience, the two federal antitrust agencies–the FTC and the Antitrust Division of the Justice Department—have long suggested that states should repeal or retrench their CON laws."[4]

Further, the Mercatus Center's Matthew Mitchell found, "By limiting supply, CON regulations increase per-unit healthcare costs. Even though CON regulations might reduce overall healthcare spending by reducing the quantity of services that patients consume, the balance of evidence suggests that CON laws actually increase total healthcare spending."[5]

North Carolina Hospital Association: "The CON process has right-sized healthcare resources in our state, keeping costs contained and care accessible in communities."

FALSE. According to the Magnetic Resonance Imaging (MRI) Methodology Workgroup within DHHS, 15 counties in North Carolina have no hospital and no MRI service, nine counties have a hospital but no MRI service, and eight counties only have access to mobile MRI services.[6] Even when DHHS approves a CON application to add services, competitors can drag out the process for years in litigation: "In 2018, state health bureaucrats decreed that only one new mobile PET/CT scanner would be permitted in North Carolina. Three years later, health care consumers in the state still don't have that need met, and it might have to do with the nature of the legal regime itself."[7]

The Mercatus Center finds that states with CON have fewer hospitals and ambulatory surgical centers per 100,000 residents.[8] Mercatus also estimates that, without CON, North Carolina would have 55 additional hospitals, 24 of which would serve rural areas.[9]

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[1] *Rural Hospital Closures*, Univ. of N.C. Cecil G. Sheps Ctr. for Health Servs. Research, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (last visited June 13, 2022).

[2] Thomas Stratmann & Christopher Koopman, *Entry Regulation and Rural Healthcare: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals* (Mercatus Ctr. At George Mason Univ. Working Paper, 2016), *available at* https://www.mercatus.org/system/files/Stratmann-Rural-Health-Care-v1.pdf.

[3] Jack Pitsor & Anna Parham, *Repeal or Retool? States Assess Certificate of Need Laws*, Nat'l Conf. of State Leg. (Jan. 12, 2022), https://www.ncsl.org/research/health/repeal-or-retool-states-assess-certificate-of-need-laws-magazine2022.aspx.

[4] Dep't of Health & Human Servs., *et al.*, Reforming America's Healthcare System Through Choice and Competition at 50 (2018), *available at* https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.

[5] Matthew D. Mitchell, *Do Certificate-of-Need Laws Limit Spending?* (Mercatus Ctr. At George Mason Univ. Working Paper, 2016), *available at* https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v1a.pdf.

[6] N.C. Dep't of Health & Human Servs., Magnetic Resonance Imaging (MRI) Methodology Workgroup at 30 (Nov. 15, 2021), *available at* https://info.ncdhhs.gov/dhsr/mfp/pdf/2021/mri/Presentationmtg1FINAL.pdf.

[7] Jeff Moore, *Judicial opinion details cutthroat world of Certificate of Need*, The Carolina Journal (July 8, 2021) https://www.carolinajournal.com/judicial-opinion-details-cutthroat-world-of-certificate-of-need.

[8] *Supra* note 2.

[9] Matthew D. Mitchell, et al., *Certificate-of-Need Laws: North Carolina State Profile*, Mercatus Center at George Mason University, Mar. 26, 2021, https://www.mercatus.org/system/files/north-carolina_constateprofile_2020.pdf.

CASE STUDY: How CON Causes Needless Delays for Critical Care

North Carolina's certificate of need scheme actively hinders the development of health care provisions, in some cases delaying deployment of critical care services for years. In one recent case, the 2018 SMFP identified the need for one mobile PET scanner. These imaging devices are vital for diagnosing terrible, sometimes fatal ailments such as cancer, heart disease, and brain disorders, for which early detection is critical to patient outcomes. PET scanners can detect these conditions before other imaging devices.

Table 9O: Mobile Dedicated PET Scanner Need Determination
(Proposed for Certificate of Need Review Commencing in 2018)

It is determined that the service areas listed in the table below need additional mobile dedicated PET scanners as specified.

Service Area	Mobile Dedicated PET Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Statewide	1	November 15, 2018	December 1, 2018
It is determined that there is no need for additional mobile dedicated PET scanners anywhere else in the state and no other reviews are scheduled.			

But even a clear need determination cannot guarantee swift development of needed services under the CON regime. DHHS received four CON applications for the mobile PET scanner, but the competition for the CON included backdoor dealing. One applicant tried to manipulate the process by convincing a county hospital CEO who had signed a letter of support for the eventual "winner" of the CON to flip their support. When these underhanded tactics failed to win them the CON, the denied applicant embroiled the project in appeals and litigation for years. All this as patients suffered reduced access to critical health screening.

Ultimately, the Court of Appeals of North Carolina affirmed DHHS' decision in July 2021. But, because of the monopolistic nature of the certificate of need process, the project was unnecessarily in limbo for more than two years and saddled with thousands of dollars in legal costs.

> *"Years of precious resources wasted on fighting over the chance to operate a single additional mobile PET scanner in a state with over 10 million people. I don't know how anyone can look at this and think this system is working to achieve the goals for which it was designed.*
>
> *– Mitch Kokai, senior political analyst for the John Locke Foundation, in an interview with The Carolina Journal (July 8, 2021)*

North Carolina's CON regime inherently forces providers to fight each other for government favor while patients wait in the lurch for much-needed health care provisions.

2017

July 2017 — Insight Health Corp expresses concern about finding letters of support from hospitals that would host their mobile PET services due to Mobile Imaging Partners of North Carolina's alleged monopoly on such services. Three potential host sites allegedly told Insight "they would not provide documentation to support its CON application" because they feared retaliation.

2018

January 2018 — Annual State Medical Facilities Plan officially identifies a statewide need for one additional mobile PET scanner.

December 2018 — DHHS receives CON applications from four providers, including Insight Health Corp and Mobile Imaging Partners.

2019

Early 2019 — During review, one hospital that initially wrote a letter of support for Insight's application flips support after being approached by Mobile Imaging Partners.

April 2019 — DHHS approves Insight Health Corps' CON application and disapproves the other three applications.

May 2019 — Mobile Imaging Partners of North Carolina appeals to the Office of Administrative Hearings.

2020

February 2020 — Office of Administrative Hearings Judge affirms DHHS' decision.

March 2020 — Mobile Imaging Partners appeals the Administrative Law Judge's decision.

2021

June 2021 — Oral argument before the Court of Appeals of North Carolina.

July 2021 — Court of Appeals of North Carolina affirms the CON approval for Insight Health Corp.


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