

NO. COA09-844

TENTH DISTRICT

NORTH CAROLINA COURT OF APPEALS

HOPE-A WOMEN'S CANCER)
CENTER, P.A. and RALEIGH)
ORTHOPAEDIC CLINIC, P.A.,)

Plaintiffs-Appellants,)

v.)

STATE OF NORTH CAROLINA,)
et al.,)

Defendants-Appellees.)

From WAKE COUNTY
No. 08-CVS-7955

PLAINTIFFS-APPELLANTS' BRIEF

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 STATE OF NORTH CAROLINA,)
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 Defendants-Appellees.)
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From WAKE COUNTY
No. 08-CVS-7955

PLAINTIFFS-APPELLANTS’ BRIEF

QUESTIONS PRESENTED

I. Did the trial court err in ruling that the Certificate of Need Law, which contains scarce substantive guidance and is bereft of procedural safeguards, did not unconstitutionally delegate legislative authority to the executive branch in violation of Article I, Section 6 and Article II, Section 1 of the North Carolina Constitution as applied to the Appellants?

II. Did the trial court err in ruling that the Certificate of Need Law, as applied to the Appellants, did not violate Appellants' rights to procedural and substantive due process in violation of Article I, Section 19 of the North Carolina Constitution?

III. Did the trial court err in ruling that the confluence of the Certificate of Need Law, the Administrative Procedure Act, and applicable administrative rules did not violate the rights of Appellants to access to the courts under Article I, Section 18 of the North Carolina Constitution?

STATEMENT OF THE CASE

Appellants Hope-A Women's Cancer Center, P.A. ("Hope") and Raleigh Orthopaedic Clinic, P.A. (the "Clinic") commenced this constitutional challenge to certain aspects of the Certificate of Need Law, N.C. Gen. Stat. Chapter 131E, Article 9, and corresponding regulations in Wake County Superior Court on 6 May 2008. On 4 September 2008, the Chief Justice designated the case as exceptional under Rule 2.1 of the General Rules of Practice for Superior and District Courts and assigned the case to Superior Court Judge Howard E. Manning, Jr.

Appellants filed a First Amended Complaint on 31 December 2008. On 9 January 2009, Appellees filed their Answer and Motion to Dismiss. On 16 January 2009, Appellants filed a Motion for Judgment on the Pleadings. On 26 February 2009, Appellees filed a Motion for Judgment on the Pleadings.

After a hearing on 27 February 2009, Judge Manning issued a Memorandum of Decision and Order on 26 March 2009 granting Appellees' Motion for Judgment on the Pleadings and denying Appellants' Motion for Judgment on the Pleadings. Appellants filed a Notice of Appeal on 17 April 2009.

STATEMENT OF THE GROUNDS FOR APPELLATE REVIEW

The trial court's order granting Appellees' Motion for Judgment on the Pleadings is a final judgment and appeal is therefore proper in the Court of Appeals pursuant to N.C. Gen. Stat. § 7A-27(b).

STATEMENT OF FACTS

The Parties. Hope is a healthcare provider in Buncombe County that, *inter alia*, specializes in gynecologic and breast cancer treatment. (R p. 103) Based on their education, training and professional experience, the physicians at Hope have determined that a comprehensive cancer center offering diagnostic and treatment modalities, including advanced imaging, medical and radiation oncology and surgical services, in one location would enable them to provide care of the highest quality to their patients. Id. To develop a cancer center with such integrated services, Hope wishes to provide its patients with positron emission tomography (“PET”), magnetic resonance imaging (“MRI”) and linear accelerator services at the same location at which Hope now provides chemotherapy and surgical services. Id.

The Clinic is the largest orthopaedic practice in Wake County; serving patients from Wake County and a large region of eastern North Carolina. (R p. 104) Based on their education, training and professional experience, the physicians of the Clinic believe that single specialty operating rooms offer significant advantages to physicians and their patients in both the quality and the cost of necessary medical care. Id. Currently, no facility in Wake County has any dedicated ambulatory orthopaedic surgery operating rooms. Id. In order to continue to provide high quality, cost effective medical services to its patients, the

Clinic seeks to develop and open six dedicated ambulatory orthopaedic surgery operating rooms. Id.

The CON Law. Chapter 131E, Article 9 of the General Statutes (the “CON Law”) requires that healthcare providers, such as Appellants, obtain a CON prior to developing or offering “new institutional health services.” Pursuant to N.C. Gen. Stat. § 131E-176(16), the acquisition of a PET scanner, linear accelerator or MRI scanner, the establishment of a new ambulatory surgery facility, and the development of one or more operating rooms are all defined as new institutional health services requiring a CON.

The criteria used by the N.C. Department of Health and Human Services (the “Department”) in determining whether or not to grant a CON for a proposed project are contained in N.C. Gen. Stat. § 131E-183. The first of these criteria may render all other criteria irrelevant in a given case by providing that “[t]he proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a *determinative limitation* on the provision of any health service, health service facility [or] operating rooms . . . that may be approved.” N.C. Gen. Stat. § 131E-183(a)(1)(“Criterion 1”)(emphasis added).

The State Medical Facilities Plan. Pursuant to Criterion 1, the Department has consistently refused to consider for approval any CON application

for a proposed new institutional health service if the State Medical Facilities Plan (the “Plan”) currently in effect does not contain a determination that there is a need for that project. (R p. 105) As a result, Appellants and similarly-situated applicants for CONs have no opportunity to demonstrate in their applications that the new institutional health services they propose are needed, unless there has been a prior need determination for their proposed service area in the Plan. Id.

The Plan is annually developed by the Department “under the direction of the North Carolina State Health Coordinating Council” (the “Council”). (R p. 206) After approval by the Governor, the Plan is annually adopted by the Department as a rule for the review of CON applications. 10A N.C.A.C. 14C.0103(b).

The Council has been established, rescinded, and re-established several times by Executive Order of the Governor. (R p. 106) On 3 March 2008, Governor Easley issued Executive Order 139 which once again established the Council and directed it to “prepare the Annual State Medical Facilities Plan and present the plan to the Governor.” (R p. 119) Although Executive Order 139 described the categories from which the 29 members of the Council will be appointed (R p. 120), upon information and belief, 25 of the 29 members of the Council that developed the 2008 Plan simultaneously served as officers, employees, directors or medical staff members of entities engaged in providing health care services for compensation within the State of North Carolina. (R pp.

106-107, 123-126) The entities with which those members of the Council are affiliated, as well as their existing or potential competitors, are subject to regulation under the CON Law. (R p. 107) The decision of the Council in formulating the Plan therefore has a significant, direct financial impact upon those entities with which members of the Council are affiliated. Id.

N.C. Gen. Stat. § 131E-176(25) provides in pertinent part:

In preparing the Plan, the Department and the [Council] shall maintain a mailing list of persons who have requested notice of public hearings regarding the Plan. Not less than 15 days prior to a scheduled public hearing, the Department shall notify persons on its mailing list of the date, time, and location of the hearing. The Department shall hold at least one public hearing prior to the adoption of the proposed Plan and at least six public hearings after the adoption of the proposed Plan by the [Council]. The Council shall accept oral and written comments from the public concerning the Plan.

Except for the above-quoted provision of N.C. Gen. Stat. § 131E-176(25), the CON Law contains no guiding standards or procedural safeguards applicable to the development of the Plan by the Department under the direction of the Council.

The 2008 Plan provides a process by which the Council can decide, at the request of any individual, to treat a particular geographic area or institution differently from others similarly situated, stating as follows:

People who believe that unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and

policies may submit a written petition requesting an adjustment be made to the need determination given in the Proposed [Plan].

(R p. 223) The 2008 Plan further states that the Council will decide “whether or not to incorporate the recommended adjustments in the final [Plan] to be forwarded to the Governor.” (R p. 224) Nothing in the CON Law, the Administrative Procedure Act (“APA”), or any other statute provides guiding standards to determine what are “unique or special attributes of a particular geographic area or institution” or otherwise directs the Council in deciding whether to grant or deny any petition “to adjust the need determination.”

The State Government Ethics Act. The State Government Ethics Act (the “Ethics Act”), N.C. Gen. Stat. § 138A-1, *et seq.*, contains comprehensive guiding standards and procedural safeguards applicable to “[a]ny state board, commission, council, committee, task force, authority, or similar public body, however denominated, created by statute or executive order, as determined and designated by the [State Ethics Commission], except for those public bodies who have only advisory authority.” Pursuant to N.C. Gen. Stat. § 138A-2, the “purpose of this Chapter is to ensure that elected and appointed State agency officials exercise their authority honestly and fairly, free from impropriety, threats, favoritism, and undue influence.”

Among the legislative findings made by the General Assembly when it

enacted the Ethics Act is the following:

[B]ecause many public officials serve on a part-time basis, it is inevitable that conflicts of interest and appearances of conflicts will occur. Often these conflicts are unintentional and slight, but at every turn those public officials who represent the people of this State must ensure that it is the interests of the people, and not their own, that are being served. Officials should be prepared to remove themselves immediately from decisions, votes, or processes where a conflict of interest exists . . .

2005 N.C. Session Law, 2006-201.

The State Ethics Commission has determined that the Council and its members are not subject to any of the safeguards established by the Ethics Act and that the members of the Council are not “covered persons” as defined therein. (R p. 109)

Administrative Procedure Act. Chapter 150B of the General Statutes (the “APA”) contains comprehensive procedural safeguards applicable to the promulgation of rules having the force and effect of law by agencies in the state government. The development of the Plan by the Council, however, is specifically made exempt from the APA pursuant to N.C. Gen. Stat. § 150B-2(8a)(k), under which it is only necessary that “the Plan has been prepared with public notice and hearing as provided in G.S. 131E-176(25), and approved by the Governor.”

The judicial review of administrative decisions which is available under the APA is conducted upon the official record created in a contested case. See N.C.

Gen. Stat. § 150B-51(c). However, the Department's rule codified as 10A N.C.A.C. 14C.0402 provides that the "correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested case hearing." Because of this rule, persons adversely affected by arbitrary or erroneous need determinations made by the Council and included in the Plan are deprived of effective administrative or judicial review of those decisions.

Appellants' Unsuccessfully Petition to the Council. Hope petitioned the Council to adjust the Plan to show a need determination for the acquisition or a MRI scanner to be used exclusively for imaging procedures to diagnose and treat breast cancer. (R pp. 42-67) On four occasions since 2004, the Clinic has petitioned the Council to include in the Plan a determination of need for new operating rooms in Wake County. (R p. 113) The Clinic's most recent petition requested the Council determine a need for six freestanding, single specialty operating rooms in Wake County. (R pp. 68-87) Hope's petition, and all four of the Clinic's petitions, were disapproved by the Council. (R p. 113)

ARGUMENT

I. INTRODUCTION

The State of North Carolina requires that healthcare providers obtain a CON prior to developing or offering "new institutional health services," such as those that Appellants seek to develop and offer. Without a CON, Appellants are

prohibited from developing, offering, and using the medical equipment and facilities that their respective physicians have concluded would provide the best quality medical care to their patients.

Appellants believe – and seek the opportunity to prove to the State in an appropriate forum – that the new services they propose to offer would improve the quality and reduce the cost of care, offering an alternative superior to other care available to their respective markets. Appellants are effectively thwarted, however, in their efforts to better serve their patients. The CON Law as applied to the Appellants – specifically the Plan and (Criterion 1), which acts as an inflexible gatekeeper to prevent proposed projects from even being considered - is an unconstitutional delegation of legislative authority. N.C. Gen. Stat. § 131E-183(a)(1). Further, Appellees' application of Criterion 1 violates Appellants' procedural and substantive due process rights. Finally, Appellants are unconstitutionally deprived of access to the courts to challenge the need determinations contained in the Plan.

To obtain a CON, healthcare providers must submit applications to the Department, which determines whether or not to grant a CON for a proposed project based on certain statutory criteria. However, Criterion 1 restricts approval to only those applications that correspond with a need determination made in the Plan.

The Plan is developed annually by the Department “under the direction of the [Council]” and becomes effective with the Governor’s approval. At that point, under Criterion 1, the Plan becomes a barrier to market entry. Unless the Plan prospectively identifies a need for a particular new institutional health service, a CON application must be rejected even if it meets all other statutory criteria for approval. The Council and its members, therefore, wield extraordinary power to determine the number, type and location of new institutional health services in North Carolina.

The Council operates without adequate guidance from the General Assembly regarding the criteria and procedure used to make the need determinations contained in the Plan. Moreover, other than certain requirements for public notice and hearing, the General Assembly has uniquely exempted the Council from the comprehensive procedural safeguards contained in the APA, which are otherwise applicable to the promulgation of rules having the force and effect of law. Additionally, the need determinations in the Plan are not subject to challenge in hearings before the Office of Administrative Hearings because the Department’s rules provide that the “correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested case hearing.” 10A N.C.A.C. 14C.0402.

Against this backdrop of unusually broad discretion and power, the Council

is not comprised of neutral and independent civil servants. Rather, 25 of the Council's 29 current members also serve as officers, directors, or employees of entities engaged in providing health care services for compensation within the State. These members' businesses provide services which may be protected from competition by provisions of the Plan that they collectively develop. Despite actual or apparent conflict of interests, however, the Council and its members are exempt from the Ethics Act, which was enacted to ensure "that elected and appointed State agency officials exercise their authority honestly and fairly, free from impropriety, threats, favoritism, and undue influence." Members of the Council are free to participate in the consideration of proposals to adjust the need determinations for particular health care equipment, facilities, or services in the following year's Plan, even when such proposals would directly affect the market share and financial performance of the healthcare provider with which they are affiliated, by which they are compensated, and to which they owe a fiduciary duty.

This unholy convergence of circumstances results in an unconstitutional delegation of legislative authority, unconstitutional violations of Appellants' procedural and substantive due process rights, and an unconstitutional denial of access to the courts for redress of grievances. These unconstitutional acts manifest themselves in a Plan annually crafted by, and approved for the benefit of, entrenched healthcare providers in the State, either by strategically approving

determinations of need in such a way that makes it more likely the entrenched providers will “win” the CON to meet those needs, or in a way that protects the entrenched providers against potential competition from other providers. Both ends disadvantage the North Carolina patient population. The trial court erred when it denied Appellants’ motion for judgment on the pleadings and granted Appellees’ motion for judgment on the pleadings.

II. THE STANDARD OF REVIEW

A court’s review of a motion for judgment on the pleadings is “limited to the facts properly pleaded in the pleadings before [the court], inferences reasonably drawn from such facts and matters of which the court may take judicial notice.” Wilson v. Crab Orchard Development Co., 276 N.C. 198, 206, 171 S.E.2d 873, 878-79 (1970). The appellate court reviews *de novo* rulings on motions for judgment on the pleadings. Toomer v. Branch Banking & Trust Co., 171 N.C. App. 58, 66, 614 S.E.2d 328, 335 (2005).

III. THE TRIAL COURT ERRED WHEN IT DENIED APPELLANTS’ MOTION FOR JUDGMENT ON THE PLEADINGS AND GRANTED APPELLEES’ MOTION FOR JUDGMENT ON THE PLEADINGS BECAUSE, AS APPLIED IN THIS CASE, THE CON LAW DELEGATES LEGISLATIVE AUTHORITY TO THE COUNCIL IN VIOLATION OF ART. I, § 6 AND ART. II, § 1 OF THE CONSTITUTION OF NORTH CAROLINA.

ASSIGNMENT OF ERROR NOS. 1 and 5 (R pp. 637-639)

Under our State Constitution, the default position is that the power to legislate is vested solely in the General Assembly. In recognition of the

complexities of the modern state, our Supreme Court has allowed the General Assembly to make limited delegations of legislative authority in certain circumstances. Only where the General Assembly has provided both substantive guidance and procedural safeguards against substantive abuse, however, is the Legislature's delegation of rulemaking authority deemed to be constitutional.

Article I, § 6 of the North Carolina Constitution provides: "The legislature, executive, and supreme judicial powers of the State Government shall be forever separate and distinct from each other." Additionally, Article II, § 1 of the North Carolina Constitution provides that "[t]he legislative power of the State shall be vested in the General Assembly, which shall consist of a Senate and a House of Representatives." Under these two constitutional provisions, the legislative power cannot be delegated without substantive standards and procedural protections. Heritage Village Church & Missionary Fellowship, Inc. v. State, 40 N.C. App. 429, 442-44, 253 S.E.2d 473, 481 (1979), aff'd, 299 N.C. 399, 263 S.E.2d 726 (1980).

The statutory delegation of authority to the Council to develop the Plan, which is in turn treated as the fixed policy of the State, fails to contain any meaningful or helpful guidance on the substantive issues that the Plan must address. Of further concern, the delegation to the Council is also accompanied by exemptions from the procedural safeguards and protections against conflicts of

interest that apply to virtually every other administrative agency, board or council of the State. The delegation is therefore both too broad and too likely to result in substantive abuse to be consistent with the State's constitutional plan.

A. The Delegation of Legislative Authority to the Council Must Include Substantive Guidance and Procedural Safeguards in Order to be a Constitutional Delegation of Legislative Authority.

Our Supreme Court has held that “the constitutional inhibition against delegating legislative authority does not preclude the legislature from transferring adjudicative and rule-making powers to administrative bodies *provided such transfers are accompanied by adequate guiding standards to govern the exercise of the delegated powers.*” Adams v. N.C. Dept. of Natural and Economic Resources, 295 N.C. 683, 697, 249 S.E.2d 402, 410 (1978) (emphasis added) (citing Hospital v. Davis, 292 N.C. 147, 232 S.E.2d 698 (1977); Guthrie v. Taylor, 279 N.C. 703, 185 S.E.2d 193 (1971)). The test of whether a delegation of legislative authority to an administrative body is constitutional “is whether the delegation is accompanied by adequate guiding safeguards. If so, the delegation will be upheld.” In re Broad and Gales Creek Comm. Ass'n, 300 N.C. 267, 273, 266 S.E.2d 645, 650 (1980).

Our Supreme Court has noted that:

[w]e concur in the observation that “[t]he key to an intelligent application of this [test] is an understanding that, while delegations of power to administrative agencies are necessary, such transfers of power should be closely monitored to insure that the decision-making by the agency is not arbitrary and unreasoned and that the

agency is not asked to make important policy choices which might just as easily be made by the elected representatives in the legislature.”

Adams, 295 N.C. at 697-98, 249 S.E.2d at 411 (quoting Glenn, THE COASTAL MANAGEMENT ACT IN THE COURTS: A PRELIMINARY ANALYSIS, 53 N.C. L. Rev. 303, 315 (1974)).

In reviewing whether a delegation of legislative authority is constitutional, courts look to find both *substantive guidance* to the administrative body and *procedural safeguards*. Adams, 295 N.C. at 698, 249 S.E.2d at 411. “We thus join the growing trend of authority which recognizes that the presence or absence of procedural safeguards is relevant to the broader question of whether a delegation of authority is accompanied by adequate guiding standards.” Id.

B. The General Assembly Has Not Given the Council the Substantive Guidance or the Procedural Safeguards to Make its Authority a Constitutional Delegation of Legislative Authority.

In the CON Law, the General Assembly has delegated to the Department the power to review specific CON applications, and to determine whether the new facilities proposed in these applications are needed, based on the detailed criteria set forth in N.C. Gen. Stat. § 131E-183(a). However, the provisions of the CON Law at issue here convert this delegation of an appropriate administrative function – to find facts in specific cases and to apply substantive criteria prescribed by the General Assembly – into an unlawful delegation of the legislative power to a group

of private, self-interested individuals to determine what medical facilities are needed throughout the State. This delegation cannot withstand scrutiny under our Constitution and the cases construing it.

This Court has held that the delegation of broad legislative power to entities like the Council is unconstitutional.

[T]he General Assembly cannot delegate to an administrative board the power to legislate. If the General Assembly sets a policy and gives an administrative board the power to find facts which enable the board to carry out the legislative policy that is not a delegation of legislative power. The General Assembly must prescribe the standard for an administrative board with sufficient definitiveness so that the board is bound by the legislative policy and cannot under the name of finding facts actually set the policy.

Farlow v. N.C. State Bd. of Chiropractic Examiners, 76 N.C. App. 202, 211, 332 S.E.2d 696, 702 (1985)(citations omitted).¹

The broad, policy-making authority delegated to the Council is particularly offensive to constitutional standards in the present context because it involves the

¹ See, e.g., Northampton County Drainage Dist. No. One v. Bailey, 326 N.C. 742, 392 S.E.2d 352 (1990); Bulova Watch Co., Inc. v. Brand Distr. of N. Wilkesboro, Inc., 285 N.C. 467, 206 S.E.2d 141 (1974); State v. Williams, 253 N.C. 337, 117 S.E.2d 444 (1960); Harvell v. Scheidt, 249 N.C. 699, 107 S.E.2d 549 (1959); Taylor v. Carolina Racing Ass'n, 241 N.C. 80, 84 S.E.2d 390 (1954); Kinston Tobacco Bd. of Trade v. Liggett & Myers Tobacco Co., 235 N.C. 737, 71 S.E.2d 21 (1952), cert. denied, 344 U.S. 866 (1952); State v. Harris, 216 N.C. 746, 6 S.E.2d 854 (1940); Revco Southeast Drug Centers, Inc. v. N.C. Bd. of Pharmacy, 21 N.C. App. 156, 204 S.E.2d 38 (1974).

power to prevent individual applicants, such as the Appellants, from exercising their fundamental right to engage in an otherwise lawful business. As our Supreme Court has held:

Where such a power is left to the unlimited discretion of a board, to be exercised without the guide of legislative standards, the statute is not only discriminatory but must be regarded as an attempted delegation of a legislative function offensive both to the State and Federal Constitution.

While the power to make rules and regulations to carry into effect the laws confided to them for administration is often given to administrative bodies, and while in instances there may be some doubt as to whether the proposed regulation is legislative in character or in pursuance of a delegable power, *it is clear that in a statute of this kind, giving the important power of admitting or excluding persons from a business, trade, or profession, only the Legislature can create the standards and provide the reasonable limits within which the power must be exercised.*

State v. Harris, 216 N.C. at 754-55, 6 S.E.2d at 860 (emphasis added)(citations omitted).

The Council's development and the Department's use of the Plan as "a determinative limitation" on the number and types of CONs that will be granted converts the Department's properly delegated authority – to review specific proposals and determine whether they meet the criteria listed in N.C. Gen. Stat. § 131E-183(a) – into an unconstitutional grant of authority for the Council to determine statewide policy setting the type and location of new facilities and

services. The provisions of the CON Law at issue here permits the Council to make “need determinations,” but specify neither the factors to be considered nor the methodologies to be used by the Council in making those determinations.² Although the Council is directed to hold public hearings and receive public comments on its initial determinations in a Plan, no statute requires the Council to approve any meritorious change suggested by an interested party. Following approval by the Governor, the Council’s need determinations are given the force and effect of law. In a subsequent CON application, Criterion 1 prevents the applicant from rebutting a determination in the Plan that there is no need for the service it proposes. Thus, the Council is given unlimited discretion and the power to prescribe the type and location of new medical facilities which may be developed in the State.

Because the great majority of the members of the Council is comprised of citizens employed by private businesses rather than officers of state government, this attempted delegation of legislative authority is void on its face. The most suspect type of legislative delegation is to private individuals or entities. “Delegations of administrative authority are suspect when they are made to private

² Even if the Executive Orders issued from the Governor establishing the Council contained additional guidance (which they do not), this would not save the CON Law from its unconstitutional state. Delegations of legislative authority require substantive guidance from the *legislature*; executive orders are delegations of *executive* authority, and cannot be a substitute for legislative guidance.

parties, particularly to entities whose objectivity may be questioned on grounds of conflict of interest.” 2 Am.Jur.2d Administrative Law § 76, p. 98. The affiliation of members of the Council with existing healthcare providers, and the Council’s exemption from the protections contained in the Ethics Act, make any need determinations made by the Council inherently subject to abuse.

Because attempted delegation of legislative authority to private citizens or entities is so much more suspect than attempted delegation to a subordinate government agency, the rule forbidding such delegation is absolute: delegation of private parties is forbidden, whether or not adequate guiding standards are provided. Wilcher v. Sharpe, 236 N.C. 308, 312, 72 S.E.2d 662, 665 (1952)(“Where the effectiveness of an ordinance determining the use of property for a lawful purpose is conditioned upon the assent or permission of private persons, . . . it must be held invalid, as it involves the delegation of legislative power to private individuals.”). Accord Bulova Watch Co., Inc., 285 N.C. at 475, 206 S.E.2d at 147.

Legislative authority cannot be delegated even to an administrative agency unless adequate guiding standards and procedural safeguards are imposed to govern the exercise of the delegated authority. See, e.g., N.C. Turnpike Authority v. Pine Island, Inc., 265 N.C. 109, 143 S.E.2d 319 (1965). Thus, even if the Council was regarded as an agency of state government, the attempted delegation

here is nevertheless clearly improper, because no guiding standards or procedural safeguards are in place to prevent arbitrary or self-serving decisions. Adams, 295 N.C. at 698, 249 S.E.2d at 410. In short, delegation of legislative authority without adequate guiding standards “is unconstitutional and void, because it fails to furnish a uniform rule of action and leaves the right of property subject to the despotic will of [those] who may exercise it so as to give exclusive profits or privileges to particular persons.” State v. Tenant, 110 N.C. 609, 612, 14 S.E.2d 387, 388 (1892). See also In re Application of Ellis, 277 N.C. 419, 425, 178 S.E.2d 77, 80 (1970).

The delegation in this case is clearly improper because no guiding standards or procedural safeguards preclude arbitrary or self-interested decisions by the Council. It is clear that the Council is expected to make decisions with far-reaching consequences for the citizens of this State, with absolutely no guiding standards established by the General Assembly.

This lack of adequate substantive guidance for the Council’s decisions is exacerbated by a corresponding lack of procedural safeguards to ensure that it acts reasonably and even-handedly. The exemption of the Council from the Ethics Act, and the exemption of the Plan from the requirements of the APA, means that *no* safeguards are in place to “encourage adherence to legislative standards” and prevent “arbitrary and unreasoned” decisions. See Adams, 295 N.C. at 696-98,

249 S.E.2d at 410-11. As our Supreme Court foresaw in another context, the predictable result of the unfettered discretion given to the Council to make need determinations are decisions “to give exclusive profits or privileges to particular persons.” See In re Application of Ellis, 277 N.C. at 425, 178 S.E.2d at 80. Unfortunately, anti-competitive schemes such as this have become distressingly common in the CON area, and reflect the “capture” of government power to serve the interest of industry insiders, as opposed to the public they purport to serve.³

In summary, the CON Law, as applied in this case, permits the Council, in its virtually unfettered discretion, to make need determinations which have the

3

The development of hospital regulation through certificate-of-need closely resembles a phenomenon familiar to observers of regulation: Industries frequently seek government regulation to prevent entry by potential competitors, to raise standards, and to place a floor under prices. Hospital planning agencies can be analogized to other regulatory agencies . . . that characteristically develop close relationships with the industries and occupations that they regulate. The metaphor of “capture” has often been used to describe the process by which governmental regulatory agencies come to share the interest and viewpoint of the regulated industries.

Sallyanne Payton & Rhoda M. Powsner, REGULATION THROUGH THE LOOKING GLASS: HOSPITALS, BLUE CROSS, AND CERTIFICATE-OF-NEED, 79 Mich. L. Rev. 203, 262-63 (1980); See also, Joshua A. Newberg, IN DEFENSE OF ASTON PARK: THE CASE FOR STATE SUBSTANTIVE DUE PROCESS REVIEW OF HEALTHCARE REGULATION, 68 N.C. L. Rev. 253 (1990); Stigler, THE THEORY OF ECONOMIC REGULATION, 2 Bell J. Econ. & Manag. Sci. 3, 3 (1971).

effect of law in preventing would-be providers from developing otherwise lawful healthcare facilities to serve the citizens of North Carolina. Neither adequate guiding standards nor procedural or other safeguards are provided to prevent the Council from making arbitrary or unreasoned decisions, or determinations which benefit the self-interest of its members. Therefore, the CON Law, as applied in this case, violates the constitutional prohibition on the delegation of legislative power.

C. *Frye Reg'l Med. Ctr., Inc. v. Hunt* is inapposite to this case.

Our Supreme Court has issued one opinion that directly touches on the Council and its development of the Plan. *Frye Reg'l Med. Ctr., Inc. v. Hunt*, 350 N.C. 39, 510 S.E.2d 159 (1999) decided the limited question of whether, under N.C. Gen. Stat. § 131E-176(25), the Governor must simply approve or reject the Plan as prepared by the Council, or whether she may make a substantive change to the proposed Plan prior to approval. As explained below, *Frye* does not control here, and it offers little useful guidance as to the constitutional issues raised in the instant appeal.

In *Frye*, the Governor approved the Plan after amending it to include a finding of need for additional open heart surgery services in the Catawba County area, where the Council had specifically rejected such a finding. Frye Regional Medical Center, which had already received a CON to provide open heart surgery

services in that area, and which had aggressively opposed the request to the Council by competing Catawba Memorial Hospital for a finding of additional need, brought suit challenging the Governor's authority under N.C. Gen. Stat. § 131E-176(25) to do anything other than approve or reject the Plan as developed by the Council. The trial court entered a preliminary injunction order, explaining:

The sole basis of my determination is my conclusion that the Governor has no authority, as a matter of law, to amend the [Plan]. I specifically do not reach the other factual and legal issues raised by the parties.

Frye, 350 N.C. at 41, 510 S.E.2d at 161. The trial court certified the question for immediate review by the Supreme Court. The Supreme Court noted that “the *narrow issue* before us is the correctness of the superior court's conclusion.” Id.

At the trial court below in the instant matter, Appellees argued that Frye is the “seminal case on the role of the Council regarding the [Plan] process.” Far from being the seminal case, the Frye Court was not confronted with, and consequently did not consider, the constitutional question of whether the power of the executive branch (including the Governor, the Department, and the Council) to create the Plan, as presently delineated in N.C. Gen. Stat. §§ 131E-176(25) and 131E-183(a)(1), is an unconstitutional delegation of legislative authority. Frye has little, if any, bearing on the issues in this appeal.

IV. THE TRIAL COURT ERRED WHEN IT DENIED APPELLANTS' MOTION FOR JUDGMENT ON THE PLEADINGS AND GRANTED APPELLEES' MOTION FOR JUDGMENT ON THE PLEADINGS BECAUSE,

AS IT OPERATES WITH RESPECT TO THE APPELLANTS, THE NORTH CAROLINA CON PROCESS DENIES DUE PROCESS OF LAW.

ASSIGNMENT OF ERROR NOS. 2 and 5 (R pp. 637-639)

The freedom to contract and to engage in lawful business activity without unreasonable interference by the government is guaranteed by both Art. I, § 1 and Art. I, § 19 of the North Carolina Constitution. As our Supreme Court has explained:

Article I, Section 1 of the North Carolina Constitution provides that “life, liberty, the enjoyment of the fruits of their own labor, and the pursuit of happiness” are among those rights of the people that are inalienable. Section 19 of the same Article provides that “[n]o person shall be . . . deprived of his . . . liberty, or property, but by the law of the land.” The “law of the land,” like “due process of law,” serves to limit the state’s police power to actions which have a real or substantial relation to the public health, morals, order, safety or general welfare.

These constitutional protections have been consistently interpreted to permit the state, through the exercise of its police power, to regulate economic enterprises provided the regulation is rationally related to a proper governmental purpose. This is the test used in determining the validity of state regulation of business under both Article I, Section 1, and Article I, Section 19. Inquiry is thus twofold: (1) is there a proper governmental purpose for the statute, and (2) are the means chosen to effect that purpose reasonable?

Poor Richard’s, Inc. v. Stone, 322 N.C. 61, 64, 366 S.E.2d 697, 698-99 (1988)

(citations omitted).

Under this two-pronged test, an unreasonably restrictive statute or regulation

is invalid, even if the governmental purpose is legitimate. “Although the object of particular legislation may well be within the scope of the police power, the legislation may yet deprive the individuals of due process of law if the means chosen to implement the legislative objective are unreasonable.” A-S-P Assoc. v. City of Raleigh, 298 N.C. 207, 217, 258 S.E.2d 444, 450 (1979).

The constitutional right to be free from unreasonable governmental interference, recognized as an aspect of due process of law, applies even in those areas of the economy, such as health care, that are subject to extensive governmental regulation. For example, in Hartford Accident & Indem. Co. v. Ingram, 290 N.C. 457, 226 S.E.2d 498 (1976), our Supreme Court determined that a statute requiring general liability insurance carriers to offer medical malpractice insurance deprived the carriers of due process.

Of course, the business of writing insurance against liability for personal injury and property damage is such that the State may lawfully regulate it in the public interest. This is axiomatic. It does not follow, however, that one engaging in such business in this State is subject to whatever regulation thereof the State may see fit to impose.

290 N.C. at 470, 266 S.E.2d at 507. Thus, even in the highly regulated field of insurance, the Supreme Court concluded that any “interference with individual liberty, or with the right of an owner of property to use it as he sees fit, must have a reasonable relation to the accomplishment of the legislative purpose and must not

be unreasonable in degree, in comparison with the probable public benefit.” Id. at 466, 266 S.E.2d at 504.

Although it is also heavily regulated, the business of health care, like the business of insurance in Hartford, remains a lawful enterprise that cannot be subjected to unreasonable or unnecessary burdens by the State. The leading decision in North Carolina applying due process principles to restrictions on the development of health care facilities is In re Aston Park Hospital, Inc., 282 N.C. 542, 193 S.E.2d 729 (1973), in which our Supreme Court struck down the predecessor to the current CON Law. In that instance, even though the Supreme Court found that there was a proper governmental purpose for the statute, it determined that the means chosen to effect that purpose were unreasonable.

Obviously, the police power extends to reasonable regulation of hospitals, both as to their construction and as to their operation. However, the fact that the business of a hospital is, *per se*, related to the public health does not mean that every regulation of its activities falls within the scope of the police power. . . . “If a statute is to be sustained as a legitimate exercise of the police power, . . . it must be reasonably necessary to promote the accomplishment of the public good, or to prevent the infliction of the public harm.”

282 N.C. at 551, 193 S.E.2d at 735 (citations omitted).

Significantly, the rationale advanced for the unconstitutional statute in Aston Park is essentially the same as the purported justification of the need determinations at issue in this case – to ensure the full utilization of existing

facilities. Our Supreme Court explained:

In support of the statute and of its action thereunder, the Medical Care Commission contends that there is a shortage of doctors, and of adequately trained hospital staff workers, especially nurses, that excess hospital construction will spread the available hospital employees more thinly and thus endanger adequate care of the patients, that the time of the doctors can be used more efficiently if the total bed capacity is concentrated, that excess bed capacity will result in a substantial amount of vacant rooms and beds, that there are certain overhead costs which increase with the number of beds whether occupied or vacant, that the overhead cost of vacant beds must be absorbed by the patients in the occupied beds and, consequently, the effect of excess hospital bed capacity will be less efficient service to patients at greater cost.

282 N.C. at 548, 193 S.E. 2d at 734. Likewise, in the present case, the only conceivable public purpose to be served by permitting the Council to enact a “determinative limitation on the provision of any health service, health service facility [or] operating rooms . . . that may be approved” would be to enhance the efficiency of existing medical facilities. However, the Supreme Court specifically determined that a restriction on the development of new hospital facilities is not a reasonable method to ensure the quality and efficiency of existing programs.

Compulsory curtailment of facilities of the care of the sick is not a reasonable choice of a remedy for a shortage of trained hospital personnel, nurses and doctors. In any event, we hold that Article I, s 19 of the Constitution of this State does not permit the Legislature to authorize a State board or commission to forbid persons, with the use of their own property and funds, to construct adequate

facilities and employ therein a licensed professional and quasi-professional staff for the treatment of sick people, who desire the service, merely because to do so endangers the ability of other, established hospitals to keep all their bed occupied.

282 N.C. at 549, 193 S.E.2d at 734.

In response to the Supreme Court's striking down of the former CON law in Aston Park, the General Assembly enacted the present CON Law in 1978. See 1977 N.C. Sess. Laws, Ch. 1182. While the instant appeal does not address the same specific issue raised in Aston Park, our Supreme Court has not repudiated or otherwise abandoned the analysis of procedural and substantive constitutional due process rights with respect to CON laws, generally, that is set forth in the Aston Park decision.

To that end, the Supreme Court's analysis in Aston Park applies with even greater force to the provisions of the CON Law at issue in this case. In Aston Park, the statute which was found to be unreasonably restrictive of the constitutional right to engage in an otherwise lawful business required a new facility to obtain a CON, but did not preclude an application for a CON from being approved. Therefore, a provider wishing to develop a new facility at least had a chance of convincing the State that the facility was needed.

By contrast, in the present case, a prospective provider is required to obtain a CON to develop "new institutional health services," but under the need

determinations of the Plan it may be impossible for that party to even apply for a CON. See, e.g., 2007 State Medical Facilities Plan, p. 145 (“It is determined that there is no need for additional units of mobile cardiac catheterization equipment anywhere in the State and no reviews will be scheduled.”). (App. p. 2) Thus, the Plan represents an even more egregious violation of the Appellants’ rights than the statute declared unconstitutional in Aston Park. As the Supreme Court explained in Aston Park, the greater the degree to which governmental action interferes with fundamental rights, the greater is the showing of necessity which must be made to find it constitutional.

Any exercise by the State of its police power is, of course, a deprivation of liberty. Whether it is a violation of the Law of the Land Clause or a valid exercise of the police power is a question of degree and of reasonableness in relation to the public good likely to result from it. To deny a person, association, or corporation the right to engage in a business, otherwise lawful, is a far greater restriction upon his or its liberty than to deny the right to charge in that business whatever prices the owner sees fit to charge for service. Consequently, such a deprivation of his liberty requires a substantially greater likelihood of benefit to the public in order to enable it to survive his attack based upon Article I, s 19 of the Constitution of North Carolina.

282 N.C. at 550, 193 S.E.2d at 735. Accord State v Harris, 216 N.C. 746, 759, 6 S.E.2d 854 (1940)(“But the power to regulate a business or occupation does not necessarily include the power to exclude persons from engaging in it . . . When this field has been reached, the police power is severely curtailed.”).

The CON Law provides fifteen separate statutory criteria for the Department's review of CON applications. See N.C. Gen. Stat. § 131E-183(a). Criterion 1, which provides a "determinative limitation" on the Department's ability to approve applications for new institutional health services, is the only one of these criteria that is written and applied in such absolute terms. If there is no "need determination" in the Plan for particular facilities, equipment, or services, then pursuant to Criterion 1, the CON application must be disapproved. However, the other fourteen criteria set forth in the CON Law make it clear that CON applications could be reviewed on a case-by-case basis without such an unequivocal and unchallengeable limitation on the health care projects that can be considered for approval by the Department.⁴ Further, the Department has promulgated detailed administrative rules that also address the need for particular

⁴ See, e.g., Criterion 3:

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

N.C. Gen. Stat. § 131E-183(a)(3). Even when there is a need determination in the Plan, the Department still reviews the proposed project for compliance with this independent criterion.

types of equipment, facilities and services. See 10A N.C.A.C. 14C.1100-.4000. In light of these numerous statutory and regulatory criteria with which a CON application must comply to be approved, it is unnecessary for the Department to utilize Criterion 1 as an inflexible gatekeeper to prevent a proposal from even being considered.

In summary, the State cannot both require a provider to obtain a CON before developing a new institutional health service and also impose a Plan that ensures that the provider's CON application will be rejected. Cf. Ashbacker Radio Corp. v. FCC, 326 U.S. 327 (1954)(holding that "where two bona fide applications are mutually exclusive the grant of one without a hearing to both deprives the loser of the opportunity which Congress chose to give him."). As this Court has recognized, even if a provider does not have an absolute right to construct a new facility, it at least has "a right to a fair review of its application." In re Denial of Request by Humana Hospital Corp., 78 N.C. App. 637, 643, 338 S.E.2d 139, 143 (1986). Because the CON Law, as applied in this case, deprives Appellants and other similarly situated persons of their right to due process it violates Article I, §§ 1 and 19 of our Constitution.

V. THE TRIAL COURT ERRED WHEN IT DENIED APPELLANTS' MOTION FOR JUDGMENT ON THE PLEADINGS AND GRANTED APPELLEES' MOTION FOR JUDGMENT ON THE PLEADINGS BECAUSE, AS APPLIED, THE CON LAW VIOLATES APPELLANTS' CONSTITUTIONAL RIGHT OF ACCESS TO THE COURTS.

ASSIGNMENT OF ERROR NOS. 3, 4 and 5 (R pp. 637-639)

Article I, § 18 of our Constitution states that the “courts shall be open,” and guarantees that citizens of this State, including corporate citizens such as the Appellants, “shall have remedy by due course of law” for injuries done to them and their property. The CON Law, the APA, and the provisions of 10A N.C.A.C. 14C.0402, as applied in this case, combine to deprive Appellants of access to the courts for redress of grievances in two fundamental ways: (1) Appellants are denied the right to a *de novo* judicial review of a contested case in which the Department does not adopt the decision of an administrative law judge (“ALJ”); and (2) Appellants are denied the right to challenge the substance of the Plan in the administrative hearing process.

In 2000, the General Assembly amended the APA to afford significant protections to petitioners in contested cases. Now, the APA contains procedural safeguards for aggrieved parties in contested cases which are designed to ensure that the aggrieved party’s complaint is reviewed by an independent ALJ and that the final decision by the agency that has aggrieved the party in the first instance is appropriately deferential to the independent decision of the ALJ. Pursuant to N.C. Gen. Stat. § 150B-36(b), after the ALJ issues his or her decision in a contested case, the agency must make a final decision in writing after a review of the official record created before the ALJ. The agency must adopt the findings of fact

contained in the ALJ's decision, unless those findings of fact are “clearly contrary to the preponderance of the admissible evidence.” Pursuant to § 150B-36(b1) and (b2), the agency must separately detail the reasons for not adopting a finding of fact made by the ALJ, the evidence in the record relied on by the agency in making that determination, and must fully detail any findings of fact the agency makes that were not previously made by the ALJ. Pursuant to § 150B-36(b3), the agency must adopt the decision of the ALJ, or must set forth its reasons for finding that such decision was “clearly contrary to the preponderance of the admissible evidence.” Pursuant to § 150B-36(d), the ALJ may grant judgment on the pleadings or summary judgment, disposing of all issues in a contested case.

Additionally, pursuant to § 150B-51(c), in contested cases where the agency does not adopt the ALJ's decision, the aggrieved party is entitled to a *de novo* review of the official record by the superior court, which shall make findings of fact and conclusions of law without deference to prior decisions in the matter.

In 2000, however, the General Assembly singled out CON decisions as the only type of administrative action to which the foregoing protections do not apply. Pursuant to § 150B-34(c), the procedural safeguard provisions of §§ 150B-36(b), (b1), (b2), (b3), and (d), and 150B-51 “do not apply” to “cases arising under Article 9 of Chapter 131E of the General Statutes.”

As a result, aggrieved parties are denied effective judicial review of CON

decisions. The Department is not bound to adopt the findings of fact made by the ALJ, and is not required to explain its decision to ignore such findings of fact to the degree required under the general provisions of the APA. Likewise, the Department is not bound to adopt the decisions of the ALJ, and is not required to explain its decision to reject the recommendation. Aggrieved parties are not able to receive a *de novo* superior court review of the Department's final decision that rejects the decision of the ALJ, but rather are only afforded a minimal review by this Court in which this Court reviews "fact-intensive issues, such as the sufficiency of the evidence and allegations that a decision is arbitrary and capricious" under the extremely deferential whole record test. Good Hope Health Sys., LLC v. N.C. Dept. of Health and Human Services, 189 N.C. App. 534, 543, 659 S.E.2d 456, 462 (2008). Only questions of law are reviewed *de novo* by the appellate courts. Id. By exempting CON determinations from the safeguards of the APA, however, the General Assembly effectively deprived aggrieved CON applicants of meaningful access to the courts in violation of the State Constitution.

Secondly, during the ALJ's review of a CON decision and the development of the record on appeal, the aggrieved party is prohibited from challenging the determinations of need set forth in the Plan or the method by which the Plan was adopted. Pursuant to the Department's rules, "[t]he correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested

case hearing.” 10A N.C.A.C. 14C.0402. Quite often, the “correctness, adequacy, or appropriateness of criteria, plans and standards” in the Plan *is* the determinative issue in a contested case. By eliminating any consideration of these issues by rule, the Department has deprived aggrieved parties of even the limited access to the courts afforded in CON cases under the APA.

CONCLUSION

Based on the foregoing facts and authorities, the Court of Appeals should reverse the decision of the trial court and remand the case for entry of judgment on the pleadings in favor of Appellants as a matter of law.

Respectfully submitted this 16th day of September, 2009.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 28(j) of the North Carolina Rules of Appellate Procedure, counsel for the Appellants hereby certifies that the foregoing Brief was prepared using the proportional type Times Roman, fourteen-point font, and contains no more than 8,750 words, exclusive of covers, indexes, tables of authorities, certificates of service, and appendixes.




Noah H. Huffstetler, III

CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that the foregoing document was served via United States mail, first class, postage prepaid upon the following counsel for Defendants-Appellees at the address set forth below.

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This the 16th day of September, 2009.



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NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL
MEDICAL FACILITIES PLANNING SECTION
DIVISION OF FACILITY SERVICES
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

Table 9X: Fixed Cardiac Catheterization Equipment Need Determination
(Scheduled for Certificate of Need Review during 2007)

It is determined that the counties listed in the table below need additional fixed Cardiac Catheterization Equipment as specified:

County	Fixed Cardiac Catheterization Equipment Need Determination *	Certificate of Need Application Due Date **	Certificate of Need Beginning Review Date
Wake	1	November 15, 2007	December 1, 2007
It is determined that there is no need for any additional fixed cardiac catheterization equipment anywhere else in the State and no other reviews will be scheduled.			

Table 9Y: Shared Fixed Cardiac Catheterization Equipment Need Determination
(Scheduled for Certificate of Need Review during 2007)

Hospital Service System	Shared Fixed Cardiac Catheterization Equipment Need Determination *	Certificate of Need Application Due Date **	Certificate of Need Beginning Review Date
It is determined that there is no need for additional units of shared fixed cardiac catheterization equipment anywhere in the State and no reviews will be scheduled.			

Table 9Z: Mobile Cardiac Catheterization Equipment Need Determination
(Scheduled for Certificate of Need Review during 2007)

Hospital Service System	Mobile Cardiac Catheterization Equipment Need Determination *	Certificate of Need Application Due Date **	Certificate of Need Beginning Review Date
It is determined that there is no need for additional units of mobile cardiac catheterization equipment anywhere in the State and no reviews will be scheduled.			
It is further determined that mobile cardiac catheterization equipment and services shall only be approved for development on hospital sites.			

*Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application Due Dates are absolute deadlines. The filing deadline is 5:30 p.m. on the Application Due Date. The filing deadline is absolute (See Chapter 3).