

NORTH CAROLINA

IN THE GENERAL COURT OF JUSTICE

SUPERIOR COURT DIVISION

WAKE COUNTY

08 CVS 007955

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

Plaintiffs, )

v. )

STATE OF NORTH CAROLINA; et al., )

Defendants, )

and )

ASHEVILLE RADIOLOGY ASSOCIATES, )  
P.A.; et al., )

Defendant-Intervenors. )

**MEMORANDUM OF DEFENDANT-  
INTERVENORS IN RESPONSE TO  
PLAINTIFFS' MOTION FOR  
JUDGMENT ON THE PLEADINGS**

Pursuant to N.C. Gen. Stat. § 1A-1, Rule 12(c), and the Court's January 5, 2009 Scheduling Order, Defendant-Intervenors<sup>1</sup> submit this memorandum in opposition to the motion for judgment on the pleadings filed by Hope-A Women's Cancer Center, P.A. ("Hope") and Raleigh Orthopaedic Clinic, P.A. ("ROC") (collectively "Plaintiffs").

**STATEMENT OF THE CASE AND STATEMENT OF FACTS**

Defendant-Intervenors incorporate by reference the Statement of the Case and Statement of Facts in their Memorandum in Support of Motions to Dismiss, served January 23, 2009.

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<sup>1</sup> Defendant-intervenors are: Asheville Radiology Associates, P.A., Blue Ridge Day Surgery Center Limited Partnership, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, Charlotte Surgery Center, Limited Partnership, Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System, The Eye Surgery Center of the Carolinas, L.P., Greensboro Specialty Surgery Center, Limited Partnership, High Point Regional Health System, Mission Hospital, Inc., The Moses H. Cone Memorial Hospital Operating Corporation d/b/a The Moses Cone Health System, North Carolina Baptist Hospital, The North Carolina Health Care Facilities Association, Inc., The North Carolina Hospital Association, Pitt County Memorial Hospital, Inc., Rex Hospital, Inc., Surgery Center of Southern Pines, LLC, Surgical Care Affiliates, LLC, Wake Forest University Health Sciences, and WakeMed.

## STANDARD OF REVIEW

A court may dispose of claims or defenses when their lack of merit is apparent from the pleadings. N.C. Gen. Stat. § 1A-1, Rule 12(c) (2008). The granting of judgment on the pleadings is proper when there are no genuine issues of material fact, but only issues of law. In determining whether there are genuine issues of fact, the court must accept as true the facts alleged by the non-moving party. Jackson v. Ass'd Scaffolders & Equip. Co., 152 N.C. App. 687, 689, 568 S.E.2d 666, 667 (2002); Gammon v. Clark, 25 N.C. App. 670, 671, 214 S.E.2d 250, 251 (1975) (party who moves for judgment on the pleadings admits the truth of the facts and reasonable inferences pled by the opposing party and the falsity of its own allegations to the extent they contradict the pleadings of the opposing party).

## INTRODUCTION

Plaintiffs amended their Complaint but still failed to state facts that will sustain their claims. The State Defendants for the most part have denied the salient allegations in the Amended Complaint, but even if they had admitted them all, the pleadings support judgment for Defendants, not for Plaintiffs.

Plaintiffs' Amended Complaint and their brief on the motion for judgment on the pleadings are full of insinuation and speculation but have few relevant facts. Even if Plaintiffs' attack on the integrity of the State Health Coordinating Council ("SHCC") members were true, it would be irrelevant because there is no allegation that the alleged potential for self-interest caused any harm to these Plaintiffs. In any event, as the Supreme Court has established, the SHCC is purely an advisory body and the final decision on the State Medical Facilities Plan ("SMFP") need determinations is made by the Governor. See Frye Reg'l Med. Ctr. v. Hunt, 350 N.C. 39, 510 S.E.2d 159 (1999). Plaintiff Hope never asked the Governor to amend the

proposed 2008 SMFP to meet its needs, and neither Plaintiff has alleged that the Governor's final decision on the 2008 SMFP was in any way erroneous, let alone corrupt. Plaintiffs do not allude to or attempt to distinguish the case precedent holding that attacks on need determinations in the SMFP are barred by sovereign immunity. See Bio-Medical Applications of North Carolina, Inc. v. N.C. Dep't of Health & Human Servs., 179 N.C. App. 483, 491, 634 S.E.2d 572, 577 (2006).

There is much else that Plaintiffs' brief ignores. There are no facts alleged, and certainly none admitted by Defendants, that would show that the SHCC, Governor, or the North Carolina Department of Health and Human Services ("the Department") actually acted out of self-interest or erred in any way in making the 2008 need determinations about which Plaintiffs complain. Instead, the brief hangs on generalities that are not accurate legally or supported factually even by Plaintiffs' own pleadings and exhibits. Contrary to Plaintiffs' assertions:

- the SHCC is not made up of private health facilities;
- the need determinations are not developed by the SHCC acting alone in a black hole of self-interest, but are based on an initial draft prepared by the Department after a public hearing, incorporating the Department's calculations using publicly reported data and following statistical-based formulae for each service; and
- those need determinations can be adjusted only based on written petitions which are publicly reviewed and commented upon in at least six more public hearings across the state.

As to the legislative delegation and due process claims, the Certificate of Need Act ("CON Act") provides unusually detailed guidance for development of the SMFP need determinations. There are also elaborate procedures for statewide public notice and hearing far in excess of anything provided by the APA for rulemaking. Hope and ROC make no mention of,

let alone any candid attempt to distinguish, the leading North Carolina cases discussed herein, which all run directly counter to the position that they ask the Court to adopt in this case. There is not a word apprising the Court that, since the re-writing and re-enactment of the CON Act to correct the flaws identified in In re Certificate of Need for Aston Park Hospital, 282 N.C. 542, 193 S.E.2d 729 (1973), the case has never been followed to declare a CON statute unconstitutional in this jurisdiction or any other. To the contrary, the CON Act's imposition of the SMFP's need determination limits has been consistently strengthened by the General Assembly, and consistently applied by the courts of this State ever since the Statute's re-enactment. In every jurisdiction in which challenges to the CON laws have been made since Aston Park, the courts have upheld the constitutionality of the CON laws and the need determination limits. Rather than deal with the current state of the law, Plaintiffs rely on cases and doctrines that have long been abrogated by statute or discarded.

While amending the Complaint, Plaintiffs nowhere mentioned the significant change in the facts. ROC-related entities applied for and received initial Departmental approval of their CON application for the Wake County operating rooms identified as needed in the same 2008 SMFP ROC challenges here. See Defendant-Intervenors' Notices of Filing, 01/23/09 and 02/10/09. In addition, Hope currently has an appeal pending in the Court of Appeals in which it requests that it be allowed to develop the same regulated services and equipment without a CON.

### ARGUMENT

#### **I. THE PLEADINGS FAIL TO SHOW ANY ACTION OR DECISION HARMING PLAINTIFFS ARISING FROM ANY ALLEGED LACK OF GUIDING STANDARDS FOR THE NEED DETERMINATIONS OR SELF-INTEREST OF ANY SHCC MEMBER.**

The Amended Complaint does not allege, and the pleadings do not show, that the need determinations contained in the 2008 SMFP were in any way factually erroneous, arbitrary or

tainted by self-interest. The Amended Complaint does not allege any instance where a SHCC member acted out of personal interest, bias, prejudice, or conflict of interest on any matter, or had any interest, direct or indirect, bearing on ROC's petition for changes in the SMFP need determinations. Hope and ROC have not alleged facts showing any decision by the SHCC that was "affected by self-interest of its members," and they certainly have not alleged that any such decision had any effect on either Plaintiff. A bare allegation that a petition for a change in the need determination was turned down, without alleging that the denial was based on bias, self-interest or other actionable impropriety, is not enough. The Amended Complaint's failure to tie the alleged lack of guiding standards in the CON Act, or the self-interest of any SHCC member, to any actual need determination, decision or action affecting Plaintiffs makes judgment for Plaintiffs impossible and makes judgment for the State Defendants unavoidable.

Plaintiffs' arguments contain two fundamental flaws. The first is that the initial draft SMFP is developed by the Department, after an initial public hearing, and its employees are indeed "neutral and independent civil servants" (see Plaintiffs' Memorandum in Support of Motion for Judgment on the Pleadings, p. 3). The Department's staff participates throughout the process of development of the SMFP, both assisting the SHCC and guiding the development of the need determinations. The Department has a statutory role, and it is the Department that applies the existing methodology to the data and calculates the need that is shown in the initial draft of the SMFP. Any departure from those need determinations is reflected on the public record for all to see and must be based on formal petitions for changes in the need determinations, upon which anyone who may be affected may comment. See N.C. Gen. Stat. §§ 131E-176(25), 131E-177.

The second and biggest flaw in Plaintiffs' argument is that the SHCC is not the final decision-maker for the SMFP, but only an advisory body to the Governor. The purely advisory role of the SHCC, in contrast to the final decision-making role of the Governor, has been elucidated by the North Carolina Supreme Court in a case which Plaintiffs do not even mention, Frye Regional Medical Center v. Hunt, 350 N.C. 39, 510 S.E.2d 159 (1999). The case settled once and for all the Governor's and the SHCC's respective roles:

The Department of Human Resources is a department of the Executive Branch of state government, with its Secretary reporting directly to the Governor as chief executive officer of the state. Although there is statutory recognition of the State Health Coordinating Council, it is essentially an advisory body created by executive order. Exec. Order No. 43 (1994). The Governor appoints its twenty seven members, designates its chair and vice chair, and sets out its duties and responsibilities. *Id.* at §§ 2, 3, 7. Under the statutes, the role of the Council and the Department is to 'prepare' or 'develop' the SMFP. N.C.G.S. §§ 131E-176(25), 131E-177(4). The Governor's role is to "approve" the SMFP. N.C.G.S. §-131E-176(25). Read in context, these statutes suggest that the Governor's role is to make the final decision concerning the SMFP's contents after it has been developed and prepared by the Department and the Council.

Frye, 350 N.C. at 44, 510 S.E.2d at 163 (emphasis added).

Advisory bodies that include members from outside of state government are expected to bring the perspectives of the various, competing sectors of the public or private organizations and institutions which they represent and the industries in which they are employed. This is the whole point of having such bodies—to bring together experts from all the various sectors to debate and arrive at the best plan to recommend to the Governor. This is also why such bodies are deliberately excluded from the State Government Ethics Act – so that the final decision-maker can have the benefit of all the members' diverse perspectives.

Furthermore, the need determinations are not adjudications of individual rights but are quasi-legislative determinations of the need in particular geographic areas for various types of

services using methodologies devised for all of the myriad items regulated under the CON Act. The only determinations that can limit entry into the market are “no-need” determinations. Even as to these, however, there is no constitutional right to develop regulated health services if the SMFP makes a determination that there is no need in the year in question.

The new exhibit attached to the Amended Complaint, and cited as the sole support for the statement that the SHCC has been captured by self-interested entities providing health care services, shows no such thing. (Plaintiffs’ Memorandum in Support of Motion for Judgment on the Pleadings. pp. 3, 8; Amend. Complaint, Ex. 4) The exhibit, consisting of a copy of a Department webpage listing 2009 SHCC members, identifies SHCC members as representatives of the N.C. Health Care Facilities Association (which represents nursing homes); the health insurance industry; the North Carolina Medical Society (which represents physicians such as Plaintiffs’ principals)<sup>2</sup>; UNC’s Sheps Center for Health Services Research; the Long-Term Care Facilities Association; the Veterans Administration; business & industry (typically companies offering employee health insurance benefits); Area Health Education Centers; the County Commissioners Association; the Association of Local Health Directors; the Home Care Association; the Hospital Association; the N. C. House of Representatives; and the N. C. Senate. (Amend. Complaint, Ex. 4)

None of the SHCC members listed in Plaintiffs’ new exhibit would be competing with either Plaintiff. On the contrary, it shows that there are no SHCC members from Buncombe County, which is Hope’s service area. The exhibit shows three of the 29 members are from

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<sup>2</sup> In fact, Hadley Calloway, M.D., one of the principals in ROC, is the immediate past president of the North Carolina Medical Society and has served on its Board since 2002. See <http://www.ncmedsoc.org/pages/public/aboutncms/leadership.html> (Ex. A to Defendant-Intervenors’ Notice of Filing dated February 13, 2009). Subsequent citations in this Memorandum to “Ex. \_\_\_” also refer to the exhibits to Defendant-Intervenors’ Notice of Filing dated February 13, 2009.

Wake County, which is ROC's service area, but of the three, one represents the Home Care Association, one the County Commissioners Association, and one is a physician at-large member. (Amend. Complaint, Ex. 4). In short, there is not one allegation of fact to show or even suggest that the 2008 need determinations at issue in this case came about because of SHCC members having any bias against Plaintiffs.

Still, in a footnote in the brief, Plaintiffs gratuitously attack one of the individual members of the SHCC, citing a Charlotte Observer website article (and reader comments) indicating that this member works for a hospital in Charlotte and evidently receives bonuses based on the hospital's revenues. This website article is not properly subject to judicial notice and should be stricken. The implications of impropriety that Plaintiffs draw from the article (because he receives bonuses based on performance, he might be inclined to use his position on the SHCC to destroy the competition) are not alleged in the Amended Complaint, which bars their consideration on this motion for judgment on the "pleadings." Given the representation of physicians such as Plaintiffs' owners on the SHCC, one could presumably imply the same thing about need determinations favoring Plaintiffs (with equal lack of support). Finally, there is no assertion that this individual, employed by a Mecklenburg County hospital, would have any competitive bias against Plaintiffs or that he did anything on the SHCC out of self-interest or remotely relevant to Plaintiffs' operations in Buncombe and Wake Counties.

Even if they had been adequately stated, the type of allegations Plaintiffs have made would not suffice to show a conflict of interest, even in an adjudicatory setting. In City of Albemarle v. Security Bank and Trust Co., 106 N.C. App. 75, 415 S.E.2d 96 (1992), a bank whose land was condemned by a city for a road construction project contended that three members of the city council had substantial conflicts of interest because they were employed as

managers by local financial institutions that were in direct competition with the bank and should have abstained from voting. The court disagreed. It held that the that the council members' "direct ties to competing financial institutions" did not constitute the required "direct and substantial interest" of a "pecuniary or personal nature" in the property being condemned and therefore were too remote to give rise to conflict of interest. 106 N.C. App. at 77-78, 415 S.E.2d at 98-99.

More fundamentally, before there can be redressable harm, there has to be actual or imminent wrong, and the wrong has to be against each Plaintiff, not a mere potential for self-interested recommendations being made against someone at some future time. There must be some facts alleged and admitted that would show bias against Plaintiffs and a resulting wrong decision, such as a vote by a specific SHCC member in a position to gain something at the expense of Plaintiffs in their actual businesses in their own market against a petition for a change in the relevant need determinations.

On the contrary, there is no allegation of fact that the SHCC or any member acted arbitrarily, without reason, or out of self-interest against either Plaintiff or that the actual need determinations in the 2008 SMFP for linear accelerators, PET scanners, and MRIs in Buncombe County and operating rooms in Wake County were arbitrary, erroneous or otherwise improper. There is no allegation that any SHCC member is employed by or owns any facility competing against Plaintiffs, which is the basis of Plaintiffs' competitive bias claim. There are not even any allegations regarding which SHCC members were involved in the 2008 SMFP from which the complaint arises. Oddly enough, in amending their Complaint, Plaintiffs deleted the references to members of the SHCC for the 2008 SMFP and substituted allegations and an exhibit relating

to the SHCC members involved in the 2009 SMFP, even though the Amended Complaint purports to address the need determinations in the 2008 SMFP.

Lacking facts and law, Plaintiffs employ cases that have no relevance to the SHCC, in which a purely private person or firm was in effect given a legislative or adjudicative power over another private entity, usually in the context of a rather out-dated approach to constitutional interference with contract. These cases largely involve private business action delegated to private parties rather than a public body, such as in Bulova Watch Co., Inc. v. Brand Distributors of North Wilkesboro, Inc., 285 N.C. 467, 206 S.E.2d 141 (1974), and Carter v. Carter Coal Co., 298 U.S. 238 (1936). (See Plaintiffs' Memorandum in Support of Motion for Judgment on the Pleadings, pp. 19-20). In Carter, the authority to set hours and wages fell entirely on private parties. Moreover, the Supreme Court's analysis of "economic substantive due process" used in this and other so-called "Lochner-era" cases was abandoned shortly thereafter during the Roosevelt era, beginning with West Coast Hotel Co. v. Parrish, 300 U.S. 379 (1937) (Ex. C).<sup>3</sup> See also RUI One Corp. v. City of Berkeley, 371 F.3d 1137, 1171 (9th Cir. 2004) (Ex. B).

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<sup>3</sup> Carter was distinguished by the Supreme Court three years later, just after West Coast Hotel, in a North Carolina case coming out of the Fourth Circuit, Currin v. Wallace, 306 U.S. 1 (1939), aff'g 95 F.2d 856 (4th Cir. 1938):

The argument that there is an unconstitutional delegation of legislative power is ... untenable. This is not a case where Congress has attempted to abdicate, or to transfer to others, the essential legislative functions ... [L]egislation must often be adapted to conditions involving details with which it is impracticable for the legislature to deal directly. We have said that-'The Constitution has never been regarded as denying to the Congress the necessary ... flexibility and practicality, ... to perform its function in laying down policies and establishing standards, while leaving to selected instrumentalities the making of subordinate rules within prescribed limits and the determination of facts to which the policy as declared by the legislature is to apply. Without capacity to give authorizations of that sort we should have the anomaly of a legislative power which in many circumstances calling for its exertion would be but a futility'....In such cases `a general provision may be made, and power given to those who are to act under such general provisions, to fill up the details'...

...This is not a case where a group of producers may make the law and force it upon a minority (see Carter v. Carter Coal Co., 298 U.S. 238, 310, 318) ...

Currin, 306 U.S. at 15-16 (Ex. D). For several decades up until 1937, the Court invalidated economic regulation, as exemplified in Lochner v. New York, 198 U.S. 45 (1905) (Ex. E). West Coast Hotel represented the end of that trend.

Likewise, Plaintiffs incorrectly cite Wilcher v. Sharpe, 236 N.C. 308, 72 S.E.2d 662 (1952), and Bulova for the proposition that the Legislature may never delegate its authority to private entities or citizens, even if adequate guiding standards are provided. (Plaintiffs' Memorandum in Support of Motion for Judgment on the Pleadings, p. 19) Wilcher involves a situation entirely distinguishable from the instant matter. In Wilcher, the defendant wanted to build a mill that the plaintiffs, adjacent property owners, argued should be enjoined because a) it might cause a nuisance and b) it was prohibited by a town ordinance that required the consent of neighboring property owners before a mill could be built in the town. Id. at 311-12, 72 S.E.2d at 665. The town ordinance contained no guidance whatsoever on the "consent" issue and left that determination totally in the hands of adjoining landowners. The North Carolina Supreme Court summarily determined that the ordinance could not be upheld as a zoning regulation or exercise of the town's police power and ultimately refused to enter an injunction on the grounds that the threat of a future nuisance, not one presently injuring the rights of the town's people, was not sufficient to support an injunction. Id. at 312, 72 S.E.2d at 665. While the Court's opinion did address delegation of legislative power, it contained only the following summary statement on that issue: "[w]here the effectiveness of an ordinance determining the use of property for a lawful purpose is conditioned upon the assent or permission of private persons, such as the owners of adjacent property, it must be held invalid, as it involves the delegation of legislative power to private individuals." Id. at 312, 72 S.E.2d at 665.

Likewise, Plaintiffs have distorted the holding and applicability of the Supreme Court's holding in Bulova to the current case. Under the North Carolina Fair Trade Act at issue in Bulova, the producer (Bulova) made a contract with a single retailer to charge the retail price set by Bulova. The retailer then gave notice of his "Fair Trade" contract to any other retailers in the

State who had not signed the contract and thereby unilaterally made it unlawful for other retailers to sell at any lower price even though they had made no contract with Bulova or the retailer. Id., 285 N.C. at 474-475, 206 S.E.2d at 147. The retailers who had not contracted with Bulova and who had purchased their watch inventory from other legitimate sources had no right to be heard by anyone and could only sell at the price fixed by these third parties. Id. That is what is meant by a delegation to a private party. The Supreme Court held that the non-signer provision of the Fair Trade Act was in violation of the North Carolina Constitution, Article II, § 1, because it delegated legislative power to a private corporation and deprived the non-signers of liberty. However, in so doing, the Court explained that “the Legislature may not vest in a private corporation the authority to determine ‘in its absolute or unguided discretion’ the price at which another, with whom it has no contractual relation, may sell to a willing buyer an article lawfully acquired and owned by him.” Id. at 475, 206 S.E.2d at 147 (citing Wilcher, 236 N.C. at 312, 72 S.E.2d at 662) (emphasis added).

Thus, contrary to the assertions of Plaintiffs, both Bulova and Wilcher stand for the proposition that the Legislature may not delegate its authority to private citizens or entities unless it also provides adequate guiding standards to prevent unchecked exercise of the authority. These cases do not stand for the Plaintiffs’ proposition that the Legislature may never imbue private citizens with the power to help implement legislatively-guided public policy.

In any event, the SHCC is not a private person; it is a public advisory board authorized and operated by law and constituted by executive order of the Governor. The non-delegation cases cited by Plaintiffs do not apply to a State advisory board merely because members also have employment in the same field in the private sector. If that were the case, there would be no State advisory boards and, for that matter, no non-advisory boards and commissions which do

have actual final administrative decision-making authority, such as the North Carolina Medical Board or various regulatory commissions whose members are expected to include those employed in the industry. See, e.g., Adams v. N.C. Dep't of Natural & Human Res., 295 N.C. 683, 700-01, 249 S.E.2d 402, 412 (1978) (discussed below in Section II-A). On the contrary, the use of advisory committees composed of various members of the industry is a widely approved method for increasing participation by those affected in this type of quasi-legislative process. See Bernard Schwartz, Administrative Law § 4.10, at 189 (3d ed. 1991) (Ex. H); Town of Spruce Pine v. Avery County, 346 N.C. 787, 791-93, 488 S.E.2d 144, 147-48 (noting with approval that procedural safeguards before rules were adopted included seven meetings with Watershed Protection Advisory Council, which included members of special interest groups as well as state and local government representatives). For all these reasons, Plaintiffs claim must fail.

**II. THE PLEADINGS FAIL TO STATE A CLAIM OF IMPROPER DELEGATION OF LEGISLATIVE AUTHORITY TO DETERMINE NEED BECAUSE THE CON ACT PROVIDES BOTH ADEQUATE GUIDING STANDARDS AND PROCEDURAL SAFEGUARDS.**

Plaintiffs contend there are inadequate statutory guidelines or procedural safeguards to ensure that the need determinations in the SMFP are not arbitrary, unreasoned or affected by the self-interest of SHCC members. At the outset, Plaintiffs concede that the Legislature may delegate adjudicative and rulemaking powers to administrative bodies provided such transfers are accompanied by adequate guiding safeguards to govern the exercise of the delegated powers. (Plaintiffs' Memorandum in Support of Motion for Judgment on the Pleadings, p. 15). They argue, however, that adequate guiding standards do not accompany the SMFP development process involving the SHCC.

Plaintiffs' improper delegation argument is based on Article I, Section 6 of the North Carolina Constitution, which provides that the legislative, executive and judicial branches of government "shall be forever separate and distinct from each other." The SHCC's role in assisting the Department's calculation of need for new health services, and then submitting the resulting, general need determinations to the Governor for his final approval, is entirely consistent with North Carolina law. "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 this is not a delegation of legislative power" in violation of state constitutional provisions on separation of powers. See Farlow v. N.C. State Bd. of Chiropractic Examiners, 76 N.C. App. 202, 211, 332 S.E.2d 696, 702 (1985), rev. denied, 314 N.C. 664, 336 S.E.2d 621 (1985); see also N.C. Const. art. 1, § 6.

**A. The Delegation of Authority in the CON Act Provides Detailed Guidance to Formulate Need Determinations.**

Our courts have explained the meaning of "adequate guiding standards" necessary to ensure the constitutional sufficiency of a delegation of power by the Legislature to a quasi-governmental body consisting in part of private persons:

In the search for adequate guiding standards the primary sources of legislative guidance are declarations by the General Assembly of the legislative goals and policies which an agency is to apply when exercising its delegated powers. . . . When there is an obvious need for expertise in the achievement of legislative goals the General Assembly is not required to lay down a detailed agenda covering every conceivable problem which might arise in the implementation of the legislation. It is enough if general policies and standards have been articulated which are sufficient to provide direction to an administrative body possessing the expertise to adapt the legislative goals to varying circumstances. . . .

Adams, 295 N.C. at 698, 249 S.E.2d at 411 (emphasis added).

In our view the declarations of legislative findings and goals, articulated in [the statute] . . . are 'as specific as the circumstances

permit.’ . . . [T]he process of developing and adopting detailed land use guidelines for the complex ecosystem of the coastal area is an undertaking that requires much expertise. Legislative recognition of this need is reflected in the composition of the CRC, which is to consist of fifteen members—twelve of whom are required to have expertise in different facets of coastal problems . . . The goals, policies and criteria outlined in [the statute] provide the members of the CRC with an adequate notion of the legislative parameters within which they are to operate in the exercise of their delegated powers.

Id. at 700-01, 249 S.E.2d at 412 (citations omitted). “In fact, it is precisely this need to deal with individual factual circumstances, as in the case of applications for permits . . . which makes the task impossible for the legislature to manage alone.” Matter of Broad & Gales Creek Community Ass’n, 300 N.C. 267, 274, 266 S.E.2d 645, 651 (1980).

The CON Act provides constitutionally-sufficient standards to guide the Department’s and the SHCC’s respective roles in proposing SMFP need allocations for the Governor’s eventual adoption, rejection or modification. N.C. Gen. Stat. §§ 131E-175, 131E-183, 131E-177. The principal underlying legislative guidelines in N.C. Gen. Stat. § 131E-175 and N.C. Gen. Stat. § 131E-177, as well as in the criteria for application review in N.C. Gen. Stat. § 131E-183, is simple. As indicated by the name “A Certificate of Need,” the idea is to limit development of the more costly health services designated by the General Assembly to those that are needed: “The fundamental purpose of the certificate of need law is to limit the construction of health care facilities in this state to those that the public needs and that can be operated efficiently and economically for their benefit.” Humana Hosp. Corp. v. N.C. Dep’t of Human Res., 81 N.C. App. 628, 632, 345 S.E.2d 235, 237 (1986).

The law’s guiding principles, embedded in the legislative findings of fact in N.C. Gen. Stat. § 131E-175, enunciate standards for health services facilities planning, including:

- “Control costs, utilization, and distribution of new health service facilities;”

- Assure citizens “economical and readily available health care;”
- Prevent “geographical maldistribution of these facilities and services” and improve “access to all population groups, especially those that have traditionally been medically underserved;”
- Take into account the “needs of rural North Carolinians;”
- Prevent “proliferation of unnecessary health service facilities,” “underuse of [existing] facilities,” excess capacity, “unnecessary use of expensive resources and overutilization of health care services;”
- Avoid the “economic burden on public,” patients, health insurance subscribers, health plan contributors, and taxpayers caused by “excess capacity of health service facilities;” and
- Evaluate new services as to “need, cost of service, accessibility to services, quality of care, feasibility, and other criteria” so that “only appropriate and needed health services are made available in the area to be served.”

N.C. Gen. Stat. § 131E-175 (emphasis added).

The statute’s guiding standards for measuring need include improving geographic access; providing access to rural and financially underserved populations; maintaining minimum utilization levels by existing providers; avoiding over-supply that leads to over-utilization and unnecessary expenditures; and avoiding investment in unneeded expensive facilities that would encourage overutilization. N.C. Gen. Stat. §§ 131E-177, 131E-175, 131E-183. Many of the same legislative goals and standards that apply in review of individual applications under N.C. Gen. Stat. § 131E-183(a) are also applied in making the need determinations in the SMFP. See, e.g., “Basic Principles Governing Development of This Plan” at [http://facility-services.state.nc.us/medical\\_plan/](http://facility-services.state.nc.us/medical_plan/) (last accessed Feb. 10, 2009) (Ex. F)

Based on the standards of “need, cost of services, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the [Department] pursuant to provisions of this Article,” the Department conducts statewide registration and inventories of regulated services and equipment, develops policies, standards, and criteria for

health services planning, including the SMFP, and develops need determinations for the regulated health services and equipment, “which shall include consideration of adequate geographic location of equipment and services.” N.C. Gen. Stat. §§ 131E-175(7), 131E-177(1), (4); see also N.C. Gen. Stat. § 131E-175(25) (Department acts with the SHCC to prepare the SMFP for the Governor’s approval).

The cases are clear that the Legislature is not required slavishly to repeat the guiding standards in every section of the Act and for every delegated action that must be taken in implementing the Act; the program as a whole is guided throughout by the same goals and standards for implementation enunciated in Sections 131E-175, 131E-177, 131E-183. See State ex rel. Utilities Comm’n v. Empire Power Co., 112 N.C. App. 265, 435 S.E.2d 553 (1993) (Commission may rely upon other more general statutory provisions to interpret and implement process not otherwise described in section providing for it). The Court in Frye also recognized the ability of the Department, SHCC, and Governor to identify and follow the legislative policies in establishing the need determinations. Frye, 350 N.C. at 43, 510 S.E.2d at 162 (While DHHS prepares the SMFP “to effectuate the legislative purpose,” the Governor makes the final decision to ensure “that the SMFP comports with the general health policies and goals of the state”).

Given the number and range of regulated health services, as defined at N.C. Gen. Stat. § 131E-176(16), the standards outlined are sufficient to guide any need determination and as a practical matter could not reasonably be more specific, given the variety of services covered and the annually changing circumstances. Determining need for some 25 or more regulated types of facilities, equipment, and services, often in as many as 100 service areas statewide, and doing so every year, is not a practical legislative function. Its delegation to the SHCC, Department, and Governor recognizes the complex, detailed, and specific fact-finding detail in such an

undertaking. Town of Spruce Pine v. Avery County, 123 N.C. App. 704, 712, 475 S.E.2d 233, 238 (1996), rev'd on other grounds, 346 N.C. 787, 488 S.E.2d 144 (1997) (quoting Adams, 295 N.C. at 697, 249 S.E.2d at 410) (Legislature may delegate “a limited portion of its legislative powers to administrative agencies so that these agencies may exercise their expertise in complex matters with which a legislative body cannot deal directly”). Because the SMFP is revised and issued on an annual basis, it does not lend itself to the more time-consuming process involved in adoption of permanent rules. Moreover, the procedure for formulation of the need determinations each year is more thorough and affords more due process than the rulemaking process. See N.C. Gen. Stat. § 131E-176(25). (See Section II-B, below.)

If a particular need determination were facially and fundamentally unconstitutional, by denying entry based on an inherent suspect classification such as race or religion, it would likely be subject to review. Otherwise, however, the Supreme Court’s decision in Frye limits a court’s ability to review the Governor’s discretionary decisions reflected in the SMFP need determinations.<sup>4</sup> The Governor’s need determinations, developed with assistance from the Department and the SHCC, merely state that in a given year, based on existing and target capacity and utilization for that service and the projected population in the area, a particular health planning area does not need more of a particular service or equipment. See Bio-Medical, 179 N.C. App. at 490, 634 S.E.2d at 577 (“[T]he plan is a snapshot in time intended to enable the Department to ‘[d]evelop policy, criteria, and standards for health service facilities planning[,]’ among other things. N.C. Gen. Stat. § 131E-177(4) (2003).”). Such a conclusion is

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<sup>4</sup> In Frye, plaintiff raised specific, verified allegations of undue influence in the Governor’s unilateral, unannounced change to the proposed SMFP to add a need determination applicable to one particular hospital represented by the Governor’s legislative counsel. The change was palpably contrary to the statistical data showing no need. Even so, the allegations were not sufficient to support judicial review on due process, equal protection or any other grounds. See discussion in Section II-A.

essentially quasi-legislative, not adjudicatory, and its merit is not ordinarily subject to critique and invalidation by the courts. See id.

Thus, even if the role given the Governor were ignored and we assumed the statute left the final determination to the Department or the Department and SHCC alone, a challenge to a statute based on an improper delegation claim turns on whether the Legislature provided adequate guiding standards to the administrative agency making the final decision. The North Carolina courts have found guidance adequate in statutes with standards that are broader and much less defined than those of the CON Act. Legislative findings, such as those detailed in the CON Act in N.C. Gen. Stat. § 131E-175, are sufficient. See Town of Spruce Pine, 123 N.C. App. at 712-13, 475 S.E.2d at 238 (primary source for guiding standards are General Assembly's declarations of the legislative goals and policies, quoting Adams, 295 N.C. at 698, 249 S.E.2d at 411).

**B. The Statutory Procedures Provide Ample Public Notice, Comment, and Hearing in the Development of the SMFP Need Determinations.**

The General Assembly has expressly approved the specific procedures long used by the SHCC and the Department in the development of the SMFP by incorporating them into the CON Act. 2003 Sess. Laws, §§ 1, 12, 13. The process far exceeds the ordinary APA procedures for rulemaking in terms of opportunity for notice and comment as well as petitioning for changes. The procedures include at least one public hearing even before the draft SMFP can be issued, and then after the proposed plan is issued, there must be at least six more public hearings across the State, which are announced and publicized in local newspapers. The draft of the upcoming SMFP is published widely for comment and sets out the methodology and the data used in calculating the statistical need. There are procedures for anyone to petition for need determinations to be made or changed and for methodologies to be modified. The public and

providers such as plaintiffs are entitled to submit, and the SHCC must consider, both oral and written comments. N.C. Gen. Stat. § 131E-176(2). The annual development of the SMFP is a transparent, accessible process that clearly provides constitutionally-sufficient due process for any quasi-legislative delegated power. Due process in the rulemaking context is, after all, simply notice and an opportunity to comment, but not necessarily to prevail.

The SMFP must meet these rigorous standards in lieu of the permanent rulemaking process. See N.C. Gen. Stat. § 150B-2(8a)k. As long as these procedures are followed, and there is no allegation in the Amended Complaint that they were not, the APA provides that no further rulemaking procedures under the APA are required for the SMFP. N.C. Gen. Stat. § 150B-2(8a)k (the term “rule” in the APA does not include the SMFP “if the Plan has been prepared with public notice and hearing as provided in N.C. Gen. Stat. § 131E-176(25), reviewed by the Commission for compliance with N.C. Gen. Stat. § 131E-176(25), and approved by the Governor”).

Other than review based on suspect criteria or other obvious constitutional failing, there is ordinarily no right of judicial review of the need determinations. (See Section II-A.) Having provided an adequate procedure for notice and comment in the development of the need determinations, and sufficient principles to guide the determinations of need for health services or equipment, the Legislature acted within its powers in not providing for further review of these quasi-legislative determinations. See Bio-Medical, 179 N.C. App. at 491, 634 S.E.2d at 578; Good Hope Health Sys., L.L.C. v. N.C. Dep’t of Health & Human Servs., 175 N.C. App. 296, 299, 623 S.E.2d 307, 309 (2006) rev’d on other grounds, 360 N.C. 635, 637 S.E.2d 665 (2008)

“The Governor has final authority to approve or amend the SMFP, which becomes the binding criteria for review of CON applications.”).<sup>5</sup>

Because the SHCC serves only as an “advisory body” (Frye, 350 N.C. at 44, 510 S.E.2d at 163), there is no basis to subject it to the State Government Ethics Act, which does not apply to “public bodies having only advisory authority.” N.C. Gen. Stat. § 138A-3(1c). Plaintiffs admit that the standards in that Act do not apply to the SHCC. (Amend. Complaint ¶ 31)

Finally, Plaintiffs complain that the General Assembly exempted the SMFP from APA rulemaking procedures. This is unobjectionable. The process that the SMFP must follow allows for public circulation, comment, and public hearing, and it meets and exceeds both in form and in substance the goals of the rulemaking procedures of the APA, which are simply that the public have an opportunity to provide input on proposed rules.

As a practical matter, if the SMFP, which is promulgated annually to reflect changes in utilization and need, were subject to the current rulemaking procedures under the APA, it would also be subject to substantive review by the Rule Review Commission and could not be adopted as a permanent rule in time to be used for reviews in the pertinent year.<sup>6</sup> Rulemaking takes more than 18 months under the present statutory framework of the APA. There is no reasonable way the SMFP could become effective as a meaningful permanent rule under that process and no constitutional or statutory authority requires that it be developed via that process. This is not contemplated in the CON Act and such a process would thwart the aim of having a timely need

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<sup>5</sup> The essential due process right to be heard turns upon what the United States Supreme Court has called the “recognized distinction in administrative law between proceedings for the purpose of promulgating policy-type rules or standards, on the one hand, and proceedings designed to adjudicate disputed facts in particular cases on the other.” Only in the latter case is a trial-type or evidentiary hearing required. If the action is quasi-legislative, a hearing is not constitutionally required. United States v. Florida E. Coast Ry., 410 U.S. 224, 245 (1973) (Ex. G); see also Schwartz, § 5.6 at pp. 232-33 (Ex. H).

<sup>6</sup> The APA recognizes the practical problem of timing because it allows the agency to use temporary rulemaking to amend rules on individual review criteria to coordinate with the SMFP. N.C. Gen. Stat. § 150B-21.1(a)(6).

determination for health facilities planning and application processing, and one that is insulated from pressures that can be brought to bear on behalf of individual applicants in particular cases.

In Johnston-Willis, Ltd. v. Kenley, 6 Va. App. 231, 369 S.E.2d 1 (1988), the court held that the Virginia State Health Coordinating Council was not required to have public comment or “to go through the lengthy public comment process required under the [APA]” in order to adopt the SMFP. Id. at 248, 369 S.E.2d at 10 (Ex. I). The court held: “We believe that the 1984 SMFP, which contains numerical projections and statistical methodologies, is such a technical document or regulation which the General Assembly intended to be exempted from the entire promulgation process.” Id. The court noted that changes in the State Health Plan to reflect current statistical data is not the kind of matter that requires formal amendment procedures. Id. at 248, 369 S.E.2d at 11 (citing Merry Heart Nursing & Convalescent Home, Inc. v. Dougherty, 131 N.J. Super. 412, 330 A.2d 370 (N.J. Super. 1974) (Ex. J)).

Because the SMFP is quasi-legislative (again, in that it is a general standard, not an adjudication), it is in the nature of a rulemaking. There are no constitutional procedural requirements regarding rulemaking. Bernard Schwartz, Administrative Law § 4.10 at p. 189 (3d ed. 1991) (Ex. H). “[E]xcept for specific statutory requirements, the procedure to be followed in rulemaking is largely a matter for the agency concerned.” Id. “Agencies engaged in rulemaking are, as a general proposition, no more subject to constitutional procedural requirements than is the legislature engaged in enacting a statute.” Id. § 4.10 at pp. 189, 190 (rule requiring disqualification for bias or for conflict of interest which prevails in adjudicatory proceedings has no application to rulemaking proceedings). Courts are prohibited from imposing procedural requirements on rulemaking beyond those specified by statute. See Schwartz, § 4.14 at p. 204 (Ex. H).

Hope and ROC also point to the APA amendments which increased the decision-making jurisdiction of the OAH in making decisions in contested cases, at the expense of the agency making the final decision. That issue has nothing to do with this case. CON decisions were carved out of those amendments, leaving the original scope of decision-making power of the Department intact. N.C. Gen. Stat. §§ 150B-34, 150B-36. The carve-out for CON appeals was a matter of legislative prerogative. Because the procedure under the APA for CON cases is essentially as it was before, it is as unobjectionable and unexceptional now as it was then.

The reliance in Plaintiffs' brief on an article written by state legislator, Brad Miller, purporting to enunciate the legislative intent behind the amendments to the APA, is improper.

[I]ntent must be found from the language of the act, its legislative history and the circumstances surrounding its adoption which throw light upon the evil sought to be remedied. **Testimony, even by members of the Legislature which adopted the statute, as to its purpose and the construction intended to be given by the Legislature to its terms, is not competent evidence upon which the court can make its determination as to the meaning of the statutory provision.** D & W, Inc. v. Charlotte, 268 N.C. 577, 151 S.E.2d 241; Goins v. Trustees Indian Training School, 169 N.C. 736, 86 S.E. 629. Consequently, the affidavits introduced by the plaintiff, purporting to show ... the purpose of the Legislature ... were not competent for that purpose and must be disregarded.

State ex rel. North Carolina Milk Comm'n v. Nat'l Food Stores, Inc., 270 N.C. 323, 333, 154 S.E.2d 548, 555-56 (1967) (emphasis added); see also State v. Evans, 145 N.C. App. 324, 329-30, 550 S.E.2d 853, 857-58 (2001) (testimony by legislators, commentaries printed with the General Statutes, press releases, or commission recommendations are not competent evidence for a court to base its interpretation of statute). In short, what a legislator in North Carolina says about the legislative intent is incompetent, whether by sworn affidavit in a court of law or in a law review article, and should be disregarded.

### III. THE REQUIREMENT OF THE SMFP NEED DETERMINATION AS A CONCLUSIVE LIMIT ON THE HEALTH SERVICES WHICH THE AGENCY MAY APPROVE DOES NOT VIOLATE ANY CONSTITUTIONAL RIGHT OF PLAINTIFFS.

Plaintiffs have not stated a claim for a violation of any constitutional right in the Amended Complaint. As part of Plaintiffs' "unconstitutional as applied" claim, Plaintiffs make no effort to clarify that the SMFP determinations at issue in this case impose no restriction on Plaintiffs' existing use and enjoyment of their vested property interests in their existing businesses. Their complaints in this case concern the acquisition of new equipment and construction of new facilities to expand and offer new types of medical services. See Defendant-Intervenors' Memorandum in Support of Motions to Dismiss, pp. 6-9. Without question, Plaintiffs can continue to operate their existing services. Plaintiffs can also expand and replace existing equipment with updated equipment, as long as the cost of these projects is less than \$2,000,000. Plaintiffs can acquire any new medical equipment that costs less than \$750,000 and does not specifically require a CON. Plaintiffs are only precluded from expanding into new areas that are regulated until there is a need in the annual SMFP.

The only authorities Plaintiffs offer to support their contentions are (1) the 1977 decision in Aston Park, discussed below; and (2) the outdated line of economic substantive due process cases discussed above in Section I.<sup>7</sup> Plaintiffs' reliance on Aston Park is mistaken and misleading. The constitutionality of need determination thresholds under similar certificate of need laws has been upheld in every state and federal case, of which we are aware, with the

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<sup>7</sup> Plaintiffs also cite (1) two law review articles from 1980 and 1990 and a memorandum from members of Bush Administration's Federal Trade Commission and Department of Justice, all of which oppose state CON laws; and (2) a law review article by a North Carolina legislator discussing his recollection of recent revisions to the APA, which is, as a matter of law, inadmissible and incompetent to show legislative intention, much less legislative misfeasance as Plaintiffs attempt to do. At any rate, these articles and memoranda carry no legal precedent.

exception of the Aston Park case. Aston Park was decided in North Carolina in the early 1970s and has never been followed in a CON case since.

After the decision in Aston Park, North Carolina went to federal court to challenge the later-enacted federal requirement that states wishing to participate in Medicare and Medicaid must have a CON law. The federal court upheld the validity of the CON requirement, and the United States Supreme Court affirmed. See State of North Carolina ex rel. Morrow v. Califano, 445 F. Supp. 532 (E.D.N.C. 1977) (3 judge panel), aff'd, 435 U.S. 962 (1978). The requirement of a CON program was rationally justified by the convincing evidence before Congress that overbuilding of facilities increased the cost of medical services and that the CON program was a reasonable requirement to address this problem. Id. at 535; see also Goodin v. Oklahoma ex rel. Oklahoma Welfare Comm'n, 436 F. Supp. 583, 586 (W. D. Okla. 1977) (Ex. K); Montgomery County, Maryland v. Califano, 449 F. Supp. 1230, 1247 (D. Md. 1978), aff'd, 499 F.2d 1048 (4th Cir. 1979) (law served a legitimate end of achieving more efficient and equitable organization, supply, and distribution of health resources through coordinated planning and was well within Congress' power under the welfare clause) (Ex. L).

North Carolina then adopted a new CON Act in 1977 which more closely tracked the CON legislation adopted in the other states, followed the rationale enunciated by Congress, and answered the constitutional problems about the public need for the program raised in Aston Park.

As observed by Justice Whichard:

Since Aston Park, the General Assembly has re-enacted the CON law and made the explicit findings discussed above which describe the relation between the purposes behind the CON law and the effect it has on individual property rights. Thus, the constitutional infirmity identified in Aston Park is not at issue here.

HCA Crossroads Residential Ctrs. v. N.C. Dep't of Human Res., 327 N.C. 573, 583, 398 S.E.2d 466, 473 (1990) (Whichard, J., dissenting on other grounds against making time

limits on Agency under CON Act mandatory). See also State ex rel. Utilities Comm'n v. Empire Power Co., 112 N.C. App. 265, 275, 435 S.E.2d 553, 558 (1993) (General Assembly “rendered moot” the holding in Aston Park by repealing the statute on which it was based and later enacting a more detailed CON Act); cf. Williamson v. Snow, 239 N.C. 493, 80 S.E.2d 262 (1954) (upholding constitutionality of delegation to Medical Care Commission of power to decide whether a hospital was needed; contrary to Aston Park court’s attempt to distinguish it, the holding on this issue did not depend on or mention expenditure of public money). The 1977 CON Act, as amended, is still in place today.

No court has followed Aston Park’s finding of unconstitutionality of the CON Act and, as indicated by Morrow, the case has been discredited or distinguished as a basis for overturning CON laws. See, e.g., Goodin, 436 F. Supp. at 585, nn. 1-2 (expressly declining to follow Aston Park and agreeing with other cases upholding constitutionality of state CON law as valid exercise of state police power bearing “reasonable relation to the health, safety and welfare of [the] community...” (Ex. K); Merry Heart Nursing & Convalescent Home, 131 N.J. Super. 412, 330 A.2d 370 (upholding state CON law and finding holding in Aston Park “not persuasive and at variance with the law of this State. The power of the State to legislate in the field of public health is no longer open to question. Williamson v. Lee Optical, 348 U.S. 483 (1955).” (Ex. J).

Use of need determination limits has been consistently found to have a constitutionally-rational basis and generally is not even subject to judicial review on the merits. See, e.g., Rapides Gen. Hosp. v. Robinson, 488 So.2d 711, 715 (La. Ct. App. 1986), cert. denied, 489 So.2d 1276 (La. 1986) (Governor’s moratorium on approval of CON applications is under his constitutional grant of power to execute laws and not subject to judicial interference) (Ex. M); Mount Royal Towers, Inc. v. Alabama State Bd. of Health, 388 So. 2d 1209, 1215 (Ala.

1980) (denying claim that CON law violated due process clause of the state constitution because, although the statute's restriction of entry into a field of economic endeavor may infringe on individual contract and property rights, there was no indication that elimination of surplus facilities through the CON law was not logically calculated to reduce medical costs caused by duplication of services) (Ex. N); Attoma v. State Dep't of Social Welfare, 270 N.Y.S.2d 167, 171-72, 26 A.D.2d 12, 18 (N.Y. App. 1966) (the legislatively-identified proliferation of health facilities beyond the needs of the geographical area, with resulting spiraling costs, bore a reasonable relation to the welfare of the community; thus, the regulation is valid exercise of the police power) (Ex. O).

The wisdom vel non of the CON program is a legislative matter. We are not moved by its federal sacking, ... nor by the powerful policy arguments that may be leveled against it, made in the name of deregulation of enterprise. The program is a constitutionally permissible stratagem for addressing the health care needs of the people. ... It was on our statute books at all times relevant and remains so. We have faithfully enforced it in the past. ... We will continue to do so until the Legislature directs otherwise. [Citations omitted.]

Mississippi State Dept. of Health v. Southwest Mississippi Reg'l Med. Ctr., 580 So.2d 1238, 1240 (Miss.1991) (upholding CON agency's denial of application for failure to show it met 300,000 population base threshold requirement, which is similar to the type of threshold set by the SMFP) (Ex. P).

The statutory threshold qualification of compliance with the SMFP also has been upheld consistently and repeatedly in North Carolina. "An application for a certificate of need for a proposed project must comply with 'applicable policies and need determinations in the State Medical Facilities Plan.' N.C. Gen. Stat. 131E-183(a)(1)." Presbyterian-Orthopaedic Hosp. v. N.C. Dep't of Human Res., 122 N.C. App. 529, 534, 470 S.E.2d 831, 834 (1996). In In re Total

Care, Inc., 99 N.C. App. 517, 393 S.E.2d 338 (1990), the Court of Appeals acknowledged the importance of the SMFP:

The SMFP is prepared by the Health Resources Development Section of the Division of Facility Services of the Department of Human Resources. The plan is developed under the direction of the North Carolina Health Coordinating Council and approved by the Governor pursuant to G.S.131E-176(24) and (25). Under G.S. 131E-177 the legislature has delegated all health services planning and development of need projections to the Department. **The SMFP is the official statement of projected need for health services.** The SMFP methodology for projecting need for home health agencies is basically the same today as when it was first employed in 1983. SMFP at 70.

Id. at 521, 393 S.E.2d at 341 (emphasis added).

More recently, in Bio-Medical, the Court of Appeals upheld dismissal of a declaratory judgment action against the Department and its officials attacking a need determination for dialysis stations, on grounds that the defendants were immune from such suit by the doctrine of sovereign immunity. 179 N.C. App. at 490-91, 634 S.E.2d at 577-78.

Courts in other states similarly uphold strict application of the need determinations in the state health plan. See, e.g., Princeton Cmty. Hosp. v. State Health Planning & Dev. Agency, 174 W. Va. 558, 564, 328 S.E.2d 164, 170 (1985) (neither the CON agency nor the court is empowered to issue a CON “without clear findings and conclusions of compliance” with the state health plan) (Ex. Q). In Statewide Health Coordinating Council v. General Hospital of Humana, Inc., 280 Ark. 443, 449, 660 S.W.2d 906, 910 (1983), the court reversed the CON agency’s grant of the CON, where the proposal exceeded the standard contained in the State Health Plan. The Arkansas court held that the agency was not free to disregard the plan. Its reasoning mirrors the legislative findings of fact in the North Carolina CON Act and recounts the legislative conclusion that:

[C]ompetition among hospitals, unlike competition in the market place, does not reduce cost of in-patient hospital services to the consuming public. . . .[S]uch competition actually increases hospital charges. . . . Hospitals compete not for patients but for doctors, who usually select the patient's hospital. Hospitals vie with one another in acquiring expensive equipment, with unnecessary and costly duplication of facilities. . . .

Id. at 446, 660 S.W.2d at 908-09 (Ex. R). See also Nursing Home of Dothan, Inc. v. Alabama State Health Planning & Dev. Agency, 542 So.2d 935, 939 (Ala. Civ. App. 1988), aff'd, Ex parte Nursing Home of Dothan, Inc., 542 So.2d 940 (Ala. 1989) (CON application was properly denied solely for failure to comply with the state health plan) (Ex. S); Gulf Court Nursing Ctr. v. Dep't of Health & Rehab. Servs., 483 So.2d 700, 706-07 (Fla. App. 1985) (Ex. T); St. Mary's Hosp. v. State Health Planning & Dev. Agency, 178 W. Va. 792, 797, 364 S.E.2d 805, 810, nn. 4-5 (1987) (Ex. U).

The statutory criterion making the SMFP need determinations a conclusive threshold is entirely consistent with the expressed intent of the law and has an entirely rational basis. It prevents ad hoc determinations that would undermine the statewide, systematic, unified approach to health services planning that the General Assembly found better promotes the public health and economic interests outlined in the findings. Not only do the statute's words express the rationale for making the SMFP need determinations binding, but their use is rationally related to the harms to the public interest that the law is expressly intended to address: "The reason behind such a requirement is to prevent the proliferation of unnecessary health care facilities and equipment, which would result in costly duplication and underuse of facilities." Good Hope Health Sys., 175 N.C. App. at 300, 623 S.E.2d at 310 (citing N.C. Gen. Stat. §§ 131E-175, 131E-183(a)(1)).

The restrictions on development in the CON Act are not "unreasonable in degree in comparison to the probable public benefit" as alleged by Plaintiffs. Amend. Complaint ¶ 54.

The statutory findings are in line with reported studies. See Defendant-Intervenors' Memorandum in Support of Motions to Dismiss, pp. 27-28. In fact, one of the articles cited by Plaintiffs points to the recognized public benefits of CON laws, noting that the rationale for the law "is as great as ever," and that, in the face of the "dramatic increases" in spending and expansion of unneeded facilities occurring upon repeal of the CON law in some states after repeal of the federal requirement during deregulation in the Reagan Administration, other states decided against repeal of their CON laws. J. Simpson, Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control, 19 Ind. L. Rev. 1025, 1081-82 (1986) ("It should be apparent that certificate of need regulation continues to satisfy a wide range of state policy roles. Id. at 1087.") (Ex. V). Regulation of MRIs, such as Hope wishes to acquire, demonstrates the benefits of the law because MRIs are often subject to conspicuous overutilization and unnecessary expense to Medicare and other payors.<sup>8</sup>

Significantly, the Amended Complaint's only counterweight to these public benefits is the allegation that this regulation restricts Plaintiffs' "fundamental right to carry out their otherwise lawful business activities." Amend. Complaint ¶54. Modern courts do not regard such economic regulation as implicating a fundamental right in the constitutional sense. Affordable Care, Inc. v. N.C. State Bd. of Dental Examiners, 153 N.C. App. 527, 537, 571 S.E.2d 52, 60 (2002); see also Bio-Medical, 179 N.C. App. at 490, 634 S.E.2d at 577-78. Neither substantive nor procedural due process rights are infringed by entry restriction regulations which serve a rational legislative purpose, especially in the fields of public health and public economic welfare. In Bio-Medical, the court dismissed the dialysis provider's claim that a need determination violated its constitutional rights, noting that "the right allegedly violated is

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<sup>8</sup> Medicare Payment Advisory Comm'n, Report to Congress: Medicare Payment Policy, Ch. 2B p.79, Ch. 3 pp. 143, 154-70 (Mar. 1, 2005) (given unjustified 15-20% annual growth in MRIs, CMS must tighten reimbursement rules) ([www.medpac.gov/publications/Congressional\\_reports/Mar05\\_EntireReport.pdf](http://www.medpac.gov/publications/Congressional_reports/Mar05_EntireReport.pdf)) (Ex. W).

not constitutionally protected.” Id. (citing Coleman v. Whisnant, 225 N.C. 494, 506, 35 S.E.2d 647, 655-56 (1945)). As observed in one of the cases relied upon by Plaintiffs in the case at bar: “[I]t is the function of the Legislature, not of the courts, to determine the economic policy of the state and this court may not properly declare a statute invalid merely because the court deems it economically unwise.” Bulova, 285 N.C. at 477, 206 S.E.2d at 149.

Similar to the need determinations addressed in the Total Care decision quoted above, the need methodologies for the equipment and operating rooms at issue here have been in place for years. While the General Assembly has made other amendments to the CON Act over the years, it enacted no amendments indicating any dissatisfaction with the SHCC, the SMFP, the need determinations, or the methodologies used, and the only amendments in that regard statutorily confirmed the procedures used for the SMFP and strengthened the SMFP need determinations as a conclusive limit, leaving the Department with no discretion to avoid them. See, e.g., 2001 N.C. Sess. Laws 242, § 3.

As Defendant-Intervenors discussed in their previous memorandum of law, North Carolina’s CON Act has a rational basis which the Legislature has spelled out in plain words and strengthened over a long history.<sup>9</sup> The current CON Act details many reasons for using statewide planning to develop need determinations. The General Assembly has made plain the reasons for the imposition of the need determinations and that the CON Act’s purpose is to address the problems which the free market could not fix. It has provided guiding standards for determining need, reinforced the mandatory nature of the need determinations by amendments, provided for ample public notice, comment, and hearing, and has done everything in its power to

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<sup>9</sup> N.C. Gen. Stat. § 131E-183(a)(1); see 1991 Sess. Laws, Ch. 701, '2 (ratified July 16, 1991, effective October 1, 1991); see also 1993 Sess. Laws, '6 (ratified and effective March 18, 1993). The Bill making the 1991 amendment was entitled: "An Act to ... **Make Clear that the State Medical Facilities Plan Limits the Number of ... Facilities that May be Approved.**" (1991 Sess. Laws, Ch. 701, '1, at p. 1092.).

meet any conceivable constitutional objection. Plaintiffs' frustration and impatience with the CON regulatory framework does not make it unconstitutional. No facts are alleged in the Amended Complaint that would support a claim that the 2008 need determinations violated any constitutional provision.

**IV. THERE IS NO REQUIREMENT OF CASE-BY-CASE ADJUDICATION TO CHALLENGE THE GOVERNOR'S NEED DETERMINATIONS AND THE AGENCY'S RULE PROPERLY IMPLEMENTS THE STATUTORY CONCLUSIVENESS OF THE SMFP.**

Defendant-Intervenors' memorandum in support of their motion to dismiss addressed plaintiffs' due process attack on the Agency rule, 10A N.C. Admin. Code § 14C.0402, which forecloses an applicant from attacking, and the Agency or an ALJ from overruling, the need determinations in the course of the Agency review of an individual CON application. See Defendant-Intervenors' Memorandum in Support of Motions to Dismiss, pp. 34-35. As discussed there, the Agency's rule does not deprive Plaintiffs of access to the courts or prevent the courts of law from being open. It simply implements the statutory mandate which forbids the Department, in its adjudication on individual CON applications, to depart from the need determinations in the SMFP. N.C. Gen. Stat. § 131E-183(a)(1).

As held in Bio-Medical, there is no constitutional requirement that the substantive merits of the need determinations be subject to judicial review. Need determinations are quasi-legislative, general provisions that are not typically subject to review in the absence of a statutory provision for review or a constitutionally-suspect classification. They are not rules of the agency that under the APA may be voided in a contested case, but they are adopted by reference in the statute, which the Agency has no authority to invalidate. The courts in North Carolina have repeatedly and approvingly applied this rule recognizing that "the use of the required SMFP methodology" and the correctness of the SMFP "shall not be an issue in a

contested case hearing.” Britthaven, Inc. v. N.C. Dep’t of Human Res., 118 N.C. App. 379, 387-88, 455 S.E.2d 455, 462, disc. rev. denied, 341 N.C. 418, 461 S.E.2d 754 (1995) (quoting 10 N.C.A.C. 3R .0420 (1989))<sup>10</sup>; Charter Pines Hospital, Inc. v. N.C. Dep’t of Human Res., 83 N.C. App. 161, 175, 349 S.E.2d 639, 648 (1986), disc. rev. denied, 319 N.C. 105, 353 S.E.2d 106 (1987) (only application and not use of SMFP methodology could be challenged in a contested case hearing).

The legislative amendments to strengthen the conclusiveness of the need determinations, mentioned earlier, make it clear that the Legislature did everything in its power to ensure that the Department and the courts do not engage in ad hoc, case-by-case adjudications over developing facilities in excess of the limit set by the need determinations established through the statewide annual planning. Plaintiffs’ arguments are without merit.

### CONCLUSION

For the foregoing reasons, Defendant-Intervenors respectfully request that judgment on the pleadings be entered against Plaintiffs and in favor of Defendants and Defendant-Intervenors, or in the alternative that the Court enter an order dismissing the Amended Complaint based on the pending motions to dismiss.

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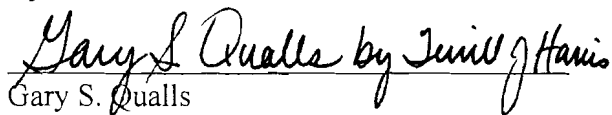
<sup>10</sup> 10 N.C.A.C. 3R. 0420 is now 10 N.C.A.C. 14C. 0420.

This the 13th day of February, 2009.

**K&L GATES LLP**

*Counsel to The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System, High Point Regional Health System, Rex Hospital, Inc., and Pitt County Memorial Hospital, Inc.*

By:

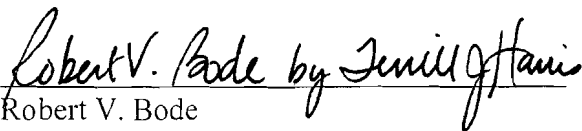


Gary S. Qualls  
N.C. State Bar No. 16798  
Colleen M. Crowley  
N.C. State Bar No. 25375  
William W. Stewart, Jr.  
N.C. State Bar No. 29594  
430 Davis Drive, Suite 400  
Morrisville, NC 27560  
Telephone: (919) 466-1182  
Facsimile: (919) 516-2072

**BODE, CALL & STROUPE, LLP**

*Counsel to NCHA, Inc., d/b/a North Carolina Hospital Association, North Carolina Baptist Hospital, and Wake Forest University Health Sciences*

By:

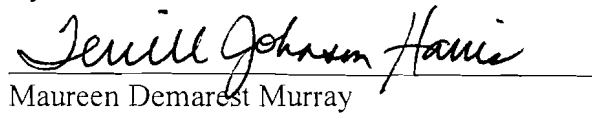


Robert V. Bode  
N.C. State Bar No. 6040  
Diana Evans Ricketts  
N.C. State Bar No. 6138  
S. Todd Hemphill  
N.C. State Bar No. 10360  
3105 Glenwood Ave., Suite 300  
Raleigh, NC 27602  
Telephone: (919) 881-0338  
Facsimile: (919) 881-9548

**SMITH MOORE LEATHERWOOD LLP**

*Counsel to WakeMed, Mission Hospital, Inc., and The Moses H. Cone Memorial Hospital Operating Corporation d/b/a The Moses Cone Health System*

By:

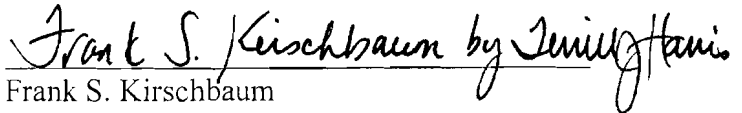


Maureen Demarest Murray  
N.C. State Bar No. 9195  
Terrill Johnson Harris  
N.C. State Bar No. 17472  
Allyson Jones Labban  
N.C. State Bar No. 32573  
Post Office Box 21927  
Greensboro, NC 27420  
Telephone: (336) 378-5200  
Facsimile: (336) 378-5400

**KIRSCHBAUM, NANNEY, KENNAN  
& GRIFFIN, PA**

*Counsel for Asheville Radiology Associates, P.A., Blue Ridge Day Surgery Center Limited Partnership, Charlotte Surgery Center, Limited Partnership, The Eye Surgery Center of the Carolinas, LP, Greensboro Specialty Surgery Center, Limited Partnership, Surgery Center of Southern Pines, LLC, and Surgical Care Affiliates, LLC*

By:



Frank S. Kirschbaum  
N.C. State Bar No. 23225  
2418 Blue Ridge Road, Suite 200  
Raleigh, NC 27607  
Telephone: (919) 719-2400  
Facsimile: (919) 846-3619

**POYNER SPRUILL LLP**

*Counsel for The North Carolina Health Care  
Facilities Association, Inc.*

By:



Kenneth L. Burgess

N. C. State Bar No. 12340

P.O. Box 10096

Raleigh, NC 27605-0096

Telephone: (919) 783-2917

Facsimile: (919) 783-1075

CERTIFICATE OF SERVICE

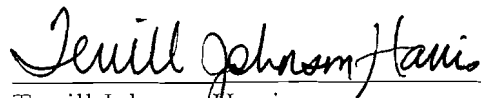
The undersigned hereby certifies that on this day a true copy of the foregoing document was served on the following by United States Mail, First Class postage pre-paid, and addressed as follows:

Noah H. Huffstetler, III  
Wallace C. Hollowell, III  
Denise M. Gunter  
Nelson, Mullins, Riley & Scarborough, LLP  
4140 Parklake Avenue  
Glen Lake One, Suite 200  
Raleigh, NC 27612  
*Counsel for Plaintiffs*

Robert F. Orr  
Jason B. Kay  
333 Six Forks Road, Suite 180  
Raleigh, NC 27609  
*Counsel for Plaintiffs*

Mark A. Davis  
Special Deputy Attorney General  
Angel Gray  
Assistant Attorney General  
N.C. Department of Justice  
P.O. Office Box 629  
Raleigh, NC 27602  
*Counsel for Defendants*

This the 13th day of February, 2009.

  
\_\_\_\_\_  
Terrill Johnson Harris