

STATE OF NORTH CAROLINA

GENERAL COURT OF JUSTICE

COUNTY OF WAKE

SUPERIOR COURT DIVISION

FILE NO. 20 CVS 005150-910

JAY SINGLETON, D.O., and
SINGLETON VISION CENTER, P.A.,

Plaintiffs,

vs.

NORTH CAROLINA DEPARTMENT
OF HEALTH AND HUMAN
SERVICES; JOSH STEIN, Governor of
the State of North Carolina, in his
official capacity; DEVDUTTA
SANGVAI, North Carolina Secretary of
Health and Human Services, in his
official capacity; PHIL BERGER,
President Pro Tempore of the North
Carolina Senate, in his official capacity;
and DESTIN HALL, Speaker of the
North Carolina House of
Representatives, in his official capacity,

Defendants.

MOTION TO INTERVENE AS AMICI
CURIAE BY STATE TREASURER
BRADFORD B. BRINER AND STATE
EMPLOYEES ASSOCIATION OF
NORTH CAROLINA, INC.

State Treasurer Bradford B. Briner (“Treasurer Briner”) and the State Employees Association of North Carolina, Inc. (“SEANC”), through their respective undersigned counsel, hereby move pursuant to N.C. Gen. Stat. § 1A-1, Rule 24, and N.C. Gen. Stat. § 1-260 to intervene in the above-captioned matter as *amici curiae* to support Plaintiffs’ opposition to Defendants’ motion to dismiss Plaintiffs’

complaint. In support of this motion, Treasurer Briner and SEANC respectfully show the following:

DESCRIPTION OF PARTIES AND NATURE OF ACTION

Parties and Movants

1. Treasurer Briner is the duly elected Treasurer of the State of North Carolina. As the keeper of the public purse, Treasurer Briner is also a fiduciary for the North Carolina State Health Plan for Teachers and State Employees (“State Health Plan”) pursuant to N.C. Gen. Stat. § 135-48.2 (2025). Consisting of almost 750,000 members, including active and retired members, the Plan is one of the largest purchasers of healthcare in North Carolina and is funded almost entirely by its members and the taxpayers of North Carolina.

2. Treasurer Briner seeks to intervene to support Plaintiffs’ contention that Defendants’ motion to dismiss should be denied. In Treasurer Briner’s view, Dr. Singleton has properly alleged that the Certificate of Need (“CON”) law has an improper purpose and is not a reasonable means of achieving even its asserted purpose. This Court should deny Defendants’ motion to dismiss Plaintiffs’ complaint and permit this action to proceed to discovery.

3. Treasurer Briner is joined in this effort by the State Employees Association of North Carolina, Inc. (“SEANC”). SEANC is a North Carolina not-for-profit corporation whose members are current and retired State employees. SEANC has more than 42,000 active members, of whom roughly 23,000 are current employees of the State of North Carolina and 19,000 are retired employees of the State. The guiding purpose of SEANC is the promotion of the best interests of

current, retired, and future employees of the State of North Carolina. Nearly all of SEANC's members are members of the State Health Plan. Indeed, membership in the State Health Plan is part of what they work for. SEANC's members have a substantial interest in the ongoing fiscal integrity of the State Health Plan, which is heavily dependent on the overall cost of healthcare. SEANC seeks to intervene for the limited purpose of endorsing the Treasurer's efforts to influence the State's healthcare policy through his support of Plaintiffs in this case.

LEGAL AUTHORITIES AND RELEVANT FACTS

Permissive intervention

4. The Treasurer and SEANC should be permitted to intervene pursuant to Rule 24 of the North Carolina Rules of Civil Procedure, which provides as follows:

(b) Permissive Intervention—Upon timely application anyone may be permitted to intervene in an action:

. . .

(2) *When an applicant's claim or defense and the main action have a question of law or fact in common. . . .* In exercising its discretion the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties.

N.C. Gen. Stat. 1A-1, Rule 24 (emphasis added).

5. The Plaintiffs in this action challenge the constitutionality of North Carolina's CON law regime, N.C. Gen. Stat. § 131E-175, *et seq.*, under, *inter alia*, the Fruits of Their Own Labor Clause in Article I, § 1, of the North Carolina Constitution and the Law of the Land Clause in Article I, § 19, of the North Carolina Constitution.

6. Defendants have moved under Rule 12(b)(6) to dismiss Plaintiffs' complaint, contending that it fails to state a claim upon which relief can be granted.

7. In their proposed intervention as *amici curiae*, Treasurer Briner and SEANC intend to support Plaintiffs' position by demonstrating that Plaintiffs' complaint has properly stated a claim under the aforementioned clauses of the North Carolina Constitution and that Defendants' motion to dismiss Plaintiffs' complaint should therefore be denied.

8. Treasurer Briner and SEANC will address the same set of factual and legal issues as those already being addressed by the parties.

9. Moreover, the Treasurer has previously filed a brief as *amicus curiae* in this matter. *See* Motion for Leave to File Brief as *Amicus Curiae, Singleton v. N.C. Dep't of Health and Human Svcs.*, 260PA22 (N.C. Aug. 15, 2022). This Court has also previously permitted intervention by several other parties that are interested in the constitutionality of the CON law for the purpose of filing written briefs. Therefore, intervention by the Treasurer and SEANC for a similar limited purpose is appropriate.

10. Moreover, this motion to intervene is timely. Pursuant to this Court's Scheduling Order entered on October 13, 2025, "all amicus briefs in opposition" to Defendants' motion to dismiss "shall be filed by November 5, 2025 at 5:00 pm ET." This motion to intervene has been filed on November 5, 2025, in compliance with that deadline.

11. Counsel for Defendants consent to Treasurer Briner and SEANC's intervention as *amicus curiae* in this case.

12. Thus, Treasurer Briner and SEANC's motion to intervene pursuant to N.C. Gen. Stat. § 1A-1, Rule 24(b)(2) should be granted.

WHEREFORE, based on the foregoing, Treasurer Briner and SEANC respectfully request that this Court allow them to intervene by permission of this Court, and to participate as *amici curiae* in this proceeding by presenting a written brief showing that Plaintiffs' complaint has properly alleged claims under the Fruits of Their Own Labor Clause and the Law of the Land Clause and that Defendants' motion to dismiss Plaintiffs' complaint should be denied. Treasurer Briner and SEANC's proposed brief is attached as Exhibit A.

Respectfully submitted,

TREASURER BRADFORD B. BRINER

STATE EMPLOYEES ASSOCIATION
OF NORTH CAROLINA, INC.

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CERTIFICATE OF SERVICE

I hereby certify that on November 5, 2025, I served a copy of the foregoing document via email as follows:

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EXHIBIT A

STATE OF NORTH CAROLINA

GENERAL COURT OF JUSTICE

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SUPERIOR COURT DIVISION

FILE NO. 20 CVS 05150

JAY SINGLETON, D.O., and
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BRIEF OF AMICI CURIAE
STATE TREASURER BRADFORD B. BRINER AND
STATE EMPLOYEES ASSOCIATION OF NORTH CAROLINA, INC.

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INTEREST OF AMICI CURIAE

As keeper of the public purse, State Treasurer Bradford B. Briner (“Treasurer Briner”) is a fiduciary for the North Carolina State Health Plan for Teachers and State Employees (“State Health Plan”) pursuant to N.C. Gen. Stat. § 135-48.2 (2025). Consisting of almost 750,000 members, including active and retired members, and their dependents, the Plan is one of the largest purchasers of healthcare in North Carolina and its costs are a significant portion of the State’s budget. In the most recent fiscal year ending June of 2025, the Plan’s expenditures totaled \$4.5 billion, the vast majority of which are associated with medical and pharmacy claims. As a fiduciary, Treasurer Briner is concerned for the solvency of the Plan, which is funded in large part by taxpayers of this State, and he is also concerned with the costs of healthcare borne by the Plan’s members, who are hardworking public servants.¹

Treasurer Briner is joined in this effort by the State Employees Association of North Carolina, Inc. (“SEANC”). SEANC is a North Carolina not-for-profit corporation whose members are current and retired State employees. SEANC has more than 42,000 active members, of whom roughly 23,000 are current employees of the State of North Carolina and 19,000 are retired employees of the State. The guiding purpose of SEANC is the promotion of the best interests of current, retired, and future employees of the State of North Carolina. Nearly all of SEANC’s members are members of the State Health Plan. Indeed, membership in the State

¹ No person or entity other than amici curiae or amici curiae’s counsel wrote any part of this brief or contributed any money to support the brief’s preparation.

Health Plan is part of what they work for. SEANC's members have a substantial interest in the ongoing fiscal integrity of the State Health Plan, which is heavily dependent on the overall cost of healthcare. SEANC joins this brief for the purpose of endorsing the Treasurer's efforts to influence the State's healthcare policy through his support of Plaintiffs in this case.

QUESTION PRESENTED

Have Plaintiffs stated a claim upon which relief can be granted under the Fruits of Their Own Labor Clause, Article I, § 1, of the North Carolina Constitution, and the Law of the Land Clause, Article I, § 19, of the North Carolina Constitution, when Plaintiffs allege that the Certificate of Need law does not have a proper governmental purpose, nor is it a reasonable means of achieving a proper governmental purpose, if such purpose is assumed?

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs argue that the Certificate of Need ("CON") law, N.C. Gen. Stat. § 131E-175, *et seq.*, improperly infringes on their rights and the rights of other persons like them to "enjoy the fruits of their own labor," N.C. Const. art. I, § 1, free from deprivation of that right except pursuant to the "law of the land," *id.* at § 19. Although the CON law's stated purpose is to lower healthcare costs while increasing access, the CON law's actual purpose is to protect institutionalized and incumbent healthcare providers at the expense of would-be competitors, those who need healthcare, and taxpayers.

Further, even assuming the CON law's stated purpose is its actual purpose, the CON law is not a reasonable means of achieving that purpose. Rather than

lowering healthcare costs and improving access to healthcare, the CON law has the opposite effect—it raises costs and diminishes access. In addition, the CON law effectively prohibits new providers from entering the market, imposing a draconian burden. Thus, in the Treasurer’s view, Plaintiffs’ complaint alleges colorable claims under both the Fruits of Their Own Labor Clause and the Law of the Land Clause of the North Carolina Constitution. The Treasurer therefore supports Dr. Singleton’s contention that this Court should deny Defendants’ motion to dismiss.

ARGUMENT

I. Standard of Review

When considering a motion to dismiss under Rule 12(b)(6),² a trial court may only dismiss a complaint that “fails to state a claim upon which relief can be granted.” *Howell v. Cooper*, 919 S.E.2d 212, 218 (N.C. Aug. 22, 2025) (cleaned up) (quoting N.C. Gen. Stat. § 1A-1, Rule 12(b)(6)). The only purpose of such a motion “is to test the *legal* sufficiency of the pleading to which it is directed . . . not the facts which support [that pleading].” *Id.* at *4 (quoting *White v. White*, 296 N.C. 661, 667 (1979)).

When reviewing a motion to dismiss under Rule 12(b)(6), a “court considers ‘whether the allegations of the complaint, if treated as true, are sufficient to state a claim upon which relief can be granted under some legal theory.’” *Cheryl Lloyd Humphries Land Inv. Co., LLC v. Resco Prods., Inc.*, 377 N.C. 384, 387 (2021) (quoting *Coley v. State*, 360 N.C. 493, 494–95 (2006)). So long as a complaint

² Plaintiffs’ brief in opposition to Defendants’ motion to dismiss provides a sufficient description of the relevant factual and legal history of this case.

“state[s] enough to give the substantive elements of at least some legally recognized claim,” it is not subject to dismissal under Rule 12(b)(6). *Stanback v. Stanback*, 297 N.C. 181, 204 (1979).

A complaint is only subject to dismissal:

[W]hen it appears *certain* that plaintiffs could prove no set of facts which would entitle them to relief under some legal theory; (2) *no* law exists to support the claim made; or (3) the complaint on its face discloses facts that necessarily defeat the claim.

Howell, 919 S.E.2d at 219 (citing *U.S. Bank Nat’l Ass’n v. Pinkney*, 369 N.C. 723, 726 (2017)). Therefore, so long as the facts alleged in a complaint “tend to show a colorable legal claim and allow a defendant to understand the claim’s nature and prepare its defense,” the complaint should survive a motion to dismiss. *Id.*

II. Framework for Constitutional Claims

Plaintiffs’ complaint alleges that the CON law violates the fundamental right to earn a living under the North Carolina Constitution. “Our state constitution enshrines the fundamental right to ‘conduct a lawful business or to earn a livelihood’ as one of the ‘first principles of freedom.’” *Id.* at 220 (quoting *N.C. Bar & Tavern Ass’n v. Stein*, 919 S.E.2d 684, 693 (2025)). “The protections afforded to this right, which are guaranteed by both the Fruits of Their Own Labor Clause and the Law of the Land Clause, represent ‘the supreme expression of the people’s will.’” *Id.* at 222 (quoting *Cmty. Success Initiative v. Moore*, 384 N.C. 194, 211 (2023)).

Article I, Section 1, which contains the Fruits of Their Own Labor Clause, states as follows: “We hold it to be self-evident that all persons are created equal; that they are endowed by their Creator with certain inalienable rights; that among

these are life, liberty, *the enjoyment of the fruits of their own labor*, and the pursuit of happiness.” N.C. Const. art. I, § 1 (emphasis added). Article I, Section 19, which contains the Law of the Land Clause, states that “[n]o person shall be . . . deprived of his liberty, . . . but by the *law of the land*.” N.C. Const. art. I, § 19. Claims based upon these rights are considered jointly under both clauses “because the test applied to determine the validity of a state action burdening the fundamental right to earn a living when the State is acting as a regulator or sovereign is the same under both the Fruits of Their Own Labor Clause and Law of the Land Clause.” *Howell*, 919 S.E.2d at 220 (citing *Poor Richard’s, Inc. v. Stone*, 322 N.C. 61, 64 (1988); *see also The North Carolina State Constitution* 46–47 (2d ed. 2013)).

These constitutional protections “bar[] state action burdening [legitimate economic] activit[y] unless ‘the promotion or protection of the public health, morals, order, or safety, or the general welfare makes it reasonably necessary.’” *Kinsley v. Ace Speedway Racing, Ltd.*, 386 N.C. 418, 424 (2024) (quoting *State v. Ballance*, 229 N.C. 764, 768 (1949)); *see also Poor Richard’s*, 322 N.C. at 64. “[T]he mere interference with this fundamental right by the government is all that is required’ to warrant review under the state constitution.” *Howell*, 919 S.E.2d at 220 (quoting *N.C. Bar & Tavern*, 919 S.E.2d at 693).

Thus, to survive constitutional scrutiny under th[ese] provisions, the challenged state action must be reasonably necessary to promote the accomplishment of a public good, or to prevent the infliction of a public harm. This test involves a ‘twofold’ inquiry: (1) is there a proper governmental purpose for the statute, and (2) are the means chosen to effect that purpose reasonable?

Kinsley, 386 N.C. at 424 (cleaned up) (quoting *Poor Richards*, 322 N.C. at 61); *see also N.C. Bar & Tavern*, 919 S.E.2d at 694 (“[T]h[is] legal standard . . . is not rational basis.”).

To begin the analysis on the first element, a court must first “identify the State’s actual purpose for the constraint on private business activity.” *Kinsley*, 386 N.C. at 424; *accord N.C. Bar & Tavern*, 919 S.E.2d at 693 (“[W]e initially look at the actual purpose proffered by the government.”). To start, the State is permitted to simply assert the purpose of the statute and is not initially required to produce evidence proving the real purpose. *Kinsley*, 386 N.C. at 425. A plaintiff, however, “may rebut that asser[t]ed purpose] with evidence demonstrating that the State’s asserted purpose is not the true one, and instead the State is pursuing a different, unstated purpose.” *Id.*; *accord N.C. Bar & Tavern*, 919 S.E.2d at 693.

After identifying the true purpose for the statute, a court must then determine whether that purpose is a “proper governmental purpose.” *Poor Richard’s*, 322 N.C. at 64. “Proper purposes are those that ‘promote the accomplishment of a public good, or . . . prevent the infliction of a public harm,’” and “must address the public interest.” *Kinsley*, 386 N.C. at 425 (quoting *Ballance*, 229 N.C. at 770); *see Ballance*, 229 N.C. at 769 (“An exertion of the police power inevitably results in a limitation of personal liberty, and legislation in this field ‘is justified only on the theory that the social interest is paramount.’” (quoting *State v. Mitchell*, 217 N.C. 244, 7 S.E.2d 567, 571 (1940))). If a court determines that the

identified purpose is not a proper governmental purpose, then the inquiry ends. Otherwise, the inquiry continues to the second step.

Having determined a statute's true purpose is a proper governmental purpose, a court then inquires as to whether "the means chosen to effect that purpose are reasonable." *Kinsley*, 386 N.C. at 426 (quoting *Poor Richard's*, 322 N.C. at 64); see *Howell*, 919 S.E.2d at 221 (examining whether the Governor's "executive orders' closures of bars were a reasonable means to effect the purpose of limiting COVID-19's spread"). At this stage, "the court conducts a 'fact-intensive analysis' to answer two 'fact-specific questions.'" *Id.* (quoting *Kinsley*, 386 N.C. at 426).

First, the court determines how effective the state action is at achieving the desired public purpose. Second, the court determines the extent of the burden the state action places on the targeted businesses. Taking these considerations together, the court must then decide whether, given all the options available, it was reasonable for the State to choose the selected approach. Ultimately, this is a question of degree, and the court must judge the means employed by balancing the public good likely to result against the burdens resulting. *Notably, the State's police power is severely curtailed when the government endeavors to exclude persons from engaging in an ordinary business or occupation.*

Id. (cleaned up) (emphasis added).

III. Analysis

The legislature asserted in the 1970s that the CON law does have a proper governmental purpose, but as Plaintiffs demonstrate, it does not. Moreover, even assuming the CON law does have a proper governmental purpose, it is not a reasonable means of achieving that purpose.

(A) The General Assembly asserted that the CON law is intended to lower healthcare costs and make healthcare easier to access.

The legislature asserted its purpose for the CON Law through its findings of fact codified at N.C. Gen. Stat. § 131E-175, as Plaintiffs allege in their complaint, Plaintiffs' First Amended Complaint ¶ 49, *Singleton v. N.C. Dep't of Health and Human Svcs.*, 20 CVS 005150-910 (N.C. Super. June 16, 2025) ("Complaint"), and the Court of Appeals noted in its decision in this matter, *see Singleton v. N.C. Dep't of Health and Human Svcs.*, 284 N.C. App. 104, 2022-NCCOA-412, ¶ 33 ("In enacting the CON law, the General Assembly made voluminous findings of fact . . ."). As Plaintiffs allege, those findings of fact were adopted after the Supreme Court of North Carolina declared the prior version of the CON law, which lacked such findings, unconstitutional. *See id.* ¶¶ 41, 43–44, 48–49; *In re Certificate of Need for Aston Park Hosp., Inc.*, 282 N.C. 542 (1973).

In those findings of fact, the General Assembly stated, *inter alia*, that the existing methods of health care financing "limit[] the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities." Section 131E-175(1) (2025). The General Assembly also found that "the increasing cost of health care services . . . threatens the health and welfare of this State in that citizens need assurance of economical and readily available health care." Section 131E-175(2).

According to the General Assembly's findings of fact, if the allocation of health care resources were left to the free market, "geographical maldistribution . . . would occur," creating "less than equal access to all population groups." Section

131E-175(3). This maldistribution would threaten “the welfare of rural North Carolinians,” Section 131E-175(3a), and an excess of available health care resources would “lead[] to unnecessary use of expensive resources and overutilization of health care services,” Section 131E-175(4), thus driving up costs. Therefore, the General Assembly concluded:

That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.

Section 131E-175(6), (7). Therefore, according to the General Assembly, the CON law’s asserted purpose is to protect the health and welfare of citizens of North Carolina by ensuring ready access to health care services and lowering the cost of those services by preventing duplicative and needlessly expensive utilization. *See* Complaint ¶ 49.

(B) Plaintiffs allegations successfully rebut the General Assembly’s asserted purpose by demonstrating that the CON law’s actual purpose is not a proper governmental purpose.

Plaintiffs, however, may rebut the State’s asserted purpose to demonstrate that what has been asserted is not the true purpose, and that the law in fact serves

some other purpose. At later stages of the litigation, Plaintiffs would be required to come forth with actual evidence to rebut the State's asserted purpose. At this stage, however, Plaintiffs' factual allegations, including those related to the veracity of the State's asserted purpose of the CON law, are treated as true.

Treated as true, Plaintiffs' allegations demonstrate that, regardless of its purpose in 1978, time has demonstrated that the CON law is not intended to reduce healthcare costs and increase access but rather is intended to protect institutionalized and incumbent healthcare providers at the expense of would-be competitors, the public who consume healthcare services in North Carolina, and the taxpayers of our State.

Plaintiffs allege that the legislature initially adopted the CON law in 1971 as part of "a national movement during the mid-1960s by state and local governments," Complaint ¶ 37, based on a theory "that government planners could control healthcare costs by restricting supply and dividing the provision of healthcare services into discrete geographical regions," *id.* ¶ 38. When that original version of the CON law was challenged under Article I, §§ 19, 32, and 34, of the North Carolina Constitution, *id.* ¶ 41, the Supreme Court of North Carolina "agree[d]" that the original CON law was "in excess of the constitutional power of the Legislature," *id.* ¶ 43 (quoting *Aston Park*, 282 N.C. at 548).

Subsequently, the United States Congress was "grappling with a related issue" around the reimbursement methodology for the federal Medicare and Medicaid programs, *id.* ¶ 45, and "saw CON requirements as a potential means of

holding providers accountable for inefficient expenditures,” *id.* ¶ 46. Congress thus passed the “National Health Planning and Resource Development Act of 1974 (NHPRDA), which required states to adopt CON laws in order to receive federal healthcare subsidies and guaranteed funding for the administration of state CON laws that met certain federal guidelines.” *Id.* ¶ 47. The General Assembly then “re-enacted North Carolina’s CON regime specifically in response to the NHPRDA,” Complaint, ¶ 48, albeit this time with the findings of fact now codified at N.C. Gen. Stat. § 131E-175, *id.* ¶ 49.

As Plaintiffs allege, “[w]hatever their truth [when they were adopted] in 1978, these ‘findings of fact’ are false as a matter of fact today.” Complaint ¶ 50; *id.* ¶ 144 (“The CON law’s ‘findings of fact,’ both generally and as applied to Plaintiffs, are false.”). In fact, “[t]here is no evidence, and Defendants will be unable to produce any evidence, that the CON requirement lowers costs, increases access to care, or helps real patients in any way.” *Id.* ¶ 142. Thus, the General Assembly’s asserted purpose, that the CON law lowers costs and increases access to care, cannot be the true purpose of the CON law.

Instead, as Plaintiffs allege,

North Carolina’s CON law is fundamentally anticompetitive: Established providers are insulated from competition in their service areas; aspiring providers are prevented from participating in the healthcare market solely because other providers got there first; and when state planners project a “need” for a new service or facility—which they usually do not—incumbent providers are given every opportunity to thwart, undermine, and frustrate potential competitors’ applications, while at the same time exerting their considerable economic advantage

to obtain the new CON for themselves—and thus, retain their monopoly status.

Id. ¶ 95. Thus, “[t]he CON law’s true purpose and real-world effect is to protect established healthcare providers from competition, and economic protectionism is not a legitimate basis for preventing Plaintiffs from using their own property to provide safe and affordable outpatient eye surgeries to patients who need them.” *Id.* ¶ 147; *see Pinnacle Health Servs. of N.C. LLC v. N.C. Dep’t of Health and Hum. Servs.*, No. 285A23, 2025 WL 2942992, at *1–2 (N.C. Oct. 17, 2025) (slip op.) (noting that, although “[t]he CON [law] was enacted with laudable goals: to control healthcare costs [and] to facilitate access to health service facilities,” it nonetheless “can be easily manipulated” to serve other purposes).

Therefore, because the CON law does not promote the public good nor prevent a public harm, but rather promotes anticompetitive behavior by institutionalized and incumbent healthcare providers to the detriment of North Carolina citizens, taxpayers, and other healthcare providers, it does not serve a proper governmental purpose. *See Roller v. Allen*, 245 N.C. 516, 525 (1957) (concluding a statute was unconstitutional where that statute “ha[d] as its main and controlling purpose not health, not safety, not morals, not welfare, but a tight control of tile contracting in perpetuity by those already in the business.”).

- (C) **The CON law is not a reasonable means of achieving the General Assembly’s stated purpose, even assuming that purpose is the CON law’s true purpose.**

The CON law is not a reasonable means to address the goals of increasing access to healthcare services while lowering the cost of those services, even

assuming those are indeed the actual purpose of the CON law. First, the CON law is ineffective at achieving its asserted purpose—rather than lowering costs and increasing access, the CON law makes healthcare more expensive and harder to access. Second, the CON law places an immense burden on the targeted businesses—it precludes them from entering the market entirely, unless DHHS both determines there is a need for additional services and eventually awards that CON to the particular business.

i. The CON law is not effective at its asserted purpose because it increases costs and makes healthcare more difficult to access.

Plaintiffs allegations demonstrate how, in its real-world effects, the CON law makes healthcare more expensive and harder to access. Plaintiff Dr. Jay Singleton is a licensed ophthalmologist who is qualified to conduct eye surgeries. Complaint ¶ 20. Plaintiff Singleton Vision Center, P.A. (“Center”) is fully accredited, meets nationally recognized safety standards, and meets the requirements necessary under state law to obtain a license as an ambulatory surgical center. *Id.* ¶¶ 28, 29. Nonetheless, because he cannot obtain a CON, the CON law largely precludes Dr. Singleton from conducting surgeries at the Center, except for a limited number of “incidental” surgeries. *Id.* ¶¶ 2, 12, 96, 100, 102, 112.

The patients who are fortunate enough to receive one of those limited, incidental number of surgeries, “are billed thousands of dollars less per procedure than they would have been charged at CarolinaEast,” the only facility in the area with a CON for these procedures. *Id.* ¶ 114. For example, Dr. Singleton only charges \$1,800 total for cataract surgery, whereas the facility fee alone at CarolinaEast is

almost \$6,000. *Id.* ¶ 24. Many of the patients who received a surgery at the Center “have told Dr. Singleton they would not otherwise have been able to afford an operation at CarolinaEast and so would have either gone without necessary care or substantially delayed their procedures. *Id.* ¶ 115.

Thus, as it stands, care for these patients is less affordable and more difficult to access because the CON law precludes Dr. Singleton from operating a formal surgery program at the Center. Complaint ¶¶ 24, 115, 117. Conversely, “if Dr. Singleton is permitted to run a ‘formal’ surgery program at the Center, more patients in the . . . area will be able to obtain the outpatient eye surgeries they need at an affordable price.” *Id.* ¶ 116. Thus, as alleged by Plaintiffs, the CON law is ineffective at its stated purpose, and in fact has the opposite effect—it raises the cost of healthcare and makes healthcare more difficult to access.

The Treasurer, as a fiduciary for the State Health Plan, has observed this firsthand. In part due to its highly restrictive CON law, *id.* ¶ 63, North Carolina is one of the most expensive states in the country for healthcare services. The State Health Plan in particular has consistently faced rising medical costs. In the 2014-2015 fiscal year, the Plan’s expenditures were approximately \$3 billion dollars, the vast majority of which were associated with medical and pharmacy claims. In the most recent fiscal year, ending June 30, 2025, the Plan incurred approximately \$4.5 billion in expenditures. Thus, over the past decade, the Plan’s annual expenditures have ballooned by approximately 50%.

To curb the rate at which those costs rise, the State Health Plan is pursuing a strategy to address the very issue raised by Dr. Singleton—the discrepancy in cost between services provided at a hospital system and those provided at an independent facility. *See* Att. 1, SHP Board of Trustees March Presentation, at 2; Att. 2, SHP Board of Trustees May Presentation at 2.³ As the State Health Plan’s Executive Administrator has discussed at recent meetings of the State Health Plan’s Board of Trustees, certain commodity services provided at a facility associated with a hospital system can cost up to five times as much as those provided at an independent facility. *See* Att. 3, SHP Board of Trustees August

³ Generally, on a Rule 12(b)(6) motion, a court is limited to considering the four corners of the complaint, in addition to any documents attached thereto. *See Blue v. Bhiri*, 381 N.C. 1, 6 (2022). A court may, however, consider matters outside the complaint if the court can properly take judicial notice thereof pursuant to Rule 201 of the North Carolina Rules of Evidence. *See* N.C. Gen. Stat. § 8C-1, Rule 201; *QUB Studios, LLC v. Marsh*, 262 N.C. App. 251, 260 (stating that, on a Rule 12(b)(6) motion to dismiss, courts “ordinarily examine . . . matters of which a court may take judicial notice” (quoting *Tellabs, Inc. v. Makor Issues & Rights*, 551 U.S. 308, 322 (2007))). Under Rule 201, a court may take judicial notice of “adjudicative facts,” which are, *inter alia*, facts that are “capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned.” *Id.*

“North Carolina [c]ourts have long held that ‘important public documents will be judicially noticed.’” *Anderson Creek Partners, L.P. v. County of Harnett*, 275 N.C. App. 423, 429 (2020) (quoting *State ex rel. Utils. Comm’n v. S. Bell Tel. & Tel. Co.*, 289 N.C. 286, 287 (1976))). Important public documents include documents of a public body that are available for public review as public records under North Carolina’s Public Records Act, N.C. Gen. Stat. § 132-1, *et seq.* *See Anderson Creek*, 275 N.C. App. at 429 (“These documents are subject to public review, N.C. Gen. Stat. § 132-1, and their existence is therefore not subject to reasonable dispute.”); *State v. Harwood*, 243 N.C. App. 425, 427 (2015) (taking judicial notice of “fact[s] from the Department of Public Safety website’s offender search results”).

The materials included as Attachments 1, 2, and 3 are presentations from meetings of the State Health Plan’s Board of Trustees (“Board of Trustees”) from March 7, 2025, May 20, 2025, and August 15, 2025, respectively. The Board of Trustees is an entity of the State of North Carolina subject to the Public Records Act. *See* N.C. Gen. Stat. § 135-48.20(a) (“There is established the Board of Trustees of the State Health Plan for Teachers and State Employees.”); N.C. Gen. Stat. § 132-1(a). Each presentation was posted publicly to the State Health Plan’s website prior to each meeting, was presented publicly at the respective Board of Trustees’ meetings, and remains available on the State Health Plan’s website for public review. Because these documents are important public documents subject to public review, their existence is not reasonably in doubt, and this Court may take judicial notice of the contents thereof. *See Anderson*, 275 N.C. App. at 428-29.

Presentation, at 2 (“Delta between cost of commodity services UP TO 5X in some areas.”)).

For example, an MRI performed for a Plan member at a standalone radiology center on average costs \$872, while that same procedure performed at an outpatient hospital facility costs, on average, \$1,252, a 44% increase. *Id.* at 4. A colonoscopy performed for a Plan member at a freestanding center on average costs \$1,000, while that same procedure performed at an outpatient hospital facility costs, on average, \$3,500, a 250% increase. *Id.* at 3. Thus, the Plan concluded that “steering [MRI and] colonoscopy services away from a hospital setting may save money for both the Plan and member.” *Id.* at 3–4 (cleaned up)).

As it stands, these costs, which exist in part due to the CON law, are helping drive the Plan’s medical inflation. To lower that medical inflation, the State Health Plan hopes to steer more of its members to lower cost facilities. *See* Att. 1, at 2; Att. 2 at 2; Att. 3 at 3, 4). If a CON were not required, and there were more facilities that could provide the same commoditized service at a more competitive cost, then the market could more readily adapt to create such capacity. As it stands, the market cannot readily adapt because, as the Supreme Court of North Carolina recently recognized, the CON law restricts the market’s dynamism. *See Pinnacle Health Servs.*, No. 285A23 at *1–2 (noting that “[t]he CON law is essentially a form of market control” and that “health care providers cannot simply develop, acquire, or expand health care facilities or services based on market demand”).

Thus, the Treasurer, as the elected official with a fiduciary duty for the State Health Plan, has observed the same phenomena as Plaintiffs—the CON law is ineffective at its asserted purpose, and in fact has the opposite effect of raising the cost of healthcare and making healthcare more difficult to access.

ii. The CON law imposes a severe burden on the targeted businesses because those entities are precluded from entering the marketplace.

In addition to having the opposite effect of its stated purpose, the CON law is also incredibly burdensome on the targeted businesses—without a CON, new providers are entirely precluded from entering the market or operating their business at all. As Plaintiff alleges, prior to the application process even beginning, DHHS must determine that there is a “need” for the proposed services in the relevant service area. Complaint ¶¶ 68–71. If DHHS never makes that determination, then no one can obtain a CON, including new providers, who are thus barred from entering the market. *Id.* ¶ 72.

DHHS’ determination that there is a “need” for new services is only the beginning of “an expensive, burdensome, and fundamentally anticompetitive application process.” *Id.* ¶¶ 73, 94. That process begins at DHHS, and entails review by the North Carolina Office of Administrative Hearings, as well as the North Carolina Court of Appeals and, potentially, the Supreme Court of North Carolina. *Id.* ¶¶ 73–87. “[C]ompetitive reviews and contested cases are extremely common, often require the assistance of experienced legal counsel to litigate effectively, and can take many years and hundreds of thousands of dollars to resolve.” *Id.* ¶ 89.

“[E]stablished providers are usually quick to apply for any new CONs and almost always prevail over aspiring market entrants.” *Id.* ¶ 94. These established providers then use the CON process, including the ensuing judicial review, “in an attempt to stonewall the introduction of new, competing healthcare services.” *Id.* ¶ 92. Thus, even if DHHS determines there is a need, as Plaintiffs allege, successfully obtaining the CON is an arduous process that is often fruitless for new providers.

Nor are Plaintiffs’ allegations mere conjecture—this exact scenario is playing out in Wake County at the time of this filing. WakeMed is a “community health system” in Wake County. *See* Att. 4, *App’t’s Brief of WakeMed, Duke Univ. Health Sys., Inc. v. N.C. Dep’t of Health & Human Servs.*, No. COA25-558 (N.C. Ct. App. Aug. 13, 2025, 6.⁴ WakeMed wants to expand its offering of oncology services by acquiring “a linear accelerator (LINAC) to provide radiation oncology.” *Id.* at 2. Because “[a] LINAC is a ‘new institutional health service’” under the CON law, WakeMed is required to obtain a CON before it can acquire one. *Id.* at 8.

All nine LINACs in WakeMed’s service area are currently owned by either Duke or UNC Health. *Id.* Duke and UNC Health each “already have CON approval

⁴ As stated above in footnote 2, when considering a motion to dismiss under Rule 12(b)(6), courts may take notice of “adjudicative facts” under Rule 201, or those facts which are “capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” N.C. Gen. Stat. § 8A-1, Rule 201. Under precedent from the Court of Appeals, sworn filings from another proceeding that are publicly available, bear file stamps from the clerk of that court, and display the proper file number may be judicially noticed. *See State v. Watson*, 258 N.C. App. 347, 352–53 (2018). Attachment 4 cited in this section contains portions of a sworn filing with the Court of Appeals that is publicly available on the Court of Appeals’ electronic docket, bears the file stamp from the Clerk of the Court of Appeals, and has the proper file number. Accordingly, this Court may take judicial notice of the facts referenced herein from Exhibit 4.

to acquire another LINAC each but have not yet acquired or put them into operation.” *Id.* Because WakeMed lacks a LINAC, it refers 80–85 percent of its cancer patients who need radiation therapy to Duke . . . providing a significant revenue stream for Duke,” potentially as much as \$30 million annually. *Id.* at 9.

Duke and UNC Health originally opposed WakeMed’s petition asking DHHS to determine there was a need for another LINAC. *Id.* at 10. DHHS nonetheless determined there was a need, and WakeMed applied for the new CON. *Id.* at 10–11. Naturally, despite having originally opposed WakeMed’s petition, Duke and UNC Health both applied for the CON as well. *Id.* at 11. Although DHHS approved the WakeMed application for the CON, *id.*, Duke filed a petition for a contested case hearing, and the administrative law judge “reversed the award of the CON to WakeMed,” *id.* at 14. WakeMed then appealed to the Court of Appeals, where the case is currently being briefed.

Thus, just as Plaintiffs allege, the CON law is currently operating to prevent WakeMed from expanding its offering of radiation oncology merely because WakeMed lacks the CON required to obtain a LINAC. As Plaintiffs’ allegations predict, two larger health systems have opposed WakeMed’s efforts to obtain a LINAC, first by opposing the determination of need, then by applying for the CON themselves after having said there was no need, and then, after losing the battle for the CON, vigorously litigating the matter. Meanwhile, Duke already has five LINACs, UNC Health already has four, and each has a CON for another LINAC they have not yet obtained. WakeMed, on the other hand, does not have, and is

barred by the CON law from obtaining, a LINAC, and has no way to predict if approval will ever be provided. In the meantime, WakeMed is referring patients to Duke, to the tune of \$30 million annually.

As both Plaintiffs' allegations and WakeMed's predicament exemplify, the CON law is incredibly burdensome on healthcare providers that wish to provide new services—the CON law prevents them from entering the market at all. Further, as described above, the CON law is also ineffective at achieving its asserted purpose, but has the opposite effect—rather than lowering the cost of and increasing access to healthcare, the CON law raises costs and makes healthcare more difficult to access. Thus, even assuming the CON law has a proper purpose, which it does not, it is not a reasonable means of achieving that purpose.

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CONCLUSION

Therefore, the Treasurer contends that Plaintiffs have sufficiently alleged that the CON law fails on both elements—it does not have a proper governmental purpose, and, even assuming it does, it is not a reasonable means to achieve that assumed purpose. Having properly pleaded both elements, Plaintiffs’ complaint states a colorable claim under both the Fruits of Their Own Labor Clause and the Law of the Land Clause of the North Carolina Constitution. Therefore, the Treasurer supports Plaintiffs’ contention that Defendants’ motion to dismiss should be denied.

Respectfully Submitted,

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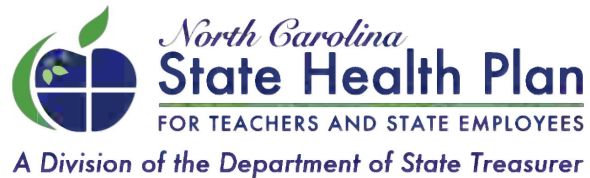
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Attachment 1

State Health Plan Board of Trustees Meeting

March 7, 2025



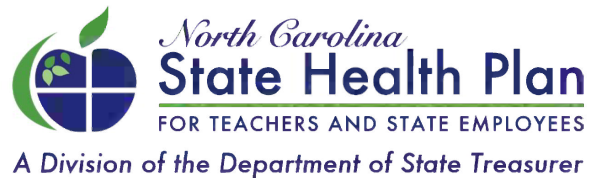
Options to Consider for 2026 and Beyond

- Imaging and Laboratory Steerage Opportunity
- Tiering the network – incenting use of lower cost providers
- Narrowing the formulary – less choice but steeper discounts
- Weight Management program around GLP-1

Attachment 2

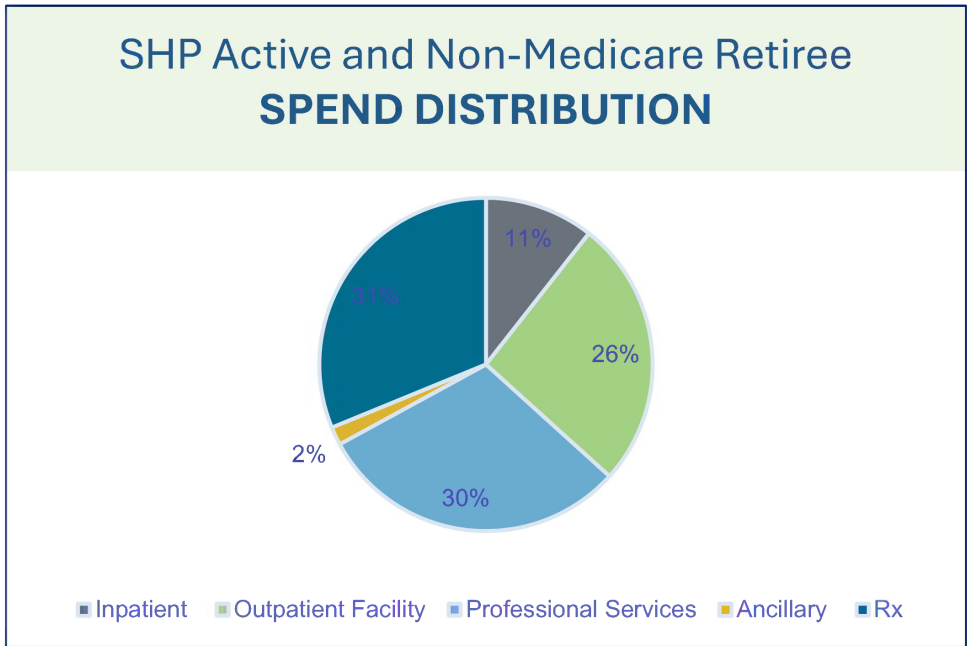
State Health Plan Board of Trustees Meeting

May 20, 2025



Where is the Money Going and What is Driving Spend?

We re-oriented from a plan where the cost is primarily in Inpatient spend to a smoother distribution between Outpatient Facility, Professional Services, and Rx. This re-calibrates our strategy from a hospital-focused approach to an approach focused on steering impactable care to the **RIGHT SITE OF SERVICE** with the **RIGHT PARTNER** who commits to quality and value.

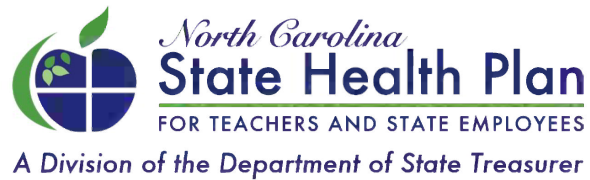


TOP IMPACTABLE CATEGORIES	Percent of SPEND	Percent of MEDICAL SPEND
INPATIENT	10.6%	15.4%
Surgical	5.1%	7.3%
Maternity and Neonate	1.7%	2.5%
OUTPATIENT FACILITY	26.1%	37.9%
Surgery	9.4%	13.7%
Radiology	3.1%	4.5%
Lab/Pathology	1.0%	1.5%
PROFESSIONAL SERVICES	30.3%	44.1%
E&M and Preventive	11.8%	17.1%
Procedural	3.8%	5.5%
Mental Health	3.4%	4.9%
Office Administered Drugs	2.5%	3.7%
Therapies	2.4%	3.5%
Radiology	2.0%	2.9%
Lab/Pathology	1.6%	2.3%

Attachment 3

State Health Plan Board of Trustees Meeting

August 15, 2025



Strategic Approach



STEERAGE AND SCALE:

REDUCE TOTAL SPENDING to Invest in Population Health

- Delta between cost of commodity services **UP TO 5X** in some areas.
- Surgical and procedural rates generally done at scale (by entity) **NOT BY QUALITY** and **NOT CONTEMPLATING STEERAGE** or picture beyond the transaction.



POPULATION HEALTH:

REDUCE NEED TO SPEND IN THE LONG-TERM

- The cheapest surgery is the one someone **NEVER** needs.
- We want to **IMPROVE ACCESS** to low acuity, less invasive care to reduce the future need for high acuity, more complex care.
- We need to strive to make **HIGHER QUALITY OF LIFE** accessible and easier as it will benefit Plan stakeholders; we need to build a model that also sustains those who deliver care.

Variability by Cost: Colonoscopy

In-Network Providers in the Triangle Area

Servicing Provider Type	Avg. Cost /Visit	Portion of Services	Dollar Range of Cost/Visit – Top 20 Providers
Outpatient Hospital	\$3,500	25%	\$4,000 -\$8,000
Freestanding Center	\$1,000	75%	\$750 - \$2,200
Total	\$1,600	100%	n/a

STEERING COLONOSCOPY SERVICES AWAY FROM A HOSPITAL SETTING MAY SAVE MONEY FOR BOTH THE PLAN AND MEMBER.

- Preventive services provided by in-network providers are available at no charge to the member.
- Diagnostic services provided by an in-network outpatient hospital are subject to coinsurance after deductible, which varies by plan.
- Diagnostic services provided by a freestanding center are subject to coinsurance after deductible, which varies by plan.

Variability by Cost: MRI

In-Network Providers in Mecklenburg and Gaston Counties

Servicing Provider Type	Avg. Cost/Visit	Portion of Services	Dollar Range of Cost/Visit - Top 10 Providers	Avg. Plan Paid/ Visit	Avg. Member Share/ Visit
Outpatient Hospital	\$1,252	54%	\$900-\$2,700	\$624	\$619
Standalone Radiology Centers	\$872	46%	\$500-\$1,400	\$344	\$524
Total	\$1,078	100%	n/a	\$496	\$576

STEERING MAGNETIC RESONANCE IMAGING (MRI) SERVICES AWAY FROM A HOSPITAL SETTING MAY SAVE MONEY FOR BOTH THE PLAN AND MEMBER.

Attachment 4

No. COA25-558

NORTH CAROLINA COURT OF APPEALS

DUKE UNIVERSITY HEALTH
SYSTEM, INC.,

Petitioner-Appellant,

v.

NORTH CAROLINA DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, DIVISION OF HEALTH
SERVICE REGULATION,
HEALTHCARE PLANNING AND
CERTIFICATE OF NEED SECTION,

Respondent-Appellant,

and

WAKEMED,

Respondent-Intervenor-
Appellant.

From the Office of Administrative

Hearings

24 DHR 03708

Final Decision of Administrative Law

Judge Michael C. Byrne

20 February 2025

APPELLANT'S BRIEF OF WAKEMED

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No. COA25-558

NORTH CAROLINA COURT OF APPEALS

DUKE UNIVERSITY HEALTH
SYSTEM, INC.,

Petitioner-Appellant,

v.

NORTH CAROLINA DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, DIVISION OF HEALTH
SERVICE REGULATION,
HEALTHCARE PLANNING AND
CERTIFICATE OF NEED SECTION,

Respondent-Appellant,

and

WAKEMED,

Respondent-Intervenor-
Appellant.

From the Office of Administrative

Hearings

24 DHR 03708

Final Decision of Administrative Law

Judge Michael C. Byrne

20 February 2025

APPELLANT'S BRIEF OF WAKEMED

INTRODUCTION

WakeMed has built a thriving cancer center with medical and surgical oncology services but cannot offer the full range of cancer treatment without a

linear accelerator (LINAC) to provide radiation oncology.¹ Duke already has four LINACs and approval for a fifth that should already have been in operation, but for repeated delays by Duke. Duke also directly benefits from WakeMed's inability to offer radiation oncology in the form of a steady stream of WakeMed patient referrals and tens of millions in revenue annually. Accordingly, Duke has repeatedly moved to block WakeMed from obtaining its own LINAC, first by opposing the opportunity for any provider to apply for a LINAC, then by reversing course and applying for the only available CON to acquire a *sixth* LINAC that it does not need, and again by appealing the Agency's decision to approve WakeMed to obtain a LINAC. The Final Decision in this case plays into Duke's consistent efforts to block competition and prevent WakeMed from developing the full range of cancer care by making multiple errors of law to reverse the Agency's decision.

The Final Decision is subject to reversal on several grounds. First, the ALJ's conclusion that Duke proved substantial prejudice to its rights pursuant to N.C. Gen. Stat. § 150B-23(a) is error of law [App. 5]. The only harm Duke complains of is that the Agency denied Duke's CON application for a sixth LINAC and instead approved WakeMed's application, paving the way for WakeMed to compete with Duke as a provider of LINAC services to cancer

¹ Radiation oncology (or "radiation therapy") is the use of radiation to treat cancer. (T(5)p 867).

patients. However, the law is clear that neither is sufficient to show substantial prejudice.

Second, Duke's CON application was rightly denied because the Agency reasonably and appropriately determined that the application did not conform with Criterion 3 (N.C. Gen. Stat. § 131E-183(a)(3) [App. 1] or with 10A NCAC 14C .1903 [App. 9] ("Performance Standard") for several independent reasons. All of the Agency's findings of Duke's nonconformity were rational, made in good faith, and consistent with the Agency's statutory authority. There was no valid basis under N.C. Gen. Stat. § 150B-23(a) to reverse the Agency's decision [App. 5]. Nevertheless, the Final Decision attempts to justify reversing the CON award to WakeMed by repeatedly and impermissibly substituting the ALJ's own judgment for the Agency's on determinations properly within the Agency's expertise and discretion. By doing so, the ALJ treated the contested case hearing as a *de novo* review, and failed to give the Agency decision due regard as required by the Administrative Procedure Act.

Finally, the Final Decision erred by ruling that the Agency improperly applied an "unpromulgated rule" by considering Duke's previous statements that there was no need for a new LINAC. The Agency considered Duke's previous statements in its effort to reconcile conflicting information in its fact-specific review of Duke's application where it took the opposite position.

Consequently, the Agency's analysis did not meet the definition of a "rule" within the meaning of N.C. Gen. Stat. § 150B-18.

All capitalized defined terms used in this brief and the Agency's appellant brief are given the same meanings.

STATEMENT OF THE ISSUES

- I. Whether the OAH's final decision in this case ("Final Decision") erred in concluding that the Agency applied an unpromulgated rule to Duke's certificate of need application.
- II. Whether the Final Decision failed to give due regard to the Agency's demonstrated knowledge and expertise with respect to facts and inferences within the specialized knowledge of the Agency, as required under N.C. Gen. Stat. § 150B-34(a), and instead impermissibly conducted a *de novo* CON review.
- III. Whether the Final Decision erroneously concluded that Duke's rights were substantially prejudiced by the Agency's decision.

STATEMENT OF THE CASE

This appeal arises from the Final Decision of the Office of Administrative Hearings dated 20 February 2025, in which Administrative Law Judge Michael C. Byrne reversed the decision of Respondent Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") which had awarded a Certificate of Need ("CON") to WakeMed to develop an additional linear accelerator ("LINAC") in Wake County.

The contested case challenged the Agency's 27 September 2023 decision in a competitive CON review in which both Duke and WakeMed applied to acquire a new LINAC. (*See, e.g.*, R pp 5-6). The review was based on an adjusted need determination in the annual State Medical Facilities Plan ("Plan") for one new LINAC in Franklin and Wake Counties ("Service Area 20") that resulted from a petition by WakeMed. (Doc.Ex. 362). The Agency both concluded that Duke's application was not approvable as submitted and that WakeMed's application was the most comparatively favorable proposal and therefore awarded the CON to WakeMed. (R p 6).

Duke filed a petition for contested case hearing on 27 October 2023. (R pp 4-116). Following a contested case hearing, the ALJ concluded that the Agency erred by applying an unpromulgated rule to Duke's application (i.e., requiring it to explain its apparent change in position regarding the need for additional LINAC services), by faulting Duke for what the ALJ found were typographical errors that had no impact on its conformity review, and by finding that Duke's required utilization projections were inadequate. (R p 406-69). The ALJ also concluded that the Agency's errors substantially prejudiced Duke's rights. (*Id.*). He determined, however, that he did not have sufficient evidence to determine which applicant would have been approved but for the Agency's errors and therefore did not order that the LINAC be awarded to any

party. (R p 453). All parties timely appealed the Final Decision to this Court on 21 March 2025 and 24 March 2025. (R pp 471-90).

STATEMENT OF THE GROUNDS FOR APPELLATE REVIEW

Appeals of Final Decisions rendered in cases brought pursuant to N.C. Gen. Stat. § 131E-188(b) lie directly to the Court of Appeals pursuant to N.C. Gen. Stat. § 7A-29(a).

STATEMENT OF FACTS

A. Linear Accelerators and Cancer Care

WakeMed and Duke are both hospital systems offering a variety of healthcare services in Wake County. WakeMed is a large community health system that has provided care to Wake and surrounding counties since 1961. (Doc.Ex. 518-19). Its mission is to provide compassionate, high-quality healthcare for all. (T(5)p 873; *see also* Doc.Ex. 518-19, 710). WakeMed's patients are disproportionately uninsured or underinsured, minority, and/or lower income. (Doc.Ex. 518-19). While WakeMed has developed a thriving oncology practice, it cannot offer fully integrated and comprehensive cancer treatment to its patients without a LINAC. (Doc.Ex. 501-02, 710-11).

Multidisciplinary care is vital to cancer treatment. There are three central pillars of cancer care: medical oncology, surgical oncology, and radiation oncology. (T(5) pp 875-76). A LINAC is used to provide radiation oncology, producing radiation to treat cancer patients. *See* N.C. Gen. Stat. §

131E-176(14g). At least 50 percent of cancer patients require radiation therapy. (T(4) p 802; T(5) p 891). Since 2022, WakeMed has served thousands of cancer patients and provides both surgical and medical oncology. (Doc.Ex. 501, 710; T(5) pp 846-51). Obtaining a LINAC would provide WakeMed the missing third pillar of cancer care: radiation oncology. (Doc.Ex. 710; T(5) pp 877-78, 929).

Patients' difficulty accessing cancer care is what led WakeMed to develop its own cancer program. (T(5) p 917). Without a LINAC, WakeMed must refer (send) its patients to either Duke or UNC/Rex for radiation therapy. (Doc.Ex. 501; T(5) p 853). However, referring radiation therapy patients to other providers is inadequate—dividing cancer care between multiple health systems (called fragmentation of care) hinders communication and leads to delays in care, higher cost, poor outcomes and poor patient and family experience, as WakeMed has encountered. (T(5) pp 925-926). WakeMed's patients wait *more than three times longer* than the average patient in the service area to begin radiation therapy. (Doc.Ex. 509-11; T(5) pp 880-82). Also, WakeMed cancer patients who need radiation could avoid significant barriers posed by having to travel to another system for treatment if WakeMed had a LINAC. (Doc.Ex. 501; T(5) pp 948-50).

B. CON Regulation of LINAC

Regulatory barriers have thus far prevented WakeMed from obtaining the LINAC it needs to better serve its patients. A LINAC is a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16), and thus a healthcare provider must obtain a CON before acquiring one. And a provider may not even apply for a LINAC CON unless the Plan has identified a need for one in the service area it wants to serve.² N.C. Gen. Stat. § 131E-183(a)(1) [App. 1].

C. Current LINAC Duopoly

All the LINACS in Service Area 20 are owned by either Duke or UNC/Rex. (Doc.Ex. 2097). As of 2023, they operated a combined nine LINACs in Service Area 20. (*Id.*³). Duke Raleigh Hospital operated four, and UNC/Rex operated five. (T(3) pp 478, 611-12; Doc.Ex. 2097).

In addition to those nine, Duke and UNC/Rex already have CON approval to acquire another LINAC each but have not yet acquired or put them into operation. (*Id.*). Duke obtained approval to acquire its new LINAC in

² The Plan (or “SMFP”) is published annually with inventories and utilization data for the services, facilities, and equipment that are subject to CON regulation. N.C. Gen. Stat. §§ 131E-176(17), (25); 131E-177(4). “Need determinations” in the Plan are official determinations that certain additional services, facilities, and equipment (including LINAC) are needed in defined service areas. (See Doc.Ex. 2092-2105).

³ As reflected in the Plan, operational LINACs list numbers of procedures while LINACs that are not operational list procedures as “0.” (*Id.*).

April 2021 which is to be moved from Franklin County to a new center called “Duke Cancer Center Green Level” in Cary (“Duke Green Level”). (Doc.Ex. 2291-94, 3119). Duke originally projected the LINAC to be operational by July 2023. (Doc.Ex. 2296). However, Duke delayed the project multiple times and, as of May 2024, did not expect the approved LINAC to be in service until 2029. (*E.g.*, Doc.Ex. 2295-2303; T(3) pp 630-31).

UNC/Rex’s new LINAC was approved in 2016 to be placed in Holly Springs. (Doc.Ex. 70, 2097). As of late 2023, UNC/Rex had made no apparent progress to develop its approved LINAC. (Doc.Ex. 360, 368).

Without its own LINAC, WakeMed refers 80-85 percent of its cancer patients who need radiation therapy to Duke (T(5) pp 853-54), providing a significant revenue stream for Duke. Since 2020, patients referred from WakeMed have represented nearly a quarter of Duke’s radiation consultations and up to \$30 million of Duke’s gross revenue annually. (T(3) pp 601-02, 606-07)

D. 2023 SMFP – Adjusted Need Determination and Duke’s Opposition

Need determinations for LINACs in the Plan are typically made when a statistical methodology based on population data and the utilization data for existing and approved LINACs produces certain results. (Doc.Ex. 2093-94, 2104-05). However, the standard need methodology did not produce a need

determination for Service Area 20 in the 2023 Plan, partly because two LINACs had previously been approved but were not yet developed, skewing the utilization data. (Doc.Ex. 2104).

Knowing it could not apply for a CON without a need determination, WakeMed petitioned to include a need determination for one LINAC in Service Area 20 despite the methodology (an adjusted need determination). (Doc.Ex. 171-85). Explaining why another LINAC was needed despite the results of the methodology, WakeMed pointed to (among other things) access disparities resulting from two systems' control of all the LINACs. (Doc.Ex. 183). Both Duke and UNC/Rex had not yet acquired the previously-approved LINACs, and both serve fewer of the underserved population than WakeMed. (Doc.Ex. 171-72, 180-82).

Both Duke and UNC/Rex *opposed* WakeMed's petition. (Doc.Ex. 190-98, 288-91). In its opposing comments, Duke pointed out that two previously approved LINACs were "under development" and not yet available, and stated that "no need exists for additional [LINAC] equipment in the service area." (Doc.Ex. 288).

Nevertheless, the responsible committee and the full State Health Coordinating Council determined that having a LINAC is now the standard of care for cancer programs and voted to include the adjusted need determination in the 2023 Plan. (Doc.Ex. 377, 2105, 2383-84; T(2) pp 363-64; T(6) p 1081).

E. The CON Review

WakeMed applied for the LINAC when applications were due. Despite their previous positions that no more LINACs were needed, and despite both holding approvals for LINACs not yet in operation, both Duke and Rex also applied. The review was deemed competitive because only one application could be approved. (Doc.Ex. 360). In competitive reviews, the Agency reviews each application individually to assess its conformity with the applicable review criteria. (T(1) pp 91-92). No application for a CON may be approved unless it complies (or “conforms”) with all of the statutory review criteria and the Agency’s rules. N.C. Gen. Stat. § 131E-183(a), (b) [App. 1]. After its conformity analysis, the Agency conducts a comparative analysis to determine which application is best. (T(1) pp 91-92).

In this review the Agency found the WakeMed Application fully conforming to all applicable review criteria and Agency rules and found both the Duke and Rex Applications nonconforming to Criterion 3 (N.C. Gen. Stat. § 131E-183(a)(3) [App. 1]) and related criteria, and Agency rule 10A NCAC 14C .1903(5) [App. 9]. (Doc.Ex. 360-443). Accordingly, the Agency approved the WakeMed Application and denied the Duke and Rex Applications. (Doc.Ex. 441-43).

F. Duke's Nonconformity to Criterion 3

Even where there is a need determination in the Plan, Criterion 3 requires an applicant to demonstrate that patients need its specific proposed project. The Agency analyzes whether an applicant has demonstrated need in two parts: (1) whether the applicant has shown a qualitative need for its proposal via its narrative description of need, and (2) a quantitative analysis of the applicant's utilization projections. (T(6) pp 1036-37).⁴ The Agency rejected both Duke's narrative discussion of qualitative need and its quantitative utilization projections as unreasonable and inadequately supported. (Doc.Ex. 383-88).

As it related to qualitative need, the Agency noted that just a few months earlier, Duke had taken the position that no additional LINACs were needed in the service area when it opposed the need determination, yet its application made no effort to explain why it now believed the LINAC it was proposing to acquire was needed. (Doc.Ex. 384-85). Additionally, the Agency found that the application's reliance on an MRI referral network and proximity to primary care providers lacked an obvious nexus to whether patients needed another LINAC at Duke. (*Id.*).

⁴ Duke's unreasonable and inadequately supported utilization projections were also the reason Duke was found nonconforming with the Agency's rules, which are a separate requirement. (*See* Section IV in the Agency's brief being filed separately).

As it related to quantitative need, the Agency concluded that Duke's projections of the number of procedures its LINAC would perform were not based on reasonable and supported assumptions. (Doc.Ex. 387-88). Duke's methodology for projecting utilization of the LINAC was based on the assumption that patients would shift their care from other LINACs in the service area to the new Duke LINAC. (Doc.Ex. 1772, 1830-32). But the Agency found problems with the specific assumptions. First, the Agency noted discrepancies between the stated methodology for assuming patients living in certain ZIP codes would shift their care to the new LINAC and the way in which those shifts were actually projected. (Doc.Ex. 387-88). Second, the Agency found some of Duke's assumed shifts to be unreasonable. (Doc.Ex. 388). For example, Duke projected a lower percentage shift of patients from ZIP codes close to the proposed LINAC (and far from other LINACs) than from ZIP codes that were further away from the proposed site (and close to other LINACs). (Doc.Ex. 1830-32). The Agency concluded that the problems it identified with Duke's projections affected its conformity not only with Criterion 3, but also with the Performance Standard. (Doc.Ex. 382-89).

Any of these conclusions, standing alone, rendered the Duke application unapprovable, but the Final Decision rejected all of these conclusions. With respect to qualitative need, it concluded that faulting Duke for not explaining its prior contention that no additional LINACs were needed amounted to an

unpromulgated rule. (R pp 457-58). Second, the Final Decision found that the references to MRI services were merely a typographical error and that Duke's reliance on primary care was adequately explained, so neither could be held against Duke. (R pp 429, 458-59). With respect to quantitative need, the Final Decision concluded that Duke's expert witness "persuasively demonstrated" that Duke's utilization projections "were sufficient to be found conforming with" Criterion 3. (R p 459). Based on this analysis, the ALJ found that the Agency had erred in finding Duke nonconforming and unapprovable. (*Id.*). However, the ALJ also found that he could not determine whether Duke or WakeMed would have been awarded the CON but for the errors he identified. (R p 453). He therefore reversed the award of the CON to WakeMed but did not order the CON to be awarded to Duke. (R p 468).

ARGUMENT

I. Standard of Review

The ALJ's Final Decision (made pursuant to General Statutes § 150B-34) is the subject of this appeal. Accordingly, this Court may reverse a final decision if:

the findings, inferences, conclusions, or decisions are

- (1) In violation of constitutional provisions;
- (2) In excess of the statutory authority or jurisdiction of the agency or administrative law judge;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;