

IN THE COURT OF APPEALS OF NORTH CAROLINA

2021-NCCOA-536

No. COA20-759

Filed 5 October 2021

Office of Administrative Hearings, No. 20 DHR 549

WAKE RADIOLOGY DIAGNOSTIC IMAGING LLC, Petitioner,

v.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTH CARE PLANNING AND CERTIFICATE OF NEED, Respondent, and THE BONE AND JOINT SURGERY CLINIC, LLP, Respondent-Intervenor.

Appeal by petitioner from final decision entered 12 June 2020 by Administrative Law Judge Stacey Bice Bawtinhimer in the Office of Administrative Hearings. Heard in the Court of Appeals 10 August 2021.

Wyrick Robbins Yates & Ponton LLP, by Frank Kirschbaum and Charles George, for petitioner-appellant.

Attorney General Joshua H. Stein, by Assistant Attorney General Bethany A. Burgon, for respondent-appellee.

Brooks, Pierce, McLendon, Humphrey & Leonard, L.L.P., by James C. Adams, II, and Forrest W. Campbell, Jr., for intervenor-appellee.

DIETZ, Judge.

¶ 1 In North Carolina, health care providers cannot acquire a new MRI scanner (or most other types of medical equipment) without permission from the State in the form of a “certificate of need.” In the typical scenario, State health experts would first

determine that there is a need for another MRI scanner in a particular community, and then interested providers would apply to the State and fight over whose application should be accepted, with the winner ultimately getting the new piece of equipment.

¶ 2 This case is not the typical scenario. Fifteen years ago, State health experts identified a need for a “demonstration project” in Wake County. That project required a provider to acquire an MRI scanner solely for extremity scans, not whole-body scans. State health officials wanted to use the demonstration project to assess whether this type of limited-use MRI scanner would save patients money.

¶ 3 Bone and Joint Surgery Clinic received a certificate of need for use with this demonstration project and acquired an MRI scanner. The certificate of need stated that the MRI machine would create a “diagnostic center” at Bone and Joint’s location to carry out the demonstration project. Many years later, during an office move, the MRI scanner was destroyed. Bone and Joint got permission to replace it with a more advanced MRI machine, but only if it used the new machine for the limited functions in the existing certificate of need.

¶ 4 The following year, State health experts ended the demonstration project and recategorized Bone and Joint’s MRI scanner as just another scanner of the many located in Wake County. Bone and Joint then applied for a new certificate of need that removed the existing restrictions, so it could use its current MRI scanner to its

full capabilities. The agency approved that request.

¶ 5 As a result, Bone and Joint acquired a whole-body MRI scanner without having to compete with other health care providers to get it. Wake Radiology Diagnostic Imaging, one of those potential competitors, challenged the agency's decision. An administrative law judge ruled against Wake Radiology and this appeal followed.

¶ 6 We affirm. By law, State regulators can change the scope of an existing certificate of need if the change was proposed "within one year after the project was completed" and the change concerned "the addition of a health service that is to be located in the facility . . . that was . . . developed in the project." N.C. Gen. Stat. § 131E-176(16)(e).

¶ 7 Here, within one year after the demonstration project ended, Bone and Joint applied for a change to offer additional MRI services at the diagnostic center created when it initially acquired its limited-use MRI scanner. That application falls squarely within the plain language of N.C. Gen. Stat. § 131E-176(16)(e) and we therefore hold that the agency properly issued the challenged certificate of need. Wake Radiology contends that this plain reading of the statute creates a loophole, allowing an end-run around the intended need determination and competitive review process. That is not a concern for this Court. We interpret the law as it is written. If that interpretation results in an unintended loophole, it is the legislature's role to address it.

Facts and Procedural History

¶ 8 In 2006, Bone and Joint Surgery Clinic applied for a certificate of need (CON) to obtain a .23T fixed extremity MRI scanner to be used for a “demonstration project” under the State Medical Facilities Plan. The Department of Health and Human Services awarded Bone and Joint the requested CON in March 2007.

¶ 9 The designated scope of this CON was to “[a]cquire a fixed extremity MRI scanner resulting in the establishment of a diagnostic center.” The CON imposed a number of conditions on Bone and Joint designed to achieve the goals of the demonstration project.

¶ 10 First, it limited the use of the .23T MRI scanner to extremity scans and not “whole body scans.” Second, it required Bone and Joint to conduct a “research study” meant to provide insight into the “convenience, cost effectiveness and improved access” provided by this limited-use MRI machine. The ultimate goal was to “demonstrate any cost savings to the patient or third party payer” from this sort of use of an MRI scanner.

¶ 11 Finally, the CON required Bone and Joint to submit annual reporting to both DHHS and the State Health Coordinating Council for three years. Although this reporting requirement lasted only for three years, the demonstration project continued, and Bone and Joint continued to use the .23T MRI scanner for many years after the reporting requirement ended.

¶ 12 In 2016, nearly a decade after receiving the initial CON, Bone and Joint applied for an exemption from CON review to purchase a replacement .23T MRI scanner machine for the same purpose and use as the existing machine. DHHS granted this exemption with no appeal.

¶ 13 Then, in 2018, Bone and Joint's existing .23T MRI machine was destroyed during an office move. Bone and Joint again applied for a CON exemption to obtain replacement equipment. This time, Bone and Joint asked to purchase a 3.0T MRI scanner—a machine with greater imaging functionality than its existing .23T MRI scanner—but only for the same use and purpose as its existing machine. DHHS granted this exemption as well.

¶ 14 Wake Radiology appealed this agency decision as an “affected person” under N.C. Gen. Stat. § 131E-188(b). In 2019, an administrative law judge concluded that, although the 3.0T MRI scanner had greater capabilities than the .23T MRI scanner it would replace, it still constituted “replacement equipment under N.C. Gen. Stat. § 131E-176(22a).” But the ALJ also ruled that “operation of the replacement MRI is conditioned on conformance with the March 28, 2007 Certificate of Need”; that the new 3.0T “MRI must be used for the same diagnostic or treatment purposes”; and that Bone and Joint “is entitled to use the 3.0 Tesla to perform only the types of studies previously done with the extremity scanner it replaces, unless and until the certificate of need is modified or replaced.” Again, there was no appeal of this decision.

¶ 15 Several months later, on 29 May 2019, the State Health Coordinating Council declared that the 2007 demonstration project concerning Bone and Joint's MRI scanner was now complete. As a result, Bone and Joint's 3.0T MRI machine moved from the demonstration project category into the State's regular MRI inventory category in the 2020 State Medical Facilities Plan. This decision was approved by the Governor.

¶ 16 On 15 August 2019, Bone and Joint applied to DHHS for a new CON so that it could use the 3.0T MRI scanner to its full capability, consistent with its designation in the State Medical Facilities Plan.

¶ 17 The agency reviewed the application and determined that a need assessment and full competitive review process were not required. But the agency chose to solicit public comment and hold a public hearing on the matter under N.C. Gen. Stat. § 131E-185, although the agency believed it was not legally required to do so. Wake Radiology submitted public comment opposing the application.

¶ 18 On 7 January 2020, the agency approved Bone and Joint's application. Wake Radiology timely filed a contested case petition in the Office of Administrative Hearings. An ALJ rejected Wake Radiology's argument and entered summary judgment for the agency, determining that the agency had the authority to issue the CON under either N.C. Gen. Stat. § 131E-176(16)(b) as an "expansion of use" or N.C. Gen. Stat. § 131E-176(16)(e) as a "change in project" for a "new institutional health

service.” Wake Radiology timely appealed the ALJ’s decision to this Court.

Analysis

¶ 19 The parties in this case concede that there are no genuine issues of material fact and Wake Radiology’s arguments on appeal all assert that the ALJ made errors of law. We review the agency’s determination of these legal questions, at the summary judgment stage, under a *de novo* standard of review. *Blue Ridge Healthcare Hosps. Inc. v. North Carolina Dep’t of Health & Hum. Servs.*, 255 N.C. App. 451, 456, 808 S.E.2d 271, 274 (2017); N.C. Gen. Stat. § 150B-51(b).

¶ 20 We begin with the ALJ’s determination that the agency had the authority to expand the scope of use for Bone and Joint’s MRI scanner through a CON under N.C. Gen. Stat. § 131E-176(16)(e). Wake Radiology concedes that, if Bone and Joint’s application falls under this statutory provision, the agency was permitted to issue a CON with the expanded scope of use—essentially a modification of the earlier CON—without a traditional need determination or competitive review process. But Wake Radiology argues that this statutory provision does not apply, and that the General Assembly could not have intended for this provision to apply, in a case like this one. We therefore begin our analysis by examining N.C. Gen. Stat. § 131E-176(16)(e) and its place in this complex series of statutes governing certificates of need.

¶ 21 In North Carolina, health care providers cannot acquire or replace most of their medical equipment and facilities without permission from State regulators. That

permission comes in the form of a certificate of need awarded by the State. The General Statutes provide that no person “shall offer or develop a new institutional health service without first obtaining a certificate of need” from the Department of Health and Human Services. N.C. Gen. Stat. § 131E-178(a).

¶ 22 Accompanying this provision is a lengthy definitional statute identifying the types of medical facilities and equipment that are considered “new institutional health services.” N.C. Gen. Stat. § 131E-176(16). Among those definitions is subsection (16)(e), which provides that a “new institutional health service” includes a “change in a project” proposed “within one year after the project was completed” if the change is “the addition of a health service” located at the facility developed during the project:

The following definitions apply in this Article:

...

(16) New institutional health services. – Any of the following:

...

e. A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion

thereof, that was constructed or developed in the project.

N.C. Gen. Stat. § 131E-176(16)(e).

¶ 23 The agency, and the ALJ, determined that Bone and Joint's application fell within this statutory language because Bone and Joint applied for the CON within one year after the demonstration project for its existing MRI ended and Bone and Joint requested a change to provide additional health services at the diagnostic center established through its initial CON.

¶ 24 Wake Radiology argues that this determination is wrong for several reasons. First, it argues that Section 131E-176(16)(e) does not apply because the change to the CON was not proposed within one year after the "project" was completed. In May 2019, the State Health Coordinating Council ended the demonstration project for Bone and Joint's MRI scanner, with the Governor's approval, and moved that MRI machine from the demonstration project category to the general inventory category in the State Medical Facilities Plan. Within one year of that action, Bone and Joint applied for the broader CON for its 3.0T MRI scanner.

¶ 25 But Wake Radiology contends that "the project for which the 2007 CON was issued was for a fixed extremity MRI scanner, and that 'project' was completed long before 2019." Specifically, it argues that the "project" referenced in the statutory provision ended either when Bone and Joint acquired the MRI scanner in 2007 or, at the latest, when the three-year data collection and reporting period described in the

CON expired in 2010. This is so, Wake Radiology argues, because the State Health Coordinating Council's decision "to end the project twelve years after it started in 2007, and several years after its completion, does not change the completion date of the project to 2019." The State Health Coordinating Council, in Wake Radiology's view, "is essentially an advisory body created by executive order" and its decisions are "irrelevant" to the legal question of when a project ends under the CON statutes.

¶ 26 We are not persuaded by Wake Radiology's argument. When the language of a statute is clear and unambiguous, courts must construe the statute using its plain meaning. *Total Renal Care of North Carolina, LLC v. North Carolina Dep't of Health & Hum. Servs.*, 242 N.C. App. 666, 672, 776 S.E.2d 322, 326 (2015). "When examining the plain language of a statute, undefined words in a statute must be given their common and ordinary meaning." *Krishnan v. North Carolina Dep't of Health & Hum. Servs.*, 274 N.C. App. 170, 172, 851 S.E.2d 431, 433 (2020).

¶ 27 The ordinary meaning of a "project" is "a specific plan or design" or "a planned undertaking: such as a definitely formulated piece of research." *Merriam-Webster's Collegiate Dictionary* (11th ed. 2003). Here, Bone and Joint's initial CON did not function like a typical CON for an MRI scanner. Ordinarily, when a provider obtains a CON for an MRI scanner, the "project" is the acquisition of the MRI scanner itself. Once the provider acquires the MRI scanner, it can offer any procedures it chooses.

¶ 28 Bone and Joint's original CON was different. In 2006, the State Medical

Facilities Plan included a need determination for a “demonstration project” for a fixed extremity MRI scanner in Wake County. Bone and Joint applied for a CON based on that need assessment and its original CON contained conditions that related to that demonstration project. For example, Bone and Joint could not perform “whole body scans” with its MRI; it was required to “conduct an organized research study” during its use of the MRI to assess “the convenience, costs effectiveness and improved access provided by a fixed extremity MRI scanner”; and it was required to “provide annual reports” about its research “for a 3-year reporting period from the date of installation.” Thus, unlike a typical CON, in which the “project” is completed upon construction or acquisition of the facility or piece of equipment at issue, this project was ongoing—it was a “demonstration project” that State health experts used to assess the benefits of this type of limited-use, fixed extremity MRI scanner. That ongoing project continued until the same State health experts who created it (the State Health Coordinating Council, subject to approval by the Governor) decided to end it.

¶ 29 In short, applying the ordinary meaning of the word “project” to the circumstances surrounding this particular CON, we conclude that the “project was completed,” as that phrase is used in N.C. Gen. Stat. § 131E-176(16)(e), when the State Health Coordinating Council chose to end the demonstration project, and corresponding research study, for Bone and Joint’s MRI scanner.

¶ 30 Wake Radiology next argues that, even if Bone and Joint applied for the CON within one year after the project was completed, the new CON was not for “the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.” N.C. Gen. Stat. § 131E-176(16)(e). Specifically, Wake Radiology contends that “under no plausible interpretation could a demonstration project for an extremity MRI scanner be considered a ‘facility’ that was ‘constructed or developed in the project.’”

¶ 31 This argument, too, ignores a key feature of Bone and Joint’s CON. The initial CON expressly stated that its “scope” was for “a fixed extremity MRI scanner resulting in the establishment of a diagnostic center/Wake County.” In other words, the CON itself acknowledged that, once Bone and Joint acquired the limited-use MRI scanner, it necessarily created a “diagnostic center” wherever that MRI scanner was located. The term “health service facility” in the statute is defined to include a “diagnostic center.” N.C. Gen. Stat. § 131E-176(9b). Thus, when the agency removed the limitations on the MRI scanner’s use in the new CON, the effect was to permit Bone and Joint to add additional health services (the expanded functionality of its 3.0T MRI scanner) at a diagnostic center (the one expressly created in the CON through the acquisition of and use of the MRI scanner). We thus conclude that the new CON concerned “the addition of a health service that is to be located in the facility . . . that was . . . developed in the project.” N.C. Gen. Stat. § 131E-176(16)(e).

¶ 32 Lastly, we address a policy argument that runs throughout Wake Radiology's challenge to the ALJ's decision. The argument, in essence, is that the agency's actions in this case would "interpret out of existence" a central feature of the CON laws: the notion that, before a new piece of medical equipment (say, a whole-body MRI scanner) is purchased in our State, there must be a need determination by State regulators and an opportunity for all the interested medical providers to apply for the right to acquire it. Those medical providers get to fight it out in a complicated regulatory process to see who comes out on top and gets the State's permission to acquire the machine.

¶ 33 So, the argument goes, applying the plain language of N.C. Gen. Stat. § 131E-176(16)(e) to this case creates a loophole in the usual process. Bone and Joint got a new, whole-body MRI scanner (which, to be fair, it already possessed, but with restrictions on use) without affording Wake Radiology and other providers who may want a new MRI machine the chance to compete for the right to acquire it instead.

¶ 34 There is a fatal flaw in this policy argument: The role of the courts is to interpret statutes as they are written. We cannot reject what is written to avoid a loophole that we, or the parties in a lawsuit, believe might undermine the legislature's policy goals. *Sykes v. Vixamar*, 266 N.C. App. 130, 138, 830 S.E.2d 669, 675 (2019). This is particularly true for a complicated regulatory regime like our State's certificate of need laws—a regime that has spawned a legion of lawyers and

other experts who learn to navigate the intricate language chosen by our General Assembly. The role of the judicial branch is not to speculate about the consequences of the language the legislature chose; we interpret that language according to its plain meaning and “if the result is unintended, the legislature will clarify the statute.” *Wells Fargo Bank, N.A. v. Am. Nat’l Bank & Tr. Co.*, 250 N.C. App. 280, 287, 791 S.E.2d 906, 911 (2016).

¶ 35 Accordingly, we hold that the agency had the legal authority to issue the challenged CON to Bone and Joint. That CON was authorized by N.C. Gen. Stat. § 131E-176(16)(e) because Bone and Joint sought a “change in a project that was subject to certificate of need review and for which a certificate of need was issued,” the change was proposed “within one year after the project was completed,” and the change concerned “the addition of a health service that is to be located in the facility . . . that was . . . developed in the project.” *Id.* Because we conclude that the ALJ’s decision on this ground was correct, we need not address Wake Radiology’s challenges to the ALJ’s alternative grounds to uphold the agency decision.

Conclusion

¶ 36 We affirm the final decision.

AFFIRMED.

Judges COLLINS and GORE concur.