Medstar Health, et al v. Maryland Health Care Commission, et al, No. 37, Sept. Term 2005.

THE MARYLAND HEALTH CARE COMMISSION ACTED WITHIN ITS AUTHORITY WHEN IT PROMULGATED A REGULATION THAT ESTABLISHED A THRESHOLD TEST THAT ALLOWED THE COMMISSION TO CONSIDER PROPOSALS FOR ESTABLISHING NEW CARDIAC SURGERY PROGRAMS IN REGIONS WHERE ONE OR MORE EXISTING PROGRAMS FAILED TO MEET LONGSTANDING MINIMUM VOLUME STANDARDS FOR TWO CONSECUTIVE YEARS; ANY PROPOSAL FOR A NEW PROGRAM WOULD STILL HAVE TO SATISFY AN EXTENSIVE REVIEW THAT WOULD ADDRESS ALL OF THE REQUIRED STATUTORY FACTORS CONTAINED IN THE COMMISSION'S ENABLING STATUTE.

In the Circuit Court for Howard County
Case No. C-04-58068

IN THE COURT OF APPEALS OF MARYLAND

No. 37

September Term, 2005

MEDSTAR HEALTH, ET AL.

v.

MARYLAND HEALTH CARE COMMISSION, ET AL.

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

JJ.

Opinion by Wilner, J.
Bell, C.J., Cathell and Battaglia, JJ., Dissent

Filed: March 7, 2006

We are faced, for the second time in three years, with a challenge to a part of the State Health Plan (SHP) dealing with cardiac surgery services in the Washington, D.C. metropolitan area. Some of the contextual background to this case was set forth in *MedStar v. Health Care Commission*, 376 Md. 1, 827 A.2d 83 (2003) (*MedStar I*), which involved an attack on the 2001 SHP. The challenge here is to the 2004 SHP. We need not repeat all that was covered in *MedStar I* and shall recite only what is particularly relevant to the issues raised here by appellants MedStar Health and Washington Adventist Hospital.

BACKGROUND

In conformance with the National Health Planning and Resources Development Act of 1974 and through the enactment of what is now Maryland Code, title 9, subtitle 1 of the Health-General Article, the General Assembly created and has periodically revised a comprehensive regime for regulating health care resources in Maryland. There are two principal, and inter-related, components of the regulatory scheme – the SHP, designed to identify the health needs and resources throughout the State, and a Certificate of Need (CON) program, designed to allocate and ration health care resources in conformance with the SHP.[1]

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[1] The SHP itself recognizes its dual purpose: to establish health care policy to guide the actions of the Commission and other health-related public agencies, and to serve as "the legal foundation for the Commission's decisions in its regulatory programs." *See State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services*, incorporated by reference into COMAR 10.24.17.02 A(2) (March 15, 2004). To achieve the second objective, the SHP "contains policies, standards, and methodologies that the Commission uses in making Certificate of Need decisions. *Id*.

The development and implementation of both components were, and to a large extent still are, entrusted to the Maryland Health Care Commission, created by the Legislature as an independent unit within the State Department of Health and Mental Hygiene.[2]

The SHP is in the form of regulations incorporated by reference in COMAR, title 19, subtitle 24, chapters 07 through 18. Chapter 17 deals with Cardiac Surgery and Therapeutic Catheterization Services (SHP-Cardiac Services). In conformance with the legislative finding expressed in § 19-102(a) 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 needs of the citizens of this State," the Commission is required to review the SHP annually and update it at least every five years. *See* § 19-118(a) and (b). In 1999, the Commission decided to revise the cardiac services part of the Plan on a tri-annual basis. In 2001, it revised the 1998 plan, and in 2004, it revised the 2001 plan.

As noted, the CON program is an allocation and rationing device, designed to assure that health care resources, which are expensive to create and maintain, are sufficient to meet the public need, but not excessive. The law requires a person to obtain a CON issued by the Commission before developing, operating, or participating in the creation or relocation of any health care facility or health care service offered by a health care facility. § 19-120.

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[2] As we shall point out later, in 2001, the General Assembly transferred much of the general health planning responsibility to the Department of Health and Mental Hygiene.

Section 19-118(a) requires that the SHP include "[t]he methodologies, standards, and criteria for certificate of need review." Those standards must "address the availability, accessibility, cost, and quality of health care" and are to be "reviewed and revised periodically to reflect new developments in health planning, delivery, and technology." § 19-118(d). Section 19-120(c) directs the Commission to adopt regulations for "applying for and issuing certificates of need." *See*, in general, *Adventist v. Suburban*, 350 Md. 104, 711 A.2d 158 (1998).

In conformance with the legislative direction, now found in § 19-117(a), to designate health service areas in the State, the Commission, for purposes of SHP-Cardiac Services, has divided the State into four service regions – Western Maryland, Metropolitan Washington, Metropolitan Baltimore, and Eastern Shore. The Metropolitan Washington region comprises five Maryland counties – Calvert, Charles, Montgomery, Prince George's, and St. Mary's – and the District of Columbia. It is the only one of the four regions that includes an area outside of Maryland – the District of Columbia – in which the Commission has no jurisdiction but nonetheless considers facilities and resources located there in devising the SHP.

After considerable study, the Commission, several years ago, reached the conclusion that it was generally preferable, as a matter of public policy, to support a small number of high-volume cardiac surgery programs than a large number of lower volume programs. In furtherance of that conclusion, the Commission adopted and maintains, as part of the 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.

When the Commission's 2001 SHP-Cardiac Services plan was developed and promulgated, six hospitals in the Metropolitan Washington Region performed open heart procedures. Two of those hospitals were located in Maryland (Washington Adventist in Montgomery County and Prince George's Hospital Center in Prince George's County); the other four were in the District of Columbia. The number of procedures performed by those hospitals in the relevant years was as follows:[3]

Hospital	1999	2000	2001	2002	2003
Prince Geo. Hosp. Ctr	120	155	150	159	155
Wash. Advent. Hosp.	817	802	770	739	721
Georgetown Univ. Hosp.	140	122	269	260	92
Geo. Wash. Univ. Hosp.	85	103	177	190	261
Howard Univ. Hosp.	50	45	20	23	16
Wash. Hosp. Ctr.	2,950	2,631	2,324	2,252	2,152

When the Commission undertook to revise the Cardiac Services part of the 1998 State Health Plan, the law required that the SHP include the "[i]dentification of unmet needs, excess services, minimum access criteria, and services to be regionalized." *See* former

[3] The data for 1999 are taken from the record in *MedStar I*, *supra*, 376 Md. at 31-32, 827 A.2d at 102. The data for 2000 through 2003 are in the record in this case. At some point in 2003, Georgetown University Hospital was acquired by MedStar, which took over the cardiac services program there. That program was closed by MedStar in 2003. There are thus now only five hospitals performing open heart surgery in the Metropolitan Washington area, two in Maryland and three in the District.

Health-General Article (2000 Repl. Vol.) § 19-121(2)(iii). At the time, there was no *actual* "unmet need" in the Metropolitan Washington Region. The data showed a projected need in the Region for 4,251 procedures and a capacity, based on the number of procedures actually being performed, of 4,432 cases.

In an asserted effort to improve accessibility and cost, however, the Commission adopted a new methodology for measuring available capacity. Instead of determining capacity based on the number of procedures actually being performed by the six hospitals in the Region, it created an artificial cap, for each hospital, of the higher of 800 cases or 50% of the projected gross regional need. The effect of that cap was to reduce, for purposes of calculating the regional capacity, the number of procedures performed at Washington Hospital Center (WHC) – the only hospital affected by the cap – from 2,950 cases (the number actually performed in the base year) to 2,126 cases (50% of the projected regional need). That served to reduce the Commission-determined regional capacity from 4,432 cases to 3,608 cases and thus show an unmet need of 643 cases (4,251 need less 3,608 capacity). The mere existence of that artificially created unmet need would allow the Commission to issue a CON to one or more additional hospitals to conduct open heart surgery in the region.

WHC was, and remains, an affiliate of MedStar, and, on behalf of its affiliate, MedStar challenged the new methodology, contending that it was unauthorized, arbitrary, and capricious. That led to *MedStar I*, in which this Court, sharply divided, agreed that the "objective, hard evidence" showed that there was either "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." *MedStar I*, *supra*, 376 Md. at 24-25, 827 A.2d at 97-98. The Court concluded that "the Commission adopted a standard that created a need for additional capacity by disregarding that hard, objective evidence" and thus finding a deficit that was contrary to fact. *Id*. at 25, 827 A.2d at 98. The Court stated that it could discern no reason for the new methodology other than to promote competition and terminate the dominance of WHC, and declared that the methodology ran afoul of the Commissions's stated policies and commitment to support a small number of higher volume cardiac service programs. On that ground, the Court effectively invalidated that part of the Commission's 2001 SHP-Cardiac Services.

MedStar I was filed in June, 2003. Work on revisions to the 2001 SHP-Cardiac Services plan had already commenced, but under a somewhat different regime. In its 2001 Session, the General Assembly made a number of modifications to the governing statutes in title 19, subtitle 1, some of which were to implement a shifting of part of the Commission's planning responsibilities to the Department of Health and Mental Hygiene. *See* 2001 Md. Laws, ch. 565 (Senate Bill 786); Fiscal Note (Revised) to SB 786; House of Delegates Environmental Matters Committee Floor Report on SB 786; and Maryland Health Care Commission Bill Analysis on SB 786. One of the changes was the deletion in what was former § 19-121 (present § 19-118) of the requirement that the Commission include in its SHP an identification of unmet needs. Under the 2001 (and current) law, the SHP was to

include only "[t]he methodologies, standards, and criteria for certificate of need review" and "[p]riority for conversion of acute capacity to alternative uses where appropriate." § 19-118(a)(2). The Commission's standards for CON review were still required to address the "availability, accessibility, cost, and quality of health care." § 19-118(d)(2)(i).

Prior to the enactment of ch. 565, the Commission created an Advisory Committee to study and develop recommendations. The Steering Committee of that Advisory Committee presented its recommendations to the Commission in June, 2003. A draft revised plan was submitted for informal comment in July; comments from eighteen organizations and individuals were received and considered; and, in September, 2003, Commission Staff released its analysis of those comments. At its October 20, 2003 meeting, the Commission discussed and adopted the draft Plan and, in conformance with the relevant requirements of the Administrative Procedures Act, caused it to be published in the Maryland Register and submitted for review to the General Assembly's Joint Committee on Administrative, Executive and Legislative Review. Following the conclusion of the formal comment period, the Commission held two further meetings. On January 8, 2004, it considered written comments from 89 organizations and individuals and heard 31 oral presentations on behalf of 19 organizations. At its February 20, 2004 meeting, following a presentation by its Deputy Director addressing the various comments, the Commission formally adopted the revised plan, to take effect March 15, 2004. *See* 31 Md. Reg. 449 (March 5, 2004).

As was the case with *MedStar I*, MedStar let no moss grow on the plan. On the very

day it became effective, MedStar filed suit in the Circuit Court for Howard County seeking a declaratory judgment that the plan was invalid. In May, Suburban Hospital, Inc. was allowed to intervene as a defendant and Adventist Healthcare, Inc. (Washington Adventist Hospital) was permitted to intervene as a plaintiff. In March 2005, acting on cross-motions for summary judgment, the court upheld the validity of the 2004 SHP-Cardiac Services, declaring that it was "consistent with the Commission's statutory authority." MedStar and Adventist appealed, and we granted *certiorari* prior to any proceedings in the Court of Special Appeals. We shall affirm the judgment of the Circuit Court.

DISCUSSION

The 2004 SHP-Cardiac Services under attack here maintains its commitment to high volume programs. Policy 1.0 provides that "[t]here should be a minimum of 200 open heart surgery procedures annually in any institution in which open heart surgery is performed for adult patients." The minimum for open heart procedures in institutions performing only pediatric open heart surgery is set at 130 annually. *See* Policy 1.1. Policy 1.5 provides that "[t]he establishment of a new cardiac surgery program should permit existing programs to maintain patient volumes of at least 350 cases or more annually." The complaint by MedStar and Adventist centers on one provision in the plan dealing with the issuance of a new CON to perform open heart surgery. COMAR 10.24.17.05 B, captioned "Consideration of New Program," provides, in relevant part:

> "The Commission will consider a new program in a Regional Service Area under the following circumstances
>
> (1) One or more existing programs in a Regional Service Area have not met the minimum volume standards for the past two consecutive years.
>
> (2) For the purpose of determining compliance with the minimum volume standards, the Commission will not consider the volumes achieved by a newly-approved program during that program's first two years of operation."

The basis for that provision is explained in other parts of the Plan. In the section dealing with "Legal Authority and Overview," COMAR 10.24.17.02 B, the Plan notes that § 19-103(c)(2) gave the Commission a "broad statutory mandate" to "[p]romote the development of a health care regulatory system that provides for all Marylanders, financial and geographic access to quality health care at a reasonable cost." To achieve that objective, the plan "stresses the importance of access by Maryland residents to quality cardiac surgery programs at a cost that benefits the entire health care system," and, in that regard, notes that a policy that results in a populous region "having either a very small number of programs that achieve large volumes or having a number of programs that consistently fail to achieve minimum volumes may reflect a sub-optimal balancing of cost, access, and quality."[4] The

[4] The concern about the effect on accessibility and cost of having only a "very small number" of programs in a populous area is well illustrated by the data for the Washington Metropolitan Region. For the two most recent years considered by the Commission in the development of the 2004 plan (2001 and 2002), only three hospitals in that Region, which contains almost half the population of the State, had met the minimum number of procedures in both years – Adventist located in Maryland and WHC and

(continued...)

explanation continues:

> "For this reason, the Chapter provides that the Commission can consider applications for a new cardiac surgery service in a region in which one or more providers have failed to meet the minimum volume requirements. *Access to a cardiac services program that consistently fails to meet minimum-volume requirements is not considered access to a high quality cardiac surgery program*. In those circumstances, *the consideration* of a new program that must meet minimum volume requirements is appropriate."

(Emphasis added).[5]

MedStar views the provision, even with this explanation, as a "fundamental flaw." Although it seems to have no problem with the policy statements requiring an annual minimum of 200 procedures in hospitals performing adult open heart surgery, and indeed

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[4](...continued)
Georgetown located in the District, and the Commission was aware that MedStar had terminated the Georgetown program, leaving only two hospitals that would likely maintain the minimum volume. The data for 2003 confirms that prospect. None of the other four hospitals then performing adult open heart surgery in the Region had performed 200 or more procedures in both years. Taking the two years together, that left the entire Region with access to only two "high quality cardiac surgery program[s]."

[5] That point is made as well in the section of the plan dealing with Issues and Policies (COMAR 10.24.17.04). As an introduction to the minimum procedure Policies (Policies 1.0 through 1.5), the Commission notes:

> "The relationship between volume and quality is a key consideration in planning for specialized cardiac care services. For this reason, the Chapter provides that the Commission can consider applications for new cardiac surgery service in a Region in which one or more providers have failed to meet minimum volume requirements. Access to a cardiac service program that consistently fails to meet minimum volume requirements is not considered access to a high quality cardiac surgery program."

lauded those policies in *MedStar I*, it now proclaims that "[t]he 200 Surgery Threshold is not among the factors the General Assembly directed the Commission to consider in the CON application process" and that, by adopting under-performance within a Region as an "artificial gatekeeper" for the consideration of any new CON, the Commission has "placed the 200 Surgery Threshold ahead of the statutory factors – availability, accessibility, cost and quality." Adventist makes a similar argument – that the 2004 plan "ignores hard objective evidence and violates the Commission's own policies and enabling law by using a meaningless hypothesis that one low volume program in a region equates to a region-wide lack of 'access' to quality programs." In making those arguments, appellants have mis-characterized the nature and effect of the provision they challenge.

COMAR 10.24.17.05 is, indeed, a gatekeeper, and that is all that it is. With the "unmet need" criterion from the 2001 plan deleted, there is no reason, under the 2004 plan, for the Commission even to consider a new CON in a region if all of the existing programs in that region are performing at least 200 open heart procedures (or 130 procedures in a pediatric program), and that is all that the challenged provision states. Only if there are one or more programs in the region not meeting the minimum requirement – a requirement that finds a wealth of support in the medical literature and in the record in both this case and in *MedStar I* – will the Commission even consider a new CON application. The COMAR provision neither discards nor denigrates any other criterion or consideration relevant to the approval of a new CON. It does not place the 200-procedure requirement *ahead* of any other

requirement for a CON.

This is clear from other provisions in the 2004 plan that MedStar and Adventist simply ignore. In the "Statement of Principles" section of the Plan (COMAR 10.24.17.03 B(3)), the Commission declared that "[a]ny expansion in 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." (Emphasis added). It noted that, when an existing program does not meet the required minimum volumes, the Commission was limited in its responses. Obviously, it has no control whatever over programs operating in the District; nor did it have any authority to withdraw a CON for a Maryland-based program that was issued prior to December 1, 1997. Accordingly, it stated, the Commission would use other strategies to balance access, quality, and cost, including "an examination of actual program utilization and 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*. . ." (Emphasis added).

In the actual "Approval Policies" part of the Plan (COMAR 10.24.17.05 C), the Commission made abundantly clear that under-utilization of one or more existing programs would not alone justify approval of new programs. Approval Policies (2), (3), and (4) state:

> "(2) Approval of New Program. The Commission will approve the establishment of a new cardiac surgery program in a Regional Service Area projected to have a stable or declining open heart surgery utilization *only if* the Commission determines that the establishment of a new program will demonstrably benefit the service area population in access, quality, and/or cost

> effectiveness, and the value of that benefit is greater than any increased cost that may result from distributing the projected open heart surgery cases over a larger number of programs in the Region.
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> (3) Number of New Programs Allowed. The Commission will approve only one new adult or pediatric cardiac surgery program at a time in each Regional Service Area. After a new program has been approved the Commission will not consider an additional program in that Regional Service Area until the new program has been in operation for at least three years.
>
> (4) Minimum Volume Standards. The Commission will approve a cardiac surgery program only if an applicant demonstrates that the proposed program can retain sufficient patients to meet the minimum start-up volume of 200 cases annually."

(Emphasis added).

In furtherance of Approval Policy 2, the Certificate of Need Review Standards (COMAR 10.24.17.06 A and B) require that all applicants for the establishment of a cardiac surgery program "must meet all standards set forth in this section." Two of those standards are particularly relevant. One, Standard (6)(b), requires that, if one or more programs in the Region are not operating above minimum volumes, the applicant "offer evidence as to why an application should be approved, *which should include, but not be limited to, issues of quality, need, and access*." (Emphasis added). Standard (7) requires an applicant for a new open heart program to "provide a detailed description of the manner in which the new program will demonstrably benefit the population of the Regional Service Area *in access, quality, and/or cost effectiveness*." (Emphasis added). The documentation must include the

identification of any operating cardiac surgery program in the Region that has failed to meet the minimum volume standard in the three most recent calendar years for which discharge abstract data are available and a "detailed description of the evidence and methods used to estimate the potential benefit to the Maryland population in the Region and the potential cost to Maryland of establishing the new program."

These various provisions demonstrate the limited gatekeeping function of the challenged part of the plan (COMAR 10.24.17.05 B(1)). Unless there is an under-performing program in the Region, no new CON application will be considered; if there *is* such an under-performing program, the Commission may *consider* a new application, but may not grant it unless the applicant satisfies the full panoply of requirements, including a demonstration of access, quality, and cost effectiveness. The existence of an under-performing program is in no way a substitute for, or excuses compliance with, the substantive requirements for any new CON. The inclusion of that gatekeeping provision was not haphazardly or capriciously done, but was (1) recommended by the Commission Staff, (2) the subject of comment that was fairly considered by the Commission, and (3) approved for legality by the Attorney General.[6]

The standard for judicial review of administrative agency regulations is both limited

[6] On December 12, 2003, Assistant Attorney General Kathryn M. Rowe advised a member of the General Assembly that what was then the *proposed* revision was lawful and not contrary to *MedStar I*. The views expressed in Ms. Rowe's letter opinion were confirmed in an Opinion of Attorney General J. Joseph Curran and his Chief Counsel for Opinions and Advice, Robert N. McDonald, on January 21, 2004.

and deferential. We have long espoused the view that, in reviewing regulations, the adoption of which is quasi-legislative in nature, "the judiciary's scope of review is limited to assessing whether the agency was acting within its legal boundaries." *Dep't of Nat. Res. v. Linchester*, 274 Md. 211, 224, 334 A.2d 514, 522 (1975); *also Fogle v. H & G Restaurant*, 337 Md. 441, 454, 654 A.2d 449, 455 (1995). We added in *Fogle* that "courts should generally defer to agencies' decisions in promulgating new regulations because they presumably make rules based on their expertise in a particular field" and 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. *See also Lussier v. Md. Racing Commission*, 343 Md. 681, 690, 684 A.2d 804, 808 (1996).

MedStar's and Adventist's protestations notwithstanding, there is clear legislative authority for the Commission's regulation. Section 19-118(d)(2) not only authorizes, but mandates, that the Commission adopt standards in the SHP that "address the availability, cost, and quality of health care," and that is precisely what it has done. *See also* § 19-103(c)(2). It has determined, based on voluminous medical evidence, that programs consistently performing fewer than 200 open heart procedures a year do not constitute high quality programs, and that, where that deficiency exists, it is empowered to *consider* whether a new program, capable of performing the minimum number of procedures, should be authorized. As we have indicated, the Commission may not actually authorize a new

program unless it is assured from the evidence presented in support of the application that the population in the Region will be benefitted in terms of access, quality, and cost. The regulation is fully consistent with the statutory mandate.

JUDGMENT OF THE CIRCUIT COURT FOR HOWARD COUNTY AFFIRMED, WITH COSTS.

IN THE COURT OF APPEALS OF MARYLAND

No. 37

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v.

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Bell, C.J.
Raker
Wilner
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Harrell
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Greene,
JJ.

Dissenting Opinion by Bell, C. J.,
which Cathell and Battaglia, JJ., join.

Filed: March 7, 2006

The majority is correct, we are faced for the second time in three years with a challenge to the State Health Plan ("SHP") dealing with cardiac surgery services in the Washington, D.C. metropolitan area. In MedStar v. Maryland Health Care Commission, 376 Md. 1, 827 A.2d 83 (2003) ("MedStar I"), we did indeed state that "the issue to be addressed...is whether there is unmet need for cardiac surgery services in the Metropolitan Region." 376 Md. at 24, 827 A.2d at 97. We then determined that the 2001 SHP, the Plan then in effect, artificially created a need and, thus, only promoted competition. 376 Md. at 25, 827 A.2d at 98. It, we concluded, thereby ran afoul of the Commission's own policy of supporting a small number of high volume cardiac surgery programs, rather than a large number of lower volume programs. 376 Md. at 25, 827 A.2d at 98.

Today, we are presented with virtually the same issue, although today, it is presented in a different statutory and regulatory context. Unlike the 2001 SHP, the 2004 SHP, the Plan in effect now, does not require the SHP to identify "unmet needs, excess services, minimum access criteria and services to be regionalized." See Maryland Code (1982, 2000 Replacement Volume) § 19-121 (a) (2) (iii) of the Health General Article. That requirement was amended out of the enabling statute. Thus, the majority, in analyzing the 2004 SHP, is now convinced that the present SHP satisfies, and is consistent with, the Commission's stated, and unchanged, policy favoring sustaining a small number of high-volume cardiac surgery programs as opposed to a large number of lower volume programs. __ Md. __, __, __ A.2d __, __ [slip op. at 16] (2006). I am baffled as to how this can be so. At issue is the issuance of a Certificate of Need ("CON"). At bottom, a certification, or determination, of

need is necessary for the issuance of a CON, notwithstanding the deletion of an explicit reference to that requirement. This new plan, moreover, does nothing to sustain currently existing high-volume cardiac surgery programs, or to eliminate underachieving ones. Its purpose seems to be, as it was in MedStar I, simply to create a need for a new cardiac surgery program, even if doing so is anti-factual, so that a new cardiac surgery program can be established in suburban Maryland. Given that the record reflects that the need for cardiac services in the region is flat and, more to the point, that it is being met, an additional program can be sustained only by successfully competing for cases already being handled by existing programs. Thus, the plan still functions to, and has the effect of promoting, competition.

A.

Ultimately, this case involves the granting of a CON to Suburban Hospital, which is located in Montgomery County, to establish another cardiac surgery program within a region, designated by the SHP as the Metropolitan Washington region,[1] that already has five such

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[1]COMAR 10.24.17.04I, as relevant, provides now, as it did when MedStar v. Maryland Health Care Commission, 376 Md. 1, 827 A.2d 83 (2003) was decided:

> "Because cardiac surgery is a specialized health service appropriate for regional planning, the Commission allocates cardiac surgery programs on a regional basis. Regional Service Areas are established after considering optimal patient migration patterns on reasonable travel times, and adequate population size in each Region necessary to sustain a cardiac surgery program.
>
> "Four Regional Service Areas are designated for the planning of adult cardiac surgery services:
>
> > "Eastern Shore Region: Cecil, Kent, Queen Anne's, Caroline, Talbot, Dorchester, Wicomico, Worcester, and Somerset

cardiac surgery programs. Maryland's CON process is regulated by the Maryland Health Care Commission ("Commission"). In MedStar I, we explained that "[t]he 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.'" 376 Md. at 3, 827 A.2d at 85. "[B]efore a hospital servicing this state may offer any regulated medical services it must apply for, and be granted, a CON from the Commission." 376 Md. at 4, 827 A.2d at 85. Notwithstanding the aforementioned amendments to the enabling statute and those made subsequently to the Code of Maryland Regulations ("COMAR"), that continues to be an accurate description of the CON purpose and process. "Access," on which the majority and the appellants focus, is but a subset of need and, thus, must be established as a prerequisite for the issuance of a CON.

At the time MedStar I was argued, the Commission was required to adopt an SHP every five years. § 19-121(a)(1). Section 19-121(a)(2) prescribed the contents of the SHP. It provided:

> "(2) The plan shall include:
>
> > "(i) A description of the components that should comprise the health care system;

> Counties.
> "Metropolitan Baltimore Region: Baltimore City and Carroll, Harford, Baltimore, Howard, and Anne Arundel Counties.
> "Metropolitan Washington Region: Washington, D.C. and Montgomery, Prince George's, Calvert, Charles, and St. Mary's Counties in Maryland.
> "Western Maryland Region: Garrett, Allegany, Washington, and Frederick Counties."

> "(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."

Pursuant to that statute, the Commission developed the 2001 SHP, and consistently, amended the COMAR 10.24.17.04, the section that outlined how a CON application would be evaluated. Under the 2001 SHP, CON approval required the calculation of need within a region pursuant to formulae prescribed in the SHP. COMAR 10.24.17.04C (3) (a). The applicable formulae related both to the "capacity" of the region's hospitals and the region's "need" for cardiac surgerical services. They were, respectively:

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

> "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."

COMAR 10.24.17.04E (6).

The 2001 regulations had the effect of creating an artificial "need" in the region where none existed. Washington Hospital Center performed 2950 surgeries in 1999. Once the projected need for the region was determined to be 4251 surgeries, the Commission capped Washington Hospital Center's surgery capacity at 2126, or one-half of the projected gross need for the region, as COMAR 10.24.17.04E (4) (i) required. The Commission thus determined, pursuant to the capacity regulation, that the other hospitals in the region were able to provide a total of 1482 surgeries. Cumulating these numbers, the Commission established that the region's hospitals were able to perform only 3608 surgeries, 643 fewer cases than the region's projected capacity, and found, therefore, sufficient "need" to grant a CON to at least one new program in the region. The Commission, through the promulgation of COMAR 10.24.17.04E (4) (i), was thus enabled to ignore that, by accounting for Washington Hospital Center's full performance in 1999, the region's projected need was not only being satisfied, but being exceeded.

Nevertheless, pursuant to this data, the Commission granted Suburban Hospital a CON. MedStar Health ("MedStar"), appellant in both MedStar I and in this case, owner of the Washington Hospital Center and other hospitals in Maryland and the District of

Columbia, filed suit immediately, challenging amended COMAR 10.24.17.04E. The majority opinion in MedStar I was the result of that challenge.

We held that the amended regulation was anti-factual, and, thus, inconsistent with the policy basis for the 2001 SHP. We explained:

> "[T]he 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 .... [T]he 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.' ..While it acknowledges the conflicting evidence on the subject, the Commission accepted the advice ... 'minimum caseloads play a critical role in promoting quality of care for specialized cardiac care services,' ... 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.'"

376 Md. at 22-23, 827 A.2d at 96-97 (citations omitted). Further, we held that "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." 376 Md. at 24, 827 A.2d at 97. Accordingly, we concluded that the Commission's tactic of creating an artificial need when there was, in fact, a negative

net need, and granting a CON to a new cardiac surgery program in a region where, in fact, one was unnecessary, flew in the face of the established policy, and was implemented for no reason other "than to promote competition and, perhaps, thereby terminate the dominance of the Washington Health Center." 376 Md. at 25, 827 A.2d at 98.

Since the decision in MedStar I, pursuant to 2001 Md. laws, ch. 565, effective July 1, 2001, § 19-121 was amended and redesignated as § 19-118. The pertinent provision of the successor statute, § 19-118 (a) (2) now provides:

> "(2) The plan shall include:
>
> > "(i) The methodologies, standards, and criteria for certificate of need review; and
> >
> > "(ii) Priority for conversion of acute capacity to alternative uses where appropriate."

As presently formulated, therefore, the pertinent section of § 19-118 does not contain the requirement that the Commission identify unmet needs. That means, according to the appellees, apparently confirmed by the majority, __ Md. at __, __ A.2d at __ [slip op. at 11], that the Commission no longer is required to look for "unmet need," and, thus, is no longer bound by any "legislative directive regarding the optimal number of cardiac surgery programs." This is supported, they submit, by the fact that COMAR 10.24.17 was amended pursuant to this new statute, and the challenged provisions in COMAR 10.24.17.04E, which were the subject of the challenge in MedStar I, were removed in developing the 2004 SHP.[2]

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[2]COMAR 10.24.17.04E now only contains two provisions, neither of which involves need assessments. Instead, the section, entitled "On-Site Cardiac Surgical

Under the 2004 SHP, a different CON evaluation process is articulated. It is prescribed in COMAR 10.24.17.05B[3] and 10.24.17.05C.[4] Under these two provisions, a CON application will be considered in a region if at least one existing cardiac surgery

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Backup in Hospitals Performing Percutaneous Coronary Intervention," now merely describes two procedures, Primary Percutaneous Coronary Intervention and Elective Percutaneous Coronary Intervention, and the contexts that provide for their safe implementation.

[3]COMAR 10.24.17.05B provides, as relevant:

"B. Consideration of New Program. The Commissioner will consider a new program in a Regional Service Area under the following circumstances

"(1) One or more existing programs in a Regional Service Area have not met the minimum volume standards for the past two consecutive years.

"(2) For the purpose of determining compliance with the minimum volume standards, the Commission will not consider the volumes achieved by a newly-approved program during that program's first two years of operation."

[4]COMAR 10.24.17.05C provides, as relevant:

* * * *

"(2) Approval of New Program. The Commission will approve the establishment of a new cardiac surgery program in a Regional Service Area projected to have stable or declining open heart surgery utilization only if the Commission determines that the establishment of the new program will demonstrably benefit the service area population in access, quality, and/or cost effectiveness, and the value of that benefit is greater than any increased cost that may result from distributing the projected open heart surgery cases over a larger number of programs in the Region.

"(3) Number of New Programs Allowed. The Commission will approve only one new adult or pediatric surgery program at a time in each Regional Service Area. After the new program has been approved the Commission will not consider an additional program in that Regional Service Area until the new program has been in operation for at least three years.

"(4) Minimum Volume Standards. The Commission will approve a cardiac surgery program only if an applicant demonstrates that the proposed program can retain sufficient patients to meet the minimum start-up volume of 200 cases annually."

program, other than a newly approved one, in a Regional Service Area has failed to meet minimum volume standards for two consecutive years, COMAR 10.24.17.05B, and will approve one such program if doing so "will demonstrably" improve the region's "access, quality, and/or cost-effectiveness," which benefit also outweighs the costs of adding the new program. COMAR 10.24.17.05C. For purposes of COMAR 10.24.17.05B, the threshold for triggering CON consideration and justifying a new cardiac surgery program is 200 cases. See COMAR 10.24.17.04A (3).[5]

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[5] The policies governing minimum volume standards for cardiac surgery programs are set out in COMAR 10.24.17.04A (3):

"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 institutions 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 procedures is performed.

"Policy 1.3 A Certificate of Need issued by the Commission 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.

"Policy 1.4 There should be a minimum of 200 per cutaneous coronary intervention procedures performed annually in any institution in which elective angioplasty procedures are performed.

"Policy 1.5 The establishment of a new adult cardiac surgery program should permit existing programs operating at volumes of at least 350 cases or more annually to maintain patient volumes of at least 350 cases annually."

The language of these policies, generally, is identical to its 2001 counterpart.

Pursuant to these new provisions, the Commission considered Suburban Hospital's CON application. Noting that, in the Metropolitan Washington region as designated in the SHP, of the five cardiac surgery programs in that region, only two, Washington Hospital Center and Washington Adventist Hospital, consistently performed above the 200 case threshold, while three of the five performed consistently below the 200 surgery minimum required by the regulations, and, as such, a new cardiac surgery program could be considered for the region, the Commission once again granted a CON to Suburban Hospital, the beneficiary of the CON in MedStar I.

B.

The problem, once again, is that the Commission has ignored the actual needs of the region for another cardiac surgery program. Instead, it relies on a formula in which the factual basis for the CON decision is secondary and, in fact, may even be presaged or rendered irrelevant by the formula itself. The Commission argues, essentially adopted by the majority, __ Md. at __, __ A.2d at __ [slip op. at 11], that the appellants fail to recognize that the changes to the SHP have eliminated the "unmet needs" language, and thus, because the 2004 SHP does not contain "the only provision of the Commission's enabling statute that was cited by [the] Court as a basis for invalidating the 2001 Plan Chapter in MedStar I," it is not subject to invalidation. The appellees, and the majority, however, ignore that the rationale for MedStar I was primarily that the formula for assessing need adopted by the 2001 SHP and reflected in the COMAR regulations was anti-factual. In that case, we held

that the Commission used "regulatory sleight of hand" in order to grant a CON to Suburban where a CON was unnecessary. It was this action that ultimately ran afoul of the Commission's policy and commitment to supporting a small number of higher volume cardiac surgery programs rather than a large number of programs performing at minimum or lower volumes, and that I believe has recurred in this case, albeit using a different, but no less inappropriate, "regulatory sleight of hand."

The majority maintains that COMAR 10.24.17.05 is merely a gatekeeper and nothing more, and that "[i]t does not place the 200-procedure requirement ahead of any other requirement for a CON." __ Md. at __, __ A.2d at __ [slip op. at 12]. Moreover, it asserts, the 2004 SHP is faithful to, and honors, its commitment to high volume programs. __ Md. at __, __ A.2d at __ [slip op. at 8]. To support this conclusion, the majority cites to Policy 1.0, 1.1, and 1.5, supra at note 5, which, as detailed earlier, establish minimum utilization levels for cardiac programs. __ Md. at __, __ A.2d at __ [slip op. at 8]. The majority also relies on COMAR 10.24.17.02B and COMAR 10.24.17.04A (3). In COMAR 10.24.17.02B, noting the mandate that § 19-103 (c) (2) of the Maryland Health-General Code authorizes the Commission to "[p]romote the development of a health care regulatory system that provides for all Marylanders, financial and geographic access to quality health care at a reasonable cost," __ Md. at __, __ A.2d at __ [slip op. at 9], the regulation provides the rationale for adding new programs in regions where the need is flat:

> "This Chapter stresses the importance of access by Maryland residents to quality cardiac surgery programs at a cost that benefits the entire health care system. The Chapter addresses the importance of properly balancing these

> considerations, noting that a policy that results in a populous region having either a very small number of programs that achieve large volumes or having a number of programs that consistently fail to achieve minimum volumes may reflect a sub-optimal balancing of costs, access, and quality. For this reason, the Chapter provides that the Commission can consider applications for a new cardiac surgery service in a region in which one or more providers have failed to meet the minimum volume requirements. Access to a cardiac services program that consistently fails to meet minimum-volume requirements is not considered access to a high quality cardiac surgery program. In those circumstances, the consideration of a new program that must meet minimum volume requirements is appropriate."

The majority perceives COMAR 10.24.17.04A (3) to be consistent, rationalizing a SHP that accounts for, and addresses, "a policy that results in a populous region 'having either a very small number of programs that achieve large volumes or having a number of programs that consistently fail to achieve minimum volumes,"' as such policy '"may reflect a sub-optimal balancing of cost, access, and quality.'" __ Md. at __, __ A.2d at __ [slip op. at 9], citing 10.24.17.04A (3).[6] Agreeing with the notion that "[a]ccess to a cardiac service

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[6]In this COMAR section, the commission acknowledges that the "relationship between minimum volume guidelines and risk-adjusted mortality for CABG surgery is a critical measure of quality" and states its preference "for public policy to support higher-volume cardiac surgery programs rather than programs performing at minimum or lower volumes." Nevertheless, it baldly states: "At the same time, it would not be appropriate to concentrate volumes in a manner that would inappropriately restrict access," followed by the example offered in COMAR 10.24.17.02B, but with no further explanation.

Further, the majority, in referencing this COMAR section, skips from the Commission's finding that "having either a very small number of programs that achieve[s] large volumes or having a number of programs that consistently fail[s] to achieve minimum volumes may reflect sub-optimal balancing of cost, access, and quality," directly to a block quote seemingly justifying the Commission's power to grant a CON based solely on these considerations.

The majority, however, glosses over a significant portion of COMAR 10.24.17.04A (3) that survived the SHP revision. The portion unmentioned, which we

program that consistently fails to meet minimum volume requirements is not considered access to a high quality cardiac surgery program,"the majority concludes that the use of the 200 procedure threshold is a valid gatekeeping provision for the evaluation of new CON applications and that such function is within the Commission's power. __ Md. at __, __ A.2d at __ [slip op. at 10-11]. It further notes that the appellants fail to recognize that this gatekeeping provision is consistent with other COMAR and SHP provisions, and that it does not diminish the power of the Commission to determine whether a CON should be granted. __ Md. at __, __ A.2d at __ [slip op. at 11-12].

The majority explains that, with the identification of "unmet needs" provision removed from the Commission's enabling statute, there is no reason that the Commission cannot use a previously established minimum volume standard as a gatekeeper standard to be utilized in the determination to consider a CON application. __ Md. at __, __ A.2d at __ [slip op. at 11]. It holds that the threshold is not placed ahead of any other requirement for a CON, emphasizing that after this gatekeeper function has been satisfied, the Commission still has to evaluate other factors, such as quality and access, before a CON can be approved:

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referred to in MedStar I. 376 Md. at 23, 827 A.2d at 96-97, details the substance and importance of the theory relating to program volume and quality. The majority specifically ignores the Commission's explicit finding that "[w]hile these considerations must be balanced with the need to provide appropriate access to both interventional cardiology and cardiac surgery systems, a system of higher volumes programs is preferable to a system where all hospitals perform at only the minimum volume." COMAR 10.24.17.04A (3) (emphasis added). Not only does the omitted section stress the fact that the "small number of larger volume programs" theory is still a significant consideration, but it also undermines the majority's and the appellees' attempt to present the "lack of access" as the primary goal in CON authorization, when, in fact, it is not.

> "Unless there is an underperforming program in the Region, no new CON application will be considered; if there is such an under-performing program, the Commission may consider a new application, but may not grant it unless the applicant satisfies the full panoply of requirements, including a demonstration of access, quality and cost effectiveness."

__ Md. at __, __ A.2d at __ [slip op. at 14].

The majority concludes its defense of the judgment below by asserting that the Commission's promulgation of the critical COMAR regulations was within its authority. And they are justified, it says, because the Commission "has determined, based on voluminous medical evidence, that programs consistently performing fewer than 200 open heart procedures a year do not constitute high quality programs, and that, where that deficiency exists, it is empowered to consider whether a new program, capable of performing the minimum number of procedures, should be authorized." __ Md. at __, __ A.2d at __ [slip op. at 15-16].

C.

I disagree. First, the formula developed in this case and its application process is as much anti-factual as the formula and implementation in Medstar I; the use of the 200 case threshold as a gatekeeper suffers from the same flaw as the "capacity/need" formula utilized in Medstar I. As in that case, the COMAR regulations now in effect allow, and even encourage, the Commission to use an anti-factual standard, unsupported by evidence, to trigger its CON application process. Rather than a formula designed to ensure that a CON would be entertained and ultimately granted, the Commission uses in this case a threshold that it knows will be met and, thus, ensures the consideration of CON applications and

ultimately the grant of a CON. I have no doubt that, in theory, as the appellants and the majority remind us with respect to this case, the Commission was not required, in Medstar I, to issue a CON simply because it found a need. __ Md. at __, __ A.2d at __ [slip op. at 11-12]. It was required there, as it was required in this case, to determine that the successful applicant met the prescribed criteria. In my view, in short, the use of the 200 case threshold as a gatekeeper does not survive Medstar I analysis.

The majority, like the appellees, counters this challenge by emphasizing, first, that the striking of the "unmet needs" portion of the enabling statute allows the Commission more discretion in establishing the SHP, and second, that the use of a 200-procedure standard as a minimum threshold is valid, based on substantial factual evidence that a program unable to sustain 200 procedures is "low quality." In addition to rejecting both premises, I respond, neither of these arguments overcomes the anti-factual foundation on which the new CON process is based: that the under-performance of one hospital in a Region somehow equates to a Region-wide "lack of access."

The purpose of a SHP is implicit; it necessarily exists to guide the Commission in addressing the needs of the citizens of Maryland. MedStar I, 376 Md. at 28, 827 A.2d at 100. Section 19-102 of the Maryland Health-General Code, captioned General Assembly findings; purpose of subtitle, states:

> "(a) The General Assembly finds that the health care regulatory system in this State 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.

> "(b) The purpose of this subtitle is to establish a streamlined health care regulatory system in this State in a manner such that a single State health policy can be better articulated, coordinated, and implemented in order to better serve the citizens of this State."

(Emphasis added).

The CON process itself is a gatekeeper. It exists in order to permit the Commission to determine factually the existence of, and then supplement, any deficiency of service in Maryland. The appellees, and the majority, are trying to circumvent the previous express mandate to identify "unmet needs" and the continuing policy of supporting "a small number of high volume programs" by stating that their new policy goal is to address a Region's "access" problems. Indeed, the new COMAR regulations state:

> "[I]t is preferable for public policy to support high-volume cardiac surgery programs rather than programs performing at minimum or lower volumes. At the same time, it would not be appropriate to concentrate volumes in a manner that would inappropriately restrict access."

COMAR 10.24.17.04A (3). Striking the provision specifying the "identification of unmet needs" from the Commission's enabling statute and altering the language of the SHP to include other policy factors in the consideration of a CON, however, does not, in any way, change the inherent responsibility of the Commission to address the "need." Nor does it insulate the CON application review process from critical review or the formula triggering CON review immune from challenge.

The Commission argues that under the 2004 SHP, "the Commission can consider applications for a new cardiac surgery service in a region in which one or more providers have failed to meet the minimum volume requirements," because "[a]ccess to a cardiac

services program that consistently fails to meet minimum-volume requirements is not considered access to a high quality cardiac surgery program." COMAR 10.24.17.02B. That very well may be so - a hospital that does not perform 200 procedures can be, and under the applicable regulations, must be considered as under-performing. But even assuming the validity of the threshold, which I do not concede, that does not mean that the 200 procedure threshold for CON consideration necessarily and inexorably equates the under-performance of one hospital with a region-wide lack of access. That one or more hospitals in the region under-performs leaves the possibility that the other hospitals in the region can, and, in fact, do compensate for whatever insufficiency there may be in the case capacity of the under-performing hospitals. That is the case here. The assumption, as a result, therefore, ignores, or at least does not address, whether there actually is any true lack of access or outstanding need.

The Commission, aware that the CON process necessarily must address need, attempts to circumvent MedStar I and to avoid addressing need by focusing on "access," a subset of need. It suggests that its primary goal is to provide for areas which have a "lack of access." "Lack of access," to the Commission, is the result whenever, by using a minimum case-quality threshold as its standard, a hospital - any hospital - with an existing cardiac surgery program in a region fails to achieve the minimum number of procedures. The majority accepts these conclusions. __ Md. at __, __ A.2d at __ [slip op. at 10].

Missing from the analysis is some consideration or proof of whether the under-performance of one hospital truly results in a region-wide lack of access. As I see it, under

the logic of MedStar I, it is quite clear that equating, without some kind of factual analysis into whether, or not, there is an actual "lack of access," one hospital's under-performance with a region-wide lack of access without accounting for the strong performance of other hospitals in the region is not appropriately done.

The majority makes the point that, when a program fails to meet minimum requirements, the Commission has limited options, not possessing the authority to withdraw the CON from those hospitals. __ Md. at __, __ A.2d at __ [slip op. at 12]. That, again, is correct, but I say, so what? What the majority does not explain is how adding another CON to the region serves, or tends, to solve, or ameliorate, the under-performance of the existing programs. All the majority and the Commission offer is a strategy of attempting to balance and enhance access without negatively impacting quality and cost. That balance, when another program is added to the region, need not be positive. While one of the possible outcomes of the strategy may be the economic force out of the under-performing programs and another, the redistribution of the case load away from the dominant hospitals into the under-performing ones, both arguably what the Commission seeks, a third result is equally possible: there may be created yet another under-performing hospital. In any event, whatever the ultimate result, what is inexorable under the Commission approach is the generation of competition, the stoking of which is not, or ought not to be, the object of the SHP, the COMAR regulations or the policies of the Commission.

Moreover, because all available evidence supports a declining need for cardiac surgery services in the region, the redistribution of cases that naturally will result from the

addition of a new program in the region may well decrease the number of procedures performed at regional hospitals, risking thereby the decrease in the quality of service each of these hospitals offers and the impairment of access to high quality programs overall.[7]

The majority also ignores the argument that under the current system of CON application review, the historically low volume program at Howard University becomes a "furnace" for the region, permitting, more likely ensuring, a CON review will occur every year when review is permitted under the SHP,[8] no matter how many new programs are added. The Commission cannot be allowed such unbridled discretion.

Finally, any argument that adding a new program will increase geographic access undermines the purpose of having a regionalized system to begin with. By dividing Maryland into four separate Regional Service Areas, the SHP is already accommodating for any potential pitfalls in geographic access. As COMAR 10.24.17.04I puts it:

> "The Commission, in establishing the following regionaliztion policies, allocates the need for cardiac surgery to achieve a balance between considerations of patient access and the need to maintain program caseloads."

Moreover,

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[7]I am aware that, pursuant to COMAR 10.24.17.04A (3), policy 1.5, the establishment of a new program should allow programs performing at 350 cases or better to maintain at least the 350 case level. There is no evidence, so far as I am aware, on the issue and, in any event, it is difficult to conceive how that policy can, or will, be enforced.

[8]Since a new proposal is three years to achieve the standard, and only one program can be added at a time, reviews would be automatic every three years.

> "Analysis of travel time data to existing cardiac surgery programs indicates that virtually all Maryland residents are within a two-hour, one-way driving time to at least one hospital that provides adult cardiac surgery services. Almost 90 percent of the pediatric population is also within a two-hour, one-way driving time of a facility offering pediatric cardiac surgery services. The overwhelming majority of Maryland residents of Maryland residents have access within reasonable driving times to more than one hospital that offers cardiac surgery services."

Id.

The 2004 SHP provides no analysis as to whether the under-performing hospitals, in fact, suffer from low quality, and, as the appellants state, "ignores hard objective evidence and violates the Commission's own policies and enabling law by using a meaningless hypothesis that one low volume program in a region equates to a region-wide lack of 'access' to quality programs." Assuming that what the 2004 SHP does is simply to move the need-generating regulation one step away from the actual approval of a CON, as in MedStar I, to a gatekeeping function through which a CON is considered, that fact does not diminish the anti-factual nature of the regulation.

D.

I stated in MedStar I that "[i]t is undisputed that this Court has the right to determine for itself whether an administrative regulation exceeds the power of the agency." 375 Md. at 26, 827 A.2d at 98, see also Maryland Code (1984, 1999 Replacement Volume) § 10-125 of the State Government Article.[9] The question whether a particular regulation is arbitrary

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

> "(d) Subject to § 10-128 of this subtitle, the court shall declare a provision of a regulation invalid if the court finds that:

or unreasonable, or not fairly within the scope of the delegated power, is subject to judicial review. Givner v. Commissioner of Health, 207 Md. 184, 192, 113 A.2d 899, 903 (1955). The courts will "generally defer to agencies' decisions in promulgating new regulations because they presumably make rules based upon their expertise in a particular field." Fogle v. H & G Restaurant, Inc., 337 Md. 441, 455, 654 A.2d 449, 456 (1995). Moreover, the promulgation of regulations must include "adequate standards set up to guide [the administrative entity] in ascertaining the basic facts upon which [its] regulations are predicated." Givner, 207 Md. at 191, 113 A.2d at 902.

This Court held in State Department of Health v. Walker, 238 Md. 512, 523, 209 A.2d 555, 561 (1965), that a state agency's ad hoc rejection of sewage disposal systems applications was illegal where it was unable to prove using legally admissible evidence that the systems did not meet the standards imposed. Decisions made by agencies that are unsupported by substantial evidence are not within the exercise of sound administrative discretion, and are arbitrary and illegal acts. 238 Md. at 523, 209 A.2d at 561, citing Hammond v. Love, 187 Md. 138, 49 A.2d 75 (1946). To be sure, the Commission has the power to promulgate reasonable regulations according to its statutory authority. The

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> "(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."

Commission, however, cannot promulgate regulations that ignore actual evidence and that permits the Commission to make ad hoc decisions.

As in MedStar I, the Commission's adoption of the new COMAR regulations under the 2004 SHP was not the exercise of any expertise to which this Court is required to defer, and, instead, was an arbitrary determination which does not take account of, or relate, to any actual facts. 375 Md. at 26, 827 A.2d at 98. Because the new COMAR regulations are inherently arbitrary, they are an abuse of administrative discretion. The Commission clearly ignores the actual evidence that the need for cardiac services in the region is declining. Further:

> "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. ... [I]t 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."

376 Md. at 27, 827 A.2d at 99.

Judge Cathell and Judge Battaglia join in this dissenting opinion.