STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

BETHESDA HEALTHCARE SYSTEM, INC.,	)	
	)	
Petitioner,	)	
	)	
vs.	)	Case No. 01-2665RP
	)	
AGENCY FOR HEALTH CARE ADMINISTRATION,	)	
	)	
Respondent,	)	
	)	
and	)	
	)	
TENET HEALTHSYSTEM HOSPITALS, INC., d/b/a DELRAY MEDICAL CENTER; FLORIDA HEALTH SCIENCES, INC., d/b/a TAMPA GENERAL HOSPITAL; INDIAN RIVER MEMORIAL HOSPITAL, INC., d/b/a INDIAN RIVER MEMORIAL HOSPITAL; MARTIN MEMORIAL MEDICAL CENTER; LAWNWOOD MEDICAL CENTER, INC., d/b/a LAWNWOOD REGIONAL MEDICAL CENTER; and COLUMBIA/JFK MEDICAL CENTER LIMITED PARTNERSHIP, d/b/a JFK MEDICAL CENTER,	)	
	)	
Intervenors.	)	
_____	)	

FINAL ORDER

Pursuant to notice, the Division of Administrative Hearings, by its designated Administrative Law Judge, Eleanor M. Hunter, held a final hearing in the above-styled case on September 10 through 14, 2001, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUES

1. Whether proposed rule amendments to Rule 59C-1.033(7)(c) and (7)(d), Florida Administrative Code, published in the Notice of Change on June 15, 2001, constitute an invalid exercise of delegated legislative authority.

2. Whether the proposed rule is invalid due to the absence of a provision specifying when the amendments will apply to the review of certificate of need applications to establish open heart surgery programs.

PRELIMINARY STATEMENT

On June 29, 2001, Boca Raton Community Hospital, Inc. ("Boca Raton"), filed a Petition for Administrative Determination of Invalidity of Proposed Rules pursuant to Sections 120.54, 120.56, 120.569, 120.57, and 120.595, Florida Statutes, challenging the validity of proposed amendments to the rule governing open heart surgery programs in Florida, Rule 59C-1.033, Florida Administrative Code. The case was assigned Division of Administrative Hearings (DOAH) Case No. 01-2526RP. On July 3, 2001, Punta Gorda HMA, Inc. ("Punta Gorda HMA"), filed a Petition for Administrative Determination of Invalidity of Proposed Rule Amendments pursuant to Sections 120.56, 120.569, 120.57, and 120.595, Florida Statutes, also challenging the validity of proposed rule amendments to Rule 59C-1.033, Florida Administrative Code. The case was assigned DOAH Case No. 01-2620RP. On July 5, 2001, Bethesda Healthcare System, Inc. ("Bethesda"), filed a Petition for Administrative Determination of Invalidity of Proposed Rule Amendments pursuant to Sections 120.54, 120.56, 120.569, and 120.57, Florida Statutes, challenging the validity of proposed Rule 59C-1.033(7), Florida Administrative Code. The case was assigned DOAH Case No. 01-2665RP. Having responsibility for the rule and proposed amendments, the Agency for Health Care

Administration ("AHCA" or "Agency") was named Respondent in each case.

On July 10, 2001, Tenet Healthsystem Hospitals, Inc., d/b/a Delray Medical Center ("Delray") filed a Petition to Intervene. On July 11, 2001, Indian River Memorial Hospital, Inc., d/b/a Indian River Memorial Hospital ("IRMH") and Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital ("Tampa General") filed petitions to intervene. On July 12, 2001, Martin Memorial Medical Center, Inc. ("Martin Memorial") filed a Petition to Intervene. By Orders dated July 20, 2001, the cases were consolidated and interventions granted.

On August 3, 2001, Columbia/JFK Medical Center Limited Partnership, d/b/a JFK Medical Center ("JFK"), and Lawnwood Medical Center, Inc., d/b/a Lawnwood Regional Medical Center ("Lawnwood"), filed petitions to intervene. These were granted by Order entered on August 27, 2001.

On behalf of the Florida Society Thoracic and Cardiovascular Surgeons, Inc. ("FSTCS" or "the Society"), a petition to intervene was filed on August 17, 2001. It was granted on September 5, 2001.

On August 20, 2001, HMA filed a Notice of Voluntary Dismissal of its Petition, and an Order Closing File in DOAH Case No. 01-2620RP was entered on August 27, 2001. On September 7, 2001, Boca Raton filed a Notice of Voluntary

Dismissal of its Petition in DOAH Case No. 01-2526RP. Based on the Notice of Voluntary Dismissal, filed on behalf of Boca Raton Community Hospital, Inc., on September 7, 2001, the file in the DOAH Case No. 01-2526 RP, is closed.

This case proceeded to final hearing on Bethesda's challenge to the proposed rule amendments in DOAH Case No. 01-2665RP. The hearing was held from September 10 through 14, 2001, Tallahassee, Florida.

At the final hearing, Bethesda presented the testimony of Peggy Miller Cella, an expert in health care planning; John Davis; Elizabeth Dudek; and Jeffrey N. Gregg. Bethesda's Exhibits numbered 1-30 were received into evidence.

AHCA presented the testimony of John Davis, the Agency's Health Services and Facilities Consultant; Elizabeth Dudek, an expert in health planning and AHCA Assistant Deputy Secretary; and Jeffrey N. Gregg, an expert in health care planning and AHCA Bureau Chief. AHCA's Exhibit numbered 1 was proffered, while AHCA Exhibits numbered 2, 3, 10-19, 22, 24, 33, 35, and 38 were received into evidence.

Delray presented the testimony of Sharon Gordon-Girvin, an expert in health care planning. Delray's Exhibits numbered 1 and Composite 2 were received into evidence.

IRMH presented the testimony of James Talano, M.D., a medical expert in cardiovascular disease and its treatment,

invasive and non-invasive, and in cardiac imaging for open heart surgery; and Ronald Luke, J.D., Ph.D., an expert in health care planning. IRMH's Exhibits numbered 1, Composite 2 (excluding page 16) and 3 were received into evidence.

Martin Memorial presented the testimony of Jay Cushman, an expert in health care planning. Martin Memorial's Exhibits 1-11, 13, and 14 were received into evidence, while Martin Memorial's Exhibit 12 was proffered.

The FSTCS presented its exhibits numbered 1-5 which were received into evidence.

The transcript of the final hearing was filed on September 28, 2001, followed by the parties' proposed final orders on October 12, 2001.

FINDINGS OF FACT

1. The Agency is responsible for administering the Health Facility and Services Development Act, Sections 408.031-408.045, Florida Statutes. The goals of the Act are containment of health care costs, improvement of access to health care, and improvement in the quality of health care delivered in Florida.

2. AHCA initiated the rulemaking process by proposing amendments to existing Rule 59C-1.033, Florida Administrative Code, the rule for determining the need for adult open heart surgery (OHS)[1] services, which currently provides, in part, that:

(7) Adult Open Heart Surgery Program Need Determination.

(a) a new adult open heart surgery program shall not normally be approved in the district if any of the following conditions exist:

1. There is an approved adult open heart surgery program in the district.

2. One or more of the operational adult open heart surgery programs in the district that were operational for at least 12 months as of 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than 350 adult open heart surgery operations during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool; or

3. One or more of the adult open heart surgery programs in the district that were operational for less than 12 months during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than an average of 29 adult open heart surgery operations per month.

(b) Provided that the provisions of paragraphs (7)(a) and (7)(c) do not apply, the agency shall determine the net need for one additional adult open heart surgery program in the district based on the following formula:

NN =((Uc x Px)/350)) -- OP>=0.5

Where:

1. NN = The need for one additional adult open heart surgery program in the district projected for the applicable planning horizon. The additional adult open heart

surgery program may be approved when NN is 0.5 or greater.

2. Uc = Actual use rate, which is the number of adult open heart surgery operations performed in the district during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool, divided by the population age 15 years and over. For applications submitted between January 1 and June 30, the population estimate used in calculating Uc shall be for January of the preceding year; for applications submitted between July 1 and December 31, the population estimate used in calculating Uc shall be for July of the preceding year. The population estimates shall be the most recent population estimates of the Executive Office of the Governor that are available to the department 3 weeks prior to publication of the fixed need pool.

3. Px = Projected population age 15 and over in the district for the applicable planning horizon. The population projections shall be the most recent population projections of the Executive Office of the Governor that are available to the department 3 weeks prior to publication of the fixed need pool.

4. OP = the number of operational adult open heart surgery programs in the district.

(c) Regardless of whether need for a new adult open heart surgery program is shown in paragraph (b) above, a new adult open heart surgery program will not normally be approved for a district if the approval would reduce the 12 month total at an existing adult open heart surgery program in the district below 350 open heart surgery operations. In determining whether this condition applies, the agency will calculate (Uc x Px)/(OP+1). If the result is less

than 350 no additional open heart surgery program shall normally be approved.

3. Based on the issues raised by the Petitioner, Bethesda, and the factual evidence presented on these issues, AHCA must demonstrate that its proposed amendments to the existing OHS rule are valid exercises of delegated legislative authority or, more specifically, that it (a) followed the statutory requirements for rule-making, particularly for changing a proposed rule; (b) considered the statutory issues necessary for the development of uniform need methodologies; (c) acted reasonably to eliminate potential problems in earlier drafts of the proposed rule; (d) used appropriate proxy data to project the demand for the service proposed; (e) appropriately included county considerations for a tertiary service with a two-hour travel time standard; and (f) was not required to include a provision advising when CON applications would be subject to the new provisions.

Rule challenges and rule development process

4. The existing rule was challenged by IRMH on June 27, 2000, in DOAH Case No. 00-2692RX. Martin Memorial intervened in that case, also to challenge the rule. Like IRMH, Martin Memorial was an applicant for a certificate of need (CON), the state license required to establish certain health care services, including OHS programs, in Florida. Both are located

in AHCA health planning District 9, as is the Petitioner in this case, Bethesda. AHCA entered into a settlement agreement with IRMH and Martin Memorial on September 11, 2000, which was presented when the final hearing commenced on September 12, 2000.

5. Prior to the rule challenge settlement agreement, staff at AHCA had been discussing, over a period of time, possible amendments to the OHS rule to expand access and enhance competition. Issues raised by AHCA staff included the continued appropriateness of OHS as a designated tertiary service and the anti-competitive effect of the 350 minimum volume of OHS cases required of existing providers prior to approval of a new provider in the same district. The staff was considering whether the rule was too restrictive and outdated given the advancements in technology and the quality of OHS programs.

6. The relationship of volume to outcomes was considered as various studies and CON applications were received and reviewed, as was the increasing use of angioplasty also known as percutaneous coronary angioplasty, referred to as PTCA or simply, angioplasty, as the preferred treatment for patients having heart attacks. Angioplasty can only be performed in hospitals with backup open heart services. During an angioplasty procedure, a catheter or tube is inserted to open a clogged artery using a balloon-like device, sometimes with a

stent left in the artery to keep it open. Discussions of these issues took place at AHCA over a period of years, during the administrations of the two previous Agency heads, Douglas Cook and Reuben King-Shaw.

7. In August 2000, AHCA published notice of a rule development workshop to consider possible changes to the OHS rule. Because it could not get the parties to settle DOAH Case No. 00-2692RX at the time, rather than proceed with the workshop while defending the existing rule, AHCA cancelled the workshop.

8. As a result of the September 11, 2000, settlement agreement, on October 6, 2000, AHCA published a proposed rule amendment and notice of a workshop, scheduled for October 24, 2000. That version of a proposed rule would have changed Subsection (7)(a) of the OHS Rule to allow approval of "additional programs" rather than being limited to approval of one new program at a time in a district.

9. The October proposal would have also eliminated OHS from the list of tertiary health services in Rule 59C-1.002(41). Tertiary health services are defined, in general, in Subsection 408.032(17), Florida Statutes, as follows:

> "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such

> service. Examples of such services include, but are not limited to, organ transplantation, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

10. With this statutory authority, AHCA adopted Rule 59C-1.002(41), Florida Administrative Code, to provide a more specific and complete list of tertiary services:

> The types of tertiary services to be regulated under the Certificate of Need Program in addition to those listed in Florida Statutes include:
>
> 1. Heart transplantation;
> 2. Kidney transplantation;
> 3. Liver transplantation;
> 4. Bone marrow transplantation;
> 5. Lung transplantation;
> 6. Pancreas and islet cells transplantation;
> 7. Heart/lung transplantation;
> 8. Adult open heart surgery;
> 9. Neonatal and pediatric cardiac and vascular surgery; and
> 10. Pediatric oncology and hematology.

11. As an additional assurance that tertiary services are subject to CON regulation, the tertiary category is specifically listed in the projects subject to review in Subsection 408.036, Florida Statutes.

12. The October 2000 version included a proposal to increase the divisor from 350 to 500 in the formula in Subsection (7)(b), to represent the average size of existing OHS programs, but to decrease from 350 to 250, the minimum number required of an existing provider prior to approval of a new program in Subsection (7)(a)2. The definition of OHS would have been amended to add an additional diagnostic group, DRG 109, to delete DRG 110 and to eliminate the requirement for the use of the heart-lung by-pass machine during the surgery. Most controversial in the October version was a separate county-specific need methodology for counties which have hospitals but not OHS programs, in which residents are projected to have 1,200 annual discharges with a principal diagnosis of ischemic heart disease.

13. On October 24, 2000, AHCA held a workshop on the proposed amendments. At the workshop, AHCA Consultant, John Davis, outlined the proposed changes. As a practical matter, eight Florida counties are not eligible to provide OHS because they have no hospitals. When Mr. Davis applied the county-specific need methodology, as if it were in effect for the planning horizon of January 2003, six Florida counties demonstrated a need for OHS: Hernando, Martin, Highlands, Okaloosa, Indian River, and St. Johns. Two of these, Martin and Indian River are in AHCA District 9. AHCA has already approved

an OHS program for Martin County, at Martin Memorial. Mr. Davis also presented a simplified methodology for reaching the same result.

14. In support of the proposed rule, AHCA received data, although not adjusted by the severity of cases, showing better outcomes in hospitals performing from 250 to 350 OHS, as compared to larger providers. Although the majority of heart attack patients are treated with medications, called thrombolytics, for some it is inappropriate and less effective than prompt, meaning within the so-called "golden hour," interventional therapies. In these instances, angioplasty is considered the most effective treatment in reducing the loss of heart muscle and lowering mortality.

15. Opposing the proposed rule at the October workshop, Christopher Nuland, on behalf of the FSTCS, testified that OHS is still a highly complex procedure, that it requires scarce resources, equipment and personnel, and should, therefore, be available in only a limited number of facilities. In general, however, the opponents complained more about process rather than the substance of the proposal. Having petitioned on October 13, 2000, for a draw-out proceeding instead of the workshop, those Petitioners noted that AHCA had obligated itself to predetermined rule amendments based on the settlement agreement, regardless of information developed in the workshop. The draw-

out Petitioners were the Florida Hospital Association, Association of Community Hospitals and Health Systems of Florida, Inc., Delray, Lakeland Regional Medical Center, Punta Gorda HMA, Charlotte Regional Medical Center, JFK, HCA Health Services of Florida, Inc., d/b/a Regional Medical Center Bayonet Point; Tampa General and the FSTCS.

16. While agreeing that OHS is complex and costly, supporters of the proposed rule, particularly the declassification of OHS as a tertiary service, noted that many cardiologists are now trained to do invasive procedures. In support of fewer restrictions on the expansion of OHS programs in Florida, other witnesses at the October workshop discussed delays and difficulties in arranging transfers to OHS providers, possible complications from deregulated diagnostic cardiac catheterizations at non-OHS provider hospitals, and hardships of travel on patients and their families, especially older ones.

17. On December 22, 2000, AHCA published another proposal, which retained most of the October provisions, continuing the elimination of OHS from the list of tertiary services, the addition of DRG 109, the deletion of DRG 110, the elimination of the requirement for the use of a heart-lung by-pass machine, and the authorization for approval of more than one additional OHS program at a time in the same district. The minimum number of OHS performed by existing providers prior to approval of a new

one continued from the October 2000 version, to be decreased from 350 to 250, and the divisor in the numerical need formula continued to be increased from 350 to 500. As in the October version, the requirement that existing providers be able to maintain an annual volume of 350 OHS cases after approval of a new program was stricken.

18. The separate need methodology for counties without an OHS program was simplified, as proposed by Mr. Davis, and was as follows:

> (c) Regardless of whether need for additional ~~a new~~ adult open heart surgery programs is shown in paragraph (b) above, need for one ~~a new~~ adult open heart surgery program is demonstrated for a county that meets the following criteria:
>
> 1. None of the hospitals in the county has an existing or approved open heart surgery program;
>
> 2. Residents of the county are projected to generate at least 1200 annual hospital discharges with a principal diagnosis of ischemic heart disease, as defined by ICD-9-CM codes 410.0 through 414.9. The projected number of county residents who will be discharged with a principal diagnosis of ischemic heart disease will be determined as follows:
>
> PIHD = (CIHD/CoCPOP X CoPPOP)
>
> Where:
>
> PIHD = the projected 12-month total of discharges with a principal diagnosis of ischemic heart disease for residents of the county age 15 and over;

CIHD = the most recent 12-month total of discharges with a principal diagnosis of ischemic heart disease for residents of the county age 15 and over, as available in the agency's hospital discharge data base;

CoCPOP = the current estimated population age 15 and over for the county, included as a component of CPOP in subparagraph 7(b)2;

CoPPOP = the planning horizon estimated population age 15 and over for the county, included as a component of PPOP in subparagraph 7(b)2;

If the result is 1200 or more, need for one adult open heart surgery program is demonstrated for the county ~~will not normally be approved for a district if the approval would reduce the 12 month total at an existing adult open heart surgery program in the district below 350 open heart surgery operations. In determining whether this condition applies, the agency will calculate (Uc X Px)/(OP + 1). If the result is less than 350 no additional open heart surgery program shall normally be approved~~.

(d) County-specific need identified under paragraph (c) is a need occurring because of the special circumstances in that county, and exists independent of, and in addition to, any district need identified under the provisions of paragraph (b).

(e) A program approved pursuant to need identified in paragraph (c) will be included in the subsequent identification of approved and operational programs in the district, as specified in paragraph (a).

19. On January 17, 2001, a public hearing was held to consider the December amendments. Opponents complained that the proposals resulted from a private settlement agreement rather

than a public rule development workshop as required by law. They noted that declassification of OHS as a tertiary service is contrary to the recommendations of AHCA's CON advisory study group and the report of the Florida Commission on Excellence in Health Care, co-chaired by AHCA Secretary Reuben King-Shaw, created by the Florida Legislature as a part of the Patient Protection Act of 2000. The risk of inadvertently allowing some OHS procedures to become outpatient services was also raised, because of the statute that specifically states that tertiary services are CON-regulated.

20. The reduction from 350 to 250 in the annual volume required at existing programs prior to approval of new ones was criticized for potentially increasing costs due to shortages in qualified staff, including surgical nurses, perfusionists, recovery and intensive care unit nurses, who are needed to staff the programs.

21. The potential for approval of more than one program at a time, under normal circumstances, was viewed as an effort to respond to the needs of two geographically large districts out of the total of eleven health planning districts in Florida. That, in itself, one witness argued demonstrated that more than one approval at a time should be, as it currently is, a not-normal circumstance.

22. The combination of the district-wide and county-specific need methodologies was criticized as double counting. The district formula which relied on the projected number of OHS, overlapped with the county formula, which used projected ischemic heart disease discharges, to the extent that the same patient hospitalization could result in first, the diagnosis, and then the OHS procedure. Approximately, eighteen percent of diagnosed ischemic heart disease patients in Florida go on to have OHS. The county-specific methodology was also characterized as inappropriate health planning based on geo-political boundaries rather than any realistic access barriers.

23. Although 500, the average size of existing programs was the proposed divisor in the formula, and 250 was the threshold number existing providers, the proposal included the deletion of any provision assuring that existing programs maintain some minimum annual volume, which is 350 in subsection 7(e) of the current rule. AHCA representatives testified that the proposal to delete a minimum adverse impact was inadvertent. The combined effect of a district-wide need methodology, an independent but overlapping county need methodology, and the absence of an adverse impact provision, created concern whether approvals based on county need determinations could reduce volumes at providers in adjacent counties to unsafe levels.

24. Some health planners predicted that, as a consequence of adopting the December draft, like the October version, a number of new OHS programs could be coming into service at one time, seriously draining already scarce resources. One witness, citing an article in the Journal of the American Medical Association, testified that higher volume OHS providers, those over 500 cases, do have better outcomes, and that the relationship persists for angioplasties, including those performed on patients having heart attacks.

25. Florida has 63 or 64 OHS programs. Of those, 25 to 30 percent have annual OHS volumes below 350 surgeries a year. The demand for OHS is increasing slowly and leveling off. AHCA was warned, at the January public hearing by, among others, Eric Peterson, Professor of Cardiology, Duke University Medical Center (by videotaped presentation); and Brian Hummel, M.D., a Cardiothoracic Surgeon in Fort Myers, President of the Florida Society of Thoracic and Cardiovascular Surgeons, that simultaneously easing too many provisions of the OHS rule was a risk to the quality of the programs and the safety of patients.

26. Among other specific comments made at the January public hearing related to the December proposal were the following:

> This change would authorize a county-specific methodology to support approving a program on the theory that that county needs

better access to open heart surgery program. Yet there is no inquiry under the proposed provision into how accessible adjacent programs are or, indeed, how low the volumes of adjacent programs are. Most blatantly, the county provision requires double counting and double need projections. (AHCA Ex. 7, p. 14, by Elizabeth McArthur).

The proposed rule creates an exemption for counties that are currently without open heart surgery programs. One can only surmise that the purpose of this exemption is to improve access, and certainly improving access is an appropriate goal and it is possible that there are few situations around the state where access to open heart surgery is a concern, but the proposed rule is completely inadequate and a thoroughly inappropriate way to identify which situations those are . . . (AHCA Ex. 7, p. 26, by Carol Gormley).

With the county exemption provision, the Agency has stumbled on an entirely new method for estimating need. In fact, the only good thing about this provision is that it demonstrates that the Agency actually can look at some alternative ways to estimate need, and the use of data about incidence of ischemic heart disease might be one of those. Certainly it should be explored if there is ever a valid planning process that addresses open heart surgery. However, the proposed rules cobble together the county-based epidemiology with the district-wide demand based formula, and I believe that this method is not applicable for evaluating access to care.

It is not applicable because the provision only considers the population's rate of ischemic heart disease and does not even attempt to assess the extent to which county residents with ischemic disease are, in fact, already receiving open heart surgery. Therefore, a determination that county

residents generate at least 1,200 ischemic heart disease discharges annually does nothing to indicate whether or not they experience any barriers to obtaining that needed service.

* * *

Another problem with county exemption permission [sic: provision] is that the addition of this assessment, quote "regardless of the results of the district need formula," end quote, constitute double counting of a need in districts where counties without programs are located. (AHCA Ex. 7, p. 27-30, by Carol Gormley).

* * *

As further evidence of the benefits of limiting open heart surgery to a few high volume programs, the Society would like to place into record the following articles.

The first one you've heard on several occasions is the Dudley article, "Selective referral to high volume hospitals."

The second, from Farley and Osminkowski, is, "Volume-outcome relationships and in-hospital mortality: Effective changes in volume over time," from Medicare in January of 1992.

There's another article from Grumbach, et al., "Regionalization of cardiac surgery in the United States and Canada," again from JAMA.

Another article from Hannon, et al., "Coronary artery bypass surgery: The relationship between in-hospital mortality rate and surgical volume after controlling for clinical risk factors," Medical Care.

Hughes, et al., "The effects of surgeon volume and hospital volume on quality care

in hospitals," again from Medical Care; finally, Riley and Nubriz, "Outcomes of surgeries among Medicare aged: Surgical volume and mortality."

Each of these scholarly articles comes to the same inevitable conclusion: outcomes improve as the volume of cardiac surgeries in any given program and hospital increases, therefore increasing the number of hospitals in which these services are provided inevitably will lead to an increase in morbidity. (AHCA Ex. 7, p. 83-84, by Christopher Nuland).

* * *

27. On or before the January public hearing, AHCA also received the following written comments:

Martin Memorial supports the exception provision for Counties that do not have an open heart surgery program and have a substantial number of residents experiencing cardiovascular disease. This provision ensures an even dispersion of programs, and that adequately sized communities are not denied open heart surgery. (Martin Memorial Ex. 6, Letter of 10/24/2000, from Richard M. Harman, Chief Executive Officer, Martin Memorial, to Elizabeth Dudek)

* * *

Adding new open heart surgery programs to counties that currently lack programs will increase geographic access to coronary angioplasty services as well as open heart surgery. Primary angioplasty is now the treatment of choice for a significant percentage of patients presenting in the emergency department with acute myocardial infarction (patients who would otherwise be treated with thrombolytic drugs to dissolve blood clots in occluded coronary arteries). Thus, the provision of the proposed

> regulations that addresses the need for open heart surgery at a county level will also increase access to life-saving invasive cardiology services. The effect of the proposed rule changes is to slightly broaden the circumstances in which the Agency would see presumed need for new programs. Initially, the increase in the number of programs presumed to be needed would be only five. These potential new approvals would be in counties which currently have no programs. This is consistent with the reasoning that supports removing open heart surgery from the list of tertiary procedures. All else equal, distributing new programs to counties where they already exist is reasonable in light of the goal of improving geographic accessibility of advanced cardiology services.
>
> As with the other draft proposed rule changes, there is no certainty that any programs will be approved on the basis of the county-specific need formula in (7)(c). These proposed programs would still have to meet the statutory and rule criteria. As discussed above, a number applications for programs have been ultimately denied even when presumed need was shown by the need formula. We recommend adoption of this additional formula for demonstrating need. (IRMH Ex. 1, p. 25, Comments of Ronald Luke, J.D., Ph.D., 10/24/2000)

28. In what could be interpreted as an admission that the process resulting in the development of the earlier drafts was flawed, Jeff Gregg, Chief of the AHCA CON Bureau, concluded the January public hearing by saying,

> . . . in terms of the analysis that the Agency did about the proposed rule, I would simply have to tell you that CON staff was not involved in that analysis, and that's CON staff including myself. So I cannot

> elaborate on what went into it. But having said that, I do want to assure you that CON staff will be involved in further analysis and we will do our best to consider all the points that have been made and present them as clearly and concisely as we can in assisting the Agency to formulate its response to this hearing. (AHCA Ex. 7, p. 86).

29. The December draft was also challenged by a number of Petitioners in DOAH Case No. 01-0372RP, filed on January 26, 2001, and ten other consolidated cases. In response to the criticism that the adverse impact provision should not have been deleted and because that omission was unintended, AHCA published another proposed amendment to the OHS rule, on May 4, 2001, reinstating a minimum adverse impact volume, this time set at 250 OHS operations, down from 350 in the existing rule.

30. On May 31, 2001, AHCA and the other parties to DOAH Case No. 01-0372RP and the consolidated cases entered into another settlement agreement, which provided:

> that in an effort to avoid further administrative proceedings, without conceding the correctness of any position taken by any party, and in response to materials received in to the record on or before the public hearing, the Agency for Health Care Administration agrees to publish and support . . . The Notice of Change . . . (Bethesda Ex. 34, p. 2-3).

In upholding that agreement, AHCA superseded or revised all prior drafts and published a notice of change on June 15, 2001. In this final version, AHCA limited normal approval of a new OHS

program to one at a time, used 500 as the numeric need formula divisor, increased the required prior-to-approval OHS minimum volume at mature existing providers from 250 in the October version to 300 (down from 350 in the existing rule) and for non-mature programs from a monthly average of 21 in the October draft to 25 (down from 29 in the existing rule), retained the classification of OHS as a tertiary service, and altered the separate, independent county need methodology to make it a county preference.

31. The June 15th version, containing Subsections 7(c) and 7(d), which are challenged in this case is as follows:

> (7) Adult Open Heart Surgery Program Need Determination.
>
> (a) An additional open heart surgery programs shall not normally be approved in the district if any of the following conditions exist:
>
> 1. There is an approved adult open heart surgery program in the district;
>
> 2. One or more of the operational adult open heart surgery programs in the district that were operational for at least 12 months as of 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than 300 adult open heart surgery operations during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool;
>
> 3. One or more of the adult open heart surgery programs in the district that were operational for less than 12 months during

the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than an average of 25 adult open heart surgery operations per month.

* * *

(b) Provided that the provisions of paragraphs (7)(a) do not apply, the agency shall determine the net need for an additional adult open heart surgery programs in the district based on the following formula:

NN=[(POH/500)-OP]≥ 0.5
where:

1. NN = the need for an additional adult open heart surgery programs in the district projected for the applicable planning horizon. The additional adult open heart surgery program may be approved when NN is 0.5 or greater.

2. POH = the projected number of adult open heart surgery operations that will be performed in the district in the 12-month period beginning with the planning horizon. To determine POH, the agency will calculate COH/CPOP x PPOP, where:

a. COH = the current number of adult open heart surgery operations, defined as the number of adult open heart surgery operations performed in the district during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool.

b. CPOP = the current district population age 15 years and over.

c. PPOP = the projected district population age 15 years and over. For applications submitted between January 1 and June 30, the population estimate used for CPOP shall be

for January of the preceding year; for applications submitted between July 1 and December 31, the population estimate used for CPOP shall be for July of the preceding year. The population estimates used for COP and PPOP shall be the most recent population estimates of the Executive Office of the Governor that are available to the agency 3 weeks prior to publication of the fixed need pool.

3. OP = the number of operational adult open heart surgery programs in the district.

(c) In the event there is a demonstrated numeric need for an additional adult open heart surgery program pursuant to paragraph (7)(b), preference shall be given to any applicant from a county that meets the following criteria:

1. None of the hospitals in the county has an existing or approved open heart surgery program; and

2. Residents of the county are projected to generate at least 1200 annual hospital discharges with a principal diagnosis of ischemic heart disease, as defined by ICD-9-CM codes 410.0

(d) In the event no numeric need for an additional adult open heart surgery program is shown in paragraphs (7)(a) or (7)(b) above, the need for enhanced access to health care for the residents of a service district is demonstrated for an applicant in a county that meets the criteria of paragraph (7)(c)1. and 2. above.

(e) An additional adult open heart surgery program will not normally be approved for the district if the approval would reduce the 12 month total at an existing adult open heart surgery program in the district below 300 open heart surgery operations.

32. Bethesda objects to Subsections 7(c) and 7(d) as invalid. It challenges the rule promulgation process as a sham, having resulted from settlement negotiations rather than from statutorily mandated considerations and processes. That charge was, in effect, conceded by AHCA, as related to the October draft. That version carried over into the December draft, essentially unchanged, but did gain support at the October workshop.

33. The October and December versions are not at issue in this proceeding. The proposed rule amendments at issue in this proceeding must have been supported by information provided to AHCA before or during the January public hearing.

34. The proposal at issue differs substantially from the terms of the September settlement agreement, but is precisely what was attached to the May 31, 2001, settlement agreement. For example, the settlement agreement of September 11, 2000, included a proposal to reduce the prior minimum volume of cases at existing OHS providers from 350 to 250, but in May and June, that number was set at 300. AHCA, in the September settlement agreement, was to eliminate any limitation on the number of additional programs approved at a time, but the May and June version retains the one-at-a-time provision of the existing rule. AHCA agreed to determine county numeric need independent of and in addition to district numeric need, in September, but

that provision is, in the May 31st and June 15th version, a preference. In September 2000, AHCA agreed to delete adult OHS from the list of tertiary services in Rule 59C-1.002(41), but it is a tertiary service in the May and June version.

35. Bethesda is correct that the records of the October workshop and January public hearing contained criticisms of the county need methodology but no specific proposal to modify it into a preference. The first draft of that concept is the May 31, 2001, settlement agreement. (See Findings of Fact 26 and 27).

Statutory rule-making issues

36. Subsection 408.034(3), Florida Statutes, provides that:

> The Agency shall establish, by rule uniform, need methodologies for health care services and health facilities. In developing uniform need methodologies, the agency shall, at a minimum, consider the demographic characteristics of the population, the health status of the population, service use patterns, standards and trends, geographic accessibility, and market economics.

37. As required by statute, AHCA considered the demographics and health status of the population and examined, as a part of the rule adopting process, age-specific calculations of ischemic heart disease. AHCA relied on statistical evidence of the relationship of ischemic heart

disease and OHS. In 1999, for example, there were 33,027 OHS in Florida, and 25,257 of those patients had a primary diagnosis of ischemic heart disease.

38. Consideration of service use patterns, and standards and trends related to OHS led AHCA to increase the divisor in the numeric need formula to maintain the average size of 500 surgeries for existing providers.

39. The availability of more reliable data than that collected when the existing rule was promulgated allowed AHCA to propose reliance on residential use rates. The trend towards the use of angioplasty, as a preferred treatment for heart attack patients, and the need for timely geographical access to care are major factors for AHCA's proposal to consider a county services within the normal need analysis or as a not normal indication of a need for enhanced access when a county has a critical mass of heart disease patients. Geographical accessibility is also addressed in the travel time standard in the existing rule, which the proposal would not change.

40. AHCA received testimony on the issue of market economics and health status, related to care for indigent and minority patients in not-for-profit, county-funded hospitals, and related to reimbursement formulas. The record demonstrates that AHCA was provided with evidence on the effect of scare resources on the costs of operating OHS programs.

County-specific need methodology in earlier drafts as compared to the county preference in 7(c) and the need for enhanced access in 7(d)

41. Bethesda alleges that the county preference in the June version is essentially another need methodology, like the county-specific need methodology in the earlier versions of the proposed rule. Bethesda also contends that a preference for a hospital because it is in a county which does not have an open heart program over a reasonably accessible facility in an adjoining county in the same district is irrational health planning which could lead to a maldistribution of programs.

42. The county-specific need methodology was first included in the September settlement agreement, and the preference in 7(c) and need for access in 7(d), originated after the January 17, 2001, public hearing. During the public hearing, counsel for the Florida Hospital Association complained that the county-specific need methodology precluded any inquiry into accessibility and volumes at adjoining programs. Another representative of the Florida Hospital Association surmised that the goal of the county exemption was improved access but explained that it was an inappropriate means to identify access concerns. For example, while Hernando County would qualify for need with the separate methodology, most of its residents, 97 percent receive OHS services at a hospital in another

district which is only 13 miles from the population center. (See Finding of Fact 26).

43. The preference under normal circumstances in Subsection 7(c) and finding of need for enhanced access in Subsection 7(d), must be supported by evidence that county boundaries, in general, do create valid access issues. On or before the January workshop, information provided to AHCA indicated that some special inquiry into access issues related to CON applications for programs in counties without OHS programs is warranted. See Finding of Fact 27).

44. AHCA found correctly that counties matter for several reasons. First is the fact that emergency services are funded and organized by counties, in general, and operated by municipal and county agencies. Approximately 60 percent of heart attack patient discharges in Florida are admitted through emergency rooms. Emergency heart attack patients who live in counties with OHS programs are twice as likely to be taken to a hospital with OHS as those who live in counties without an OHS provider. Second, whether a patient is taken to an OHS provider affects the care received. The probability of having an angioplasty performed is almost 50 percent greater for residents of counties with OHS programs as compared to those in counties without an OHS program. Third, some health care reimbursement plans and

health care districts are operated within counties, limiting financial access to out-of-county hospitals.

45. AHCA has always considered whether or not a county has an OHS program as a part of access issues. The issue of greater access to OHS was the basis for AHCA's initial consideration of the possibility of easing the OHS rule. With the May and June draft, it has codified and specified when that policy will apply. AHCA's deputy secretary noted that geographic access in the absence of numeric need was the basis for approvals of OHS CONs for Marion County, and for hospitals located in Naples and Brandon. In each instance, the applicants argued a need for enhanced access.

46. AHCA has experience in applying preferences as a part of balancing and weighing criteria from statutes, rules and local health plans, particularly to distinguish among multiple applicants. In the totality of the review process, other factors which Bethesda's expert testified should be considered, including financial, racial and other potential access barriers, are not precluded.

47. Preferences related to specific locations within health planning areas are included in CON rules governing the need for nursing home beds and hospices. Bethesda noted that these are not tertiary services, suggesting that a county location preference is inappropriate for tertiary services, but

similar preferences for OHS exist in some of the local health plans. In AHCA District 1, the CON allocation factors for OHS and cardiac catheterization services include a preference for applicants proposing to locate in a county which does not have an existing OHS program. In District 4, the preference favors an applicant located in a concentrated population area in which existing programs have the highest area use rates. District 5 is similar to District 4, supporting OHS projects in areas of concentrated population with the highest use rates. The District 8, like District 1, preference goes to the applicant located in a county without an OHS program. There is no evidence that the existing preferences have been difficult to apply within the context of other CON criteria for the review of OHS applications. In effect, the proposed amendments establish an uniform state-wide county preference which is more concrete in terms of the requirements for a potential patient base.

48. Bethesda has questioned the rationale for standards which are, in effect, different in Subsection 7(c) as compared to Subsection 7(d). The lower requirement, according to Bethesda, 1200 ischemic heart diagnoses, in 7(d), applies when there is no numeric need. But, the 500 divisor and 300 minimum at existing providers, when combined with 1200 ischemic heart diagnoses is a heavier burden to meet in 7(c), although under normal circumstances. Bethesda did not adequately explain

reasons for this objection to the proposed rule. In addition, it is not inconsistent logically for AHCA to require applicants to demonstrate lower numeric need in situations in which AHCA has determined that these will be, in general, a greater need for enhanced access.

49. Bethesda also raised a concern for the eventual maldistribution of programs as a result of the county preference. In 1999, Palm Beach county residents received 2700 OHS, or an average of 900 cases for each of the three programs. The total for District 9 was 3800 cases in 1999. When 500 St. Lucie County resident cases, in which Lawnwood is an OHS provider, are combined with 2700 Palm Beach resident cases, that leaves only 650 resident cases from Okeechobee, Indian River and Martin Counties. If programs are approved in all three, then the total will be inadequate for each to reach 300 cases, while, presumably, the demand in Palm Beach could be increasing disproportionately and not be met adequately. Disproportionate need, the appropriate dispersion of programs, and the benefits of enhanced competition are among the factors which AHCA can consider along with county need when choosing among competing applicants.

1200 ischemic heart disease discharges

50. The proposed amendments require a projection that residents will reach a threshold of 1200 cases of ischemic heart

disease discharges as a condition for the entitlement to the numeric need preference or to demonstrate a not normal need for enhanced access. In general, ischemic heart disease, which is also known as coronary heart disease, is characterized by blocked arteries which, in turn, limit blood to heart muscles causing first the onset of angina from acute coronary syndrome, progressing on to acute myocardial infarction, or a heart attack.

51. The use of heart disease as a proxy for OHS utilization is consistent with AHCA's use of live births in pediatric open heart surgery and pediatric cardiac catheterization rules, deaths in the hospice rule, and related diagnoses in organ transplantation rules rather than actual utilization. It was supported by information received during or before the January workshop (See Finding of Fact 26 and 27).

52. Bethesda's criticism of the use of a proxy per se is also not well-founded because any single statistical approach could be misleading. For example, historic use rates can understate future use with a growing service or an artificially imposed access limit. Using heart disease data in a preference or a need for enhanced access as opposed to a need formula or conclusive finding allows more flexibility in determining need in conjunction with other significant factors.

53. One of Bethesda's expert health planners was also critical of the use of 1200 ischemic heart disease diagnoses as inadequate for projecting OHS cases, and for not equating to approximately 300 annual OHS cases, the minimum required of existing providers in Subsection 7(a) and the minimum adverse impact allowed in Subsection 7(e).

54. Based on actual historical Florida data, 1200 ischemic heart disease diagnoses on average resulted in 207 OHS in 1997, 203 in 1998, and 203 in 1999. Ischemic heart disease has approximately an 18 to 20 percent conversion rate to OHS, and results in a total of 76 to 80 percent of all OHS cases. OHS cases from other diagnoses added statistically another 54 OHS in 1997, 59 in 1998, and 61 in 1999, to those from ischemic heart disease, giving, in each year a total less than 300.

55. Bethesda presented evidence of wide variations in the ischemic heart disease to OHS conversion ratios from county-to-county. For example, only 14 percent of Bradford County ischemic heart diseases converted to OHS, and only 11 percent of the 700 cases in Columbia County converted to OHS. In Columbia County, the average state conversion rate of 20 percent yields 140 cases but, in reality, there were only 78 OHS cases from Columbia County in 1999. Bethesda's expert concluded that conversion ratio discrepancies resulting in the approval of a program that cannot achieve 300 OHS, as required in Subsection

7(a)2. and 7 (e), of the proposed rule, could bar the approval of new programs when needed in the district and would not be of minimum required quality.

56. Bethesda also proved that the accuracy of projected OHS cases can also be affected by patterns of patient migration for health care, particularly if in- and out-migration do not offset each other. In counties with OHS programs, the average out-migration for acute care is 10.7 percent, varying widely from 3.8 percent in Alachua County to 70 percent in Seminole County. In counties without an OHS provider, average out-migration for acute care is 44 percent, but ranges from 17.6 percent in Indian River County to 98 percent in Baker County. An average of 18 percent of the residents of Florida counties with OHS programs have their surgeries performed elsewhere.

57. Like out-migration, in-migration for acute care, for ischemic heart disease care, and for OHS varies from county to county in Florida. Counties without OHS programs have acute care in-migration from lows of 5.3 percent for Flagler County up to highs of 40 percent for Columbia County. In counties with OHS, in-migration for acute care is as low as 8 percent for Brevard and Polk, and as high as 60 percent for Alachua County. Similarly, in-migration, as determined by ischemic heart disease discharges averages 19.4 percent in counties without OHS programs and approximately 25 percent in those with OHS.

In-migration for OHS, averages 35.7 percent for the state, but that is derived from a range from 9.2 percent in Pinellas County to 74 percent in Alachua and Leon Counties.

58. Bethesda demonstrated, patterns of migration for health care vary throughout Florida, but there are trends due to the presence of OHS programs. Average net in-migration to counties with OHS is 29 percent, and is positive in sixteen of the twenty-four counties with OHS programs.

59. All of these differences can be considered within the regulatory scheme proposed by AHCA. The issue of whether 1200 residential ischemic heart disease diagnoses is, in fact, the critical mass of prospective OHS patients needed or is deceptive due to migration patterns, due to access to alternative providers or any other review criteria listed in rule or statutes can be considered on a case-by-case basis with the proposed amendments.

60. Bethesda's specific concern is that Indian River with well over 1200 ischemic heart disease discharges could be approved even though that represented only 255 OHS cases, and that if Indian River is approved under the county preference provision, then Bethesda would not be approved under normal circumstances until Indian River achieved and was projected to maintain 300 OHS cases a year. That Bethesda may be delayed in meeting the requirements for normal need is likely, but that

appears to be a function of its location as compared to existing providers as much as it is the result of the county preference. Bethesda is not precluded, however, under either the existing or proposed rules from demonstrating not normal circumstances in District 9 for the issuance of an OHS CON to Bethesda.

61. Bethesda's assumption that 300 is the minimum volume required for adequate quality is not supported by studies from various professional societies. The American College of Cardiology, the American Heart Association, and the Society of Thoracic Surgeons set minimums of 200 to 250 annual hospital cases as the volumes necessary to maintain the skills of the staff. The American College of Surgeons, in 1996, published their opinion that 100 to 125 cases per hospital is sufficient for quality, while at least 200 cases a year are needed for the economic efficiency of a program.

62. AHCA has never used the required and protected volumes as the volume which must also be projected for a new programs. In the current OHS rule, the volume required is 350 a year for existing programs but that has not been required of applicants. In the recent approval of an OHS CON for Brandon Regional Hospital, the applicant projected reaching 287 cases in the third year of operation.

County preference, tertiary classification and travel time

63. Bethesda argued that the tertiary classification, suggesting a regional approach, is inconsistent with having a county access provision. Bethesda correctly noted that the county provision first appeared in a draft which included the elimination of OHS from the list of tertiary services. But AHCA proposes to establish the county preference and to maintain OHS on the list of tertiary services under Rule 59C-1.002(41), and to maintain the two-hour drive time standard in Rule 59C-1.033(4)(a).

64. Substantial information, mostly from medical doctors and studies linking morbidity to low volume, supports the view that OHS continues to be a complex service. Obviously, those services in the tertiary classification range in complexity and availability from OHS at the lower level to organ transplantation at the upper level.

65. The tertiary classification is justified to assure AHCA's continued closer scrutiny of OHS CON applications. It is also consistent with the increase in the need formula divisor to 500, which together serve as restrains on the approval of additional programs.

66. AHCA reasonably concluded, based on case law and precedents with local health plan that it is not inconsistent to

apply county preferences to OHS while it is classified a tertiary service.

67. The two-hour travel time standard, is as follows:

> Adult open heart surgery shall be available within a maximum automobile travel time of 2 hours under average travel conditions for at least 90 percent of the district's population.

68. The counties most likely qualify for the preference, based on meeting or exceeding 1200 residential ischemic heart disease diagnoses, are Citrus, Martin, Hernando, St. Johns, Highlands, Indian River, and Okaloosa. The population centers in each of these counties are well within two hours of an existing provider. Citrus County, in which there is an approved but not yet operational OHS program, is about an hour's drive from Marion County. Hernando is approximately 25 minutes from the Pasco County provider. The population center of St. Johns County is approximately 40 minutes away from Duval County OHS providers. Okaloosa County is approximately a one-hour drive away from Escambia County OHS providers.

69. In District 9, Indian River is approximately a 30-minute drive from the Lawnwood OHS program. Martin Memorial, is an approved provider, is approximately 20 miles or 35 minutes from Lawnwood and 30 miles or 40 minutes from Palm Beach Gardens, another existing OHS provider.

70. In the next three to five years, it is foreseeable that Okeechobee County in northwestern District 9 could qualify for the county preference. Adjacent to Okeechobee, Highlands County's population can drive either an hour and thirty minutes to a Charlotte County OHS program or an hour and twenty minutes to a Polk County facility.

71. The evidence related to travel times, according to one of Bethesda's experts, demonstrates that the county preference is not needed to assure access which is already provided for each and every likely qualifying county. But the population centers in the entire state of Florida are all within the two-hour travel standard, and there has been no suggestion that Florida cease approval of new OHS programs.

72. Bethesda's contention that no need exists for enhanced access if the travel time standard is met, and its claim that the rule is internally inconsistent with a county preference and two-hour drive time are rejected. Two hours is, as the rule clearly states, a "maximum" not a bar, and has never been interpreted by AHCA as a bar, to more proximate locations. Any other interpretation is an impossibility considering the numerous counties across the state with multiple programs, including Dade, Broward, Palm Beach, Hillsborough, Pinellas, Orange, Volusia, Duval, and Escambia, among others.

73. AHCA can appropriately and consistently establish reasonable guidelines for choosing among applicants to enhance access within the maximum travel standard.

74. There is no language in the proposed rule indicating when it will take effect. Although the issue was raised in Bethesda's petition, it failed to provide evidence or legal arguments at hearing or subsequently to support its objection to the omission.

75. AHCA's deputy secretary testified that the agency reviews applications using need methodology rules in effect when the applications are filed. Before new rules are applied, applicants are given the opportunity to reapply to address new provisions in a rule.

CONCLUSIONS OF LAW

76. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of these proceedings. Sections 120.56, 120.569, and 120.57(1), Florida Statutes.

77. As the parties stipulated, the hospitals which participated in the proceeding as Petitioners or Intervenors are substantially affected by the proposed amendments, having applied for CONs to establish OHS programs or having existing OHS programs.

78. The FSTCS demonstrated its standing to intervene with documents supporting the contentions in its petition that (1) a substantial number of its members are the surgeons ultimately responsible for the care of OHS patients in facilities regulated by the state; and (2) that a profileration of programs and lower volumes can adversely affect the quality of care.

79. At this point in the proceedings, the issue is limited to whether AHCA has acted in excess of its delegated legislative authority to change its proposed rule without reinitiating the rulemaking process. Changes in a proposed rule which are material changes made as a result of off-the-record private negotiations, not supported by the record are invalid. That approach to rulemaking defeats the purposes for requiring notice and an opportunity for public comment before a rule is adopted. Department of Health and Rehabilitative Services v. Florida Medical Center, 578 So. 2d 351 (Fla. 1st DCA 1991).

80. Bethesda has met the initial burden of going forward to present evidence in support of its objections to the proposed rule amendments to Rule 59C-1.033 7(c) and 7(d), Florida Administrative Code, with the exception of any reasons why Subsections 7(c) and 7(d) must have the same numerical effect.

81. Bethesda has not met the burden of going forward with facts or legal arguments to support its objection to the absence of a provision in the rule specifying when it be applied to CON

applications. As a matter of law, this state follows the general rule that a change in statutes and agency rules during the pendency of an application is operative to that application. Lavernia. V. Department of Professional Regulation, 616 So. 2d 53 (Fla. 1st DCA 1993), rev. denied, 624 So. 2d 267 (Fla. 1993). Agency for Health Care Administration v. Mount Sinai Medical Center, 690 So. 2d 689 (Fla. 1st DCA 1997).

82. Section 120.52(8), Florida Statutes, provides, in part, that:

> "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by 120.54(3)(a)1.;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by Section 120.54(3)(a)1.;
>
> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;
>
> (e) The rule is arbitrary or capricious;
>
> (f) The rule is not supported by competent substantial evidence; . . .

In Agrico Chemical Co. v. State, Dept. of Environmental Protection, 365 So. 2d 759 (Fla. 1st DCA 1978), cert. denied 376 So. 2d 74 (Fla. 1979), a capricious action was described as one taken without thought or reason, and an arbitrary decision as one not supported by fact or logic. The court described competent substantial evidence as that which a reasonable person would accept as support for a conclusion.

83. The law on changing proposed rules, in Subsection 120.54(3)(d)1., is as follows:

> (d) Modification or withdrawal of proposed rules.--
>
> 1. After the final public hearing on the proposed rule, or after the time for requesting a hearing has expired, if the rule has not been changed from the rule as previously filed with the committee, or contains only technical changes, the adopting agency shall file a notice to that effect with the committee at least 7 days prior to filing the rule for adoption. Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material received on or before the date of the final public hearing, or must be in response to a proposed objection by the committee.

The statute limits changes to proposed rules to avoid unexpected changes in intent but it allows some agency flexibility to incorporate ideas derived from public input. See Dept. of

Health and Rehabilitative Services v. Florida Medical Center, 578 So. 2d 351 (Fla. 1st DCA 1991), and the cases cited therein.

84. AHCA met the burden of proving that it considered the factors required in Subsection 408.034(3), Florida Statutes.

85. AHCA met the burden of proving that the use of 1200 ischemic heart disease discharges among residents as a proxy for a critical mass of OHS patients is supported by the facts and rational. That portion of the proposal is supported by competent substantial evidence, is not vague, arbitrary or capricious, and is within AHCA's rulemaking authority.

86. AHCA met the burden of proving that a county-specific considerations are logical and rational, even though OHS is a tertiary service with a two-hour travel time standard. AHCA received competent, substantial evidence to support some kind of county-specific provision. The approach is not irrational, vague, arbitrary or capricious.

87. The more difficult issue is whether AHCA's change from the county-specific need methodology originally proposed, to a preference and a county need for enhanced access has adequate support in the record or, should have been the subject of new rulemaking proceedings.

88. The criticisms of the methodology: (1) that the need determination should include an inquiry into how accessible adjacent programs are and what their volumes are; (2) that it

was inappropriate to identify access concerns; (3) that the method did not evaluate access to care; (4) that it did not indicate whether or not there were real barriers; and (5) that the problem was the "regardless of district need" language have to be considered along with the record in support of the original proposal for some kind of county level inquiry.

89. In Florida Automobile Underwriters Association, Inc. v. Department of Insurance, 1995 WL 1052833, DOAH Case No. 94-5604RP (F.O. 1/23/95), public hearing complaints that a word was misleading and a form too long, which led the agency to add a modifier for the word and to shortened the form, were sufficient record support for changing a proposed rule.

90. A proposed CON rule based on a policy of avoiding "the unnecessary duplication of services" could not, however, be changed into a policy of "fostering competition among providers," without the agency's beginning the rulemaking process anew. In particular, the Notice of Change expressed the intent "to allocate the projected growth in the number of cardiac catheterization admissions to new providers regardless of the ability of existing providers to absorb the projected need." DHRS v. Florida Medical Center, supra.

91. In Adam Smith Enterprises, Inc. v. State, Department of Environmental Regulation, 553 So. 2d 1260 (Fla. 1st DCA 1989), an agency used five years in a formula as a "compromise"

after initially proposing to use ten years based on research showing that from ten to fifteen years was the appropriate time for cleanup of groundwater contaminants. Five years was not supported by any facts or reason.

92. In this case, there is no change in the direction of the agency's proposals as there was in the Florida Medical Center case. AHCA set out to and still proposes to expand access to OHS programs, to reexamine whether rules should be relaxed, and to consider whether counties have OHS programs in the review process. This case is, therefore, factually more akin to the Florida Automobile Underwriters case. Most of the criticisms of the earlier drafts focused on keeping county considerations more on a par with other access factors, which AHCA accomplished with the shift from a need methodology to a preference and an access finding.

93. The preference in Subsection 7(c) and the determination of a need for enhanced access in Subsection 7(d) proposal are logical and reasonable, not arbitrary or capricious. The fact that the language first appeared in the May settlement agreement between AHCA, IRMH, and Martin Memorial was obviously intended, in part, to benefit IRMH and Martin Memorial at the expense of Bethesda and any other Palm Beach County providers. That, in and of itself, does not negate the fact that the language is also a reasonable, logical response to

public comments and, therefore, supported by competent, substantial record evidence.

94. By a preponderance of the evidence, AHCA has demonstrated that the proposed amendments to Rule 59C-1.033(7)(c) and (7)(d) are not invalid exercises of delegated legislative authority.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that:

1. The proposed amendments to Rule 59C-1.033(7)(c) and (7)(d) are not invalid. Bethesda's Petition for an Administrative Determination of Invalidating of an Agency Rule is dismissed.

2. The file of the Division of Administrative Hearings in Case No. 01-2526RP is closed.

DONE AND ORDERED this 15th day of November, 2001, in Tallahassee, Leon County, Florida.

ELEANOR M. HUNTER
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 15th day of November, 2001.

ENDNOTE

1/ At all times in this Order references to open heart surgery mean adult open heart surgery.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a notice of appeal with the Clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.