# H.B. 76's Trojan Horse: An Analysis of Certificate of Need Reform in North Carolina*

*In a majority of states, healthcare organizations and providers cannot simply open a new facility, expand, or buy an expensive diagnostic machine just because they want to and have the funds to do so. Instead, states have implemented regulatory requirements that require interested parties to prove why they should be allowed to go ahead with additions and expansion—and even compete with each other to do so. Certificate of Need ("CON") is the process by which states regulate (and restrict) the expansion, acquisition, or creation of healthcare facilities and services. Proponents of CON argue that without regulation expansion in the healthcare industry will cause the maldistribution of healthcare services and result in higher prices for consumers. However, others argue that the regulation of expansion in the healthcare industry causes monopolies, unfairly infringes on the rights of providers who want to expand their practices, and prevents the healthcare market from achieving optimal efficiency.*

*In March 2023, North Carolina's House Bill 76 ("H.B. 76") significantly reformed North Carolina's CON statute, and, over a multiyear period, it will relax CON regulation of several healthcare services and facilities. This Comment analyzes these reforms and raises questions about their practical implementation. However, a major question remains. Are H.B. 76's reforms a first, weakening step towards the end of CON altogether, or perhaps a trap aimed at distracting proponents of CON from attempts to further erode the law? There has been vocal opposition and legal and legislative challenges to CON in North Carolina for decades. This Comment contextualizes H.B. 76's reforms around this opposition. It then argues that while H.B. 76's regulatory reforms are generally positive for North Carolinians, CON should ultimately remain law in North Carolina, both due to its impact on healthcare access and its ability to be utilized to address various health policy goals.*

*After many years have slipped by, the leaders of the Greeks,*
*opposed by the Fates, and damaged by the war,*
*build a horse of mountainous size, through Pallas's divine art,*
*and weave planks of fir over its ribs*:
*they pretend it's a votive offering: this rumour spreads.*
*They secretly hide a picked body of men, chosen by lot,*
*there, in the dark body, filling the belly and the huge*
*cavernous insides with armed warriors.*
*[. . .]*
*Then Laocoön rushes down eagerly from the heights*
*of the citadel, to confront them all, a large crowd with him,*
*and shouts from far off: "O unhappy citizens, what madness?*
*Do you think the enemy's sailed away? Or do you think*
*any Greek gift's free of treachery? Is that Ulysses's reputation?*
*Either there are Greeks in hiding, concealed by the wood,*
*or it's been built as a machine to use against our walls,*
*or spy on our homes, or fall on the city from above,*

*or it hides some other trick: Trojans, don't trust this horse.*
*Whatever it is, I'm afraid of Greeks even those bearing gifts."*[1]

## INTRODUCTION

Access to healthcare services has been recognized as one of the most important fundamental human rights and has been deemed as such by the United Nations and its World Health Organization.[2] Despite this recognition, many individuals have difficulties accessing healthcare services, for a variety of reasons. One of these reasons is geographic access. In the most rural areas of the United States, people have access only to the most basic of healthcare treatments.[3] Rural communities often struggle to retain healthcare providers and facilities due to the financial challenges of operating in these communities.[4] Even if healthcare is available, individuals living in rural or remote areas may need to travel long distances to gain access to it. If more complex and sophisticated treatment is needed, patients may even need to travel hours or across state lines, which can be incredibly difficult for those with busy jobs, disabilities, or other obligations such as childcare. While the emergence of telemedicine and other remote technologies may fill in the gaps, there is no substitute for in-person care by a healthcare provider.[5] Those who are

1. VIRGIL, THE AENEID, bk. 2, 39–40 (A.S. Kline trans., 2002).

2. The United Nations' Universal Declaration of Human Rights states that:

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

G.A. Res. 217 (III) A, art. 25, Universal Declaration of Human Rights (Dec. 10, 1948); *see also Human Rights*, WORLD HEALTH ORG. (Dec. 1, 2023), https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health [https://perma.cc/RT9S-MC7J (staff-uploaded archive)].

3. *See Why Health Care Is Harder to Access in Rural America*, U.S. GOV'T ACCOUNTABILITY OFF.: WATCHBLOG (May 16, 2023), https://www.gao.gov/blog/why-health-care-harder-access-rural-america [https://perma.cc/Q68K-VXFC (staff-uploaded archive)].

4. Low patient volumes often lead to higher costs and may in turn further limit the ability for rural facilities to offer specialized services and care. Zachary Levinson, Jamie Godwin & Scott Hulver, *Rural Hospitals Face Renewed Financial Challenges, Especially in States That Have Not Expanded Medicaid*, KAISER FAM. FOUND. (Feb. 23, 2023), https://www.kff.org/health-costs/issue-brief/rural-hospitals-face-renewed-financial-challenges-especially-in-states-that-have-not-expanded-medicaid/ [https://perma.cc/TQ5Z-58T5 (staff-uploaded archive)].

5. While telehealth appointments may be very effective for quick follow-up calls or the provision of care for specialties like dermatology where visual diagnosis is feasible through a webcam, there are many things that a provider *cannot* fully evaluate in a remote setting. For example, providers cannot listen to heart or lung sounds through remote visits. J. Jeffery Reeves, John W. Ayers & Christopher A. Longhurst, *Telehealth in the COVID-19 Era: A Balancing Act to Avoid Harm*, 23 J. MED. INTERNET RSCH., Feb. 2021, at 1, 2. But there are other limitations that may make treatment or diagnosis difficult such as disruption to internet connection, poor lighting that makes visualization of the patient difficult, or a patient's need to find a caregiver to assist them with the telehealth call. *Id.*

economically disadvantaged are further challenged by the financial costs associated with traveling to receive healthcare. This disadvantage does not even account for the actual cost of the healthcare services, which can be financially devastating for individuals and families if they lack adequate insurance coverage.

On March 27, 2023, North Carolina Governor Roy Cooper signed House Bill 76 ("H.B. 76")[6] into law, expanding the state's Medicaid program.[7] This was lauded as a major accomplishment in promoting health access and equity in North Carolina, enabling hundreds of thousands of North Carolinians who had previously been ineligible for Medicaid to apply for its services.[8] By increasing access to Medicaid, North Carolina's lawmakers ensured that many more financially disadvantaged individuals were able to access healthcare. This applied to North Carolinians in urban areas as well as the most rural areas of the state. However, the third part of the Bill, which received little attention, immediately implemented reforms to the state's Certificate of Need ("CON") laws.[9] The General Assembly decided to implement additional reforms on a staggered basis, so changes to North Carolina's CON statute will continue to roll out over the next few years.[10]

Many states have adopted CON laws, in what they argue is an effort to control the maldistribution of healthcare services and inflation of healthcare

6. Act of Mar. 27, 2023, ch. 7, 2023 N.C. Sess. Laws __ (codified in scattered sections of N.C. GEN. STAT. chapters 105, 108-A, 108D, 131E, 146C, 148).

7. Act of Mar. 27, 2023, pt. I; *see* Press Release, Roy Cooper, Governor, State of N.C., Governor Cooper Signs Medicaid Expansion into Law (Mar. 27, 2023), https://governor.nc.gov/news/press-releases/2023/03/27/governor-cooper-signs-medicaid-expansion-law [https://perma.cc/G6CA-4X7B (staff-uploaded archive)]. In states that have not yet expanded Medicaid, there are usually members of the population who have incomes above the Medicaid eligibility requirements set by their state but simultaneously fall below the federal poverty line. *Medicaid Expansion and What It Means for You*, HEALTHCARE.GOV, https://healthcare.gov/medicaid-chip/medicaid-expansion-and-you/ [https://perma.cc/3XAT-9HN6 (staff-uploaded archive)]. Five months after Medicaid expansion became official, over 450,000 North Carolinians had signed up for Medicaid, representing three-quarters of those newly eligible for Medicaid due to H.B. 76. Press Release, Roy Cooper, Governor, State of N.C., NC Medicaid Expansion Hits 450,000 Enrollees in Just Five Months (May 9, 2024), https://governor.nc.gov/news/press-releases/2024/05/09/nc-medicaid-expansion-hits-450000-enrollees-just-five-months [https://perma.cc/GSQ2-8EEP (staff-uploaded archive)]. Additionally, five months after expansion, Medicaid had covered over one million prescriptions for new enrollees and covered $17.9 million in dental service claims. *Id.*

8. *Medicaid Expansion and What It Means for You*, *supra* note 7. Medicaid is a dual federal and state program that aims to provide health insurance to low-income individuals. *Medicaid Eligibility*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/eligibility/index.html [https://perma.cc/9Q5P-ENPE (staff-uploaded archive)]. To qualify for Medicaid, individuals must be financially eligible, which is determined using a methodology called Modified Adjusted Gross Income. *Id.* However, states that have expanded Medicaid generally require that individuals make no more than 133% of the Federal Poverty Level to qualify for the program, which means that people with higher incomes though tenuous financial situations are still eligible. *Medicaid Expansion and What It Means for You*, *supra* note 7.

9. Act of Mar. 27, 2023, pt. III.

10. *Id.*

costs.[11] Combining theories of antitrust, economics, and health policy, CON laws have been used as a health policy tool since the mid- to late-twentieth century.[12] Under CON laws, healthcare organizations and providers[13] must receive state approval prior to opening or expanding healthcare facilities and offering certain health services.[14] Even purchases or replacements of expensive medical equipment such as radiology machines may be subject to state approval.[15] The rationale is that if hospitals, clinics, or other healthcare facilities expand too quickly, or buy too much expensive equipment, this will drive up prices for consumers. Further, CON law is used to incentivize the opening and continued operation of healthcare facilities in the rural communities that may lack adequate healthcare resources.

Broadly, H.B. 76's CON reforms change North Carolina's preexisting CON law by both exempting certain healthcare facilities from CON review and increasing the dollar threshold that is needed to trigger CON review of the purchase of expensive medical equipment.[16] They also eliminate the CON requirement for some healthcare facilities in urban areas.[17] In some respects, the reforms should increase access to much-needed healthcare, such as for mental health and substance abuse treatment.[18] However, the reforms also include changes to the CON statute that raise questions about the reforms' ultimate impact on access to healthcare, such as the relaxation of CON review for specific healthcare facilities located in urban areas and for the purchase of magnetic resonance imaging ("MRI") machines.[19]

11. DAVID S. SALKEVER & THOMAS W. BICE, HOSPITAL CERTIFICATE-OF-NEED CONTROLS 5 (1979).

12. *See infra* Section I.B.1.

13. The scope of the North Carolina CON statute extends to both healthcare organizations and providers, based on its language stating that "*no person* shall offer or develop new institutional health services without first obtaining a certificate of need." N.C. GEN. STAT. § 131E-178 (2023) (emphasis added).

14. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 10, § 710.1(c) (2024) (describing New York's CON laws). These requirements are also separate from other regulatory mechanisms that healthcare facilities must successfully navigate before opening or expanding, including significant licensure and accreditation requirements. *See* ANNE L. ROONEY & PAUL R. VAN OSTENBERG, U.S. AGENCY FOR INT'L DEV., LICENSURE, ACCREDITATION, AND CERTIFICATION: APPROACHES TO HEALTH SERVICES QUALITY 3 (1999), https://www.globalhealthlearning.org/sites/default/files/reference-files/rooneu.pdf [https://perma.cc/FGC7-TQTC].

15. For example, New York's CON statute requires state approval for the acquisition of Magnetic Resonance Imaging ("MRI") machines and computed tomography ("CT") scanners. *See* N.Y. COMP. CODES R. & REGS. tit. 10, § 710.1(c)(3). North Carolina similarly requires state approval for MRI machines and positron emission tomography ("PET") scanners. *See* N.C. GEN. STAT. § 131E-176 (2023).

16. Act of Mar. 27, 2023, ch. 7, pt. III, 2023 N.C. Sess. Laws __, __ (codified in scattered sections of N.C. GEN. STAT. chapters 131E, 148).

17. *Id.* § 3.2.(a).

18. *See id.* § 3.1.(a).

19. *Id.* §§ 3.2.(a)–(c), 3.3.(a).

H.B. 76's CON reforms not only have the potential to impact healthcare providers' bottom lines; they also can impact innovation in the healthcare market. The reforms may seem tailored, but in the aggregate, they may have the power to significantly impact access to care in North Carolina over time. These reforms may have been proposed during Medicaid expansion as they were low-hanging fruit: CON law has been debated as a policy mechanism in North Carolina and in other states for many years.[20] But there is a central tension. Individuals who live in rural communities may benefit from CON, while the providers and businesspeople tasked with providing healthcare services may feel their interests are stifled by CON. This makes the cost-benefit analysis of any CON law difficult to parse, as it is unclear how to reconcile the interests of both groups.

H.B. 76's reforms may represent a seemingly positive policy reform that sets the stage for more severe legislative and judicial actions that will ultimately lead to CON's complete demise in North Carolina. Thus, reforms to CON like the ones in H.B. 76 may represent a slippery slope, or may have the potential to have the ultimate effect of a Trojan Horse. Short term, the reforms do not entirely erode CON law in North Carolina; they are incremental and do not come close to the dismantling of CON that has occurred in other states.[21] However, increased opposition to CON laws throughout the country, as well as calls for government deregulation generally, could result in more substantial reforms in the future. And in the long term, further healthcare deregulation may be hard to resist and much more damaging to rural communities.

H.B. 76's reforms will undoubtedly change CON law in North Carolina and have immediate practical implications. There are many unanswered questions regarding the application and effect of the reforms. But H.B. 76's reforms also show how CON law, if narrowly tailored, can be calibrated to meet the needs of both patients and healthcare providers. Furthermore, they show how reforms provide an opportunity to use the CON statute to further improve healthcare access and quality for North Carolinians. Through reforms, lawmakers have the potential to use CON law as a "prize" to incentivize patient safety and healthcare innovation.

This Comment explores the implications—short and long-term—of H.B. 76's reforms to North Carolina's CON laws. It argues that CON is a valuable health policy tool that can be leveraged to improve access to healthcare throughout the state. Furthermore, it argues that while some CON reforms are

20. CON has been a hotly debated topic in North Carolina for years, such that disagreements surrounding the inclusion of the CON reforms in H.B. 76 delayed the bill's passage. *See* Lars Dolder, *This Little-Known Law Is the Reason NC Medicaid Expansion Hasn't Passed*, NEWS & OBSERVER, https://www.newsobserver.com/news/politics-government/article266128361.html [https://perma.cc/8X6S-QFUR (staff-uploaded, dark archive)] (last updated Sept. 29, 2022, 3:44 PM).

21. *See infra* Section V.A (describing the extensive repeal of CON in South Carolina).

needed in North Carolina, H.B. 76 should not serve as a Trojan Horse—a seemingly positive legislative achievement that ultimately conceals or distracts from reforms that lead to complete CON repeal. Instead, it argues that CON itself can be leveraged to implement other health policy initiatives that improve the health of all North Carolinians. Indeed, H.B. 76 provides examples of such smaller-scale reforms and improvements. Finally, H.B. 76 demonstrates the need for well-drafted reforms that provide clarity to stakeholders on how policy will be implemented in practice.

Part I provides a basic overview of CON law and its history, including the rise of CON throughout the United States in the mid-twentieth century and its enactment and contentious past in North Carolina. Part II provides a summary of the health policy theory used to support—and discredit—the implementation of CON laws. Part III highlights recent attempts to reform CON in both the legislative and judicial branches of government. Part IV provides statutory interpretation of H.B. 76's reforms. It also highlights uncertainties surrounding the law, the politics surrounding CON reform, and the policy implications of the reforms—including why there are strong arguments that CON law should remain in North Carolina. Finally, Part V argues that H.B. 76's changes to North Carolina's CON law show that nuanced reforms helping to achieve workable health policy objectives, rather than a total dismantling of CON law, may benefit North Carolinians.

## I. OVERVIEW OF CON AND THE HISTORY OF NORTH CAROLINA'S CON LAWS

CON laws and statutes have been subject to contentious debates since their enactment, resulting in many reforms and, in some cases, even repeal of such laws. According to their proponents, CON laws are a useful means of containing costs and ensuring equity in access to healthcare services.[22] However, CON's opponents argue that the laws restrict competition to the detriment of the patient-consumer; by placing guardrails on the healthcare market, providers cannot compete with each other to provide lower-cost care for consumers.[23] Further, they argue, CON laws allow large healthcare providers to retain monopolies in their markets.[24] This part begins by explaining how CON laws, especially North Carolina's, work to place controls on the opening and expansion of institutional health services. It then outlines the history of CON,

22. *See* Kersey Reynolds, Note, *Certificate of Need in South Carolina: Something Rotten in the State of Healthcare*, 74 S.C. L. REV. 601, 602 (2023).

23. *See* John Boyle, *Opinion: Is It Time to Get Rid of the Certificate of Need Program? I'd Say It's Overdue*, ASHEVILLE WATCHDOG (Apr. 22, 2024), https://avlwatchdog.org/opinion-is-it-time-to-get-rid-of-the-certificate-of-need-program-id-say-its-overdue/ [https://perma.cc/7Z2D-RJZX (staff-uploaded archive)] (suggesting that the CON system is inherently "anti-competitive").

24. *Id.*

including the original health policy rationales used to support the enactment of CON laws throughout the United States. It concludes by describing the history of CON law in North Carolina specifically, demonstrating the controversies and opposition that the CON statute has generated since its enactment.

### A. *How CON Laws Work*

CON statutes and regulations specify that healthcare organizations must submit applications both to open and expand certain types of facilities and to purchase certain medical equipment above set threshold costs.[25] In accordance with CON laws, healthcare organizations provide detailed proposals to state regulators to open, expand, or move facilities or beds,[26] operating rooms, dialysis stations, and home health services, or even purchase new equipment to serve a given community.[27] Specifically, North Carolina's CON statute regulates "new institutional health services," the definition of which encompasses a broad range of potential actions by a healthcare organization, from the purchase of an air ambulance to the relocation of a health service facility from one service area to another.[28] Often, multiple entities will vie for approval of the same expansion plans.[29] In these proposals, healthcare facility operators explain in detail why their organization should be chosen over others, and provide statistics, detailed plans, and even include letters of support from the community and its physicians.[30] State regulators review these proposals and decide whether to grant approval, often choosing among various healthcare organizations vying to open a facility in the same area.[31] In making these determinations, regulators consider projects that achieve state objectives and screen for projects that may be redundant given the resources existing in a geographic area.[32] In this way, CON is a mechanism for state government to ensure that citizens have adequate access to healthcare services, but it can also be a tool to promote other important public health objectives.[33]

25. *See* Reynolds, *supra* note 22, at 602.

26. Healthcare organizations apply for specific types of beds; therefore, a hospital might specifically apply to add inpatient psychiatric care beds if they wanted to expand their psychiatric ward, or acute care beds if they wanted to expand their intensive care unit ("ICU"). *See, e.g.*, N.C. GEN. STAT. § 131E-182 (2023).

27. Reynolds, *supra* note 22, at 602.

28. N.C. GEN. STAT. § 131E-176(16) (2023).

29. *See, e.g.*, *Latest UNC, Duke Court Battle Focuses on CON Dispute*, CAROLINA J. (May 29, 2024), https://www.carolinajournal.com/latest-unc-duke-court-battle-focuses-on-con-dispute/ [https://perma.cc/DBD9-N4NB (staff-uploaded archive)] (detailing a recent legal battle between Duke University Health System and the University of North Carolina ("UNC") Health Care System over UNC's bid to expand into Durham County).

30. N.C. GEN. STAT. § 131E-185(a1) (2023).

31. Reynolds, *supra* note 22, at 602.

32. *Id.*

33. For example, CON law is likely being used to address North Carolina's dual mental health and substance abuse crises. *See infra* Section IV.B.

In North Carolina in particular, the North Carolina State Health Coordinating Council and the North Carolina Department of Health and Human Services ("NCDHHS") prepares a State Medical Facilities Plan ("SMFP") annually for the Governor's approval.[34] The SMFP outlines the guidelines and methodologies for analyzing CON determinations.[35] Ultimately, the state will award a healthcare provider—whether a hospital, a physician group practice owner, or the owner of a specialized treatment facility—a lucrative prize: the right to buy equipment, open more beds, or open a new facility. In North Carolina, the agency that makes this determination is the Healthcare Planning and Certificate of Need section of the North Carolina Division of Health Services Regulation ("DHSR").[36] Other states have similar governmental agencies that systematically review the methodologies and analyses needed for CON determinations and ultimately decide whether to grant providers and healthcare organizations a CON once these entities have submitted a CON application.[37]

The DHSR CON section ("Agency") generally follows a two-step process to determine whether to issue a CON to an applicant.[38] First, the Agency "must determine whether the applications submitted meet the criteria set forth in N.C. Gen. Stat. § 131E-183(a)."[39] Then, if more than one applicant who has applied for a CON conforms to the applicable review criteria, the Agency may "conduct a comparison of the conforming applications to determine which applicant should be awarded the CON."[40] After reviewing all applications, the Agency issues a decision to "approve," "approve with conditions," or "deny" an application for a new institutional health service.[41]

The stakes surrounding CON determinations are incredibly high. When a healthcare organization's proposal is approved, this means that it may gain

34. *Overview of Certificate of Need (CON)*, N.C. DIV. HEALTH SERV. REGUL., https://info.ncdhhs.gov/dhsr/coneed/overview.html [https://perma.cc/53C8-EXU5].

35. N.C. DEP'T OF HEALTH & HUM. SERVS., NORTH CAROLINA 2024 STATE MEDICAL FACILITIES PLAN 2–4 (2024), https://info.ncdhhs.gov/dhsr/ncsmfp/2024/02_Proposed-2024_all_bookmarks.pdf [https://perma.cc/94VX-F3ZQ (staff-uploaded archive)] (identifying safety and quality, access, and value as basic principles underpinning all CON determinations).

36. *Overview of Certificate of Need (CON)*, *supra* note 34.

37. *See, e.g.*, *Certificate of Need (CON)*, N.Y. STATE DEP'T HEALTH, https://www.health.ny.gov/facilities/cons/ [https://perma.cc/2LGR-6ZUY (staff-uploaded archive)].

38. AH N.C. Owner LLC v. N.C. Dep't of Health & Hum. Servs., 240 N.C. App. 92, 97, 771 S.E.2d 537, 540 (2015).

39. *Id.* (citing Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Hum. Servs., 176 N.C. App. 46, 57, 625 S.E.2d 837, 844 (2006)). The application review criteria require applicants to provide an analysis of the needs of the population, the availability of resources in the surrounding area, including manpower, the costs of construction, and the quality of care provided by the applicant. N.C. GEN. STAT. § 131E-183(a) (2023).

40. *AH N.C. Owner LLC*, 240 N.C. App. at 97, 771 S.E. 2d at 540–41 (quoting *Craven Reg'l Med. Auth.*, 176 N.C. App. at 58, 625 S.E.2d at 845).

41. N.C. GEN. STAT. § 131E-186 (2023).

access to a new market. By beating out other healthcare organizations that also vied for the opportunity to expand their services, the "winning" healthcare organization may even gain a quasi-monopoly.[42] The organization is able to build a patient base for years to come, resulting in significant revenue. CON determinations can also allow organizations to build brand credibility in a geographic area, and potentially brand loyalty, as they may be able to refer patients to other facilities and providers within the organization.

When a CON determination does not go the way of an organization that has submitted such an application, there may be significant litigation.[43] This is because, following an Agency decision to issue a CON to a particular applicant, the remaining applicants are entitled to a contested case hearing at the North Carolina Office of Administrative Hearings to review the Agency's decision.[44] In these hearings, an administrative law judge determines whether the petitioner-applicants have met their burden in showing that the Agency substantially prejudiced their rights; acted erroneously, arbitrarily, and capriciously; used improper procedure; or failed to act in accordance with the law.[45] This litigation can be very contentious, with various stakeholders spending significant money on litigation costs.[46] But for healthcare organizations, these disputes are often worth pursuing,[47] given the potential revenue associated with the approval of additional beds, machinery, or other

42. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, JOINT STATEMENT OF THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION BEFORE THE ILLINOIS TASK FORCE ON HEALTH PLANNING REFORM 6–8 (2008) [hereinafter U.S. DEP'T OF JUST. & FED. TRADE COMM'N, STATEMENT BEFORE THE ILLINOIS TASK FORCE], https://www.justice.gov/archive/atr/public/press_releases/2008/237153a.pdf [https://perma.cc/U8CV-HGXT] (describing incumbent providers entering into anticompetitive agreements facilitated by the CON process).

43. *See* JAIMIE CAVANAUGH, CAROLINE GRACE BROTHERS, ADAM GRIFFIN, RICHARD HOOVER, MELISSA LOPRESTI & JOHN WRENCH, INST. FOR JUST., CONNING THE COMPETITION: A NATIONWIDE SURVEY OF CERTIFICATE OF NEED LAWS 4 (2020), https://ij.org/wp-content/uploads/2020/08/Conning-the-Competition-Report-JUNE-2023-WEB.pdf [https://perma.cc/NKH6-NV68].

44. N.C. GEN. STAT. § 131E-188 (2023).

45. *AH N.C. Owner LLC*, 240 N.C. App. at 98, 771 S.E.2d at 541 (quoting CaroMont Health, Inc. v. N.C. Dep't of Health & Hum. Servs., 231 N.C. App. 1, 5, 751 S.E.2d 244, 248 (2013)).

46. *See, e.g.*, Julie Havlak, *Certificate of Need CON: A Tangled Web of Bureaucracy, Clout, and Backroom Deals*, CAROLINA J. (Mar. 8, 2021), https://www.carolinajournal.com/certificate-of-need-con-a-tangled-web-of-bureaucracy-clout-and-backroom-deals-can-crush-competition-hurt-smaller-providers-and-endanger-patients/ [https://perma.cc/3TAC-TLR2 (staff-uploaded archive)] [hereinafter Havlak, *Certificate of Need CON*] (describing two surgeons' attempts to challenge laws requiring CON approval for certain medical facilities and equipment).

47. *See* David Ford, *Triad Hospitals Are in a High Stakes Battle over Certificate of Need – But What Is It?*, WFDD (Aug. 23, 2023, 4:35 PM), https://www.wfdd.org/story/triad-hospitals-are-high-stakes-battle-over-certificate-need-what-it [https://perma.cc/E3PJ-SGP5 (staff-uploaded archive)] ("Big health care providers want to have integrated delivery systems. That means they need a full spectrum of services in a community from hospitals to nursing homes to rehabilitation facilities. It allows them to contract with the big insurers and major federal programs to survive.").

capital investments.[48] While these regulations may seem onerous, since the inception of CON laws, there have been strong policy arguments for keeping CON law intact.

## B. *Initial CON Enactment & Litigation*

### 1. The National Origins of CON Law

CON laws first emerged in the United States as communities grappled with problems with the distribution and availability of hospital beds after the Great Depression and World War II.[49] Hospitals had fallen into disrepair; American communities celebrated the end of the war by investing money into the development of new, modern hospitals.[50] The passage of the federal Hill-Burton Act[51] in 1946 further accelerated these efforts by providing subsidies for the construction of these hospitals.[52] With so much additional funding available, the number of hospitals increased significantly, as did the number of available beds.[53]

By the 1960s, concerns emerged regarding the impact of healthcare supply on healthcare utilization. According to a 1959 paper by Milton Roemer and Max Shain, healthcare facilities will intentionally fill hospital beds if they are available, even if patients do not need such care.[54] As a result, healthcare facilities will spend money on expanding their facilities as a revenue-increasing

48. Although the litigation process can be drawn out, there are many instances where litigation can lead to the reversal of a previous decision on a CON. *See, e.g.*, *Appeals Court Throws Out Ruling Favoring Duke in CON Fight with UNC*, CAROLINA J. (Sept. 17, 2024), https://www.carolinajournal.com/appeals-court-throws-out-ruling-favoring-duke-in-con-fight-with-unc/ [https://perma.cc/3AYB-RFYW (staff-uploaded archive)].

49. Patrick John McGinley, Comment, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a Managed Competition System*, 23 FLA. ST. U. L. REV. 141, 145 (1995).

50. *Id.*

51. Hospital Survey and Construction (Hill-Burton) Act, ch. 958, 60 Stat. 1040 (1946) (codified in scattered sections of 28, 40, and 42 U.S.C.).

52. *Id.* § 602. Facilities built with Hill-Burton funds agreed to make services available to patients without discriminating on the basis of race, color, national origin, creed, or ability to pay. Kenneth R. Wing, *The Community Service Obligation of Hill-Burton Health Facilities*, 23 B.C. L. REV. 577, 581 (1982). Hill-Burton facilities also were required to provide charity care and participate in the Medicare and Medicaid programs, once these programs had been enacted. *Id.* at 615. While the Hill-Burton Act was never formally repealed, the program stopped providing funds in 1997. *Hill-Burton Free and Reduced-Cost Health Care*, HEALTH RES. & SERVS. ADMIN. (Sept. 2023), https://www.hrsa.gov/get-health-care/affordable/hill-burton [https://perma.cc/34UV-47Q4].

53. Andrea Park Chung, Martin Gaynor & Seth Richards-Shubik, *Subsidies and Structure: The Lasting Impact of the Hill-Burton Program on the Hospital Industry*, 99 REV. ECON. & STAT. 926, 927 (2017).

54. Milton I. Roemer & Max Shain, *Hospital Costs Relate to the Supply of Beds*, 92 MOD. HOSP. 71, 71 (1959).

tactic, passing the costs of expansion onto consumers.[55] Further, without government intervention, healthcare facilities tend to concentrate in urban areas.[56] In 1966, given the concerns raised in Roemer and Shain's paper, New York passed the nation's first CON law, which required state approval for the construction of hospitals and nursing homes.[57] Over the next several years, additional states followed suit by passing their own CON laws.[58]

CON law gained momentum over time, eventually leading to federal action on CON. In 1974, Congress passed the National Health Planning and Resources Development Act of 1974 ("NHPRDA").[59] The NHPRDA allocated funding for state health planning activities, but, importantly, it also "effectively required states to adopt certificate of need laws conforming to federal standards."[60] Thus, states that had not already adopted CON laws began to implement their own statutes, and by the early 1980s, all states except Louisiana had some form of CON law.[61] However, around the same time, Ronald Reagan was elected President of the United States and began a push for deregulation in all facets of government, including healthcare.[62] CON laws were among the Reagan Administration's targets.[63] By 1986, the federal government repealed the NHPRDA CON mandate, and states began to eliminate their CON requirements.[64] But a majority of states, including North Carolina, have

55. The Roemer and Shain paper led to fears that hospitals would intentionally expand to increase profits, and cause patients to use these new services, even if patients did not actually *need* these healthcare services, resulting in a "medical arms race." *See infra* Section II.A. This, health policy experts argued, would drive up profits. *See infra* Section II.A.

56. For an explanation of why healthcare facilities may concentrate in urban areas when CON law is not in place, see *infra* Section II.A.

57. Emily Whelan Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 KY. L.J. 201, 211 (2017).

58. *Id.*

59. National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (codified in scattered sections of 5, 12, 26, 31, 40, 42, 43 U.S.C.) (repealed 1986). Congress passed the National Health Planning and Resources Development Act ("NHPRDA") in recognition of the contribution of the "massive infusion of Federal funds into the existing healthcare system" to "inflationary increases in the cost of health care" and the "fail[ure] to produce an adequate supply or distribution of health resources." *Id.*

60. *See* James B. Simpson, *Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*, 19 IND. L. REV. 1025, 1026 (1986).

61. *See* Matthew D. Mitchell & Christopher Koopman, *40 Years of Certificate-of-Need Laws Across America*, MERCATUS CTR. (Sept. 27, 2016), https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america [https://perma.cc/2MHQ-EX4F (staff-uploaded archive)].

62. *See* Austin Frakt, *Reagan, Deregulation and America's Exceptional Rise in Health Care Costs*, N.Y. TIMES (June 4, 2018), https://www.nytimes.com/2018/06/04/upshot/reagan-deregulation-and-americas-exceptional-rise-in-health-care-costs.html [https://perma.cc/SER6-TNDY (staff-uploaded, dark archive)].

63. *See* Mitchell & Koopman, *supra* note 61.

64. *Id.*

retained their CON laws. As of 2024, thirty-five states and Washington, D.C. operate CON programs.[65]

2. The Origins of CON Law in North Carolina

In 1971, North Carolina enacted its first CON laws.[66] North Carolina's CON statute clearly states the General Assembly's rationale. According to the General Assembly, the "financing of health care . . . limits the effect of free market competition, government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities."[67] Therefore, "if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result."[68] The statute further outlines the General Assembly's commitment to ensuring health equity in North Carolina, stating that "access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process."[69] CON, according to the statute, is also crucial for the public welfare:

> New institutional health services to be offered within this State [should] be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria . . . in order that only appropriate and needed institutional health services are made available in the area to be served.[70]

Thus, the CON statute clearly states the legislature's intent in enacting the CON law: assessing patient need in order to ensure that new healthcare services investments further the goal of ensuring that healthcare remains accessible for all North Carolinians, including those in the most rural areas.

But the General Assembly's enactment of this statute resulted in significant North Carolina constitutional challenges to CON. In *In re Certificate*

65. *Certificate of Need State Laws*, NAT'L CONF. STATE LEGISLATURES, https://www.ncsl.org/health/certificate-of-need-state-laws [https://perma.cc/5RW5-CPRH (staff-uploaded archive)] (last updated Feb. 26, 2024).

66. *See* Act of July 21, 1971, ch. 1164, 1971 N.C. Sess. Laws 1715 (codified at N.C. GEN. STAT. §§ 90-289 to 90-291) (repealed 1973) (enacting North Carolina's first CON law which was subsequently repealed, reenacted, and codified in section 131E-175 of the General Statutes of North Carolina).

67. N.C. GEN. STAT. § 131E-175(1) (2023).

68. *Id.* § 131E-175(3).

69. *Id.* § 131E-175(3a).

70. *Id.* § 131E-175(7).

*of Need for Aston Park Hospital Inc.*,[71] the Supreme Court of North Carolina struck down the State's original CON laws based on an economic substantive due process argument.[72] The case arose from North Carolina regulators' denial of Aston Park Hospital's attempt to add beds to its facility in Asheville, North Carolina, on the basis that an expansion would create an oversupply of hospital beds.[73] Aston Park argued that this denial was unfair because, upon passage of the CON statute, the state had identified a need for ninety-four additional beds in the area and subsequently awarded these beds to a hospital whose plans were finalized prior to the passage of the statute.[74] Thus, Aston Park argued, and the superior court found, that the unfavorable agency determination was a violation of the North Carolina Constitution's sections governing the equality and rights of persons, equal protection, exclusive emoluments, perpetuities and monopolies, and legislative power.[75]

Applying the United States Supreme Court's means-ends test from *Lawton v. Steele*,[76] the Supreme Court of North Carolina stated that there was "no such reasonable relation between the denial of the right of a person, association or corporation to construct and operate upon his or its own property, with his or its own funds, an adequately staffed and equipped hospital and the promotion of the public health."[77] Thus, the CON statute was a deprivation of

71. 282 N.C. 542, 193 S.E.2d 729 (1973).

72. *Id.* at 550–51, 193 S.E.2d at 735.

73. Daryl James & Renèe Flaherty, *NC Supreme Court Gets Second Chance to Do Right Thing on CON Law*, CAROLINA J. (Sept. 18, 2023), https://www.carolinajournal.com/opinion/nc-supreme-court-gets-second-chance-to-restore-patient-rights/ [https://perma.cc/7HFX-KFSY (staff-uploaded archive)].

74. Suzanne L. Zelenka, Comment, *CONtroversy in Health Care: A Hard Look at North Carolina's Certificate of Need Laws*, 20 N.C. J.L. & TECH. 333, 353–54 (2019).

75. *See Aston Park*, 282 N.C. at 546, 193 S.E.2d at 732. The sections of the North Carolina Constitution in question were Article I, Sections 1, 19, 32, and 34, and Article II, Section 1, which are the Equality and Rights of Persons Clause, Law of the Land Clause, Exclusive Emoluments Clause, Perpetuities and Monopolies Clause, and Legislative Power Clause, respectively. *Id.*; *see also* N.C. CONST. art. I, §§ 1, 19, 32, 34; *id.* art. II, § 1.

76. 152 U.S. 133 (1894). In the *Aston Park* decision, Justice I. Beverly Lake cites the U.S. Supreme Court's decision in *Lawton v. Steele*, which uses the following means-end test to analyze economic substantive due process cases:

> To justify the state in thus interposing its authority on behalf of the public, it must appear, first, that the interests of the public generally, as distinguished from those of a particular class, require such interference; and, second, that the means are reasonably necessary for the accomplishment of the purpose, and not unduly oppressive upon individuals. The legislature may not, under the guise of protecting the public interests, arbitrarily interfere with private business, or impose unusual and unnecessary restrictions upon lawful occupations . . . .

*Id.* at 137; *Aston Park*, 282 N.C. at 551, 193 S.E.2d at 735.

77. *Aston Park*, 282 N.C. at 551, 193 S.E.2d at 735. By the time *Aston Park* was decided, the United States Supreme Court had changed its analysis of economic due process questions to a rational basis review. United States v. Carolene Prods. Co., 304 U.S. 144, 154 (1938) (finding that a law prohibiting

economic substantive due process as it denied "Aston Park Hospital the right to construct and operate its proposed hospital except upon the issuance to it of a certificate of need"; and the fear that the hospital's expansion would hurt competitors in the area was not a sufficient justification for this application of CON law.[78] The Supreme Court of North Carolina also "carefully distinguish[ed] a certificate of need requirement from the state's legitimate interest in enacting licensing requirements that govern facility quality and safety standards."[79]

However, the *Aston Park* decision ultimately lost its bite, due to the passage of the NHPRDA and North Carolina's switch to rational basis review.[80] The NHPRDA made CON and institutional health planning a federal priority, encouraging states to regulate need and to develop CON laws in exchange for federal funding.[81] In 1977, after the *Aston Park* decision and pursuant to the NHPRDA, legislators modified the CON statute to more clearly specify the relationship between CON and the government's promotion of public welfare.[82] This was enough to satisfy the rational basis standard, as it provided clarity on why such a law existed and why the government had an interest in regulating the creation of institutional health services at all.[83] Thus, the switch to rational basis review made it much easier for the state to justify its CON program such that challenges to the law would more likely fail in state court.

But the NHPRDA did not go unchallenged by states, including North Carolina. In *North Carolina ex rel. Morrow v. Califano*,[84] North Carolina challenged the constitutionality of the NHPRDA's mandate in federal court.[85] North Carolina argued that the federal government's requirement that states create CON programs in order to qualify for financial grants under federal

filled milk from entering interstate commerce was constitutional under rational basis review). However, state courts—including North Carolina's—had not yet fully switched to applying rational basis review for issues arising under their state constitutions. Reynolds, *supra* note 22, at 629 (citing Robert M. Anderson, Note, *The Judiciary's Inability to Strike Down Healthcare Service Certificate of Need Laws Through Economic Substantive Due Process: A Call for Legislative Action*, 2 CHARLESTON L. REV. 703, 717 (2008)).

78. *See Aston Park*, 282 N.C. at 551, 193 S.E.2d at 735.

79. Zelenka, *supra* note 74, at 354.

80. *Aston Park* was essentially rendered moot due to the passage of the NHPRDA and its federal CON law "mandate." *See* Reynolds, *supra* note 22, at 629; Zelenka, *supra* note 74, at 355.

81. *See* National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, § 2, 88 Stat. 2225, 2226–27 (1975) (codified as amended at 42 U.S.C. § 300k-1) (repealed 1986) (stating that "[t]he achievement of equal access to quality health care at a reasonable cost is a priority of the Federal Government").

82. Zelenka, *supra* note 74, at 355–56; James & Flaherty, *supra* note 73.

83. Hope—A Women's Cancer Ctr., P.A. v. State, 203 N.C. App. 593, 603, 693 S.E.2d 673, 680 (2010).

84. 445 F. Supp. 532 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978).

85. *Id.* at 533.

health programs violated principles of federalism and state sovereignty.[86] The United States District Court for the Eastern District of North Carolina was not persuaded by this argument, finding that the requirement was neither mandatory nor "coercive" in the constitutional sense.[87] The United States Supreme Court later affirmed this holding.[88] "The *Morrow* decision, thus, merely confirmed the legislature's federally endorsed circumvention of *Aston Park*."[89] For the next few decades, CON existed in North Carolina without significant litigation regarding its constitutionality.

In 2010, the North Carolina Court of Appeals found in *Hope–A Women's Cancer Center, P.A. v. State*[90] that the revised CON law was distinguishable from the law invalidated in *Aston Park*, as the amended statute clearly stated that the law promotes the public welfare.[91] Therefore, despite a previous, successful facial challenge to the CON statute, there was a legitimate governmental purpose for the law: to "ensure that all citizens throughout the State had equal access to health care services at a reasonable price, a situation that would not occur if such regulation were not in place."[92] Furthermore, the procedure employed by the DHSR was found to be "efficient and effective" and not in violation of due process.[93] For the time being, the opinion in *Hope* has upheld CON law as constitutional under the North Carolina Constitution, especially in light of the changes to the CON statute post-*Aston Park*. *Hope* was appealed to the Supreme Court of North Carolina, which denied review.[94] However, to

86. *Id.* According to the court, North Carolina argued that

> the requirement represents an effort to compel the State to amend its constitution and thus constitutes an unconstitutional interference with the State's legislative and constitutional processes violative of the principles of federalism and state sovereignty, as guaranteed under the due process clause, the Tenth Amendment and the Guaranty Clause of Article IV, Section 4 of the Constitution.

*Id.*

87. *Id.* at 535. The court found the economic impact of not complying with the NHPRDA as not impactful enough as to be coercive: "The actual loss to North Carolina should it lose all federal assistance health grants would be less than fifty million dollars; in 1974, its State revenues totalled some 3.1 billion dollars. The impact of such loss could hardly be described as 'catastrophic' or 'coercive.'" *Id.*

88. North Carolina *ex rel.* Morrow v. Califano, 435 U.S. 962, 962 (1978) (mem.).

89. Joshua A. Newberg, *In Defense of* Aston Park: *The Case for State Substantive Due Process Review of Health Care Regulation*, 68 N.C. L. REV. 253, 260 (1990).

90. 203 N.C. App. 593, 693 S.E.2d 673 (2010).

91. *Id.* at 607, 693 S.E.2d at 682–83 (stating that after *Aston Park*, the General Assembly revised the CON law so that it explicitly states the relationship between the purposes behind the CON law and the effect it has on individual property rights). The *Hope* court specifically pointed to the CON statute's prefatory language regarding promoting the public welfare and the geographical maldistribution of healthcare services and facilities as key to its finding of no due process violation. *Id.*

92. *Id.* at 604, 693 S.E.2d at 681.

93. *Id.* at 606, 693 S.E.2d at 682 ("This procedure is efficient and effective and we do not believe, as plaintiffs suggest, that a case by case determination of need, beyond that determined by the Plan, is required to provide an applicant with due process.").

94. *See* 364 N.C. 614, 754 S.E.2d 166 (2010) (mem.).

date, the decision in *Aston Park* has not been overturned by the Supreme Court of North Carolina. This means that in the future, the case may be revisited and reaffirmed as good law.[95]

## II. ARGUMENTS FOR AND AGAINST CON

CON is inherently a complex policy lever, based in economic theories and assumptions that can be difficult to parse. This part aims to clarify some of the policy arguments for and against implementing CON laws. It starts by explaining the strongest arguments for CON, especially those related to access to care, then moves on to arguments against CON, including those that state that CON allows monopolies to form in the healthcare market and artificially restricts patient choice.

### A. *Arguments for CON*

CON laws help to address operational issues—created by healthcare's unique economy—that have subsequent impacts on healthcare access and equity. The economic argument behind CON laws is fairly simple: healthcare policy researchers argue that, by restricting major capital expenditures and changes in healthcare services capacity, costs can be contained.[96] Underlying these theories are arguments that the duplication of healthcare services and suboptimal competition between healthcare providers can raise prices.[97] The Roemer Effect, based on the paper regarding healthcare facility use,[98] is an often-cited theory used to support CON statutes.[99] Supporting this theory,

95. *Aston Park* was cited in the Supreme Court of North Carolina's opinion in *Singleton v. N.C. Dep't of Health & Human Services*, which indicated that the court could revisit the *Aston Park* opinion in the future. Singleton v. N.C. Dep't of Health & Hum. Servs., 386 N.C. 597, 599, 906 S.E.2d 806, 808 (2024) (per curiam). In particular, it was cited after a sentence that indicates the court may have concerns regarding the constitutionality of CON. *Id.* at 599, 906 S.E.2d at 808 ("The complaint contains allegations that, if proven, could render the Certificate of Need law unconstitutional in all its applications."). For further discussion of this recent challenge to the constitutionality of the CON statute, see *infra* Section III.B.

96. SALKEVER & BICE, *supra* note 11, at 8 ("The choice of hospital investment behavior and costs as impact measures was dictated by the manifest purposes and underlying logic of certificate-of-need laws.").

97. Hahn Q. Trinh, James W. Begun & Roice D. Luke, *Hospital Service Duplication: Evidence on the Medical Arms Race*, 33 HEALTH CARE MGMT. REV. 192, 192 (2008) ("Hospital competition is associated with higher levels of duplication of inpatient, ancillary, and high-tech services. Duplication of inpatient services is associated with higher costs but also with higher operating margin. Duplication of ancillary services is associated with higher return on assets. Duplicated high-tech services are financial losers for hospitals. Higher levels of duplicated high-tech services are associated with higher cost per day, higher cost per discharge, and lower operating margin.").

98. *See supra* Section I.B.1.

99. *See* Paul L. Delamater, Joseph P. Messina, Sue C. Grady, Vince WinklerPrins & Ashton M. Shortridge, *Do More Hospital Beds Lead to Higher Hospitalization Rates? A Spatial Examination of Roemer's Law*, 8 PLOS ONE, Feb. 13, 2013, at 1.

studies show that when hospitals are allowed to increase the number of beds in their facilities unchecked, they will, resulting in higher utilization and potentially higher prices for consumers.[100]

When left to its own devices, competition between healthcare providers may not be healthy.[101] According to the "medical arms race" theory, healthcare facilities will continue to expand and spend money on improvements to their facilities to compete for referrals, in what is often referred to as "manufactured need."[102] They will pass these costs onto consumers, while simultaneously accumulating large amounts of debt.[103] Over time, these hospitals will "race to the bottom," ultimately collapsing in their inability to keep up with their competitors.[104] This occurs because the healthcare industry has its own unique economy.

Classical market behavior does not apply to the healthcare industry and its market.[105] In a regular market for general consumer goods, it is assumed that consumers are "sufficiently knowledgeable and competent to make rational and informed choices about what, when where, and why to buy."[106] However, in healthcare, physicians, not patients, decide what tests and equipment are necessary for the patients, due to the informational asymmetry between the two groups.[107] While patients may have some choice and say in their medical decisions, they do not have the same "choice" that they may have when purchasing other goods and services. This is because they also may be limited by their physicians' referrals, geographic access to certain care, or even the limitations that insurance companies place on coverage.[108] The demand for healthcare services is also inelastic: it does not decrease to the same extent that

100. *See, e.g.*, Michael Shwartz, Erol A. Peköz, Alan Labonte, Janelle Heineke & Joseph D. Restuccia, *Bringing Responsibility for Small Area Variations in Hospitalization Rates Back to the Hospital: The Propensity to Hospitalize Index and a Test of the Roemer's Law*, 49 MED. CARE 1062, 1065 (2011) (finding strong support for Roemer's Law in a study of the correlation between a hospital's propensity to hospitalize ("PTH") index and beds per potential patient); Delamater et al., *supra* note 99, at 12.

101. *See* Austin Frakt, *Hospital Competition and the Medical Arms Race*, INCIDENTAL ECONOMIST (Nov. 14, 2011), https://theincidentaleconomist.com/wordpress/hospital-competition-and-the-medical-arms-race/ [http://perma.cc/9YBF-TQV7 (staff-uploaded archive)].

102. *See* Andrew Pollack, *Medical Technology 'Arms Race' Adds Billions to the Nation's Bills*, N.Y. TIMES (Apr. 29, 1991), https://www.nytimes.com/1991/04/29/us/medical-technology-arms-race-adds-billions-to-the-nation-s-bills.html [http://perma.cc/4NMU-Z2C8 (staff-uploaded, dark archive)].

103. *See id.*

104. *See id.*

105. *See* James F. Blumstein & Frank A. Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3, 3–5 (describing the "significant ways" in which "[t]he medical marketplace deviate[s] . . . from classical market assumptions").

106. *Id.* at 4.

107. *See id.*; *see also* Lise Rochaix, *Information Asymmetry and Search in the Market for Physicians' Services*, 8 J. HEALTH ECON. 53, 53 (1989).

108. Andzrej Kozikowski, Dawn Morton-Rias, Sheila Mauldin, Colette Jeffery, Kasey Kavanaugh & Grady Barnhill, *Choosing a Provider: What Factors Matter Most to Consumers and Patients?*, 9 J. PATIENT EXPERIENCE, Jan. 19, 2022, at 1, 1–2.

prices increase.[109] This is because patients view healthcare services as essential and a matter of life and death, such that there are few substitutes. In fact, seeking healthcare services *is* often a matter of life and death. Even if the price of healthcare services or products increases exponentially, there will still be demand because people are willing to pay for essential healthcare, no matter the cost. For example, a pregnant patient is extremely unlikely to turn down obstetrics care if in active labor. Insurance coverage also blunts the actual cost of healthcare services for consumers. Thus, the traditional economic supply and demand curve cannot reliably restrain prices in the healthcare industry. For these reasons, not all economic theories apply to the healthcare market, and industry-specific economic theories have developed over time.[110]

Roemer's theory has been criticized as an over-simplification of the relationship between bed availability and utilization.[111] Health Maintenance Organizations ("HMOs") and Accountable Care Organizations ("ACOs"), new delivery and payment systems developed and heavily implemented in the 1980s and early 2000s, respectively, have changed physician incentives, such that physicians are rewarded for providing efficient care, rather than simply more care, to patients.[112] However, proponents of CON laws argue that, regardless of these changes in payment systems, incentives are still such that adding new hospital beds or equipment unchecked may result in oversaturation of resources,

109. *See generally* Randall P. Ellis, Bruno Martins & Wenjia Zhu, *Health Care Demand Elasticities by Type of Service*, 55 J. HEALTH ECON. 232 (2017) (describing the supply-demand elasticities of various healthcare services and describing emergency room care and maternity care as examples of services with extremely low elasticities).

110. JAN ABEL OLSEN, PRINCIPLES IN HEALTH ECONOMICS AND POLICY 47–60 (2d ed. 2017).

111. *See* Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, 30 ANTITRUST 50, 50–51 (2015); Tarik K. Yuce, Jeanette W. Chung, Cynthia Barnard & Karl Y. Bilimoria, *Association of State Certificate of Need Regulation with Procedural Volume, Market Share, and Outcomes Among Medicare Beneficiaries*, 324 JAMA 2058, 2067 (2020) (finding that among Medicare beneficiaries who underwent surgical procedures from 2016 to 2018, there were no significant differences in markers of hospital volume or quality between states without versus those with CON laws). *See generally* Vivian Ho, *Revisiting States' Experience with Certificate of Need*, 324 JAMA 2033 (2020) (describing recent studies regarding the impact of CON policies on health outcomes).

112. Health Maintenance Organizations ("HMOs") and Accountable Care Organizations ("ACOs") incentivize physicians to provide efficient care to patients by billing providers or organizing care at the patient level rather than per procedure or visit (fee-for-service). Thus, physicians are incentivized to only provide necessary care as to not decrease their profits per patient by increasing expenditures per patient. *See* Austin Frakt, *Accountable Care Organizations: Like HMOs, but Different*, N.Y. TIMES (Jan. 19, 2015), https://www.nytimes.com/2015/01/20/upshot/accountable-care-organizations-like-hmos-but-different.html [http://perma.cc/L9NK-VQN5 (staff-uploaded, dark archive)].

driving up prices.[113] This is particularly true because much of healthcare remains fee-for-service and is not provided through HMOs or ACOs.[114]

Healthcare's unique economy also influences access to healthcare and aspects of healthcare equity. Proponents of CON laws argue that they are important for health equity and ensuring that all communities in a state have adequate healthcare services. Specifically, they argue that if CON laws are repealed, "niche healthcare businesses" will open, such as small, privately owned ambulatory care centers or for-profit free-standing emergency department providers that focus on profitability and receive favorable insurance reimbursement for services.[115] These ambulatory care centers often provide physicians a venue to perform low-risk surgeries that allow patients to return home the same day of surgery, including laparoscopies and biopsies.[116] Many of these procedures are profitable because of sheer volume; since many of the same surgeries may be performed in a day, physicians can bill for more patients.[117] Additionally, the overhead for ambulatory care centers is significantly cheaper than that of traditional hospitals.[118] This means that a higher percentage of physicians' reimbursements are profits.[119]

113. In its 2023 Legislative Brief on Certificate of Need, the North Carolina Healthcare Association—a trade organization representing major hospital systems in the state of North Carolina—argued that, despite arguments that CON has resulted in 12,900 fewer hospital beds in North Carolina, inpatient utilization data did not support an increase in hospital beds; inpatient licensed beds had a 56% occupancy rate in 2019 and increasing the number of beds by 12,900 would result in a 36% occupancy rate. N.C. HEALTHCARE ASS'N, 2023 LEGISLATIVE BRIEF: CERTIFICATE OF NEED 2 (2023), https://www.ncha.org/wp-content/uploads/2023/01/CON_Legislative_Brief_2023.pdf [http://perma.cc/RWT6-BYMA (staff-uploaded archive)].

114. HMOs and ACOs are examples of Managed Care Organizations ("MCOs"), and Medicaid data suggest that while there are many Medicaid recipients enrolled in MCOs, there is still a significant number who are billed on a fee-for-service basis. *Share of Medicaid Population Covered Under Different Delivery System*, KAISER FAM. FOUND. (July 1, 2022), https://www.kff.org/medicaid/state-indicator/share-of-medicaid-population-covered-under-different-delivery-systems/ [http://perma.cc/N7B4-A67H (staff-uploaded archive)].

115. N.C. HEALTHCARE ASS'N, *supra* note 113, at 2.

116. *Outpatient Surgery*, JOHNS HOPKINS MED. (2024), https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/outpatient-surgery [http://perma.cc/3EA9-56B4 (staff-uploaded archive)].

117. Susan Morse, *Ambulatory Surgery Centers Compete with Hospitals for Outpatient Dollars*, HEALTHCARE FIN. NEWS (Aug. 17, 2022), https://www.healthcarefinancenews.com/news/ambulatory-surgery-centers-compete-hospitals-outpatient-dollars [http://perma.cc/UJ6Z-2N3K (staff-uploaded archive)].

118. *Id.*

119. Medicare pays physicians throughout the United States the same rate for each procedure, slightly modified by a geographic adjustment for variation in costs by geographic area. *Calendar Year (CY) 2025 Medicare Physician Fee Schedule Final Rule*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 1, 2024), https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule [https://perma.cc/QP23-6T6L]. Therefore, if overhead is lower, less money will need to be allocated to such overhead costs, resulting in higher profits.

Thus, ambulatory care centers may divert profitable procedures away from community hospitals in rural areas. In turn, community hospitals in rural areas must "face the financial crunch of being left to provide many unprofitable services . . . such as psychiatric care or obstetrics."[120] These smaller rural hospitals also do not have the option to turn away patients who show up at their emergency rooms and require these costly services.[121] Because this is financially unsustainable for these smaller rural hospitals, they are often unable to keep their doors open. This, in turn, has a chilling effect on the availability of care in acute care hospitals, which often already have negative operating margins.[122] Operators of these facilities may be deterred from opening them in rural areas, where they know that they will not be financially sustainable.[123]

There is evidence to suggest that these forces impact the distribution of healthcare services. In states without CON laws, providers concentrate in urban, well-resourced communities rather than rural, low-income communities because of the higher private insurance reimbursement they can receive, as well as the higher patient volume.[124] This is a particularly compelling argument given North Carolina's geographic makeup: a large number of rural communities, especially in the eastern coastal and western mountainous regions of the state, surrounding only a few urban, highly-populated areas.[125]

120. Mary N. Mannix, Opinion, *Certificate of Need: Law Protects Important Patient Access*, RICHMOND TIMES DISPATCH (July 12, 2015), https://richmond.com/opinion/their-opinion/guest-columnists/article_debb8025-9f8a-5a4d-8283-433f9cbced28.html [https://perma.cc/3HDK-YRRC (dark archive)].

121. The Emergency Medical Treatment and Labor Act ("EMTALA") is a federal law that mandates that hospitals provide an appropriate medical screening examination of patients that come to the emergency department. *See* Emergency Medical Treatment and Labor Act of 1986, Pub. L. No. 99-272, tit. IX, § 9121(b), 100 Stat. 164 (codified as amended at 42 U.S.C. § 1395dd).

122. There is evidence that suggests that when CON laws have been repealed in the past, there was a chilling effect on the number of acute care hospitals in rural areas. For example, when Texas ended its CON program in the 1980s, the number of rural, acute-care-hospital closures spiked. *See* N.C. HEALTHCARE ASS'N, *supra* note 113, at 2 (citing TEX. ORG. OF RURAL & CMTY. HOSPS., TEXAS RURAL ACUTE CARE HOSPITAL CLOSURES (1965–2018) (2018), https://capitol.texas.gov/tlodocs/85R/handouts/C4102018062813001/98d9e223-176e-4953-8864-ac94ece1f91c.PDF [http://perma.cc/KG4N-QVE7 (staff-uploaded archive)]); Mannix, *supra* note 120.

123. *See* Mannix, *supra* note 120.

124. *See* N.C. HEALTHCARE ASS'N, *supra* note 113, at 2. Arguably, these providers "follow the money" and open clinics in urban, wealthier areas where they can find paying customers with private healthcare insurance rather than Medicaid, since private insurance companies often pay better rates for services. *See* David Hartley, Lois Quam & Nicole Lurie, *Urban and Rural Differences in Health Insurance and Access to Care*, 10 J. RURAL HEALTH 98, 98 (1994) ("Rural areas had a higher proportion of uninsured and individually insured respondents than urban areas. Among those who purchased insurance through an employer, rural residents had fewer covered benefits than urban residents . . . and were more likely to have a deductible.").

125. *See County Data*, N.C. RURAL CTR., https://www.ncruralcenter.org/county-data/ [https://perma.cc/TF5D-WNVQ]; Jaymie Baxley, *Disparate Issues Shape Rural Health in North Carolina*, N.C. HEALTH NEWS (May 19, 2023), https://www.northcarolinahealthnews.org/2023/05/19/

B. *Arguments Against CON*

CON laws also frustrate many stakeholders,[126] who argue that the government's regulation of the allocation of healthcare resources is unnecessary interference. Due to states' limited allocation of healthcare resources in an area under CON, determinations can become quite contentious. Stakeholders want the ability to open healthcare facilities to grow their businesses and customer bases. On the patient side, they argue that patients should have more, rather than fewer, healthcare options.[127]

Opponents of CON law also argue that market forces should ultimately drive where healthcare organizations try to expand their practices. Instead of restricting the size of healthcare facilities, opponents state that the free market and competition should drive expansion.[128] This means that if a geographic area requires additional healthcare resources, healthcare organizations will be eager to open new practices or facilities in the area to meet that need.[129] But if a geographic area is already saturated with providers, operators of healthcare facilities will not expand, and new players will not enter the market. This is because the investment required to expand will not generate sufficient returns to be profitable or successful. Essentially, opponents of CON argue that CON is bad for businesses. For example, one libertarian political advocacy group, Americans for Prosperity, found that by regulating expansion through CON,

disparate-issues-shape-rural-health-in-nc/ [https://perma.cc/WWQ5-3CR5]. For further discussion of why and how CON may work to ensure rural areas receive adequate access to healthcare services, see *infra* Section V.A.

126. Many of these stakeholders include healthcare providers and organizations who feel that CON, at minimum, requires them to jump through unnecessary hoops and, at maximum, denies them business opportunities. *See, e.g.*, New Brief for Plaintiffs-Appellants at 6–11, Singleton v. N.C. Dep't of Health & Hum. Servs., 386 N.C. 597, 906 S.E.2d 806 (2024) (per curiam). For more discussion of stakeholders' recent challenges to CON in North Carolina, see *infra* Section III.B.

127. *See* CAVANAUGH ET AL., *supra* note 43, at 3.

128. *See id.* ("Predictably, restricting the supply of healthcare facilities and services harms patients and would-be providers. CONs reduce access to medical services, raise healthcare costs and stifle innovation. The only winners are existing providers who benefit from decreased competition.").

129. Though not subject to CON review, an example of a market-driven phenomenon in the healthcare industry is the retail health clinic. Retail health clinics, such as CVS's MinuteClinics, are located within retail spaces, especially pharmacies, grocery stores, and big box retailers. Kaj Rozga, *Retail Health Clinics: How the Next Innovation in Market-Driven Health Care Is Testing State and Federal Law*, 35 AM. J.L. & MED. 205, 205 (2009). They aim to save costs and earn their operators profits by providing a limited scope of services with lower-cost labor and administrative costs, while also reducing costs for their customers when compared to traditional visits to the doctor or emergency room. *Id.* at 211–12. As of 2024, CVS operated 1,100 MinuteClinics across the United States. Heather Landi, *How CVS Is Betting Big on Healthcare Services "Locally Delivered" on a National Scale*, FIERCE HEALTHCARE (May 30, 2024, 7:00 PM), https://www.fiercehealthcare.com/providers/how-cvs-betting-big-healthcare-services-locally-delivered-national-scale [http://perma.cc/8T5G-Z6S2 (staff-uploaded archive)].

NCDHHS denied $1.5 billion dollars in healthcare investment between 2012 and 2022.[130]

CON laws have also drawn scrutiny from stakeholders who argue that they allow already powerful healthcare organizations to maintain monopolies in their respective geographic areas. Incumbent lobbying groups, such as the North Carolina Healthcare Association, have sought to preserve CON laws in the interest of their large health system clients.[131] Until the recent CON reforms, these efforts had been successful, allowing already powerful organizations to retain market power. In addition, the onerous process of applying for CON determinations and the cost of litigation to appeal decisions benefit large hospital systems and healthcare organizations that can afford these costs, while smaller entities interested in entering markets may struggle with these requirements.[132] For example, a solo practitioner ophthalmologist may decide that he wants to open an ambulatory surgical center to perform procedures, which would be cheaper for patients, but he may be denied a CON to do so.[133] Instead, he would be required to perform his surgeries at a competitor, such as a hospital that is part of a larger healthcare system.[134] This ultimately leads to larger questions about anticompetitive behavior.

There is evidence that larger healthcare and hospital systems specifically aim to keep out smaller market entrants. The Federal Trade Commission and the Department of Justice Antitrust Division have even opined that CON laws may allow large healthcare organizations to create barriers to market entry and expansion.[135] There is evidence to suggest this is true; large hospital trade organizations, which lobby on behalf of a state's large hospital systems, often release reports and other materials supporting CON laws.[136] It is usually in these

130. KEVIN SCHMIDT & THOMAS KIMBRELL, AMS. FOR PROSPERITY FOUND., PERMISSION TO CARE: HOW NORTH CAROLINA'S CERTIFICATE OF NEED LAW HARMS PATIENTS AND STIFLES HEALTH CARE INNOVATION 1 (2022), https://americansforprosperity.org/wp-content/uploads/2022/11/AFPF-PermissionToCare-NC-web.pdf [https://perma.cc/T9ET-FBZN]; *see also CON Law Denies N.C. $1.5 Billion in Health Care Investment, Study Finds*, CAROLINA J. (Nov. 10, 2022), https://www.carolinajournal.com/con-law-denies-n-c-1-5-billion-in-health-care-investment-study-finds/ [https://perma.cc/U823-7TG3].

131. *See* N.C. HEALTHCARE ASS'N, *supra* note 113, at 1.

132. The costs associated with preparing CON applications can be tens of thousands of dollars. Zelenka, *supra* note 74, at 357. In 2018, a radiologist sued the North Carolina Department of Health and Human Services ("NCDHHS"), alleging that the costs associated with applying for a CON for an MRI machine would amount to $40,000 in preapplication consulting fees, not including legal and other associated costs. *See infra* Section III.B; *see also* Complaint for Declaratory and Injunctive Relief at 9, Singh v. N.C. Dep't of Health & Human Servs., No. 18CV009498 (N.C. Super. Ct. July 30, 2018), 2018 WL 5307689.

133. James & Flaherty, *supra* note 73.

134. *Id.*

135. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, JOINT STATEMENT OF THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE ON CERTIFICATE-OF-NEED LAWS AND SOUTH CAROLINA HOUSE BILL 3250, at 1 (2016).

136. *See, e.g.*, N.C. HEALTHCARE ASS'N, *supra* note 113.

large healthcare systems' interest to keep out smaller competitors. Large healthcare systems can set prices as market leaders if they are providing the largest volume of care in a community. Additionally, large healthcare systems likely have incentives to support CON laws because the laws give those systems a powerful tool: the ability to refer their patients within the same healthcare system. If a patient is scheduled to undergo a surgery at a healthcare system's ambulatory surgery facility, the patient can be referred to receive their pre-operative radiology screenings at a clinic owned by the same healthcare system. By keeping competitors out of the market, these larger players in the healthcare system can continue to shuttle referrals from one provider within the system to another. At the same time, this may be an oversimplification of the issue: incumbent health systems do not just expand to maintain monopolies or cut out their competitors. They are often guided by strategic goals that are set by their boards of directors and market research. Health systems may become stronger in a market as a result of their strategic expansion goals. But inferring a causal relationship between expansion and the creation of monopolies, or the intent to create monopolies, may be stretching this analysis a bit too far.

Finally, opponents of CON regulation argue that these laws attract corruption. As powerful players jockey for the right to build and expand hospital facilities, government officials may be particularly susceptible to lobbying efforts for these causes. It is not difficult to imagine a scenario where politicians could take bribes in order to influence the outcome of a CON determination, and this has even happened in the past.[137] Some critics have even pointed out potential biases or cronyism in the CON process, noting, for example, that in North Carolina, "[p]eople employed by or affiliated with existing healthcare providers and medical institutions make up 60% of the State Health Coordinating Council, which determines the state's need for healthcare facilities and services."[138] However, there are also guardrails in place to prevent

137. In the mid-1980s, Louisiana Governor Edwin Edwards was charged with racketeering and wire fraud for using his influence to illegally acquire and sell hospital permits from the state for $10 million in profits. *See* Dudley Clendinen, *Small Louisiana Hospital Feels Effect of Case Against Governor*, N.Y TIMES (Sept. 17, 1985), https://www.nytimes.com/1985/09/17/us/small-louisiana-hospital-feels-effect-of-case-against-governor.html [https://perma.cc/G3KU-NUR6 (staff-uploaded, dark archive)]; Julie Havlak, *Scandal and Corruption: A History of Certificate of Need Laws*, CAROLINA J. (Mar. 9, 2021), https://www.carolinajournal.com/scandal-and-corruption-a-history-of-certificate-of-need-laws/ [https://perma.cc/FS5L-95ME]. Ultimately, the case went to trial, and Edwards was not convicted because of a deadlocked jury. *See id.*

138. Members of state health planning boards have also been convicted of corruption:

> [I]n 2004, a member of the Illinois Health Facilities Planning Board was convicted for using his position on the Board to secure the approval of a CON application for Mercy Hospital. In

undue influence on the State Health Coordinating Council, as lobbyists are explicitly banned from serving on the Council.[139]

* * *

CON has many pros and cons, and they may differ depending on the stakeholder and even the circumstances of a specific portion of the CON statute. For this reason, any changes to the CON statute are sure to have wide-ranging impacts, no matter how minor a change might be. Therefore, it is important to analyze changes to the CON law from a variety of perspectives. The next part of this Comment includes a summary of more recent efforts to reform and repeal CON in North Carolina. It also provides analysis of H.B. 76's specific reforms, including how different stakeholders may benefit or be harmed by the reforms, and areas of uncertainty where it is unclear how stakeholders may be affected by the reforms.

## III. ANALYSIS OF PRIOR ATTEMPTS TO REFORM AND REPEAL CON

Given that CON is such a nuanced issue with many pros and cons, it is perhaps unsurprising that there has been a history of attempts to reform and repeal the law in North Carolina. This part begins by outlining prior legislative attempts to reform and repeal CON, as well as recent litigation regarding the constitutionality of CON laws. The arguments used in these attempts preview and help to contextualize H.B. 76's reforms.

### A. *Legislative Attempts at CON Reform and Repeal*

Prior to the enactment of H.B. 76, many of North Carolina's legislators advocated for CON reform, and many legislators still oppose the law's existence entirely.[140] H.B. 76's CON reforms likely occurred as a legislative compromise

exchange for his help, the Board member agreed to accept a kickback from the owner of the construction company that had been hired to work on the new hospital.

U.S. DEP'T OF JUST. & FED. TRADE COMM'N, STATEMENT BEFORE THE ILLINOIS TASK FORCE, *supra* note 42, at 8 (footnote omitted); *see also* Kevin Schmidt & Thomas Kimbrell, Opinion, *Covid Exposed the Damage Done by Certificate-of-Need Rules*, WALL ST. J. (Feb. 24, 2023, 6:05 PM), https://www.wsj.com/articles/covid-exposed-the-damage-done-by-certificate-of-need-rules-medicare-healthcare-covid-hospital-competition-d36251e [https://perma.cc/YEF2-UFVV (staff-uploaded, dark archive)].

139. N.C. GEN. STAT. § 131E-191.1 (2023).

140. *See, e.g.*, Rose Hoban, *Lawmakers Are Back in Raleigh with Health Care Policy Wish Lists for the Coming Year*, N.C. HEALTH NEWS (Jan. 12, 2023), https://www.northcarolinahealthnews.org/2023/01/12/lawmakers-in-raleigh-health-policy-issues/ [https://perma.cc/7XRX-5ASF] (reporting quotes from N.C. State Senator Donny Lambeth).

between North Carolina's Republican and Democratic parties.[141] Republicans have generally opposed CON, as many oppose government intervention in the free market, while Democrats have been more in favor of government regulation to achieve policy goals.[142] However, CON laws have created strange political bedfellows: rural Republicans may argue in favor of CON laws because they benefit small rural hospitals in their communities.[143] Past attempts to repeal or amend the CON law have failed even in Republican-controlled legislatures.[144] North Carolina legislators have introduced several bills to completely eliminate CON in recent years.[145] Most notably, in early 2023, prior to the addition of CON reforms to H.B. 76, legislators in the North Carolina Senate and House introduced bills meant to repeal CON completely.[146] With the passage of H.B. 76, opponents of CON could not celebrate a full repeal of CON, but they had something to look forward to: an incremental relaxation of CON law in North Carolina.

Given historical opposition to CON, it is conceivable that the legislature might resume efforts to further dismantle CON in North Carolina. However, post-H.B. 76, there has been little to no legislative focus on CON reform. Deregulation in the healthcare industry generally occurs incrementally, likely because legislators fear how the public may react to policies that could harm the

141. *See* Lauren Zola, *N.C. House Passes Bipartisan Medicaid Expansion, Bill Heads to Senate*, DAILY TARHEEL (Feb. 22, 2023), https://www.dailytarheel.com/article/2023/02/city-ncga-hb76-medicaid-expansion-north-carolina-general-assembly-senate-politics [https://perma.cc/U88Q-UPWY (staff-uploaded archive)]; *see also infra* Section IV.B.

142. *See* Boyle, *supra* note 23.

143. *See* Sarah Nagem, *Rural NC Hospitals Applaud Move Towards Medicaid Expansion – But Not a Tacked-On Change*, BORDER BELT INDEP. (June 14, 2022), https://borderbelt.org/rural-nc-hospitals-medicaid-con/ [https://perma.cc/TES8-698T]. For further discussion on why CON laws benefit rural communities, see *supra* Section II.A.

144. Bills attempting to repeal CON in the 2021–2022 North Carolina legislative session were referred to Senate and House committees but did not make further progress. *See* S.B. 309, 155th Gen. Assemb., Reg. Sess. (N.C. 2021); H.B. 410, 155th Gen. Assemb., Reg. Sess. (N.C. 2021); *see also Senate Bill 309*, N.C. GEN. ASSEMBLY, https://www.ncleg.gov/BillLookUp/2021/S309 [https://perma.cc/2DHT-AGTX] (showing that the bill stalled in committee in March 2021); *House Bill 410*, N.C. GEN. ASSEMBLY, https://www.ncleg.gov/BillLookUp/2021/H410 [https://perma.cc/7KG3-AR75] (same). There was also a bill aiming to repeal CON introduced in the 2019–2020 legislative session, which also did not make it past committee. S.B. 539, 154th Gen. Assemb., Reg. Sess. (N.C. 2019); *Senate Bill 539*, N.C. GEN. ASSEMBLY, https://www.ncleg.gov/BillLookUp/2019/s539 [https://perma.cc/36Z4-775J] (showing the bill stalled in committee in April 2019). Republican North Carolina Senator Ralph Hise has been one of the most vocal opponents of CON and has introduced bills to repeal CON for years. *See* Dan Way, *Certificate of Need May Be on the Chopping Block Again*, CAROLINA J. (Mar. 28, 2017), https://www.carolinajournal.com/certificate-of-need-may-be-on-the-chopping-block-again/ [https://perma.cc/84TA-8ZBR].

145. *See, e.g.*, S.B. 48, 156th Gen. Assemb., Reg. Sess. (N.C. 2023); H.B. 107, 156th Gen. Assemb., Reg. Sess. (N.C. 2023).

146. N.C. S.B. 48; N.C. H.B. 107.

public health when the potential upside is simply profitability.[147] Further, implementing deregulation takes time, as government agencies learn how to adapt their processes to the new mandates that they have been given by legislators. Perhaps this is why H.B. 76's reforms roll out over a multiyear period; legislators were already cognizant of the challenges of revamping the state's CON law, not to mention the public and trade-group uproar that could occur if they decided to move too quickly in implementing their reforms. This may have also been a bargaining concession that otherwise pro-CON groups were willing to give in exchange for Medicaid expansion.[148] Regardless of the reasons behind the incremental changes to North Carolina's CON law, it is conceivable that, over time, legislators may decide to pursue further, more drastic reforms, especially given past interest in entirely repealing CON.[149] Or, given the history of challenges to CON law in the courts, legislators may simply prefer to wait for the Supreme Court of North Carolina, and the court system generally, to weaken CON, rather than risk direct political backlash.[150]

### B. *Recent CON Litigation*

In recent years, solo practitioners and owners of smaller practices have filed lawsuits arguing that North Carolina's CON law violates their rights under the North Carolina Constitution. Backed by the Institute for Justice, a libertarian, nonprofit, public-interest law firm, several physicians seeking to expand their practices have filed lawsuits against the NCDHHS, alleging that the current CON statute is unconstitutional.[151] While these lawsuits have had

147. *See* Clark C. Havighurst & Glenn M. Hackbarth, *Competition and Health Care: Planning for Deregulation*, 4 REGULATION 39, 41 (1980) ("[A] powerful taboo makes it difficult to undertake, or even acknowledge the existence of, trade-offs between the lives and health of citizens on the one hand and the public's finances on the other."). Further, consider tensions that still exist post-COVID-19 pandemic, including the federal government's decision to end the COVID-19 public health emergency in 2023 despite concerns about the health risks associated with "long COVID." James Barron, *The Covid Emergency Is Over. Covid's Still Here.*, N.Y. TIMES (May 17, 2023), https://www.nytimes.com/2023/05/17/nyregion/ny-covid-emergency.html [https://perma.cc/2NMN-7MUQ (staff-uploaded, dark archive)]. The end of the public health emergency may have been an acknowledgement of the economic impact on businesses in the height of the pandemic, and continued impacts, such as remote work's impact on retail businesses and office spaces. *Id.*

148. *See* Phil Berger, Opinion, *Why I Changed My Mind on Expanding Medicaid*, CAROLINA J. (Mar. 15, 2023), https://www.carolinajournal.com/opinion/berger-why-i-changed-my-mind-on-expanding-medicaid/ [https://perma.cc/WY7N-YY2C] (describing N.C. Senator and Senate President Pro Tem Phil Berger's decade-long opposition to Medicaid expansion and his change in opinion given the inclusion of CON reform in H.B. 76).

149. *See* N.C. S.B. 309; N.C. H.B. 410.

150. For a discussion of ongoing and recent litigation regarding the state constitutionality of CON in North Carolina state courts, see *infra* Section III.B.

151. The Institute for Justice has taken on several CON cases on behalf of solo practitioners attempting to either purchase equipment under CON review or expand their practice. *See* Richard Craver, *NC Supreme Court Agrees to Address Doctor's CON Lawsuit*, WINSTON-SALEM J. (Sept. 5, 2023),

little success, the efforts generated media attention and have therefore been used as tools to advocate for the elimination of CON law.[152]

In *Singh v. N.C. Department of Health and Human Services*,[153] a Winston-Salem, North Carolina-based radiologist, Dr. Gajendra Singh, sued NCDHHS after finding the CON process for acquiring an MRI machine for his imaging practice too costly.[154] Dr. Singh had two options: either rent a machine from an organization that already had a CON for the equipment, or purchase a machine and hope that NCDHHS would allocate a CON to him.[155] Both methods would have been cost prohibitive; renting was too expensive, and the upfront costs associated with applying for a CON, along with the litigation[156] that likely would occur, would cost him tens of thousands of dollars.[157] Dr. Singh argued that the CON law, on its face and as applied, violated sections of the North Carolina Constitution.[158] Ultimately, in 2018, the superior court dismissed the constitutional challenges based on a failure to state a claim.[159] However, this case provided momentum for additional litigation aimed at dismantling North Carolina's CON law.

Recent litigation suggests that North Carolina's courts may now be willing to review CON laws. In *Singleton v. N.C. Department of Health and Human Services*,[160] a New Bern, North Carolina-based ophthalmologist argued that CON laws violated his substantive due process rights.[161] The ophthalmologist performed outpatient surgeries at the local hospital.[162] Despite not having

https://journalnow.com/news/local/nc-supreme-court-agrees-to-address-doctors-con-lawsuit/article_fdf9d018-4c10-11ee-bc6c-6b5a3d933d18.html [https://perma.cc/LX3B-7QBL (dark archive)]; Complaint for Declaratory and Injunctive Relief, *supra* note 132, at 39.

152. *See* Julie Havlak, *Winston-Salem Doctor Suing over Certificate of Need Gets First Court Win*, CAROLINA J. (Nov. 21, 2019), https://www.carolinajournal.com/winston-salem-doctor-suing-over-certificate-of-need-gets-first-court-win/ [https://perma.cc/N64D-MP5Q]; *see also* Craver, *supra* note 151.

153. No. 18CV7009498 (N.C. Super. Ct. July 30, 2018), 2018 WL 5307689.

154. *Id.* at *1–2; *see* Havlak, *Certificate of Need CON*, *supra* note 46.

155. *See* 2018 WL 5307689, at *10–11; Havlak, *Certificate of Need CON*, *supra* note 46.

156. This would be litigation against the state of North Carolina, if the CON determination did not go in Dr. Singh's favor. *See supra* Section I.A.

157. Complaint for Declaratory and Injunctive Relief, *supra* note 132, at 31.

158. Dr. Singh argued that the CON law violated North Carolina's Constitution's Anti-Monopoly Clause, Exclusive Emoluments Clause, and Law of the Land Clause, both on substantive due process and equal protection grounds. *Id.* at 34–38.

159. Brief for Providers and Providers Association as Amici Curiae Supporting Defendants at 7, Singleton v. N.C. Dep't of Health & Hum. Servs., No. 20CVS5150 (N.C. Super. Ct. June 9, 2021), 2021 WL 7186714.

160. 284 N.C. App. 104, 874 S.E.2d 669 (2022), *vacated*, 386 N.C. 597, 906 S.E.2d 806 (2024).

161. *Id.* at 111, 874 S.E.2d at 675. Singleton asserted a substantive due process claim under Article I, Section 19 of the North Carolina Constitution, known as the "Law of the Land" Clause, which is generally agreed upon as the equivalent of the Fourteenth Amendment's Due Process Clause in the United States Constitution. *Id.* at 112, 874 S.E.2d at 676; *see also* N.C. CONST. art. I, § 19.

162. *Singleton*, 284 N.C App. at 107–09, 874 S.E.2d at 672–74.

applied for a CON, he argued that he should have been able to open his own ambulatory surgical facility ("ASF"), but that he had been unable to do so because the 2021 State Medical Facilities Plan stated there was "no need" for additional operating room capacity in his geographic area.[163] Singleton argued that the CON law, as applied to him, violated the North Carolina Constitution.[164] Further, he asserted that *Aston Park*, rather than *Hope*, was the controlling law, and that *Hope* did not foreclose an as-applied challenge to the constitutionality of the statute.[165]

In its 2022 opinion, the North Carolina Court of Appeals first focused on procedural issues with Dr. Singleton's claims. The court reasoned that the administrative hearing system prescribed by the CON statute[166] is the appropriate venue for hearing Dr. Singleton's dispute, and he must exhaust that review prior to bringing a claim in state court or risk dismissal for lack of subject matter jurisdiction.[167] The North Carolina Court of Appeals also stated that Singleton should pursue other venues, such as the General Assembly and Commissions "particularly qualified for the purpose," to voice his complaints regarding CON law, rather than the judicial system.[168] The court concluded that Singleton had failed to state a claim upon which relief could be granted, as he had not actually applied for a CON or undergone the usual administrative appeals process.[169]

Additionally, the North Carolina Court of Appeals ruled that Singleton did not have a ripe constitutional procedural due process claim.[170] With regard

163. *Id.*

164. *Id.*

165. *Id.* at 107–09, 114, 874 S.E.2d at 672–74, 677.

166. N.C. GEN. STAT. § 131E-188 (2023). The CON statute allows a petition for a contested case to be filed within thirty days of the decision to issue, deny, or withdraw a CON, which then will usually result in an administrative hearing before a state administrative law judge. *Id.*

167. *Singleton*, 284 N.C. App. at 107–09, 114, 874 S.E.2d at 672–74, 677. The court stated that when the legislature has provided an effective administrative remedy by statute,

> that remedy is exclusive and its relief must be exhausted before recourse may be had to the courts. This is especially true where a statute establishes, as here, a procedure whereby matters of regulation and control are first addressed by commissions or agencies particularly qualified for the purpose. . . . Only after the appropriate agency has developed its own record and factual background upon which its decision must rest should the courts be available to review the sufficiency of its process.

*Id.* at 109, 874 S.E.2d at 673–74 (emphasis omitted) (quoting Presnell v. Pell, 298 N.C. 715, 721–22, 260 S.E.2d 611, 615 (1979)).

168. *Id.* at 109, 115–16, 874 S.E.2d at 673, 677–78 ("While . . . Plaintiffs correctly assert the CON process is costly and fraught with gross delays, and service needs are not kept current, those challenges can also be asserted before the General Assembly, Commissions, and against the agency where a factual record can be built.").

169. *Id.* at 117, 874 S.E.2d at 678 ("Plaintiffs' as-applied challenges in their complaint, taken as true and in the light most favorable to them, fail to state any legally valid cause of action.").

170. *Id.*

to Singleton's assertions that the CON law, as applied, violated North Carolina's Constitution, the North Carolina Court of Appeals reiterated the findings of *Hope*: that there was a legitimate government interest in upholding the CON law, as explained in the statute's prefatory language.[171] Thus, the court declined to apply *Aston Park* to Singleton's challenge.[172] The court also stated that the due process deficiencies that the plaintiffs asserted were no longer present in the CON statute due to the legislative amendments rationalizing CON that had been made to the statute post-*Aston Park*.[173]

But legal challenges to North Carolina's CON law may still succeed. The Supreme Court of North Carolina agreed to consider Dr. Singleton's case in 2023.[174] In a per curiam opinion filed October 18, 2024, the court vacated the decision of the North Carolina Court of Appeals and remanded the case for further proceedings.[175] The court explained that, after oral arguments, it had requested supplemental briefs from both parties to the case, as it questioned whether Singleton's challenges were as-applied, facial, or both.[176] This was a crucial question, as a facial challenge would mean that Singleton was challenging the constitutionality of the *entire* CON statute rather than its application simply to him. This type of challenge would also impact the scope of the court's review.[177]

Ultimately, the Supreme Court of North Carolina concluded that the challenges presented by Singleton were both facial and as-applied.[178] Although the plaintiff originally characterized his claim as "as-applied" and sought declaratory and injunctive relief "as applied to Plaintiffs,"[179] the court said that the "label is not what matters" when courts distinguish between facial and as-applied challenges.[180] Further, according to the court, "The complaint contains allegations that, if proven, could render the Certificate of Need law unconstitutional in all its applications."[181] Therefore, the court implicitly acknowledged that Singleton's claims could have easily applied to any physician

171. *Id.* at 115, 874 S.E.2d at 677.

172. *Id.*

173. *See id.* at 115–16, 874 S.E.2d at 677.

174. James & Flaherty, *supra* note 73; Singleton v. N.C. Dep't of Health & Hum. Servs., 385 N.C. 324, 324, 890 S.E.2d 901, 901 (2023) (mem.).

175. Singleton v. N.C. Dep't of Health & Hum. Servs., 386 N.C. 597, 599, 906 S.E.2d 806, 808 (2024) (per curiam).

176. *Id.* at 598, 906 S.E.2d at 807.

177. *Id.* at 599, 906 S.E.2d at 808.

178. *Id.* at 598–99, 906 S.E.2d at 807–08.

179. Singleton and his practice, Singleton Vision Center, P.A., are co-plaintiffs in the case. *Id.* at 597, 906 S.E.2d at 806.

180. *Id.* at 599, 906 S.E.2d at 807 (citing Doe v. Reed, 561 U.S. 186, 194 (2010)).

181. *Id.* at 599, 906 S.E.2d at 808 (citing *In re* Certificate of Need for Aston Park Hosp., Inc., 282 N.C. 542, 551–52, 193 S.E.2d 729, 735–36 (1973)).

or healthcare organization seeking a CON and implied that CON could be deemed entirely unconstitutional in the near future.

This was a significant ruling by the court—not only because it implied that the entirety of the CON statute may be found unconstitutional at a later date. Additional jurisdictional and procedural criteria apply to the case on remand because it is a "facial constitutional challenge to the validity of an act of the General Assembly."[182] While the court's per curiam opinion did not reach the merits of Singleton's constitutional arguments, there is certainly a likelihood that it will address those issues in the future—in a subsequent appeal by Singleton or a similar case brought by different parties.[183] And it is conceivable that a court that already seems unsure of the constitutionality of CON will rule that it is unconstitutional in the future. However, while *Singleton* works its way through the courts again and we wait to learn the fate of CON in North Carolina, H.B. 76's changes to the CON statute remain valid and will continue to go into effect over a multiyear period.

## IV. H.B. 76'S REFORMS

This part proceeds by outlining H.B. 76's major reforms and providing an analysis of what these reforms change in practice. It then explores the likely intent behind their enactment, as well as the questions that these reforms raise in their implementation and regarding future possibilities for reform.

### A. *Summary of H.B. 76 CON Reforms*

H.B. 76's first CON reforms went into effect immediately when the Bill became law on March 27, 2023.[184] Some of the most significant of these reforms provide concessions to certain healthcare providers, generally those who provide care at specialized, smaller facilities, rather than large hospitals.[185] H.B. 76's reforms also roll out incrementally over a multiyear period: the first reforms become effective immediately after the passage of the Bill, while additional reforms become effective two years, and later, three years after H.B. 76's passage.[186] While the CON reforms summarized below do not represent all of those implemented by H.B. 76, they provide an accounting of some of the

182. *Id.* The court cites sections 1-267.1 and 1A-1, Rule 42(b)(4) of the General Statues of North Carolina, which require the case to be heard in front of a three-judge panel in the Superior Court of Wake County. *Id.*; *see also* N.C. GEN. STAT. §§ 1-267.1; 1A-1, Rule 42(b)(4) (2023).

183. Given how contentious the *Singleton* litigation and CON litigation has been generally, it seems likely that no matter what the superior court holds, parties will continue appealing until the Supreme Court of North Carolina hears the case or an iteration of it again.

184. Act of Mar. 27, 2023, ch. 7, §§ 3.1.(a)–(e), 2023 N.C. Sess. Laws __, __ (codified in scattered sections of N.C. GEN. STAT. chapters 131E, 148).

185. *See id.*

186. *Id.* §§ 3.2.(a)–(e) (reforms effective after two years); *id.* §§ 3.3.(a)–(c) (reforms effective after three years).

most significant reforms and those that raise important policy implications and questions.

1. Immediate Reforms: Psychiatric and Chemical Dependency Treatment Centers, Monetary Threshold Increases

Prior to the reforms, North Carolina CON law defined psychiatric facilities and chemical dependency treatment facilities under the definition of a "health service facility," triggering the need for a CON.[187] Under North Carolina law, psychiatric facilities are defined as "public or private facilit[ies] . . . primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of individuals with mental illnesses."[188] Meanwhile, a chemical dependency treatment facility is a "public or private facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or a substance use disorder."[189] The first set of CON reforms remove chemical dependency treatment facilities and psychiatric facilities from the definition of health service facilities,[190] exempting them from CON review. This means that any party who wants to open these types of treatment facilities can now do so without any CON barriers.

Additional immediate reforms include increases to the monetary threshold that triggers CON review of diagnostic center[191] and replacement equipment[192] proposals.[193] The Diagnostic Center CON threshold had previously been calculated "based on either the higher of the fair market value of the [diagnostic]

187. N.C. GEN. STAT. § 131E-176(9b) (2021). The definition of health service facilities also included hospitals, nursing homes, rehabilitation facilities, ambulatory surgical facilities, among other healthcare related facilities. *Id.*

188. N.C. GEN. STAT. § 131E-176(21) (2023).

189. *Id.* § 131E-176(5a). Treatments at chemical dependency treatment facilities include "detoxification, administration of a therapeutic regimen for the treatment of individuals with chemical dependence or substance use disorders, and related services." *Id.*

190. Act of Mar. 27, 2023, § 3.1.(a).

191. *Id.* Before the reforms, a diagnostic center was defined as a:

> freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars ($10,000) or more exceeds one million five hundred thousand dollars ($1,500,000).

N.C. GEN. STAT. § 131E-176(7a) (2021).

192. Act of Mar. 27, 2023, § 3.1.(a). Replacement equipment was previously defined as "[e]quipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced." N.C. GEN. STAT. § 131E-176(22a) (2021).

193. The original $1.5 million diagnostic center threshold was increased to $3 million. Act of Mar. 27, 2023, § 3.1.(a). The $2 million replacement equipment threshold was increased to $3 million. *Id.*

equipment or the cost."[194] The increase in the replacement equipment threshold likely accounted for price increases in equipment since the last update to the CON law, but also added an annual inflation increase to the threshold.[195]

The reforms also increase the monetary threshold that triggers a review of a capital expenditure related to renovating, replacing on the same site, or expanding existing nursing homes, adult care homes, and intermediate care facilities for individuals with intellectual disabilities.[196] By excluding from CON review some capital expenditures related to residential facilities that provide care to vulnerable populations, the General Assembly may be acknowledging the increased costs of constructing, renovating and expanding facilities.[197] But these reforms may also be a mechanism for these facilities to make only cosmetic changes to justify charging higher prices for their services, which can be financially devastating for patients over time.[198] If this is the case, this would be just another example of unnecessary spending that hurts consumers' bottom lines without providing much value in exchange.

However, some of the reforms raise more policy questions than others. It is notable that the General Assembly opted to make the psychiatric and chemical dependency treatment center and diagnostic equipment purchase reforms immediate. The immediate implementation of these reforms may be due to the significant need for psychiatric and chemical dependency treatment facilities within the state. These facilities may not be as financially attractive as others because they can be resource intensive for long periods of time and do not yield much reimbursement.[199] Or perhaps these changes were a result of skillful lobbying, or a lack thereof. Prior to the reforms, pro-CON interest groups, such as the N.C. Healthcare Association, openly supported repealing

194. Bart Walker, *North Carolina Certificate-of-Need Reforms*, MCGUIREWOODS (Apr. 20, 2023), https://www.mcguirewoods.com/client-resources/alerts/2023/4/north-carolina-certificate-of-need-reforms/ [https://perma.cc/R7ER-RGL9 (staff-uploaded archive)].

195. The cost threshold inflation-adjustment is based on "using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous [date of adjustment]." Act of Mar. 27, 2023, § 3.1.(a).

196. *Id.* § 3.1.(b).

197. *See How Soaring Prices for Building Materials Impact Housing*, NAT'L ASSOC. HOME BUILDERS (July 26, 2024), https://www.nahb.org/blog/2024/07/how-soaring-prices-building-materials-impact-housing [https://perma.cc/329G-BMDV] (describing that the cost of some building materials increased as much as ninety percent in a single year during 2021).

198. Traditional health insurance plans and Medicare provide little to no coverage for long-term care costs, such that many individuals who require long-term care often exhaust their life's savings until they become eligible for Medicaid, which will cover these services. *See How Can I Pay for Nursing Home Care?*, MEDICARE.GOV, https://www.medicare.gov/providers-services/original-medicare/nursing-homes/payment [https://perma.cc/V9XX-A8P6].

199. For a discussion of the need for and incentives surrounding these treatment centers, see *infra* Section IV.B.

the CON requirement for these facilities.[200] So perhaps this was a coming together of all parties towards a noncontroversial policy solution to solve a problem and an example of effective policymaking.

If the reforms work as intended, resulting in increased access to much-needed treatment for mental health and chemical dependency, then the General Assembly's actions should be applauded. It is not possible to definitively track whether there has been a great uptick in the number of psychiatric and chemical dependency facilities or announcements of these facilities, since applications for these facilities are no longer being publicly logged.[201] Additionally, it takes time for potential market entrants to conduct market research and financial planning to determine whether to open such facilities; one would not expect facilities to be announced only several months after the enactment of the reforms. However, psychiatric and chemical dependency treatment facilities have opened and been announced post-H.B. 76.[202] While it is unclear whether some of these facilities were planned prior to the reforms, this is evidence that the reforms may be having a near-immediate impact. If there is any criticism about these particular H.B. 76 reforms, it is regarding questions raised about the implementation of the statute. For example, the statute did not state what should happen to any pending CON applications undergoing review before the reforms, nor whether the North Carolina DHSR should immediately cease review of affected applications and grant CONs to those facilities or abandon their review altogether if CONs were no longer necessary.

200. Richard Stradling, *Medicaid Expansion Agreement Would Also Change Law Governing Health Care Facilities*, NEWS & OBSERVER (Mar. 23, 2023, 11:05 AM), https://www.newsobserver.com/news/politics-government/article272662720.html [https://perma.cc/XPL5-FEE6 (staff-uploaded, dark archive)] ("The N.C. Healthcare Association, which represents the state's 130 hospitals, also said in September that it would support repealing certificate of need requirements for beds for psychiatric and chemical dependency patients."). It is also possible, however, that the N.C. Healthcare Association does not feel the need to "protect" these entities as they are not members that the association represents—the organization chiefly represents hospitals and health systems. *NCHA Members*, N.C. HEALTHCARE ASS'N, https://www.ncha.org/about-us/ncha-members/ [https://perma.cc/D5M5-2AHQ].

201. The North Carolina Division of Health Services Regulation ("DHSR") releases monthly logs of all CON applications to the public. *Application Logs*, N.C. DIV. HEALTH SERV. REGUL., HEALTHCARE PLAN. & CERTIFICATE NEED SEC., https://info.ncdhhs.gov/dhsr/coneed/applicationlogs.html [https://perma.cc/3MNB-8YB8]. The public log now shows no recent applications for these facilities, even though it likely once did. *Id.*

202. *See, e.g.*, Press Release, Carteret County, N.C., Behavioral Health Facility to Open in Carteret County (Mar. 22, 2024), https://www.carteretcountync.gov/CivicAlerts.aspx?AID=384 [https://perma.cc/VT4C-NJE3] (describing a 104-bed facility providing behavioral healthcare and substance use disorder treatment for children, adolescents, and adults in Carteret County, North Carolina); *see also* Press Release, N.C. Dep't Health & Hum. Servs., Ribbon Cutting and Open House for Alamance Behavioral Health Center (June 17, 2024), https://www.ncdhhs.gov/news/press-releases/2024/06/17/ribbon-cutting-and-open-house-alamance-behavioral-health-center [https://perma.cc/ZXL2-RPEA] (describing a new behavioral health center in Alamance County, North Carolina, offering mental health services and substance use recovery support).

### 2. Reforms Implemented After Two Years: Ambulatory Surgical Facilities, Charity Care Requirement

Two years after the passage of the reforms, "qualified urban ambulatory surgical facilities"[203] will be exempt from CON review.[204] This means that providers will be able to open ASFs in more highly populated areas of North Carolina without applying for CON approval.[205] In exchange for CON exemption, however, these qualified urban ASFs will have to provide charity care.[206] To accomplish this charity care requirement, at least four percent of these facilities' revenue must come from Medicaid and self-pay patients.[207] This

203. An ambulatory surgery facility ("ASF") is:

> [A] facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional, or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room or gastrointestinal endoscopy room and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient.

N.C. GEN. STAT. § 131E-176(1b) (2023). Colloquially, these are also referred to as ambulatory surgery centers ("ASCs"). Meanwhile, a "qualified urban ambulatory surgical facility" is one that is (a) "licensed by the Department [of Health] to operate as an ambulatory surgical facility[;]" (b) "has a single specialty or multispecialty ambulatory surgical program[;]" and (c) "[i]s located in a county with a population greater than 125,000 according to the 2020 federal decennial census or any subsequent federal decennial census." Act of Mar. 27, 2023, ch. 7, § 3.2.(a), 2023 N.C. Sess. Laws __, __ (codified at N.C. GEN. STAT. § 131E-176(21a)).

204. Act of Mar. 27, 2023, § 3.2.(a).

205. *See* Am. Counts Staff, *North Carolina: 2020 Census*, U.S. CENSUS BUREAU (Aug. 25, 2021), https://www.census.gov/library/stories/state-by-state/north-carolina-population-change-between-census-decade.html [https://perma.cc/8WEQ-GQCF]. Wake, Mecklenburg, Guilford, Forsyth, Cumberland, Durham, Buncombe, Union, Gaston, Cabarrus, New Hanover, Johnston, Onslow, Iredell, Alamance, Davidson, Catawba, Orange, Rowan, Randolph, Brunswick, and Harnett Counties are above the 125,000-person threshold for qualified urban ASFs. *Id.* Wayne, Robeson, Henderson, and Craven are the next four counties with populations just under the 125,000-person threshold. *Id.*

206. Act of Mar. 27, 2023, § 3.2.(a). The Act outlines a complex formula for the charity care requirement, described as

> the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue earned from self-pay and Medicaid cases, divided by the total earned revenues for all surgical cases, divided by the total earned revenues for all surgical cases performed in the facility for procedures for which there is a Medicare allowable fee.

*Id.* § 3.2.(c).

207. *Id.* As previously mentioned, Medicaid provides healthcare coverage to low-income individuals. *See supra* note 8. "Self-pay" is the term used to refer to individuals who do not have insurance coverage. Robin Rudowitz, Patrick Drake, Jennifer Tolbert & Anthony Damico, *How Many Uninsured Are in the Coverage Gap and How Many Could Be Eligible if All States Adopted the Medicaid Expansion?*, KAISER FAM. FOUND. (Feb. 26, 2024), https://www.kff.org/medicaid/issue-brief/how-many-uninsured-are-in-the-coverage-gap-and-how-many-could-be-eligible-if-all-states-adopted-the-

is not a significant amount of revenue, but the establishment of a charity-care requirement period will help ensure that low-income patients in urban areas also obtain access to care, despite their inability to pay.[208] It also prevents ASFs from taking only profitable patients, leaving hospitals to care for charity-care patients. Further, this charity-care requirement helps to address concerns that North Carolina's healthcare system has not been providing adequate charity care to the community.[209]

While the statute outlines how charity care is calculated from a purely technical perspective, it does not include further parameters that describe how these ASFs should solicit charity-care patients, whether providers should provide completely free care for patients or simply discount care for patients, and other uncertainties. Further, the statute does not describe how this requirement will be enforced. It is unclear whether ASFs will be required to report to the state the number of patients to whom they provide charity care or the amount of funds used to provide charity care. The revised statute also does not provide information regarding what state administrative body will oversee the monitoring of whether ASFs remain compliant with the charity-care requirement. The lack of clarity surrounding the charity-care requirement may make it possible for healthcare organizations to skirt the requirement, perhaps entirely. If there is no system of accountability to enforce the requirement, then the requirement may practically be meaningless. This would essentially allow urban ASFs to open without any barriers and would mean that the goal of improving access to healthcare and the health of North Carolina's most disadvantaged individuals would not be furthered in any meaningful way.

It also is not immediately clear why these facilities were specifically chosen to be exempt from CON review. Legislators could have decided to implement a CON carve-out for other "health service facilit[ies]" as defined in the CON

medicaid-expansion/ [https://perma.cc/4PA6-H29F]. Many individuals who are "self-pay" do not have insurance coverage because they are "too wealthy" and thus ineligible for Medicaid, but are also unable to afford private health insurance. *See id.* This means that these individuals often struggle to pay for medical expenses, since without insurance, health care costs can be extremely high. *Id.*

208. *See* Rudowitz et al., *supra* note 207.

209. The former North Carolina State Treasurer, Republican Dale Folwell, stated in 2021 that North Carolina's nonprofit hospitals were not meeting their charity care requirements to validate their tax-exempt status. Gary D. Robertson, *Report: NC Nonprofit Hospitals Falling Short on Charity Care*, ASSOCIATED PRESS (Oct. 27, 2021, 5:00 PM), https://apnews.com/article/business-health-north-carolina-e46d19334c92cda3e4820a601a4d042c [https://perma.cc/XJ8B-3ZL7]. However, it is important to note that nonprofit and tax-exempt status are easily conflated and may have been here. Hospitals may be deemed nonprofit under state incorporation laws, but exemption from federal income tax is designated by meeting the Internal Revenue Service's 501(c)(3) tax exempt status requirements. George E. Constantine, Robert L. Waldman, Janice M. Ryan & Yosef Ziffer, *The Difference Between Nonprofit and Tax-Exempt Status*, VENABLE LLP (1999), https://www.venable.com/insights/publications/1999/10/the-difference-between-nonprofit-and-taxexempt-sta [https://perma.cc/Q4KX-H73G]. Further, "charity care" is not a necessary condition of tax-exempt status for nonprofit hospitals under Internal Revenue Code § 501(c)(3) either. *See* Rev. Rul. 69-545, 1969-2 C.B. 117.

statute.[210] There is also little to no explanation of why urban ASFs were specifically carved out, though one can surmise why these facilities were chosen. Dr. Singleton's litigation against the state and public campaign against CON law was very much active during the time that Medicaid expansion was being debated and structured.[211] It is therefore possible that the General Assembly was working to appease Dr. Singleton, as well as the interest groups working to support him. The social impact of these reforms is not as strong on policy grounds as that of the chemical dependency and psychiatric treatment center reforms. The reforms, therefore, may have been an attempt to directly address Dr. Singleton's concerns, even though his proposed facility would not actually fall under the urban ASF exception.[212] Dr. Singleton wanted to open an ASF to perform surgeries on his patients in New Bern, North Carolina, which is located in Craven County.[213] Although he would not be able to open a facility under the urban ASF exemption under the new CON reforms due to a lack of population in Craven County,[214] it is conceivable that he would be able to open a facility if Craven County's population grows to 125,000 people.[215]

The exemption of urban ASFs from CON also raises additional questions about how the statute applies in practice. The statute does not clarify the extent to which these facilities are exempt from CON review. For example, it is

210. N.C. GEN. STAT. § 131E-176(9b) (2023). For example, the CON statute defines "health service facility" to include hospitals, long-term care hospitals, rehabilitation facilities, nursing homes, care facilities for individuals with intellectual disabilities, hospice facilities, among other facilities. *Id.*

211. Singleton v. N.C. Dept. of Health & Hum. Servs., 284 N.C. App. 104, 104, 874 S.E.2d 669, 669 (2022), *vacated*, 386 N.C. 597, 906 S.E.2d 806 (2024). The North Carolina Court of Appeals opinion was filed in June 2022, less than a year before H.B. 76 was signed into law. *Id.* The John Locke Foundation established its own libertarian-focused newspaper, the *Carolina Journal*, which often publishes anti-CON articles and updates the public on CON cases in active litigation. *See About Us*, CAROLINA J., https://www.carolinajournal.com/about/ [https://perma.cc/KC9Q-A2YA]. One of Dr. Singleton's attorneys, employed by the Institute for Justice, Renée Flaherty, has a byline in the *Carolina Journal* regarding the case. *See* James & Flaherty, *supra* note 73. The *Carolina Journal* has covered Dr. Singleton's case for nearly the entirety of litigation through the appeals process. *See, e.g.*, *New Bern Eye Doctor Reignites Fight Against CON Law*, CAROLINA J. (Feb. 1, 2022), https://www.carolinajournal.com/new-bern-eye-doctor-reignites-fight-against-con-law/ [https://perma.cc/6X7G-WTZ4].

212. This is not to say that these reforms will not be helpful to patients living in urban areas, as they may gain access to new facilities. *See infra* Section IV.B.

213. *Singleton*, 284 N.C. App. at 107, 874 S.E.2d at 672.

214. *See supra* note 205 and accompanying text. According to 2020 census numbers, Craven County is just under the required 125,000-person population threshold required for a county's ASFs to fall under the urban ASF definition. *Id.*

215. It is also important to note that in order to develop an ASF, facilities must have an operating room, a facility which *does* require a CON. N.C. GEN. STAT. § 131E-176(1b), (21a) (2023). Alternatively, Singleton could argue that the state should revise the need determination for this planning area to allow for more ASFs or operating rooms for the area, though this would likely be a more difficult argument. The CON planning area in question in Dr. Singleton's lawsuit included Craven, Jones, and Pamlico Counties, the latter two of which only had populations of around 10,000 people as of 2020. *Singleton*, 284 N.C. App. at 107, 874 S.E.2d at 672; *see also* Am. Counts Staff, *supra* note 205.

unclear whether an urban ASF's purchase of expensive equipment like an MRI machine, which would otherwise be subject to CON review, is no longer subject to such review under the new exemption. The General Assembly simply added a sentence to the CON law stating that the term "health service facility" does not include a qualified urban ASF; the reforms do not further describe how this may interact with other sections of the CON law.[216] Unfortunately, this lack of clarity and guidance will make it difficult for providers and healthcare organizations to understand whether they are compliant with the relevant statute.

### 3. Reforms Implemented After Three Years: Diagnostic Centers, Major Medical Equipment

Three years after the implementation of H.B. 76, CON reforms focus on MRI machines. Once again, the legislature makes a distinction between urban and rural communities. Using the same 125,000-person county threshold as used for the previous year's ASF reforms, the CON law will exempt MRI scanners purchased for use in "urban" counties from CON requirements.[217] Facilities will not be deemed "diagnostic centers" subject to CON solely "by virtue of having a magnetic resonance imaging scanner in a county with a population of greater than 125,000."[218] This means that practitioners in "urban" areas, like Dr. Singh, will be able to purchase MRIs without needing CON approval for a "diagnostic center."

In addition, "major medical equipment,"[219] which is subject to CON review, will no longer include MRIs in those "urban" counties.[220] These amendments to the CON law will effectively make it possible for a wide variety of practitioners to purchase MRI, computed tomography ("CT"), and other expensive machines without CON review. While this change will impact hospitals, it will also impact smaller practitioners in urban areas, who will now

216. *See* Act of Mar. 27, 2023, ch. 7, § 3.2.(a), 2023 N.C. Sess. Laws __, __ (codified at N.C. GEN. STAT. § 131E-176(9b)) (lacking information on how the CON reforms interact with each other).

217. The North Carolina General Assembly accomplishes these reforms by amending the definitions of "diagnostic center" and "major medical equipment." *Id.* § 3.3.(a).

218. *Id.*

219. Until these reforms become effective, "major medical equipment" is defined as: "a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than two million dollars ($2,000,000)," but this does not only include the cost of equipment itself. N.C. GEN. STAT. § 131E-176(14o) (2023). To determine whether the major medical equipment costs more than two million dollars, "the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included." *Id.*

220. Act of Mar. 27, 2023, § 3.3.(a) ("Major medical equipment does not include replacement equipment as defined in this section or magnetic resonance imaging scanners in counties with a population greater than 125,000 according to the 2020 federal decennial census or any subsequent federal decennial census.").

be able to purchase MRIs for their clinics without triggering CON review for "major medical equipment."

Once again, it is not immediately clear through a public policy lens why legislators decided to enact reforms specifically targeting MRIs. There are many other types of expensive diagnostic equipment that could have been included in these reforms, such as CT scanners, that lawmakers decided to not exempt from the "major medical equipment" definition. Perhaps, remembering Dr. Singh's complaints and lawsuit, legislators decided to provide a green light for providers to purchase MRIs for use in their urban practices.

Notably, this section of H.B. 76's CON reforms does not have a section that identifies a public health "tradeoff" that pro-CON interest groups would likely argue would be needed to offset the impact of relaxed CON requirements. In this set of reforms, there is no accompanying provision intended to impact social welfare or public health even nominally, such as the previous year's charity care requirement.[221] Further, there is no provision that outwardly aims to improve access to care for the most vulnerable populations: those who struggle with mental health and chemical dependency.[222]

### B. *H.B. 76's CON Reforms in Context: A Policy and Political Analysis*

Healthcare is an incredibly lucrative industry in North Carolina.[223] For this reason, the stakes are high, and stakeholders clearly sought to influence the scope of these reforms. Lobbying shaped the scope of H.B. 76's reforms, both relating to Medicaid expansion and CON.[224] The CON reforms were certainly a concession that Democratic lawmakers made to Republican lawmakers in

221. *Compare* Act of Mar. 27, 2023, § 3.3.(a) (relaxing CON review without including provisions that specifically assist low-income individuals), *with* Act of Mar. 27, 2023, § 3.2.(c) (creating a charity-care requirement).

222. *Compare* Act of Mar. 27, 2023, § 3.3.(a) (relaxing CON review without including provisions that specifically aim to increase healthcare access for vulnerable populations), *with* Act of Mar. 27, 2023, § 3.1.(a) (exempting psychiatric and chemical dependency treatment centers from CON review).

223. According to a study conducted between 2016 and 2017, a group of 6.3 million North Carolinians (out of the state's total population of approximately 10.2 million people) spent approximately $50 billion per year on healthcare services. *A Multi-Payer Analysis of Health Care Spending in North Carolina*, HEALTH CARE COST INST., https://healthcostinstitute.org/hcci-originals/north-carolina-health-care-spending-analysis [https://perma.cc/R7JP-F3DU]. The following individuals were not included in the study: those who were uninsured, insured through the individual insurance market, enrolled in Employer-Sponsored Insurance ("ESI") plans administered by different issuers, enrolled in Tricare (the United States' Military's health insurance mechanism), or receiving care through the United States Department of Veterans Affairs. *Id.*

224. It is not just hospital trade associations that are involved in lobbying efforts; groups representing members of the healthcare workforce may also employ lobbyists. *See, e.g.*, *Lobbyists*, N.C. NURSES ASS'N, https://www.ncnurses.org/advocacy/legislative/lobbyists/ [https://perma.cc/UB95-C7XM] (describing the lobbyists employed by the North Carolina Nurses Association). The CON law, however, explicitly bans lobbyists from being appointed to or serving on the North Carolina State Health Coordinating Council. N.C. GEN. STAT. § 131E-191.1 (2023).

exchange for Medicaid expansion.[225] Simultaneously, however, the CON reforms show how a version of CON law—nuanced and narrowly tailored—can be crucial for the public's health.

At first glance, it may seem difficult to understand why CON reform was included in a bill that expands Medicaid. But consider the actual impact of Medicaid on the state's purse strings. A bipartisan coalition of legislators simultaneously seemed to acknowledge that, over ten years after the passage of the Affordable Care Act,[226] Medicaid expansion is here to stay.[227] And, Medicaid expansion will also bring much-needed revenue to hospitals in the state, especially those in rural areas.[228] So perhaps, in the minds of CON's opponents, this was the perfect time to target CON, especially after years of repeal attempts. The negative impact on rural hospital revenue caused by relaxing CON could be balanced by the increased revenues due to Medicaid expansion. Therefore, perhaps this was an example of agile policymaking. However, the reforms should be analyzed from both a "big picture" and a more granular level.

CON laws are inherently a crude health policy lever. They do not, for example, provide any guarantees to providers that they will have the patients to "justify" what they have applied for. This is because, from an economic perspective, providers should theoretically aim to have the patients and thus reimbursement that will recoup the costs of the awarded expansions or equipment. CON laws also only minimally consider the quality of care that patients may receive after the facility is built or the equipment is placed into service.[229] This is unlike other forms of health policy mechanisms that more strongly emphasize and reward "good" practices and cost-saving while

225. *See* Andrew Cass, *How North Carolina's Medicaid Expansion Plan Would Change Its Certificate of Need Law*, BECKER'S HOSP. REV. (Mar. 3, 2023), https://www.beckershospitalreview.com/legal-regulatory-issues/how-north-carolinas-medicaid-expansion-plan-would-change-its-certificate-of-need-law.html [https://perma.cc/2BEZ-PYUB (staff-uploaded, dark archive)] (describing the "compromise" between expanding Medicaid and changing the state's certificate of need law).

226. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

227. Sheryl Gay Stolberg, *North Carolina Expands Medicaid After Republicans Abandon Their Opposition*, N.Y. TIMES (Mar. 27, 2023), https://www.nytimes.com/2023/03/27/us/politics/north-carolina-medicaid-expansion.html [https://perma.cc/2VZ8-LSMP (staff-uploaded, dark archive)].

228. *Id.*

229. *See* N.C. GEN. STAT. § 131E-183(a)(20) (2023). In reviewing an applicant's conformity with the criteria outlined in the CON statute, the Healthcare Planning and Certificate of Need section of the North Carolina DHSR requires that "[a]n applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past." *Id.* For further discussion of how the state may leverage quality more in their need determinations, see *infra* Section V.B.

penalizing "bad" quality of care and patient complications.[230] But at the same time, H.B. 76's reforms suggest that CON can be used as a helpful tool for health policy objectives so long as political considerations do not interfere too greatly with the kinds of reforms implemented.

H.B. 76's changes affect smaller practitioners most significantly. It is notable that reforms were made regarding MRI machines and ASFs specifically, given the previously discussed highly publicized litigation that had been initiated by the Institute for Justice on behalf of Drs. Singh and Singleton.[231] Furthermore, the reforms made mostly positively impact practitioners with smaller practices. Arguably, the General Assembly could have done more to dismantle CON law and massively disrupt the operations of major hospital systems in North Carolina. But it stayed away from these powerful entities, which are generally pro-CON, likely due to the lobbying efforts of the North Carolina Healthcare Association.

These reforms will still affect major hospital systems in North Carolina. Since smaller practices will be able to purchase equipment or open ASFs without CON, they may take revenue away from larger hospitals where patients would have been referred prior to the reforms. But, simultaneously, larger hospitals will also benefit from the legislation as they too, especially in urban areas, will no longer need to apply for a CON when they need to replace a broken MRI machine or want to open a screening center within an existing clinic. However, the legislation, at its core, will fundamentally make market entry easier for smaller physician practice groups and other medical facilities unaffiliated with hospitals or hospital systems, such as treatment centers.

The reforms that exempt chemical dependency treatment facilities and psychiatric facilities from CON review are important policy mechanisms for tackling major health issues faced by North Carolinians. Chemical dependency treatment facilities and psychiatric treatment facilities are often run independently of major healthcare systems, with for-profit companies

230. For example, the Comprehensive Care for Joint Replacement payment model sets target prices for lower extremity joint replacement surgeries, and rewards institutional providers for coordinating preoperative and postoperative care alongside the joint replacement surgeries themselves according to the theory that comprehensive care leads to better outcomes. *Comprehensive Care for Joint Replacement Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/priorities/innovation/innovation-models/cjr [https://perma.cc/9D5N-YF29]. The total cost of the joint replacement and associated care is then compared to the target price, and the Centers for Medicare and Medicaid Services assesses the quality of care. *Id.* Depending on the outcome of the comparison, the healthcare provider may receive additional money from Medicare or be required to repay Medicare for costs accrued. *Id.*

231. *See supra* Section III.B.

increasingly getting into the business.[232] Major healthcare systems' reticence to get into the chemical dependency and psychiatric treatment facility business may be due to the unfavorable Medicaid reimbursement associated with providing these services, as well as the complexity of operating these facilities.[233] For these reasons, existing healthcare providers are likely not offering these services in the size and scope needed to address the ongoing mental health and opioid crises. The elimination of CON approval to open such facilities is an important step to addressing these two fundamental healthcare issues in the United States and North Carolina.[234] By exempting these facilities from CON review, the number of facilities should increase, providing much-needed care for those struggling with these medical diagnoses. This exemption will be an important way to relieve pressure on the existing public health infrastructure in place to deal with these dual crises.

Relaxing CON law in urban or highly populated counties may also increase access and lead to lower prices for patients. As populations grow in urban areas, the need for healthcare increases. Artificially restricting the ability to provide care through CON law may not make sense if the demand for care is high enough. Furthermore, restricting access to care may in fact keep prices higher under the basic economic principle that opponents of CON point to: when demand increases, prices increase. Thus, allowing new entrants into the market may be beneficial for healthcare consumers by lowering prices through increased competition.[235] Even if changes in price are marginal, aggregate impacts will be felt more strongly by the larger populations that live in urban areas. And if patients in rural areas travel to these urban areas to receive care, they too may benefit from lower prices.

232. *See* Heather Saunders & Rhiannon Euhus, *A Look at Substance Use and Mental Health Treatment Facilities Across the U.S.*, KAISER FAM. FOUND. (Feb. 2, 2024), https://www.kff.org/mental-health/issue-brief/a-look-at-substance-use-and-mental-health-treatment-facilities-across-the-u-s/ [https://perma.cc/A6D6-53XQ].

233. *Id.*

234. Substance abuse treatment facilities do not only treat patients struggling with recreational drug and alcohol dependency; they can also treat patients with opioid dependence. The opioid "epidemic" has been one of the most fatal twenty-first century public health emergencies in the United States. *See* Xavier Becerra, *Renewal of Determination that a Public Health Emergency Exists*, U.S. DEP'T HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (Apr. 4, 2022), https://aspr.hhs.gov/legal/PHE/Pages/Opioid-4Apr22.aspx [https://perma.cc/X8VU-GZSX (staff-uploaded archive)] (renewing the opioid-related public health emergency pursuant to section 319 of the Public Health Service Act). From February 1st to 13th of 2023, 24.9% of adults in North Carolina reported symptoms of anxiety and/or depressive disorders. *Mental Health in North Carolina*, KAISER FAM. FOUND., https://www.kff.org/statedata/mental-health-and-substance-use-state-fact-sheets/north-carolina/ [https://perma.cc/D86U-XDZ8]. In addition, in 2021, there were 3,339 opioid overdose deaths in North Carolina, accounting for 84% of all drug overdose deaths in the state. *Id.*

235. *See* Ohlhausen, *supra* note 111, at 51–52. In addition, new entrants to the market may increase market innovation, as competitors compete for business. *Id.* at 51.

Furthermore, physical access to medical facilities is critical to ensuring that people receive care. Individuals who are disabled or lack transportation may struggle to obtain much-needed care if the one facility that has the diagnostic machine they need is not physically close to their home or workplace. But if the number of places where they can receive the care they need increases, they may no longer have to make a forty-five-minute trip to the academic medical center in their city; they may be able to go to the clinic just fifteen minutes down the road.[236] Thus, increasing the number of healthcare options in urban areas can also benefit patients from an accessibility perspective. But eliminating CON entirely in these areas, which the reforms do not come close to, could cause total chaos and overspending by both small and large healthcare facilities.[237]

* * *

H.B. 76's reforms are evidence of how CON laws of the past can be reformed narrowly to serve the public's health. Additionally, they highlight how CON laws, especially North Carolina's amended version, are still important, and how they may be leveraged to further achieve health policy objectives, including improving access to healthcare and healthcare quality. The next part discusses why the CON law should remain present in North Carolina's future.

## V. THE FUTURE OF CON LAW IN NORTH CAROLINA

Rather than view CON as purely a black-and-white economic policy that impacts the costs of healthcare, it is important to go back to the roots of CON: its role as a health policy tool. Whether or not one agrees with the economic arguments surrounding CON, H.B. 76's reforms demonstrate that CON can be leveraged to promote public health goals for the good of the state's residents. This part proceeds by first discussing why CON should not be repealed completely in North Carolina. It argues that CON still plays an important role in ensuring access to healthcare, such that we should be cautious of H.B. 76's reforms as a potential harbinger of the end of CON law in North Carolina. It then provides an example of how CON can be leveraged to improve the quality of care that North Carolinians receive and describes how policymakers can clarify and expand existing statutory language that provides minimal guidance to CON applicants.

236. One major caveat worth addressing is the fact that in many cases, patients choose where to receive care based on whether a provider accepts their insurance coverage. This may mean that even if additional providers are able to enter the market and provide relevant care after CON laws are repealed, patients may still not in reality have more access to care. Even so, aggregate forces on the market should theoretically lead to lower prices.

237. See *infra* Section V.A for a discussion of the potential impact of a complete repeal of CON law.

### A. *Why CON Law Should Not Be Repealed Entirely*

The main infrastructure of North Carolina's CON program remains intact, pending further *Singleton* litigation after the Supreme Court of North Carolina's decision to remand. However, as opposition to CON laws has grown across the United States, some states have entirely repealed their CON statutes. In 2023, one of North Carolina's neighbors, South Carolina, nearly entirely eliminated its CON law.[238] Now, the only health care facilities that require a CON in South Carolina are hospitals, home health agencies, and nursing homes.[239] Facilities also no longer have to obtain a CON to purchase expensive medical equipment or expand and open certain healthcare facilities.

The repeal of CON laws in states such as South Carolina will almost certainly increase the number of healthcare facilities.[240] But pure numerical quantity is a poor proxy for actual access. As in North Carolina, increasing the number of healthcare facilities can be helpful for health equity and access in specific situations. For example, it is important to continue to incentivize the opening of substance abuse and mental health facilities. But on the other hand, a near-total dismantling of the CON system will actually negatively impact access and affordability in rural areas, possibly creating unintended consequences that those against CON often fail to consider.

Roemer's law still arguably holds true. For example, if healthcare facilities have no restrictions on what equipment they can purchase, it is extremely likely that they will go forward with plans to buy more equipment, provided they have the funds. Certainly, there are positives associated with purchasing the newest, most innovative equipment. Sometimes, these advances can lead to better patient outcomes. In addition, these purchases can serve to market hospitals to physicians, who may refer patients to facilities for their care because of the purported "benefits" of the equipment.[241]

At other times, however, these purchases are unnecessary. Does a smaller city's hospital need to spend $20 to $150 million on a proton beam therapy

238. *Governor Henry McMaster Signs Certificate of Need Repeal*, SC.GOV (Oct. 3, 2023), https://governor.sc.gov/news/2023-10/governor-henry-mcmaster-signs-certificate-need-repeal [https://perma.cc/PX5B-437R] (describing South Carolina Governor Henry McMaster's signing of S. 164, Certificate of Need Repeal).

239. S.C. CODE ANN. § 44-7-160 (2024).

240. *See, e.g.*, Thomas Stratmann, Markus Bjoerkheim & Christopher Koopman, *The Causal Effect of Repealing Certificate-of-Need Laws for Ambulatory Surgical Centers: Does Access to Medical Services Increase?*, S. ECON. J., Apr. 30, 2024, at 1, 3 (finding that the number of ambulatory surgical centers per capita increased by forty-four to forty-seven percent statewide in states that repealed CON).

241. Again, this is tempered by the caveat that some patients may not have the opportunity to "choose" where they receive treatment because of their insurance coverage or other factors.

system[242] for cancer treatments, or does it make more economic sense for a patient to travel to a major city's academic medical center to receive that specialized care if they truly need it?[243] Furthermore, when hospitals buy this expensive equipment, the cost is inevitably passed down to the consumer, meaning that prices will increase.[244] Smaller hospitals may also lack the patient population to support the need for this expensive equipment; these funds may be better spent on initiatives for preventative care, so that patients do not need to utilize this expensive equipment in the first place. If hospitals feel the need to buy expensive equipment to attract referrals, and then feel obligated to unnecessarily use these resources to recoup their costs, then market incentives are not properly calibrated with our expectations and ethical guidelines that require that physicians act in their patients' best interests above all else.

The urban-rural distinction is also a reason to keep CON law in place. If CON law is dismantled in North Carolina, rural counties, especially those with lower-income populations, may struggle to find enough providers. CON laws incentivize providers to open facilities in rural communities by effectively restricting them from otherwise placing these resources in urban, wealthier communities that are more likely to be able to pay for care. In addition, they prevent an oversupply of ASFs in rural areas that may undercut small rural hospitals' sources of revenue. This is why many of the reforms instituted in H.B. 76 likely relaxed CON law in solely urban communities; there was an implicit acknowledgment that rural communities rely on CON law to ensure access to care. Given North Carolina's many rural counties, CON law is likely to have a greater impact on access to healthcare here than it will in states with more suburban and urban areas.[245]

Furthermore, the governmental regulatory mechanisms and structure that CON provides are helpful in times of crisis. Specifically, the COVID-19 pandemic demonstrated the need for effective CON law. Many hospitals have extremely thin margins and low cash-on-hand reserves; when profitable nonurgent procedures had to be canceled as a result of the pandemic, hospitals

242. Thomas R. Bortfeld & Jay S. Loeffler, Comment, *Three Ways to Make Proton Therapy Affordable*, 549 NATURE 451, 451 (2017). A proton beam therapy system is a form of radiation therapy used to treat cancer. *Id.* It is at the cutting edge of radiation therapy because it is more precise than traditional radiation beam therapy systems, meaning that less healthy tissue is irradiated. *Id.*

243. For patients, the cost of proton therapy is often three to four times more than the priciest X-ray treatments. *Id.* at 452. Of course, any patient would prefer to receive care closer to home. But considering a cost-benefit analysis, it may not make sense for a smaller hospital to make expensive equipment purchases, since common forms of diseases like prostate cancer can be cured just as effectively and more cheaply without the use of proton therapy. *Id.*

244. To pay for this equipment, hospitals may spread the cost of the new equipment across all service lines, so that patients that do not even utilize the equipment bear the cost.

245. North Carolina has one hundred counties, eighty of which the federal government deems rural or rural in character. *North Carolina*, RURAL.GOV, https://www.rural.gov/community-networks/nc [https://perma.cc/P34W-SWEH (staff-uploaded archive)].

were financially strained.[246] This demonstrated the delicate balance required to ensure that beds are allocated properly in healthcare facilities to ensure that there is enough capacity not only for emergent situations, but also for patients with elective procedures and chronic illnesses requiring longer stays. During the COVID-19 pandemic, many states, including North Carolina, paused their CON laws to allow healthcare facilities to quickly reallocate and increase the number of beds available to sick patients.[247] Critics of CON laws have claimed that states' decisions to pause CON laws during the COVID-19 pandemic are evidence of the burden CON law places on hospital operations in times of emergency.[248] But these arguments fail to consider the fact that if CON laws had not been in place prior to the pandemic, the situation would not have been better, and could have even been worse. Hospitals would have likely expanded and invested money in profit-generating units and services such as cardiology and orthopedics.[249] Subsequently, there could have been an undersupply of the critical, but less profitable intensive care unit beds that were needed to keep thousands of patients on ventilation and life support.[250]

Although repealing CON entirely is counterproductive to health policy objectives, there should still be critical analysis of how we can improve CON law for the better. Many of the reforms implemented in H.B. 76 are a step in the right direction and work to address critical public health needs. But this does not mean that these reforms should serve as the aforementioned "Trojan Horse," a concealed attempt at dismantling all of CON in the near future. Rather than seeing CON as a zero-sum game, legislators should look to health policy experts and borrow from other areas of health policy to achieve better health outcomes, including improved access to medical services. CON law

246. N.C. HEALTHCARE ASS'N, *supra* note 113.

247. Deb Fournier, Adney Rakotoniaina & Johanna Butler, *Anticipating Hospital Bed Shortages, States Suspend Certificate of Need Programs to Allow Quick Expansions*, NAT'L ACAD. STATE HEALTH POL'Y (Apr. 6, 2020), https://nashp.org/anticipating-hospital-bed-shortages-states-suspend-certificate-of-need-programs-to-allow-quick-expansions/ [https://perma.cc/GL66-YB2V].

248. *See* N.C. HEALTHCARE ASS'N, *supra* note 113. ("While a 2020 Mercatus report projected states with CON programs would have a higher likelihood of ICU bed shortages during the COVID-19 pandemic, not only did NC not have a shortage of ICU beds, but the CON program was also able to quickly add an additional ~5,000 beds to hospitals ahead of the surge. Furthermore, California and Texas, two states with no CON programs, experienced significant ICU bed shortages, further demonstrating CON was not a barrier during the COVID-19 public health emergency.").

249. Cardiology and orthopedics are service lines that command high profits for physicians because they result in high reimbursement from insurers. Paige Haeffele, *Average Reimbursement from Private Insurers for 18 Specialties*, BECKER'S ASC REV. (Apr. 20, 2023), https://www.beckersasc.com/asc-coding-billing-and-collections/average-reimbursement-from-private-insurers-for-18-specialties.html [https://perma.cc/UP4M-2B39 (staff-uploaded, dark archive)].

250. ICU beds are much more expensive to operate than normal hospital beds because of the additional overhead due to the complex and specialized equipment. Douglas P. Wagner, Thomas D. Wineland & William A. Knaus, *The Hidden Costs of Treating Severely Ill Patients: Charges and Resource Consumption in an Intensive Care Unit*, 5 HEALTH CARE FIN. REV. 81, 81 (1983).

should and could be used to further additional health policy goals. The next section of this Comment proposes ways to use CON to implement additional health-improving policies.

### B. *Recommendations for Further Reforms: Addressing Additional Health Policy Goals*

If North Carolina's CON law undergoes future reforms, one additional place for potential improvement would be the increased implementation of quality metrics, including the clarification of existing references to quality in the CON statute.[251] Quality of care is cited as a rationale for enacting CON in the state.[252] However, there are currently few references to quality in the CON statute, or information on how quality should be measured and assessed. As the methodology currently stands, Criterion 20 of the DHSR CON section's ("Agency") review criteria represents the one place where regulators have a statutory mandate to assess an applicant's past quality.[253] The statute lacks clarity on how the Agency should actually measure quality, simply stating that "[a]n applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past."[254]

This lack of clarity has even resulted in litigation over the meaning of Criterion 20, which has revealed the procedure that the Agency actually uses to assess the quality of CON applicants.[255] Generally, to determine whether an applicant conforms with Criterion 20, the Agency ascertains whether the applicant's facility (or facilities) have had citations for adverse events or have been penalized for past quality violations.[256] But "[i]f the applicant did not have

251. *See* N.C. GEN. STAT. § 131E-183(a)(20) (2023). In a healthcare context, quality of care assessments evaluate whether care is safe, effective, patient-centered, timely, efficient, and equitable. *Six Domains of Healthcare Quality*, AGENCY FOR HEALTHCARE RSCH. & QUALITY (Dec. 2022), https://www.ahrq.gov/talkingquality/measures/six-domains.html [https://perma.cc/W9NL-XY75]. The federal government and states use empirical data to assess these metrics and often tie healthcare facility performance to reimbursement, rewarding facilities that do well and penalizing facilities that perform poorly by manipulating their Medicare and Medicaid reimbursement. *See, e.g.*, *Hospital-Acquired Condition Reduction Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/hospital-acquired-condition-reduction-program-hacrp [https://perma.cc/5AJD-BUEY].

252. N.C. GEN. STAT. § 131E-175(7), (11) (2023).

253. *See id.* § 131E-183(a)(20). This subsection is commonly referred to as "Criterion 20" by practitioners and in litigation. As such, this Comment will use that terminology here as well.

254. *Id.*

255. *See*, *e.g.*, AH N.C. Owner LLC v. N.C. Dep't of Health and Hum. Servs., 240 N.C. App. 92, 100–25, 771 S.E.2d 537, 542–57 (2015) (describing litigation by competing nursing home operators over the CON Agency's interpretation of Criterion 20, including the geographic scope and look-back timeframe of the analysis).

256. *Id.* at 101, 771 S.E.2d at 542–43 ("The Agency would then ascertain whether the applicant's facility (or facilities) within that county, if any, had received any citations for substandard quality of

any existing facilities within that county, the Agency deemed Criterion 20 'not applicable' to the applicant."[257] The CON application requires applicants to report specified quality-related events, such as "Substandard Quality of Care as Defined by the [Federal Government]" and "State and Federal Fines."[258] The Agency procedures regarding the analysis of quality have generally been based on what it has historically done and the Agency's interpretation of the CON statute.[259]

However, considering quality of care in CON determinations could be a vehicle to positively impact public health, more should be done to clarify and expand the use of quality metrics when analyzing CON applicants.[260] Data collection has become increasingly important in our world, healthcare included, as we shift to a society that wants to prioritize statistics and metrics to better inform future actions. CON law is inherently a data-driven field already, as it uses complex formulas to consider changes in population and geographic density when determining need.[261] North Carolina could consider clarifying data collection requirements to further advance health policy goals.

For example, if patient safety and quality of care is of utmost importance, state regulators might consider clarifying the procedure—or making official the procedure—used to assess quality. This could be accomplished by amending the current CON statute to make clear how regulators intend to actually assess quality. For if quality of care is stressed as one of the most important rationales for enacting CON in the state,[262] it does not make sense that the statute does not do more to clarify the issue or provide further guidance to practitioners. Further, there is evidence to show that improving healthcare quality can actually save the healthcare system money; this is the whole proposition behind value-based care.[263]

care."); *see also* WR Imaging, LLC v. N.C. Dep't Health & Hum. Servs., 290 N.C. App. 367, 891 S.E.2d 497, 2023 WL 5691023, at *2 (2023) (unpublished table decision) (describing loss of accreditation as an adverse event that evidences a potential lack of quality care).

257. *AH N.C. Owner LLC*, 240 N.C. App. at 101, 771 S.E.2d at 543.

258. *Id.* at 104, 771 S.E.2d at 551. The "substandard quality of care" terminology used in the *AH N.C. Owner LLC* opinion is specifically applicable to long-term care facilities (such as nursing homes) as defined by the federal government. *See* 42 C.F.R. §§ 488.414, .305.

259. *AH N.C. Owner LLC*, 240 N.C. App. at 111, 771 S.E.2d at 548.

260. Other efforts to improve quality outcomes (e.g., reducing hospital acquired infections, readmissions) have been successful. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 251.

261. *See* N.C. DEP'T OF HEALTH & HUM. SERVS., *supra* note 35, at 31–36 (describing the methodology used to determine the need for acute care hospital beds and resulting allocations).

262. *Id.* at 2–4.

263. Value-based care aims to improve quality and outcomes for patients by emphasizing overall wellness, quality of care, and preventive screenings. *See Value-Based Care*, CLEV. CLINIC, https://my.clevelandclinic.org/health/articles/15938-value-based-care [https://perma.cc/2Q32-GB37] (last updated Oct. 19, 2020). Value-based care pays providers and hospitals based on outcomes, rather than on the numbers of procedures done or patients seen—and is usually facilitated by ACO payment

Currently, there is limited easily accessible information on what the DHSR CON section requires applicants to show to demonstrate that they are conforming with Criterion 20. Prior to December 2024, the forms for CON applications, which would provide information on what the Agency is looking for regarding quality, were not available online; an applicant had to contact the agency to request a copy.[264] Even with the forms accessible online, it is still difficult for applicants to understand the requirements for quality, as they must rely on a byzantine collection of judicial opinions and word-of-mouth industry knowledge for guidance. While the Agency has the right to determine its own interpretation of Criterion 20, transparency in its decision-making would likely not be opposed by those actually applying for CONs, or even those appealing its decisions.

Additionally, legislators could amend the CON statute to make the quality analysis used to determine "need" more robust. For example, rather than simply requiring applicants to report whether they have been previously cited for poor quality, regulators could require applicants to make plans to improve or maintain quality and include these plans in their CON applications. Rather than simply waiving the requirement that new market entrants provide this data, since they inherently lack the data needed to present to CON regulators, the CON statute could place some consistent quality requirements on all parties. Existing and new market entrants could both be required to present detailed plans on how they would plan to carry out quality assurance activities and post-adverse event investigations and follow up. Existing applicants could also be required to report data besides adverse events; they could provide information on their efforts to improve quality, including providing metrics on mortality and readmissions (at least for hospital applicants), as well as patient satisfaction and experience survey results. These requirements could be modified to be appropriate for smaller applicants, such as ASFs.

models. David Muhlestein, Robert S. Saunders, Kate de Lisle, William K. Bleser & Mark B. McClellan, *Growth of Value-Based Care and Accountable Care Organizations in 2022*, HEALTH AFFS.: HEALTH AFFS. FOREFRONT (Dec. 2, 2022), https://www.healthaffairs.org/content/forefront/growth-value-based-care-and-accountable-care-organizations-2022 [https://perma.cc/6LUQ-7M5D (staff-uploaded archive)] (citing S. Lawrence Kocot, Ross White, Tianna Tu & David Muhlestein, *The Impact of Accountable Care: Origins and Future of Accountable Care Organizations*, BROOKINGS INST. (May 12, 2015), https://www.brookings.edu/articles/the-impact-of-accountable-care-origins-and-future-of-accountable-care-organizations/ [https://perma.cc/HLN3-M2EN]).

264. The North Carolina DHSR website was updated on December 12, 2024, to include links to CON application forms. *Frequently Asked Questions*, N.C. DIV. HEALTH SERV. REGUL., HEALTHCARE PLAN. & CERTIFICATE OF NEED SECTION, https://info.ncdhhs.gov/dhsr/coneed/faq.html [https://perma.cc/2KVF-J3JF] (last updated Dec. 12, 2024). A previous version of the website stated that applications were only available on request to the Agency. *Frequently Asked Questions*, N.C. DIV. HEALTH SERV. REGUL., HEALTHCARE PLAN. & CERTIFICATE OF NEED SECTION, https://info.ncdhhs.gov/dhsr/coneed/faq.html [https://perma.cc/38F8-89YF] (last updated May 11, 2023).

While these changes would not supplant existing adverse event reporting requirements, they would be another way to keep CON applicants motivated to improve the health of their patients. Further, the data gathered could inform regulators of whether their need determinations seem to actually be working and having the intended consequences—regulators could track whether healthcare providers followed through with the implementation of these plans and whether they actually worked to improve quality of care. This would also incentivize high-quality care, as applicants would be incentivized to ensure that high-quality care remains a priority by being "on notice" of the requirement to provide quality data.

For these reasons, CON law is an important mechanism to ensure that people have enough access to care, and that the care provided is efficient and high quality. The dollars pumped into North Carolina's healthcare system should not be spent on duplicative services or expensive machines that will not be heavily utilized. CON law is also necessary to ensure that North Carolinians living in rural areas continue to have access to healthcare. At the same time, modest and tailored reforms, such as the changes made with the enactment of H.B. 76, should be considered on a periodic basis to ensure that both urban and rural counties have neither an undersupply nor an oversupply of healthcare options. These may include increases in the dollar threshold to trigger CON review, or exempting facilities other than psychiatric and substance abuse facilities from CON review should there be an increased demand or public health necessity. In addition, legislators may consider increasing and clarifying the inclusion of quality metrics in the determination of allocation of CONs to healthcare facilities, as another tactic to improve the healthcare of North Carolinians.

## CONCLUSION

Although H.B. 76's CON reforms were likely a concession by Democratic lawmakers in order to expand Medicaid in North Carolina, the reforms are not all bad. As these reforms continue to roll out over the next few years, urban North Carolinians can look forward to more healthcare facility options, and more may even have access to charity care. Prices could also potentially decrease due to these changes. But this does not mean that North Carolina should follow its neighbor South Carolina and dismantle CON law.

CON law is a valuable health policy tool that should and can be leveraged to increase access to healthcare. North Carolina should implement CON reforms that continue to require charity care and eliminate CON review of facilities and equipment that are in high demand or critical for the public health. North Carolina should also consider investigating how to incentivize better quality care, using CONs as the prize.

CON law is extremely nuanced and complex, and thus results in a complex mixture of pros and cons. However, efforts to further deregulate and repeal CON law will likely continue for the foreseeable future, with little acknowledgement of those complexities. One can simply look to the opinion in *Singleton* to see that CON's future in North Carolina is unclear and under scrutiny. Repealing CON entirely, however, would be a mistake, both due to CON's potential as a health policy tool, along with the bona fide public health benefits it achieves for North Carolinians. Rather than viewing CON as simply a mechanism that impacts healthcare costs, it is important to remember that these laws were also implemented to increase access to quality healthcare. For this reason, the impacts of total CON repeal could be disastrous for access to healthcare in rural areas of North Carolina. Therefore, it is imperative to be alert to future attempts to repeal CON entirely, either incrementally or in one fell swoop. For it is often when one least expects it, such as when the Greeks hid inside their hollow gift horse to the Trojans, that attacks that bring tragic damage may come.

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