MEDSTAR HEALTH v. MARYLAND HEALTH CARE COMMISSION
No. 47, September Term 2002

HEADNOTES: ADMINISTRATIVE LAW; MARYLAND HEALTH CARE COMMISSION; STATE HEALTH PLAN; REGULATION; COMAR 10.24.17; CERTIFICATE OF NEED; QUASI-LEGISLATIVE FUNCTION

Adoption of COMAR 10.24.17 is not consistent with the underlying policy assumptions of the State Health Plan, exceeds the Commission's statutory authority and is unlawful.

Circuit Court for Howard County
Case No. 13-C-01-48458

IN THE COURT OF APPEALS OF MARYLAND

No. 47

September Term, 2002

MEDSTAR HEALTH

v.

MARYLAND HEALTH CARE COMMISSION

Bell, C.J.
Eldridge
Raker
Wilner
Cathell
Harrell
Battaglia
JJ.

Opinion by Bell, C.J.
Raker, Wilner and Harrell, JJ., Dissent

Filed: June 18, 2003

The issue to be resolved in this appeal requires this Court to determine the lawfulness of a regulation, COMAR 10.24.17, the appellee, the Maryland Health Care Commission, adopted as an amendment to the State Health Plan (SHP). The appellant, Medstar Health, challenged the regulation, filing a declaratory judgment action in the Circuit Court for Howard County. It alleged that the regulation conflicted with the appellee's statutory authority, was adopted in a procedurally improper fashion, and violated the Commerce Clause of the United States Constitution. After limited discovery, the parties filed cross-motions for summary judgment. By written memorandum decision and declaratory judgment, the Circuit Court declared the regulation lawful. The appellant timely noted an appeal to the Court of Special Appeals, and, thereafter, filed a petition for writ of certiorari with this Court. This Court granted that petition prior to any proceedings in the intermediate appellate court. Medstar Health v. Maryland Health Care Commission, 369 Md. 659, 802 A.2d 438 (2002). We shall hold, contrary to the conclusion of the Circuit Court for Howard County, that the regulation is unlawful.

I.

A. Background

In 1975, Congress enacted the National Health Planning and Resources Development Act of 1974 (the "Act")[1]. In order to receive federal funding, pursuant to the Public Health Service Act and other federal programs, states were required to establish more extensive

[1] Pub. L. No. 93-641, 88 Stat. 2225 (1975) (as amended), 42 U.S.C. §§ 300k, et seq. (1982) (repealed 1986).

review processes over state health planning. The review process requirement imposed by the Act established what is known as the "Certificate of Need" ("CON") process. The CON process requires health service providers (i.e., hospitals, patient treatment centers, etc.) to obtain certification, by state regulatory agencies, before engaging in certain regulated activities (i.e., purchasing major medical equipment, offering institutional health services, and making certain capital expenditures). The CON process, as a planning tool, attempts to identify and encourage the development of needed medical services, while limiting medical services that are determined to be "unneeded." For many years, the CON process was the paradigm of health planning in this country. The federal government, however, repealed the Act in 1986 and, thus, since that time the determination of what methodology to employ for health planning has rested with the states.

Some states have chosen to abrogate their CON programs, while others have chosen to continue following the federal structure or to modify their CON program to fit local needs. Maryland continues to adhere to a CON model in the planning, development and delivery of health care services in this state. The implementation of the CON process utilized in Maryland falls under the regulatory authority of the Maryland Health Care Commission (the "Commission"). Consequently, before a hospital servicing this state may offer any regulated medical services it must apply for, and be granted, a CON from the Commission.[2]

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[2] Although the Commission does not have the authority to regulate the out-of-state activities of a non-Maryland hospital, the Commission does consider, for purposes of CON determinations, facilities and resources located outside of the State of Maryland.

B. Statutory Framework in Maryland

The Maryland General Assembly established the Commission on October 1, 1999 through legislative enactment, see 1999 Md. Laws, ch. 702; Md. Code (1982, 2000 Repl. Vol., 2001 Supp.) § 19-103 of the Health General Article, by merging the Health Resources Planning Commission and the Health Care Access and Cost Commission.[3] The Commission, which is an independent commission in the Department of Health and Mental Hygiene, § 19-103 (a) and (b), with significant responsibilities for the delivery of health care in Maryland and exercises regulatory authority over several aspects of the health care system in Maryland, is comprised of a thirteen member panel, appointed by the Governor with the advice and consent of the Maryland Senate. § 19-104.

The purpose of the Commission, as defined by the Legislature, is, in part, to:

> "Develop health care cost containment strategies to help provide access to appropriate quality heath care services for all Marylanders, after consultation with the Health Services Cost Review Commission;

This is especially true in the Washington Metropolitan area because of the number of Maryland residents who seek treatment at hospitals located in Washington, D.C.

[3] There were several predecessor commissions with different names prior to the creation of the Maryland Health Care Commission. For the sake of convenience, the term "Commission" refers to all predecessor commissions. In 2001, the Maryland General Assembly transferred some aspects of the planning functions – those that largely involve local plans and planning for licensed entities that are not required to obtain a Certificate of Need or an exemption from the CON program – from the Commission to the Secretary of Health and Mental Hygiene. See 2001 Md. Laws, ch. 565. That act also renumbered various sections in title 19, subtitle 1 of the Health-General Article. The changes effected by Chapter 565 do not affect this case.

Unless otherwise indicated, all references to the Maryland Code are to the Health-General Article, (1982, 2000 Replacement Volume), in effect when this case was decided.

> "Promote the development of a health regulatory system that provides for all Marylanders, financial and geographical access to quality health care services at a reasonable cost by:
>
> > "(i) Advocating policies and systems to promote the efficient delivery of and improved access to health care services; and
> >
> > "(ii) Enhancing the strengths of the current health care service delivery and regulatory system."

Section 19-103 (c) (1) and (2). Toward that end, the Commission is charged with participating in or performing, periodically, analyses and studies relating to:

> "(i) Adequacy of services and financial resources to meet the needs of the population;
>
> "(ii) Distribution of health care resources;
>
> "(iii) Allocation of health care resources;
>
> "(iv) Costs of health care in relationship to available financial resources; or
>
> "(v) Any other appropriate matter."

Section 19-115 (a) (2).

The Commission is also required, "[a]t least every 5 years ... [to] adopt a State [H]ealth [P]lan ...." Section 19-121 (a) (1).[4] Section 19-121 (a) (2) provides:

> "(2) The plan shall include:

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[4]Pursuant to 2001 Md. laws, ch.565, effective July 1, 2001, § 19-121 was amended and redesignated § 19-118. As indicated, we will refer to § 19-121, as that is the section that was in effect when this case was decided and that, therefore, controls its decision. See Dept. of Health and Mental Hyg. v. Campbell, 364 Md. 108, 120, n. 12, 771 A. 2d 1051, 1058, n.12 (2001).

"(i) A description of the components that should comprise the health care system;

"(ii) The goals and policies for Maryland's health care system;

"(iii) Identification of unmet needs, excess services, minimum access criteria, and services to be regionalized;

"(iv) An assessment of the financial resources required and available for the health care system;

"(v) The methodologies, standards, and criteria for certificate of need review; and

"(vi) Priority for conversion of acute capacity to alternative uses where appropriate."

The Commission uses the State Health Plan as a tool to identify the need for medical services and for evaluating CON applications submitted by health service providers. The Commission's specific mandate by the Legislature is to review and, where appropriate, issue certificates of need to permit a person to "develop[], operate[], or participate[]" in certain "health care projects." § 19-123 (e), et seq. A new cardiac surgery service is one such "health care project." §19-123 (j) (2) (iii) (2).

In addition to including methodologies, standards and criteria for CON review in the State Health Plan, the Commission is charged with developing, consistent with the State Health Plan, standards and policies relating to the CON program that "address the availability, accessibility, cost and quality of health care" and reviewing those standards and policies "periodically to reflect new developments in health planning, delivery, and technology." Section 19-122 (e) (1) and (2). Moreover, "standards regarding cost,

efficiency, cost effectiveness or financial feasibility" adopted by the Commission "shall take into account the relevant methodologies of the Health Services Cost Review Commission." Id., § 19-121 (e) (3). And the Commission is required to "adopt rules and regulations that ensure broad public input, public hearings, and consideration of local health plans in development of the State health plan." Id., § 19-121 (d).

C. Adoption of COMAR 10.24.17

The State Health Plan consists of a series of regulations adopted by the Commission or its predecessors, incorporated by reference, but not in fact, in the appropriate title, subtitle and chapters of The Code of Maryland Regulations, COMAR, here, title 10, subtitle 24, chapters 07 through 17. At issue in this case is an amendment to the regulations applicable to cardiac surgery, which is incorporated at COMAR 10.24.17, in the chapter entitled "Specialized Health Care Services - Cardiac Surgery and therapeutic Catherization Services." The amendment was to COMAR 10.24.17.04E, Methodology for Projecting Need for Cardiac Surgery, specifically, one of the assumptions underlying that methodology, the one addressing system capacity in the planning regions.[5]

As amended, the regulation states:

> "(i) The capacity of an existing cardiac surgery program is calculated as follows:

[5] The State Health Plan divides Maryland into four service regions for purposes of cardiac surgery services: Western Maryland; Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore.

> "(i) For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence;
>
> "(ii) For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint; and
>
> "(iii) The capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region."

COMAR 10.24.17.04E (4) (i).

Before the amendment, the assumption underlying system capacity was premised on there being performed, in each of the operating rooms dedicated to open heart surgery, 500 operations year, a year being defined as 250 days, it being assumed that the operating rooms were used at the rate of 2.0 cases per day, five days a week, fifty weeks per year.[6] Before and after the amendment, the assumption included "an estimate of the future number of open heart surgery cases based on an analysis of trends in regional, age-specific use rates and changes in the size and composition of the population." See, Final Report of the Technical Advisory Committee on Cardiovascular Services, December 1999, at 23. The present plan specifically provides, as to projected adult open heart surgery for Maryland residents, that it "is estimated by trending of the most recent three years of open heart surgery use rates to the target year based on the average annual percentage change in historical open heart surgery use rates for each Regional Service Area, except the Western Maryland Regional

[6] This was the assumption utilized by the Commission in its 1997 State Health Plan.

Service Area." COMAR 10.24.17.04E (4) (b) [State Health Plan at 60].[7]

Both before and after the amendment of the regulation at issue, "net need for open heart surgery cases" is determined by "subtracting the total existing capacity from the total projected number of cases." COMAR 10.24.17.04E (6), "Calculation of the Net Need for Adult Cardiac Surgery Programs." [State Health Plan at 63]. "Need for an additional cardiac surgery program exists if the net need for open heart surgery cases in a Regional Service Area is at least 200 cases." Id.

Initially, we acknowledge that the amendment of the regulation was properly done procedurally. It must be noted that the amendment was adopted only after extensive review and after receiving considerable input from a Technical Advisory Committee, Commission staff and interested parties. In fact, the process was initiated approximately two years before the amendment was adopted, when the Commission, in December 1998, convened a Technical Advisory Committee, as its predecessor had done in connection with the development of the 1997 State Health Plan. In addition to a report from that Committee, it

[7] The State Health Plan states that for purposes of "project[ing] adult open heart surgery utilization [in the Western Maryland Regional Service Area] is based on the experience in the base year." [State Health Plan at 60]. Prior to 1999, the total number of open heart surgery cases in the Western Maryland Regional Service Area was not sufficient to justify an open heart surgery program. In that same year, however, the Commission's predecessor granted a CON to the Western Maryland Health System to establish a program at Sacred Heart Hospital in Allegany County. Thus, the Commission had no historical data to use to project the future need of adult open heart surgery in that planning region.

consisted of the development of a 40-page White Paper by Commission Staff, solicitation of public comment on that White Paper and subsequent White Papers analyzing the initial comments and setting forth Staff recommendations, a public hearing, the publication of the Commission's proposed regulation pursuant to the procedure mandated by the Maryland Administrative Procedure Act. Maryland Code (1984, 1999 Replacement Volume, 2000 Suppl.) § 10-112 of the State Government Article, followed by another public hearing.

The Technical Advisory Committee questioned the appropriateness of the 1997 State Health Plan's assumption underlying the system capacity calculation for cardiac surgery services – two cases per dedicated operating room model, – suggesting that it be eliminated, and, that the "measurement of available system capacity be re-defined to incorporate other factors such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional open heart programs in Maryland." Technical Advisory Committee Final Report, at 26. Thereafter, in June 2000, following staff review of the Technical Advisory Committee's recommendations, the Commission issued a White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland, which identified issues related to planning for cardiac surgery services and policy options for addressing them. The two options the White Paper identified for determining system capacity for cardiac surgery services were: Option 1, the existing measure, utilized in the 1997 State Health Plan– the continued use of the dedicated operating room approach, White Paper at 20, – and, Option 2, "capacity based on actual service

utilization," id. at 22, a measurement based on actual service utilization. Under Option 2, which was employed in the 1990 State Health Plan, the Commission's White Paper noted, the capacity of existing cardiac OHS programs was defined as follows:

> "the greater of 350 cases per hospital or the highest actual annual volume ever attained by the hospital in the most recent years of accurate available data; or if the hospital had not performed, for the past three consecutive years, at least 200 cases per year, the capacity of that program was measured by the actual volume of cases performed in that hospital during the base year."

Commission White Paper at 22. The advantage of using Option 2 as the underlying assumption of system capacity, the White Paper argued, was that "actual performance of a program would be more indicative of what volumes are likely to be handled by the program." Id. The Commission then solicited comment on the White Paper.

Of the responses from organizations and individuals, several took advantage of the debate on system capacity to lobby for increased competition in the Metropolitan Washington planning area. In all, ten individuals or organizations submitting comments on the White Paper did so in support of defining system capacity for cardiac surgery services using either Option 1 or Option 2. The remaining five organizations that submitted comments relating to system capacity suggested using a dedicated operating room approach in conjunction with other factors to measure system capacity. As Anne Arundel Medical Center, one of the organizations advocating an approach other than Options 1 or 2 identified in the White Paper, stated, the combined effect of the CON process and the past, present and proposed methodologies "resulted in open heart surgery services being treated as a franchise, an

economic bonanza so valuable that both the 'haves' and those that desire it spent enormous and obscene amounts of time and money in the few CON proceedings the Commission's predecessor held to grant new franchises." Further, it characterized the CON process as "focus[ed] on number-driven 'need' analysis, limiting the number of hospitals with Open Heart CONs (the 'haves')," disagreed with "the concept that CON review – the before-the-fact comparison of competing applicants – is the appropriate method to design an effective system of combating heart disease," and accused that methodology of insulating those hospitals with the cardiac surgery "franchise" from competition.

Greater Baltimore Medical Center took a similar tack. Acknowledging the intent of the White Paper, it observed, nonetheless, that

> "from a practical standpoint, the policy alternatives are limited by remaining within the confines of the existing CON framework of analysis. The Commission should replace the rationing of health care represented by the existing plan in favor of adopting a patient centered, quality of care driven plan that would judge each individual hospital's ability and need to provide cardiac care."

While offering that the Commission's "policies regarding O[pen] H[eart] S[urgery] ["OHS"] should reflect a balance between the advantages of size and the advantages of choice," Holy Cross Hospital stressed that

> "[t]here is massive evidence that significant competition leads to lower cost and, when the market rewards quality, significant competition can lead to higher quality as well. Additional providers, especially independent providers, almost by definition, increase access. Thus, by balancing the advantages of size and choice, [the Commission] will balance the interests of quality, cost containment and access."

It also made clear that it did not believe that such a balanced framework currently exists and, in fact, stated that it does not, as "the current situation effectively prohibits new programs in any area which has OHS." Holy Cross noted, furthermore, its sympathy "to many of the arguments for opening the OHS market to new entrants and then judging after the fact whether they are successful and should be retained (the so-called licensure model). This approach maximizes the opportunity for choice while retaining a state review role, generally, after the fact."

While praising the "five 'right-sized' competitive programs" in Baltimore, Suburban Hospital decried the "dysfunctional Washington market,"with its dominant "single large provider,"the Washington Hospital Center.[8] Suburban advocated a capacity measure that would "permit development of a new OHS program in the D.C. region but not in Baltimore." It also lamented the assignment to the four low production programs in the region, Georgetown, George Washington, Howard and Prince George's Hospital Center, of capacity for 3000 cases when, together, during all of 1999, they performed but 395 cardiac surgeries. Suburban Hospital submitted:

> "if just 200 cardiac surgeries and 200 angioplasties were performed at either Suburban or Holy Cross instead of at the Hospital Center, savings to the Medicare program (and the American people) would be $4 million each year. These savings ... result from the rate offers that an existing Maryland-based program must make in connection with the CON approval process. This phenomenon, and price reductions in response to the new, lower-priced competition, both generate savings to payers. This is precisely what occurred

[8] The appellant owns and operates Washington Hospital Center.

> in the Baltimore market as a result of development of the two new, competitive programs at Sinai and Union Memorial during the last several years. Given this experience and the current situation in the D.C. area, it is difficult to understand why the Commission should continue a policy that: (i) protects a non-Maryland hospital from effective price competition; (ii) denies Maryland consumers meaningful choice; and (iii) causes the Medicare program to pay millions of additional dollars to a non-Maryland hospital for cardiac surgery provided to Maryland residents." (Emphasis in original).

St. Agnes Hospital, having in the past supported legislation that would have replaced CON control of cardiac surgery services with a licensure approach, was clear in advocating for an approach that was more open, more competitive. It commented:

> "St. Agnes in its oral and written comments urges the Commission to replace the existing regional plan with a patient and quality focused plan that promotes a continuum of cardiac care including coronary angiosplasty and open heart surgery in any large community hospital with the patient volumes and size to safely provide the service. The regional plan under review is based on the explicit premise that open heart surgery is an expensive tertiary level service which exhibits a high correlation between volumes and outcomes and is best served by forcing all procedures into a very small number of hospitals. On those rare occasions when new programs have been granted a CON, they have been parceled out one program at a time following protracted and expensive consolidated reviews that have pitted existing providers against all applicants, and all applicants against each other. Despite the enormous time, money, effort and goodwill expended in these past proceedings held by the Commission's predecessor, one of the only three programs ever CON approved and running has never met even the minimum volume standards adopted by the plan. A 33% failure rate is unacceptable in the allocation of such a critical resource. We believe it is fair to say that the existing open-heart CON process has lived [past] its usefulness."

Competition, and the need for it, was the theme of the Health Services Cost Review Commission's comments to the Commission, albeit with a caution. That was true of the comments of Johns Hopkins Hospital, as well, who attributed the more than 70 percent

market share enjoyed by the Washington Hospital Center and the failure of four of the Washington Region programs to meet minimum surgical volumes to the lack of competition. Thus, Johns Hopkins advocated eliminating what it termed the "flawed" dedicated operating room methodology, as a measurement of program capacity because of a hospital's ability to simply add operating rooms and thus unilaterally increase system capacity.

Anne Arundel Medical Center, Greater Baltimore Medical Center, Holy Cross Hospital, Suburban Hospital and St. Agnes Hospital all supported a capacity measure which was likely to result in competition. The one that they all favored was a cap on capacity. The group favored a cap on capacity because they objected to the assignment of more than 3000 cardiac procedures, as projected capacity in the Metropolitan Washington planning region, when in actuality, on average, more than 2500 of the procedures were performed solely by Washington Hospital Center, with the balance of the region's capacity divided among four sub-performing hospitals and one hospital performing adequately.

The written comments were augmented by oral testimony at a public hearing conducted by the Commission on July 21, 2000. At that hearing, Dr. Robert Lowery, a cardiac surgeon, employed by Washington Hospital Center, which is owned by the appellant, testified that there was adequate capacity in the Washington Metropolitan region, and no need for additional OHS programs existed in the region. Dr. Eugene Passamani. director of cardiology at Suburban Hospital, testified, consistent with Suburban's written comments, that the assignment of 3000 cases as a capacity measure did not "represent real capacity" because

at least 2500 cases were attributable solely to Washington Hospital Center.

On September 15, 2000, the Commission issued its second White Paper, analyzing the public comments and recommendations it had previously solicited on the first White Paper. Noting that both options for measuring system capacity that it had presented in its previous White Paper had significant limitations, the White Paper concluded that the chapter of the State Health Plan dealing with Open Heart Surgery should include a cap on the number of cardiac surgery procedures conducted by any one hospital in a planning region and that future capacity in that planning region be determined and computed by reference to that cap. The cap, as we have seen, supra at 7-8, provides that the "capacity of any program cannot be greater than the higher of 800 cases or 50% of the projected gross need for the planning region."

Upon release of the second White Paper, the Commission sought additional public comment, whereupon a third White Paper was issued on October 25, 2000. The staff maintained its support of the amended capacity measurement, i.e., the cap, opining that the measurement was "reasonable and appropriately balances public policy concerns," such as access, cost and equality. Final Staff Analysis at 6.

On November 21, 2000, the Commission considered the proposed amendment of the chapter and voted to publish the regulation for public comment. In compliance with § 10-110 (b) of the State Government Article, the proposed regulation was required to be submitted to the General Assembly's Joint Committee on Administrative, Executive and

Legislative Review ("AELR") at least 15 days before being submitted to the Maryland Register for publication. Thus, on December 13, 2000, the proposed OHS chapter, with its amendment to the definition of system capacity was submitted to the AELR. Thereafter, on January 4, 2001, the proposed chapter was submitted for review to the Governor, as required by §19-117(c) of the Health-General Article.

Prior to publication, the presiding Chairman of the AELR Committee sent a letter to the Governor stating the Committee's intent to conduct a "more detailed study of [the] proposed regulation." The Committee also requested that the Commission delay final adoption of the proposed regulation until the Committee completed its review. As stated by the Committee, the purpose of the delay was to "provide the Committee with an opportunity to more closely examine a number of issues, including whether the statute under which the regulation is adopted authorized the adoption and whether the regulation conforms to the legislative intent of the statute."

The AELR Committee held a hearing and received testimony on the proposed regulation on January 16, 2001. Because no further action was taken by the Committee, the proposed regulation was published in the Maryland Register on January 26, 2001. 28 Md. Reg. 126-27 (January 26, 2001). The publication of the proposed regulation commenced the 31-day period for the submission of public comments. The proposed regulation, as had been

the case with regard to the White Papers, generated considerable interest and resulted in 47 organizations and individuals submitting written comments. Additionally, the Commission held yet more public hearings. The appellant used the opportunity, again, to provide testimony and to submit written comments.

During the period for public comment, the Commission received a letter, dated March 21, 2001, from the Co-Chairs of the AELR Committee. The letter requested that the Commission modify the proposed regulation.[9] Shortly thereafter, the Commission received a follow-up letter from the Honorable Thomas V. Mike Miller, President of the Maryland Senate, which informed it that the March 21st letter did not "represent the consensus of the members" and was "advisory only," in light of the fact that the AELR Committee had not met. Two additional letters, dated April 4 and April 5, signed by the members of the House and Senate delegations to the AELR Committee, were received by the Commission. The letters confirmed Senator Miller's earlier letter indicating that the March 21st letter did not represent the views of the AELR Committee. More important, the letters requested that the Commission "withdraw the entire regulation and develop new comprehensive regulations

[9] The letter sought to have the Commission eliminate Policy 5.2 of the proposed regulation, "which states that the Commission should consider a pilot project to study the provisions of elective angioplasty without the availability of on-site cardiac surgery backup."

consistent with the counsel of the . . . [Technical Advisory Committee], especially related to the issue of measuring capacity at existing [OHS] surgery programs."

On April 19, 2001, the Commission, by an 8-1 vote, adopted COMAR 10.24.17 as a final regulation. The Notice of Final Action was published in the May 4, 2001 Maryland Register. See 28 Md. Reg. 885 (May 4, 2001). Subsequently, on May 14, 2001, the regulation became effective.

The regulation, adopted over the objection of the appellant, had the effect of reducing the Washington Metropolitan Planning Region's cardiac surgery capacity by 824 cases, the number of cases that Washington Hospital Center performed, but, because of the cap on capacity, was not allowed to count for that purpose. In 1999, that hospital performed 2950 open heart surgeries. Without the amended regulation, all of those surgeries would have been considered in determining the capacity of the Region. When the surgeries performed by the other hospitals in the Region, totaling 1212 in 1999 or, using 1997-1999 data, as the Commission did, 1482, were counted, the Region's capacity would have been 4162 or 4432 cases, respectively. The need in the Region was projected to be 4251. Under the amended regulation, because the number of surgeries performed by Washington Hospital center exceeded 50 percent of projected need for the Region, its existing and CON approved capacity was determined to be 2126, half of the projected number of cases, and 824 cases less

than its actual production. Consequently, rather than an excess of capacity over need (using 1997-99 performance figures, as the Commission did, the capacity would exceed demand by 181 cases) or need less than the threshold for consideration of a new program (using 1999 performance figures, need would exceed capacity, but only by 89 cases), see COMAR 10.24.17.04E (6),[10] application of the amended regulation resulted in a deficit of 643 cases, or the need for at least one new program in the Region. Id.

The appellant acted without delay in challenging the newly effective regulation, filing its action for declaratory judgment on the date the regulation took effect.

II.

In the trial court, the appellant argued that the regulation adopted "dramatically and unlawfully" changed the methodology for projecting need for cardiac surgery services. Such a change, the appellant argued, was not contemplated, nor authorized, by the Commission's enabling legislation. Moreover, it maintained that the regulation adopted poses a risk to patient safety. Specifically, citing to § 19-121(2) (currently, §19-118 (2), 2001 Supp.), but

[10] "Calculation of the Net Need for Adult Cardiac Surgery Programs
"(a) For each Regional Service Area, calculate the net need for open heart surgery cases by subtracting the total existing capacity from the total projected number of cases.
"(b) Need for an additional cardiac surgery program exists if the net need for open heart surgery cases in a Regional Service Area is at least 200 cases."

relying on other statutory provisions, the appellant argued that the adopted regulation violated the Commission's statutory mandate requiring it to identify unmet health care needs and to set forth the methodologies for certificate of need review.[11] Citing to the objection of the members of the AELR Committee, the appellant further noted that the regulation had been adopted without the approval of the Governor in violation of Md. Code (1984, 1999 Repl. Vol., 2000 Cum. Supp.) § 10-111.1(b) and (c) of the State Government Article.[12]

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[11] In an amended complaint the appellant added a claim alleging that the adopted regulation violated the "dormant" Commerce Clause of the United States Constitution by discriminating against Washington Hospital Center, an out-of-state business entity and was a burden on interstate commerce.

[12] Section 10-111.1(b) of the State Government Article provides:

> (b) Factors considered. -- In its review of a proposed regulation pursuant to this section, the factors the Committee shall consider shall include whether the regulation:
> (1) is in conformity with the statutory authority of the promulgating unit; and
> (2) reasonably complies with the legislative intent of the statute under which the regulation was promulgated.

Additionally, § 10-111.1(c) of the State Government Article provides:

> "(c) Notice to Governor and promulgating unit. --
> "(1) Within 5 working days after the Committee votes to oppose the adoption of a proposed regulation, it shall provide written notice to the Governor and the promulgating unit of its action.
> "(2) Upon receipt of such notice, and with written notice to the Committee and as otherwise required by law, the promulgating unit may:

The Circuit Court for Howard County, acting on cross-motions for summary judgment, entered judgment in favor of the appellee, declaring that the Commission had acted within its statutory authority in adopting COMAR 10.24.17. Moreover, the trial court determined that the regulation had been validly adopted and did not violate the Commerce Clause of the United States Constitution.

The gravamen of the appellant's complaint is that the Commission's adoption of COMAR 10.24.17 uses a regulatory created assumption to create unmet need for cardiac surgery services in the Washington Metropolitan planning region. This, the appellant argues,

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> "(i) withdraw the regulation;
> "(ii) modify the regulation, but only in accordance with § 10-113 of this subtitle; or
> "(iii) submit the regulation to the Governor with a statement of the justification for the unit's refusal to withdraw or modify the regulation.
> "(3) Following the receipt of notice under paragraph (2) (iii) above, the Governor may consult with the Committee and the unit in an effort to resolve the conflict. After written notice has been provided to the presiding officers and to the Committee, the Governor may:
> "(i) instruct the unit to withdraw the regulation;
> "(ii) instruct the unit to modify the regulation, but only in accordance with § 10-113 of this subtitle; or
> "(iii) approve the adoption of the regulation."

Although the appellant raised this issue in the trial court and repeated the claims in the Statement of the Facts section of its brief, the appellant failed to address the issue either in the Question Presented or Argument section of its brief. As we have indicated, we will decide the case on alternative grounds and, thus, not reach this issue.

allows for the creation of a new OHS programs in that planning region, despite the fact that the Commission's own data shows that no real, or actual, need for a new cardiac surgery program exists. Responding, the Commission relies on its broad authority, conferred by the Legislature, to adopt the regulation, asserting that that authority clearly permits it to do what it did. We disagree with the Commission and the trial court, and shall hold that the adoption of COMAR 10.24.17 exceeded the Commission's statutory authority. Consequently, we need not, and will not, reach the alternative grounds the appellant proffers for striking the regulation.

III.

This Court has stated that "the development, adoption, and updating of the [State Health] plan is a quasi-legislative function." Adventist v. Suburban, 350 Md. 104, 122, 711 A.2d 158, 167 (1998); see also, Fogle v. H & G Restaurant, Inc., 337 Md. 441, 453, 654 A.2d 449, 455 (1995) ("Promulgation of new regulations by agencies is one of these so-called quasi-legislative activities."); Dep't of Nat. Res. v. Linchester, 274 Md. 211, 222, 334 A.2d 514, 522 (1975) (noting "these agencies at times perform some activities which are legislative in nature and thus have been dubbed as quasi-legislative"). We have also made clear that agency regulations must be consistent with the letter and the spirit of the law under which the agency acts. Christ v. Department of Natural Resources, 335 Md. 427, 437, 644

A.2d 34, 38 (1994); Maryland State Police v. Warwick, 330 Md. 474, 481, 624 A.2d 1238, 1241 (1993); Ins. Comm'r v. Bankers Independent Ins. Co., 326 Md. 617, 623, 606 A.2d 1072, 1075 (1992).

Pursuant to State Government Article, § 10-125,[13] regulations promulgated by administrative agencies may be challenged by way of a declaratory judgment action.[14] Our

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[13] Md. Code (1984, 1999 Repl. Vol.) § 10-125 of the State Government Article, provides:

"Petition for declaratory judgment authorized

"(a) (1) A person may file a petition for a declaratory judgment on the validity of any regulation, whether or not the person has asked the unit to consider the validity of the regulation.

"(2) A petition under this section shall be filed with the circuit court for the county where the petitioner resides or has a principal place of business.

"(b) A court may determine the validity of any regulation if it appears to the court that the regulation or its threatened application interferes with or impairs or threatens to interfere with or impair a legal right or privilege of the petitioner.

"(c) The unit that adopted the regulation shall be made a party to the proceeding under this section.

"(d) Subject to § 10-128 of this subtitle, the court shall declare a provision of a regulation invalid if the court finds that:(1) the provision violates any provision of the United States or Maryland Constitution;

"(2) the provision exceeds the statutory authority of the unit; or

"(3) the unit failed to comply with statutory requirements for adoption of the provision."

[14] Similarly, we made clear in Adventist, 350 Md. at 122-125, 711 A.2d. at 166-169, it is inappropriate to use a CON contested case proceeding to challenge the "validity

scope of review in such actions is "limited to assessing whether the agency was acting within its legal boundaries." Adventist, supra, 350 Md. at 124, 711 A.2d at 167, citing Linchester, supra, 247 Md. at 224, 334 A.2d. at 524; See also Judy v. Schaefer, 331 Md. 239, 263-264, 627 A.2d 1039, 1051-1052 (1993). In Fogle, we noted that courts, when opining upon the validity of actions taken by agencies, should "defer to agencies' decisions. . . because they presumably make rules based upon their expertise in a particular field." Fogle, supra, 337 Md. at 455, 654 A.2d at 456; see also Ideal Federal v. Murphy, 339 Md. 446, 461, 663 A.2d 1272, 1279 (1995) (citing Udall v. Tallman, 380 U.S. 1, 16, 85 S. Ct. 792, 801, 13 L. Ed. 2d 616, 625 (1965) for the proposition that "[w]hen faced with a problem of statutory construction, this Court shows great deference to the interpretation given the statute by the officers or agency charged with its administration") and MTA v. King, 369 Md. 274, 288, 799 A.2d 1246, 1254 (2002). Pointedly, we added in Fogle that "[t]his is especially true of agencies working in the area of health and safety, which rely extensively on their specialized knowledge of that area in promulgating regulations." Fogle, supra, 337 Md. at 455, 654 A.2d

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and applicability of [] published needs projections contained in the existing State Health Plan." Rather, agency action taken pursuant to its quasi-legislative role (i.e., development, adoption, and updating of the State Health Plan), should be challenged either by the procedure established by "Section 19-114(c)" of the Health General Article (current version at Health-Gen. II (Supp. 2001) § 19-118 (b)) or by way of the Declaratory Judgment Action.

at 456. Moreover, where "the General Assembly has delegated . . . broad power to an administrative agency to adopt [legislative rules] or regulations [in a particular area], this Court has upheld the agency's rule or regulations as long as they did not contradict the language or purpose of the statute." Christ v. Department of Nat. Res., supra, 335 Md. at 437, 644 A.2d at 39; Lussier v. Maryland Racing Commission, 343 Md. 681, 689, 684 A.2d 804, 807-808 (1996).

In its brief, the appellant challenges the Commission to identify any provision of the statute that grants authority to the Commission "to create a need for an additional open heart surgery program where. . . the facts[] as found by the Commission show there is no need." (Appellant's Brief at 27). To that challenge, the Commission continues to rely on the deference this Court has extended to the regulations and rules promulgated by an agency, on whom the Legislature has conferred broad statutory authority. Thus, the Commission submits that it need not point to any specific statutory authorization to justify its action, maintaining that "it is sufficient for [it] to show that there is nothing in the Cardiac Surgery Chapter that contradicts either the language or the purpose of the authorizing legislation." (Appellees Brief at 18). We disagree.

While reliance upon the broad statutory authority conferred by the Legislature generally will be sufficient to justify an agency's regulation/rule making authority, logic

compels the self evident conclusion that there is an outer limit to an agency's authority. This Court's attempt to demarcate the outer limits of an administrative agency's authority has focused on whether the regulations and rules promulgated by the agency are consistent with the statutory scheme under which the agency operates. So, too, with the Commission, the question is whether the regulation at issue is consistent with the underlying policy assumptions permeating the State Health Plan and the Commission's own factual analysis undertaken with the purpose of defining unmet need for cardiac surgery services. Undertaking this analysis leads us to the conclusion that the Commission's adoption of COMAR 10.24.17 is not consistent with the underlying policy assumption of the State Health Plan and is not supported by the factual analysis developed by the Commission's Technical Advisory Committee.

The proof of the adopted regulation's inconsistency with the underlying policy assumption of the plan is evidenced by contrasting certain policy determinations pertinent to, and underlying, the Certificate of Need process in its present form with the policy determinations underlying the amended regulation. Significantly, the former policy determinations remained unchanged after adoption of the amended regulation and, thus continue to guide the CON process, of which the amended regulation is, in reality, a critical part. Not least among them is the Commission's conclusion, repeated at length in the State

Health Plan, and incorporated in its first Policy statement, that there is an "inverse relationship between volume of cardiac procedures and outcome as measured by mortality and/or complications." See COMAR 10.24.17.04B (1) [Amended State Health Plan at 20]. While it acknowledges the conflicting evidence on the subject, the Commission accepted the advice of its Technical Advisory Committee that "minimum caseloads play a critical role in promoting quality of care for specialized cardiac care services," id. at .04B (1) (c) [id. at 23], and concluded, "it is preferable for public policy to support a small number of higher volume cardiac surgery programs rather than a large number of programs performing at minimum or lower volumes." Id. [at 24]. It explained:

> "In many ways, recommended volume numbers are a surrogate measure for quality of care. The research conducted to date on the relationship between volume and outcome in many ways suggests the need for additional study of the factors involved in the process of care that contribute to improved outcomes. Although the relationship between minimum volume guidelines and risk-adjusted mortality for CABG surgery is a critical measure of quality, it is likely that volumes also relate to other dimensions of cardiac surgical program quality that are more difficult to measure. As noted in the previous report of the Technical Advisory Committee, these factors include the value of promoting higher volume angioplasty programs, the need to promote efficient utilization of the complex and limited resources required to provide high quality cardiac surgical care, and the need to encourage research and innovation in the treatment of coronary heart disease."

Id. [at 23]. Thus, the Commission established policies governing minimum utilization levels for adult and pediatric cardiac surgery programs, including:

> "Policy 1.0 There should be a minimum of 200 open heart surgery procedures annually in any institution in which open heart surgery is performed for adult patients.
>
> "Policy 1.1 There should be a minimum of 130 cardiac surgery procedures annually in any institution in which cardiac surgery is performed for only pediatric patients.
>
> "Policy 1.2 There should be a minimum of 200 adult open heart surgery procedures and a minimum of 50 pediatric cardiac surgery procedures annually in any institution in which both adult and pediatric cardiac surgery is performed."

Id. [at 23]. In addition, and consistently, to promote a system of higher volume cardiac surgery programs, the Commission established Policy 1.5: "The establishment of a new adult cardiac surgery program should permit existing programs to maintain patient volumes of at least 350 cases annually." Id. [at 25]. Together, these policy statements implement the Commission's vision of the cardiac surgery world, one in which existing programs are required to perform well above the minimum utilization level before new programs are considered. When its view of the relationship between volume and outcomes is considered, it is clear that that vision is based on, and looks to, quality concerns.

At bottom, the issue to be addressed in this case is whether there is unmet need for cardiac surgery services in the Metropolitan Region. To be sure, it is being addressed from the perspective of a regulation concerning the criteria to be applied in assessing the system capacity to handle the number of cases projected to enter the system, and, thus, may be

argued, or appear, to be only indirectly in dispute. Under the circumstances here extant, that is not at all true. There is no dispute as to what the objective, hard evidence reveals about capacity. Nor is there any dispute as to what it shows as to demand. Based on the actual performance of the hospitals authorized to perform cardiac surgery in the Region, whether using a three year or a one year period, and extrapolating from that performance, there either is an excess of capacity over demand or a slight deficit, but not enough of a deficit to justify certification of additional open heart surgery capacity. The Commission's data clearly, and expressly, reflects this fact. Its data also reflects that the demand in the Washington Region is flat, increasing by only 1.5 percent or less. Despite this hard, objective evidence and, it appears, based primarily on the comments of those few hospitals who sought increased competition and complained about the dysfunctionality in the Washington Region due to the dominance of a single hospital, the Commission adopted a standard that created a need for additional capacity by disregarding that hard, objective evidence. The appellant has it right when it points out:

> "By erasing 824 of Washington Hospital Center's cases (2,950 minus 2,126), the Commission succeeded, solely by operation of its irrebutable regulatory 'assumption,' in creating a 'net need' of 643 cases. ... Having thus created this 'net need' of 643 cases, the Commission can now conclude that a 'need' exists for an additional open heart surgery program in the Washington Region because this regulation-manufactured 'deficit' of 643 cases is more than the required safe minimum of 200 cases. .... The Commission reached its 'need

> conclusion' notwithstanding the undisputed fact that the actual, as distinguished from the regulation-manufactured, net need in the Washington Region is at most 89 cases and, if one applies the Commission's methodology, there is a negative net need — that is, capacity exceeds projected need — by 181 cases. In either case, there is, as a matter of fact, a plainly insufficient number of cases to warrant a new program."

This Court can discern no other reason for the regulation than to promote competition and, perhaps, thereby terminate the dominance of the Washington Hospital Center. The placement of a cap on the number of open heart operations that a hospital performs and, thus, for which it is given credit for having performed, does not change the fact that those operations, in fact, were performed. Nor does it reduce that hospital's capacity to perform that number of operations, and more; it simply permits another hospital or hospitals to benefit from a deemed excess capacity, to use the capacity that continues to exist, but, because of the regulation, is not allowed to be counted by the hospital that retains it. This "regulatory slight of hand" runs afoul of the Commission's own policies, see Policy 1.0; Policy 1.5, and of its commitment to "support[ing] a small number of higher volume cardiac surgery programs rather than a large number of programs performing at minimum or lower volumes." COMAR 10.24.17.04B (1) (c)[State Health Plan at 24]. It certainly is anti-factual.

It is undisputed that this Court has the right to determine for itself whether an administrative regulation exceeds the power of the agency. See § 10-125 of the State

Government Article. It is also true that, in most cases where an agency promulgates new regulations, we defer to the agency's decisions "... because they presumably make rules based upon their expertise in a particular field." Fogle v. H & G Restaurant, supra, 337 Md. at 455, 654 A.2d at 456. In the case of the Commission's adoption of COMAR 10.24.17, however, there is nothing to which to defer. The operative word in Fogle is "presumably." Here, what the Commission did required no expertise on its part; it simply made a determination that changed or, in effect, failed to give effect to an historical fact. To be sure, the fact that the Washington Hospital Center performed a specific number of procedures in a particular year does not mean that it could do so in future years. While that is, of course, true, it is simply common sense that what one has done in a prior year forms a logical basis from which to deduce what will, or can be done, in a subsequent year. Making an assumption that Washington Hospital Center will not, or can not, perform the same number of, or more, procedures, solely because of the desire to create a need not supported by the data on which the Commission has relied, and continues to rely, has much less force and is, therefore, much less reliable.

To be sure, the Commission has experimented with several different approaches to the measurement of net need in its 1990, 1997, and current Plans. It may be argued, as the appellee does, that these alternative approaches are no more arbitrary and artificial, having

no more relevance to need, than does the approach adopted by the Commission in this case. That is not a satisfactory answer. Certainly, a wrong that goes unchallenged cannot save from challenge and relief a subsequent wrong that is challenged. While actual experience may not be 100 percent determinative as to future capacity, it certainly comes a lot closer than an untested assumption, based on absolutely nothing, but the general desire to have the CON process opened up to greater accessibility and the cardiac surgery field subject to more competition. In any event, in none of the prior alternatives were the facts disregarded; it is one thing to assume something and quite another to refuse to recognize what the data that the agency collects, or requires to be collected, clearly shows. What speaks loudest is that the Commission maintained the same basic framework for CON reviews and, to achieve a result, increased competition in the Washington Region, that, at the least, is not totally consistent with the State Health Plan, simply adopted an assumption, which because it was made after the facts had been established, was a palpable fiction.

JUDGMENT OF THE CIRCUIT COURT FOR HOWARD COUNTY REVERSED; CASE REMANDED TO THAT COURT WITH DIRECTIONS TO ENTER JUDGMENT CONSISTENT WITH THIS OPINION. COSTS TO BE PAID BY THE APPELLEE.

IN THE COURT OF APPEALS OF MARYLAND

No. 47

September Term, 2002

MEDSTAR HEALTH

v.

MARYLAND HEALTH CARE COMMISSION

Bell, C.J.
Eldridge
Raker
Wilner
Cathell
Harrell
Battaglia,

JJ.

Dissenting Opinion by Wilner, J., in which Raker, J., and Harrell, J., join

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Filed: June 18, 2003

The Court reverses a determination by the Maryland Health Care Commission (MHCC) that the public health needs of the more than two million Marylanders who live in the Metropolitan Washington Region would best be served by allowing one additional hospital in that region to offer cardiac surgery services, because the Court believes that those needs are already being adequately served. With respect, I dissent.

The Court seems transfixed with the fact that, because Washington Hospital Center (WHC), which is located in the District of Columbia and thus is entirely immune from any regulation by the State of Maryland, is already performing 2,950 adult cardiac surgeries each year – more than 70% of the total number of such surgeries in the entire region – there is no need for any new program. As that hospital may expand its cardiac unit at will, without any control by the MHCC, it can, under the Court's view, not only maintain its dominance but effectively preclude any new program in the Metropolitan Washington Region of Maryland. That concerned the Commission, and it should concern the Court.

The issues raised by MedStar in this case cannot be viewed in isolation, but only in the context of the extensive set of laws and regulations governing health care policy in Maryland. In conformance with the National Health Planning and Resources Development Act of 1974, the General Assembly, through the enactment of what now appears as title 19, subtitle 1 of the Health-General Article, created and has periodically revised a comprehensive and structured regime for health care planning in Maryland. That regime is anchored in an express legislative finding, articulated in § 19-102, that the health care regulatory system "is a highly complex structure that needs to be constantly reevaluated and modified in order to

better reflect and be more responsive to the ever changing health care environment and the needs of the citizens of this State." Subject, of course, to the continuing jurisdiction and oversight of the Legislature, control over health care policy and planning is centered, at least in part, in MHCC, a unit within the Department of Health and Mental Hygiene and a successor agency to several previous commissions.

There are two major components to the regulatory system – the State Health Plan, which identifies both broadly and with particularity the health needs and resources throughout the State, and a Certificate of Need (CON) program, which allocates and rations health care resources in conformance with the State Health Plan to assure that the resources are adequate to meet the identified needs but are not excessive. The CON program, set forth in § 19-120 of the Health-General Article, requires a hospital to obtain a Certificate of Need from MHCC before it may commence certain new services, including any new cardiac surgery service. The Plan thus serves two functions: it establishes health care policy to guide the activities of MHCC and other health-related public agencies, and it serves as the legal foundation for MHCC's regulatory programs, in particular the CON program. In that latter regard, the Plan contains policies, standards, and service-specific need projection methodologies that MHCC uses in making CON decisions, including whether to permit any hospital not already having a cardiac surgery service to develop and offer one.

MHCC is charged generally, under § 19-103(c), with developing health care cost containment strategies "to help provide access to appropriate quality health care services for

all Marylanders," and with promoting the development of a health regulatory system "that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost." Section 19-115 directs the Commission to perform analyses and studies that relate to the adequacy of services and financial resources to meet the needs of the population, the distribution and allocation of health care resources, costs of health care in relation to available financial resources, and any other appropriate matter. The Secretary of Health and Mental Hygiene is required by § 19-116 to assist MHCC by providing for a study of systems capacity in health services. That study is (1) to determine for all health delivery facilities "where capacity should be increased or decreased to better meet the needs of the population," (2) to "examine and describe the implementation methods and tools by which capacity should be altered to better meet the needs," and (3) to "assess the impact of those methods and tools on the communities and [the] health care delivery system.."

Section 19-118 (formerly § 19-121) directs MHCC, at least every five years, to adopt a State Health Plan. Under former § 19-121, which controls this case, the plan was required to include, among other things, (1) the goals and policies for the State's health care system, (2) the identification of unmet needs, excess services, minimum access criteria, and services to be regionalized, and (3) the methodologies, standards, and criteria for CON review. In addition, MHCC is required to develop standards and policies, consistent with the State Health Plan, that relate to the CON program. Those standards must address "the availability,

accessibility, cost, and quality of health care" and must be reviewed and revised periodically "to reflect new developments in health planning, delivery, and technology."

The State Health Plan is in the form of regulations which, because of their bulk and accessibility in depository centers throughout the State, are incorporated by reference into the appropriate chapter of the Code of Maryland Regulations (COMAR). *See* COMAR, title10 (Department of Health and Mental Hygiene), subtitle 24 (Maryland Health Care Commission), chapters 07 through 17. Most of those chapters are topical in nature and deal with a broad type of medical service. At issue here is Chapter 17, dealing with Cardiac Surgery and Therapeutic Catheterization Services, which, for convenience, we shall refer to as SHP-Cardiac Services.

As noted, former §19-121(a)(2)(iii) required that the State Health Plan include the identification of "services to be regionalized," which, in its Plan, the Commission construed as referring to "the appropriate distribution of services with regard to their geographic location and level of care." SHP-Cardiac Services at 4, COMAR 10.24.17.02D. In conformance with § 19-121, MHCC divided the State into four service regions for purposes of SHP-Cardiac Services – Western Maryland, Metropolitan Washington, Metropolitan Baltimore, and Eastern Shore. We are concerned in this case with the Metropolitan Washington Region, which comprises Calvert, Charles, Montgomery, Prince George's, and St. Mary's Counties and the District of Columbia.

Notwithstanding that Maryland residents in the other three areas may use medical facilities or resources that are located out of State, the Metropolitan Washington Region is the only service area for which MHCC, in determining resource capacity, considers facilities and resources that are located outside the State of Maryland – in the District of Columbia. MHCC, of course, has no authority to regulate medical facilities or health care delivery in the District, but because the hospitals there serve so many Marylanders living in the Metropolitan Washington Region, the plan for that region takes account of the kinds, levels, and quality of the services rendered by those facilities in determining whether there is a need for new or additional services in the region.

Based on findings and recommendations made by well-respected medical societies, MHCC adopted the view of its Technical Advisory Committee that "minimum caseloads play a critical role in promoting quality of care for specialized cardiac care services," and thus concluded that "it is preferable for public policy to support a small number of higher volume cardiac surgery programs rather than a large number of programs performing at minimum or lower volumes." SHP-Cardiac Services at 23-24, COMAR 10.24.17.04B(1)c. In furtherance of that conclusion, MHCC adopted, as part of the current SHP-Cardiac Services, a requirement that there should be a minimum of 200 open heart surgery procedures performed annually in any institution in which open heart surgery is performed for adult patients, and that a CON for the establishment of a new cardiac surgery program will require, as a condition of issuance, that the program achieve minimum volume standards within 24

months of beginning operation and maintain the minimum utilization level in each subsequent year of operation.

At present, six hospitals perform open heart surgery in the Metropolitan Washington Region – two in Maryland and four in the District. WHC is one of those hospitals and, indeed, predominates in the performance of adult cardiac surgery. The data for 1999 show that:

(1) Prince George's Hospital Center (Md.) performed 120 adult open heart surgeries, up from 91 in 1998;

(2) Washington Adventist Hospital (Md.) performed 817, the same as in 1998;

(3) Georgetown University Hospital (D.C.) performed 140, down from 301 in 1998;

(4) George Washington University Hospital (D.C.) was assumed to have performed 85, the same as in 1998;[1]

(5) Howard University Hospital (D.C.) performed 50, up from 46 in 1998; and

(6) WHC performed 2,950, up from 2,709 in 1998, the former representing about 71% of all the adult cardiac surgeries performed in the service area.[2]

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[1] George Washington Hospital did not report data for 1999. MHCC therefore used 1998 data for that hospital. The record does not indicate how many open heart surgeries were performed at George Washington Hospital in 1999.

[2] Some evidence was presented that MedStar acquired Georgetown University Hospital, that the WHC physician group had taken over the cardiovascular programs at Washington Adventist Hospital and Georgetown and that, at least in the summer of 2000, that physician group was performing 95% of the cardiac surgery in the Metropolitan Washington Region. By way of contrast, the distribution in the Metropolitan Baltimore Region, with slightly more total

(continued...)

The State Health Plan is usually updated in segments, rather than all at one time. The most recent SHP-Cardiac Services, prior to the one now before us, was adopted in 1997; that replaced the chapter adopted in 1990. It was determined in 1997 that the cardiac surgery segment should be reviewed and updated on a three-year cycle, rather than on a five-year cycle.

A key feature of the SHP-Cardiac Services is MHCC's estimate of the expected number of open heart surgery cases in a future target year. In the 1990 plan, the Commission estimated that number based on the capacity of then-existing cardiac surgery programs, and it defined that capacity as the greater of 350 cases per hospital or the highest annual volume ever attained by the hospital in the most recent years of accurate available data (or, if the hospital had not performed at least 200 cases per year for the most recent three years, the actual volume of cases performed during the base year). The 1997 plan changed that methodology and adopted, instead, one that had two components: (1) an estimate of the demand for open heart surgery based on the Commission's analysis of trends in regional, age-specific use rates and changes in the size and composition of the population; and (2) an estimate of available system capacity based on the number of operating rooms dedicated to

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[2](...continued)
surgeries, was far more even. St. Joseph's Hospital performed 1,308 adult cardiac surgeries (29%); Johns Hopkins Hospital performed 1,100 (25%); Sinai Hospital performed 541 (12%); Union Memorial Hospital performed 893 (20%); and University of Maryland Hospital performed 596 (13%). There was no evidence of any concentration in the Metropolitan Baltimore Region in one physician group. One hospital, Peninsula Regional Medical Center, performs cardiac surgery for the Eastern Shore Area. In 1999, a CON was approved for one facility in Western Maryland.

the open heart surgery program. With respect to that second factor, the 1997 plan assumed as a benchmark that two surgeries would be performed each day, five days a week, for each dedicated operating room, producing an aggregate of 500 cases per operating room per year (5 days/week x 50 weeks/year = 250 days x two cases/day = 500).

In December, 1998, the Commission reconvened a Technical Advisory Committee (TAC) that had assisted in the development of the 1997 plan. That committee held 13 open meetings between December, 1998, and November, 1999. In its report to MHCC in December, 1999, the TAC noted a number of flaws in the then-current benchmark assumption for program capacity. Data, both nationally and in the Maryland-D.C. area, showed significant variations in actual operating room utilization, ranging, in the Maryland-D.C. area, from 0.24 cases per operating room at George Washington University to 2.07 cases per operating room at WHC. Not surprisingly, the data showed that the greater the number of cases overall, the greater the utilization per operating room. Given that significant disparity, the TAC recommended that the capacity benchmark of two cases per dedicated operating room, used in the 1997 plan, be eliminated and that the measurement of available system capacity be "redefined to incorporate other factors such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional open heart surgery programs in Maryland." FINAL REPORT OF THE TECHNICAL ADVISORY COMMITTEE ON CARDIOVASCULAR SERVICES, Maryland Health Care Commission, at 26 (1999).

The recommendations of the TAC were reviewed by the MHCC Staff which, in June, 2000, issued a White Paper that identified certain key issues and discussed various policy options for dealing with those issues. One of the issues considered was the TAC's recommendation that the benchmark assumption in the 1997 plan be eliminated. Like the TAC, the MHCC Staff also found fault with the 1997 approach. It pointed out that the number of operating rooms was but one component of an open heart surgery service – that also important were the number of open heart surgery teams and the availability of post-operative care facilities and staff.

Because open heart surgery service is staff, rather than capital, intensive, the MHCC Staff questioned whether the number of operating rooms was the most appropriate benchmark for measuring capacity. *See* WHITE PAPER: POLICY ISSUES IN PLANNING AND REGULATING OPEN HEART SURGERY SERVICES IN MARYLAND, Maryland Health Care Commission, at 21 (2000). From a regulatory point of view, the Staff raised the concern that existing programs could add dedicated operating rooms without seeking CON approval and thus expand capacity without Commission review. *Id.* The Staff pointed out the wide variations that would occur in capacity determinations depending on the benchmark assumption: at 500 cases/operating room, the capacity would be 6,500 for the Metropolitan Washington Region; at 350 (the assumption used in the 1990 plan), the capacity would be 4,550. *Id.* It offered as an alternative option the determination of capacity based on the actual performance of the program, which, in all areas of the State, was considerably less (in

the most recent three years) than the number-of-operating-rooms approach, even using the lesser benchmark of 350 per year. *Id*. at 21-22.

MHCC solicited and received comment on the White Paper, including written comment from 21 hospitals and other agencies throughout the State. Several of the hospitals attacked both the existing methodology for establishing net need and the recommended alternatives, complaining that, when coupled with the CON requirement, they served to protect a small group of hospitals – the "haves" – and unnecessarily denied freedom of choice to patients. Anne Arundel Medical Center charged that the existing CON process "has granted a franchise to a handful of hospitals, insulating them from competition, while forcing all other Maryland hospitals and, more importantly, the patients they serve, to leave their hospital, their community, their physicians, and their family support system to go to one of the chosen few for what should now be regarded as basic, if high tech, care." That hospital suggested that each program be measured by (1) the lower of its actual utilization or the utilization standard adopted under the quality of care section of the Plan, or (2) the lower of its actual utilization "or a reasonable cap on the number of procedures that will be counted at any one hospital – whether that volume cap is 350 or 500 cases or some lower number justified by the literature." St. Agnes Hospital, in Baltimore, also urged MHCC to consider a cap as an alternative in measuring a program's capacity. It recommended a cap of 400 cases or double the American College of Cardiology standard, and suggested that "[a]ny cases above that number should not be counted as existing capacity."

A cap was urged as well by Suburban Hospital, which complained in particular about the "dysfunctional" market in the Metropolitan Washington Region. Suburban noted that WHC's share of the total number of cardiac surgeries for the region had increased from 50% in 1994, to 58% in 1996, to 71% in 1999, with a corresponding decline in Washington Adventist Hospital's share from 925 surgeries in 1994 to 817 cases in 1999. It asked that a 40% cap be assigned to the capacity of each existing program in the Baltimore and Washington regions and argued that such a cap would remedy the limited choice available in the Washington area market and allow MHCC to return to a policy of managing growth in cardiac surgery program development.

Greater Baltimore Medical Center echoed the complaint that the existing program "forces people to travel outside of their community for necessary cardiac and other specialty care" and that "[h]aving additional successful interventional and open-heart programs improves access through expanded choices." It urged that additional programs could be supported under any of the need calculations under consideration and that it was only the allocation of the need and the calculation of capacity that prevented hospitals from meeting the need that exists. In that regard, it complained that both of the TAC options were unacceptable – that the dedicated operating room standard was irrelevant to patient care, that the actual utilization standard served only to protect the chosen few, and that "[i]f capacity is then measured by the number of patients treated at existing programs, without any cap on that capacity, capacity will always equal need." It explained that "as long as the 'haves' keep

their collective doors open, there will never be any 'need' in Central Maryland because the aggregate capacity of the 'haves' will always increase to consume any projected need." This was a point made by the White Paper as well.

The Health Services Cost Review Commission expressed its support of promoting competition and noted that an increased number of open heart surgery services would "increase the level of competition between programs and permit greater access for patients," although it did warn that the "proliferation of services that operate at inefficient volume levels" would not be wise. Holy Cross Hospital, which is located in the Metropolitan Washington Region, expressed its support for "a balanced system of improved access to care and increased choice of cardiac surgery services in suburban Maryland" and for "market reform to support price and service competition in this highly concentrated market." To achieve that goal, it, too, suggested a "cap" in determining capacity – to define the capacity of any program as "the higher of 800 cases or 40% of the projected gross need for the hospital's planning area."

Johns Hopkins Hospital called attention to the fact that the Metropolitan Washington Region "does not enjoy the same program balance in market share as that of metropolitan Baltimore," and that residents in the Maryland suburbs of the District "have little choice when selecting care for cardiovascular surgery." Noting the 71% market share enjoyed by WHC (which it erroneously asserted was 75%) and the 95% market share enjoyed by the one physician group based at WHC, Hopkins observed that "[w]ithout choice and competition,

the State of Maryland and its residents are placed in a vulnerable situation." It pointed out also that the State paid millions of dollars to the Washington hospitals for patients covered under Maryland entitlement programs and that those funds could remain in Maryland if residents in the Metropolitan Washington Region "had more than one viable option for cardiovascular care in Maryland hospitals."

On July 21, 2000, MHCC held a public hearing on the White Paper, at which testimony was presented from representatives of both the "haves" and the "have-nots." Two months later, the MHCC Staff released its analysis of the public comments and Staff recommendations. It noted the TAC recommendations that the 2 case/operating room benchmark be eliminated and that capacity measurement be redefined to include other factors, and observed that the public comments on the measurement issue "underscore the significant limitations of the two approaches used to date in the State Health Plan," including the fact that, under the operating room approach, "existing programs may add operating rooms without regulatory approval." WHITE PAPER: POLICY ISSUES IN PLANNING & REGULATING OPEN HEART SURGERY SERVICES IN MARYLAND, Analysis of Public Comments & Staff Recommendations, Maryland Health Care Commission, at 13 (2000). The Staff noted, in particular, the heavy, and increasing, concentration of cardiac surgery in the Metropolitan Washington Region in WHC. It found merit in the cap approach suggested by several of the hospitals and recommended that the capacity of any program not exceed the higher of 800 cases or 50% of the projected gross need for the planning region. *Id*. at 15-16.

MHCC solicited and received additional public comments on the Staff analysis, and, in October, 2000, its Staff issued a review of those comments and the Staff's own further recommendations. Some of the comments, including those from Washington Adventist Hospital and MedStar, severely criticized the Staff recommendation to impose a cap in measuring capacity, urging that it was inappropriate for MHCC to consider market share in measuring capacity. Other comments supported the concept of a cap but continued to urge that the cap be set at 40% rather than 50% of the regional need. The Staff confirmed its recommendation that, for purposes of the statistical calculation, the capacity of any program not exceed the higher of 800 cases or 50% of the projected gross need. With respect to the comment that it was inappropriate for MHCC to consider market share, the Staff noted that "planning policies governing program size [were] not unreasonable and clearly not outside the scope of the Commission's mandate."

In conformance with its views, the Staff drafted a proposed amendment to the SHP-Cardiac Services for consideration by MHCC that included, as part of the new methodology for measuring capacity, the 800 cases/50% cap on individual programs. With that cap, WHC's capacity, which otherwise would have been its actual 1999 performance of 2,950 open heart surgeries, was calculated at 2,126 cases (50% of the projected need of 4,251 cases in the Metropolitan Washington Region), a reduction of 824 cases. That served to reduce the capacity for the region from 4,432 cases to 3,608 cases. When compared to the projected need of 4,251 cases, that left a deficit of 643 cases, thereby producing a need for at least one

new program in the region. The Commission considered the Staff proposal at its open meeting on November 21, 2000, and approved it as a proposed amendatory regulation.

The proposal was sent to the AELR Committee and was published for comment in the Maryland Register. *See* Maryland Code, § 1-110 of the State Government Article; 28-2 Md. Reg. 126 (Jan. 26, 2001). Although individual members of the AELR Committee, in letters to the Governor, the presiding officers of the Senate and House of Delegates, and MHCC, expressed concern with or opposition to features of the plan, including the new methodology for measuring capacity, the AELR Committee itself never took a formal vote with respect to the proposed regulation and therefore never formally opposed its adoption. *See* Maryland Code, § 10-111.1 of the State Government Article. MHCC held another evidentiary hearing on February 8, 2001, at which 39 people testified. On April 19, 2001, MHCC considered that testimony and the further comment received with respect to the proposed regulation and, by an 8-1 vote, adopted the regulation, to take effect May 14, 2001. Notice of the final adoption was published in the Maryland Register. *See* 28-9 Md. Reg. 885 (May 4, 2001).

MedStar wasted no time in challenging the regulation, filing its action for declaratory judgment on the very day that the new regulation took effect. In its amended complaint – the one now before us – it complained (1) that the cap adopted as part of the measurement of capacity was arbitrary, capricious, and unauthorized; (2) that the regulation, having been opposed by a majority of the members of the AELR Committee and not having received the formal approval of the Governor, was not validly adopted; and (3) that the regulation

discriminated against out-of-State cardiac surgery programs in violation of Article I, § 8, Clause 3 of the U.S. Constitution (the Commerce Clause). The Circuit Court found no merit in any of those complaints and entered a declaratory judgment that: MHCC acted consistently with its statutory duties and obligations in its promulgation of SHP-Cardiac Services; that the portion thereof that relates to the establishment of cardiac surgery programs did not violate either the Commerce Clause of the U.S. Constitution or § 10-111.1 of the State Government Article; and that it was validly adopted.

MedStar's amended complaint raised two issues under Maryland law – that the cap applied to WHC was unauthorized and arbitrary and that the entire SHP-Cardiac Services was invalid because it was adopted over the opposition of a majority of the members of the AELR Committee. The second issue has effectively been abandoned and, in my view, had utterly no merit in any event.

MedStar's argument, which the Court has found meritorious, is that MHCC is required by its governing statute to determine whether there is a need for additional cardiac surgery services in Maryland and that, in determining whether such a need exists, it cannot use as a basis a number less than the number of surgeries actually being performed at the present time. There can be no lawful finding of need, the Court concludes, if the six hospitals in the region are already performing all of the open heart surgeries. Accordingly, it holds that there is no authority for MHCC to use an artificial number, which, in its view, is what a market share cap creates. The Court regards MHCC's decision to use such a cap

and, upon such use, to find a need for one additional program in the Metropolitan Washington Region, as an error of law subject to a *de novo* standard of review.

In adopting a market share cap to help measure capacity, as part of SHP-Cardiac Services, MHCC acted in a quasi-legislative capacity. *Adventist v. Suburban*, 350 Md. 104, 122, 711 A.2d 158, 167 (1998) ("The development, adoption, and updating of the [State Health] plan is a quasi-legislative function"); *see also Fogle v. H & G Restaurant*, 337 Md. 441, 453, 654 A.2d 449, 455 (1995). The cap was part of a regulation.

Although, on judicial review of a regulation, we are required to determine for ourselves whether the regulation exceeds the statutory authority of the agency (*see* State Government Article, § 10-125), we have made clear that "courts should generally defer to agencies' decisions in promulgating new regulations because they presumably make rules based upon their expertise in a particular field." *Fogle, supra*, 337 Md. at 455, 654 A.2d at 456; *see also Ideal Federal v. Murphy*, 339 Md. 446, 461, 663 A.2d 1272, 1279 (1995) (citing *Udall v. Tallman*, 380 U.S. 1, 16, 85 S. Ct. 792, 801, 13 L. Ed. 2d 616, 625 (1965) for the proposition that "[w]hen faced with a problem of statutory construction, this Court shows great deference to the interpretation given the statute by the officers or agency charged with its administration") and *MTA v. King*, 369 Md. 274, 288, 799 A.2d 1246, 1254 (2002). Pointedly, we added in *Fogle* that "[t]his is especially true of agencies working in the area of health and safety, which rely extensively on their specialized knowledge of that area in

promulgating regulations." *Fogle*, *supra*, 337 Md. at 455, 654 A.2d at 456. The Court seems to acknowledge that principle but then, in my view, effectively disregards it.

Throughout the governing statute, the Legislature has directed MHCC, in terms of both the State Health Plan and its CON review, to consider, among other things, cost, availability, and accessibility of health care services. Section 19-121(a), as it appeared before the 2001 amendments, directed that the State Health Plan include the goals and policies for Maryland's health care system, the identification of unmet needs, excess services, *minimum access criteria*, and services to be regionalized, and the methodologies, standards, and criteria for CON review. Section 19-121(e) also required MHCC to develop standards and policies consistent with the State Health Plan that relate to the CON program and directed that those standards should address the *availability, accessibility, cost, and quality* of health care.

Those directions are broad ones. The Legislature, wisely, has not chosen to direct or limit MHCC with respect to the specifics of the State Health Plan but has left those specifics to the Commission's expertise, giving force to the judgment expressed in § 19-102 that the health care regulatory system "is a highly complex structure that needs to be constantly reevaluated and modified in order to better reflect and be more responsive to the ever changing health care environment and the needs of the citizens of this State." There is, as MedStar complains, no statute that specifically authorizes MHCC to impose a market share cap in assessing capacity, but there is also no statute that forbids that approach or that

requires any other particular method of measuring capacity. There is no statute that specifically authorized the Commission to assume a capacity of 350 surgeries per hospital per year, as it did in the 1990 Plan, or to adopt a benchmark of 2 surgeries per dedicated operating room, five days a week, 50 weeks a year, as it did in the 1997 Plan. There is no statute that requires MHCC to consider the actual number of surgeries performed in District of Columbia hospitals, some of which, no doubt, involve residents from Virginia and perhaps other States and countries as well, in deciding capacity for the Metropolitan Washington Region. The fact that WHC actually performed a total of 2,950 adult open heart surgeries in 1999 does not mean that, in any future year, that hospital could accommodate 2,950 Maryland residents from the Metropolitan Washington Region who may need such surgery.

When there is a broad delegation of authority to an agency to regulate an area of activity, especially a complex area of activity, we have not required augmenting delegations dealing with specific topics included within the broad grant. *See Christ v. Department*, 335 Md. 427, 437-40, 644 A.2d 34, 38-39 (1994); *Lussier v. Md. Racing Commission*, 343 Md. 681, 688-89, 684 A.2d 804, 807-08 (1996). Rather, we have "consistently held that, where the Legislature has delegated such broad authority to a state administrative agency to promulgate regulations in an area, the agency's regulations are valid under the statute if they do not contradict the statutory language or purpose." *Lussier, supra*, 343 Md. at 688, 684 A.2d at 807.

As noted, the Commission has experimented with several different approaches to the measurement of net need in its 1990, 1997, and current Plans. Although the Court views the market share cap as arbitrary and artificial, having no relevance to need, it is no more so than the alternative approaches. Using 350 surgeries per hospital, or even the actual number of surgeries performed in a given year, as a measure of capacity or need has no direct relevance to the actual capacity of the hospitals to perform open heart surgeries or to what the need for such surgeries may be. Nor, for the reasons set forth by the TAC and the MHCC Staff, does the assumption of 500 surgeries per dedicated operating room realistically measure either capacity or need. Apart from the artificiality of that approach, it effectively allows a few hospitals to dominate the market forever and escape MHCC regulation, by simply opening new operating rooms without the need for CON approval. That prospect was particularly acute in the Metropolitan Washington Region, where one hospital, WHC, had dramatically increased its dominance from 50% to 71% in just five years.

The imposition of a market share cap was not an arbitrary or capricious decision. As noted, several hospitals in both the Washington and Baltimore metropolitan areas expressed concern over the concentration of open heart surgery, in a major area of the State comprising five counties with nearly 2 million people, in one hospital and one physician group. That concern was expressed as well by the MHCC Staff. Much of the concern was patient-related – that patients were being forced to leave their own physicians and communities to have surgery elsewhere. The result was decreased accessibility of the service to Maryland

residents and a denial of patient choice. Another concern, noted by the Health Services Cost Review Commission, was the effect the lack of competition had on the cost of the service – that "increased competitiveness may result in additional cost savings for the health care system as a whole." A market share cap was one reasonable method suggested by the MHCC Staff and by several of the hospitals to address those concerns. The hospitals recommending a market share cap urged that the cap be set at 40% of the regional need; the Commission opted for a 50% cap.

The record not only fails to support the Court's accusation of arbitrary prejudice on the part of MHCC but demonstrates precisely the opposite – that the Commission solicited and considered extensive and continuous public input and that it was guided not only by that input but as well by the views of the TAC it created and its own professional Staff. It obviously found some general merit in the view of Anne Arundel Medical Center:

> "Imposing a reasonable limit on the number of procedures counted from any one center – solely for the purpose of estimating capacity under the Plan – balances the need for access and maintaining quality. It will also provide competition to lower prices, thereby meeting all three prongs of health planning – increasing access, maintaining quality, and promoting cost efficiency."

That view, shared by many of the groups who provided comment, is consistent with and supports two of the governing principles adopted by MHCC in the SHP-Cardiac Services: (1) "Specialized health care services should be assessed as part of the overall health care delivery system" (COMAR 10.24.17.03B(2)), and (2) "Any expansion of the number

or distribution of specialized health care services should allow the proposed and existing services within the region to achieve and sustain the volumes associated with optimal health outcomes and cost-efficiency" (COMAR 10.24.17.03B(3)). In explaining the first of these principles, the Commission concluded that "[t]o avoid viewing specialized health care services in isolation, the Commission will place a high priority on systematic integration and look at the interaction of the specialized services with other components of the health care delivery system within the region." COMAR 10.24.17.03B(2). In explaining the second, it stated:

> "In measuring system capacity to determine whether additional programs should be considered, *the Commission will seek to balance access, quality, and cost considerations.* The Commission does not regulate the number of operating rooms that can be used for open heart surgery in Maryland; rather it regulates the number of open heart surgery programs. Accordingly, the measurement of system capacity must consider other factors. Those factors include actual program utilization *and the distribution of caseload levels at which it would be appropriate to consider the establishment of a new program to enhance access without negatively impacting system quality and cost*."

COMAR 10.24.17.03B(3) (emphasis added).

What all of this reveals is that the Commission attempted to achieve a balance between assuring high quality of the service, which tends toward limiting the number of programs, and assuring better access and lower cost, which tends toward greater competition and thus more programs. That is the very kind of decision that the Legislature entrusted to

MHCC's expertise and judgment. It is the kind of decision that this Court should be obliged to respect.

Because the Court strikes down the Commission's regulation on State law grounds, it does not reach MedStar's alternative complaint that the regulation constitutes an invalid attempt to regulate interstate commerce. Upon the assertion that the market share cap "is targeted deliberately and solely at a single out-of-state institution (Washington Hospital Center), and discriminates deliberately against that targeted out-of-state institution, and unlawfully favors in-state institutions at the expense of the single targeted out-of-state institution," MedStar argues that the cap violates the Commerce Clause in the United States Constitution because it "was the product of constitutionally impermissible motives and it operates in a constitutionally impermissible fashion."

The most fundamental problem with that argument is that none of its underlying premises is even marginally supported by this record. The market share cap was not targeted at any out-of-State institution; it does not discriminate against any out-of-State institution; it does not favor in-State institutions; it was not the product of Constitutionally impermissible motives; and it does not operate in a Constitutionally impermissible fashion.

Article I, § 8, Clause 3 of the United States Constitution grants to Congress the power to regulate interstate commerce. At issue is not that affirmative grant directly but the negative implication derived from it. That implication, which has received the appellation the "dormant" Commerce Clause, is to the effect that, even in situations in which Congress

has not acted either affirmatively to regulate an interstate activity or specifically to bar the States from doing so, its very power to regulate precludes the States from acting in ways that would burden interstate commerce.

Although the force of that negative implication flowed and ebbed in early Supreme Court jurisprudence, the Court, in *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 65 S. Ct. 1515, 89 L. Ed. 1915 (1945), struck a balance that continues to define what States may and may not do. The Court there noted that, in the absence of conflicting legislation by Congress, there is "a residuum of power in the state to make laws governing matters of local concern which nevertheless in some measure affect interstate commerce or even, to some extent, regulate it." *Id*. at 767, 65 S. Ct. at 1519, 89 L. Ed. at 1923. Later, in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S. Ct. 844, 847, 25 L. Ed. 2d 174, 178 (1970), the Court defined the balance thusly:

> "Although the criteria for determining the validity of state statutes affecting interstate commerce have been variously stated, the general rule that emerges can be phrased as follows: Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."

It is clear from this record that the market share cap approach was designed, and is effective, as part of an evenhanded regulation of a matter of legitimate local public interest – the assessment of health needs for the State of Maryland. Although the unusual concentration in the Metropolitan Washington Region was obviously a matter of particular

concern, the call for a market share cap came from many hospitals not in that area and was adopted as a Statewide standard. If the market in the Metropolitan Baltimore Region were to become as "dysfunctional" as that in the Metropolitan Washington Region was alleged to be, the standard would operate there as well. Should one of the Maryland-based hospitals in the Metropolitan Washington Region develop a lower cost/greater convenience/higher quality service and, as a result, increase its market share to more than 50% of the total need, it too would become subject to the market share cap. In the words of the Supreme Court in *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 87, 107 S. Ct. 1637, 1649, 95 L. Ed. 2d 67, 84 (1987) (quoting *Lewis v. BT Investment Managers, Inc.*, 447 U.S. 27, 36, 100 S. Ct. 2009, 2016, 64 L. Ed. 2d 702, 712 (1980)), the market share cap "visits its effects equally upon both interstate and local business." There is no basis in this record for a conclusion that WHC was "targeted," or that there was any effort to discriminate against it or any other hospital, in or out of Maryland.

Nor do I see any effective burden on WHC. Applying a market share cap to its program for the purpose of estimating overall capacity in the region in no way limits the number of surgeries that hospital can perform and in no way precludes, or even discourages, Maryland citizens from continuing to have their open heart surgery performed at that hospital. If, as a result of the finding of a net need for one additional program in the Metropolitan Washington Region, another program is authorized, WHC, along with the other five hospitals currently providing cardiac surgery service in the region, may face some

additional competition for patients, but I am aware of no pronouncement from the Supreme Court (and none has been cited by MedStar) to the effect that subjecting an out-of-State business to competition from an in-State business constitutes a burden on interstate commerce. It is, in fact, precisely the converse that States may not do – restrict access by out-of-State entities to in-State economic activity. I cannot conceive of how the possible allowance of a hospital to enter a restricted market, thereby subjecting that market to increased competition, can constitute an impermissible burden on interstate commerce.

The gravamen of MedStar's complaint is that MHCC created a need for an additional open heart surgery program in the Metropolitan Washington Region where none actually existed and that it created that need by manipulating the relevant data. That manipulation, MedStar complains, was unauthorized by statute and, because it operated against an out-of-State entity, violated the Commerce Clause.

My review of the record, however, shows that MHCC's alleged "manipulation" was merely the product of a considered and well-supported policy choice – that a program's capacity should be measured by its prior actual use, with a market share constraint to act as an upper limit. Such a constraint, MHCC found, was necessary to preserve access to low-cost, quality open heart surgery services. As that goal was central to the Commission's statutory purpose and responsibility, the constraint cannot be considered as unauthorized, and, as it operates neutrally and without any direct burden on any individual hospital, it cannot be said to constitute an impermissible burden on interstate commerce. MHCC's

decision to impose a market share cap merely reflects its choice between different methodologies in measuring program capacity. Its decision is not to be second-guessed by the courts.

Judges Raker and Harrell have authorized me to state that they join in this dissenting opinion.