GALLAGHER EVELIUS & JONES LLP

ATTORNEYS AT LAW

January 19, 2017

VIA EMAIL & HAND DELIVERY

Craig Tanio, MD, MBA, Chairperson c/o Ms. Ruby Potter ruby.potter@maryland.gov Maryland Health Care Commission 4160 Patterson Avenue Baltimore, Maryland 21215

> Re: Baltimore Washington Medical Center, Inc.

> > t/a University of Maryland Baltimore Washington Medical Center

Anne Arundel Medical Center

Cardiac Surgery Program CON Reviews Docket Nos. 15-02-2360 and 12-02-2361

Dear Commissioner Tanio:

On behalf of Baltimore Washington Medical Center, Inc. t/a University of Maryland Baltimore Washington Medical Center ("UM BWMC"), we write in response to your December 30, 2016 memorandum regarding schedule and procedures for the January 26, 2017 Exceptions hearing in the above-referenced Certificate of Need ("CON") review proceedings.

UM BWMC is filing a motion to strike the Recommended Decision together with this letter. As set forth more fully in that motion, the Recommended Decision relies on facts and analyses that were either not entered into the record, or were not entered in time to allow the parties to meaningfully oppose and/or respond. UM BWMC respectfully requests that you postpone the Commission's consideration of the Recommended Decision pending your ruling on the motion. This matter should be resolved before the Commission acts on the Recommended Decision.

In the event that the motion to strike is denied, UM BWMC respectfully requests that it be permitted 20 minutes for oral argument at the Exceptions hearing. UM BWMC's role in this complex, two-year review has been as both an applicant for new services and an interested party in the review of the application of Anne Arundel Medical Center ("AAMC"). As a result, its exceptions concern not only the approval of AAMC's application, but also the denial of UM BWMC's application. Under such circumstances, ten minutes of oral argument does not provide UM BWMC with sufficient time to meaningfully argue its exceptions.

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Thank you for your consideration of this request.

Sincerely,

Thomas C. Dame

Ella R. Aiken

cc: Kevin McDonald, Chief, Certificate of Need

Paul Parker, Director, Center for Health Care Facilities Planning & Development, MHCC

Suellen Wideman, Esq., Assistant Attorney General, MHCC

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Leana S. Wen, M.D., Health Commissioner, Baltimore City (w/ enclosures)

Leland D. Spencer, M.D. Health Officer, Caroline County (w/enclosures)

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Hon. Mike Pantelides, Mayor, City of Annapolis

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Jonathan Montgomery, Esq.

M. Natalie McSherry, Esq.

John T. Brennan, Jr., Esq.

IN THE MATTER OF * BALTIMORE / UPPER SHORE CARDIAC **BEFORE THE** * SURGERY REVIEW * MARYLAND HEALTH * * CARE COMMISSION Anne Arundel Medical Center Docket No. 15-02-2360 University of Maryland **Baltimore Washington Medical Center** Docket No. 15-02-2361

UNIVERSITY OF MARYLAND BALTIMORE WASHINGTON MEDICAL CENTER'S MOTION TO STRIKE THE RECOMMENDED DECISION AND DATA ENTERED INTO THE RECORD ON DECEMBER 30, 2016

University of Maryland Baltimore Washington Medical Center ("UM BWMC"), by its undersigned counsel and pursuant to COMAR § 10.24.01.10B, submits this motion to strike (i) the Recommended Decision issued on December 30, 2016 in the above-captioned proceeding; and (ii) the data entered into the record on the same date.

UM BWMC further requests the opportunity to present oral argument on its motion pursuant to COMAR § 10.24.01.10B(6).

UM BWMC's objective in filing this motion is to advance the interest of patient care, and ensure that regulatory decisions made regarding where and how cardiac surgery care is delivered are reached fairly and within the parameters of State law.

ARGUMENT

This review has been pending before the Commission since Anne Arundel Medical Center ("AAMC") and UM BWMC first filed Letters of Intent on December 8, 2014. Over the past two years, the applicants and interested parties have compiled an extensive administrative record consisting of argument and evidence in support of their applications and questioning the assumptions of opposing parties. On December 30, 2016, more than two years after the review first began, the Reviewer made a ruling to open the record and enter new evidence into it. The Recommended Decision was issued 45 minutes later, and incorporated an analysis that raises genuine issues of fact presented to the parties without providing meaningful opportunity to respond and comment. The reliance on newly disclosed and undisclosed facts that the parties have not had the opportunity to consider or oppose at the close of a two-year review is not only fundamentally unfair, but procedurally improper. As set forth more fully below, the Reviewer's actions violate the Administrative Procedures Act which governs this review, and violates the parties' rights to due process.

A. The Recommended Decision relies upon data entered into the record 45 minutes prior to its issuance, and data that is not a part of the record.

The December 30, 2016 letter ruling entered into the record (i) information obtained from Nielsen Claritas on the estimated and projected populations of Zip Code areas in this review; and (ii) audited financial statements of the applicant Maryland hospitals. <u>Id</u>. The population projections were used as part of the basis for an alternative

model under which the Reviewer assessed the applicants' ability to achieve a minimum volume of 200 open heart surgery cases in the second full year of operation. However, the analysis also relied upon other data that was not made a part of the record. At a minimum, the following data is missing from the record:

- **2015 and 2020 population projections**. The source described in the Recommended Decision, p. 28, Table 5 states, "Population data obtained from Nielsen. 2017 population interpolated using 2015 and 2020 projections supplied from vendor." The December 30, 2016 filing contained only 2014 and 2015 data.
- Washington, D.C. hospital discharge data. While the Recommended Decision states that certain tables in the minimum volume analysis were based only on the "HSCRC Discharge Data Base," that statement appears incorrect. The HSCRC Discharge Data Base supplies discharge information only from Maryland hospitals. It does not supply data concerning Maryland residents discharged from Washington, D.C. hospitals. Because the Reviewer relied on Zip Code level data for hospitals with service areas near D.C., the Reviewer either relied also upon a D.C. discharge database and did not disclose it, or the data is incomplete. The distinction is relevant to UM BWMC because the HSCRC database is more readily accessible than the D.C. discharge database. However, the distinction is immaterial to consideration of the Administrative Procedures Act the Reviewer did not enter data from either into the record.
- **CY 2020 use rates.** The most recent cardiac surgery use rates entered into the record were for CY 2019. Maryland Register, Vol. 42:3 (Feb. 6, 2015). The State Health Plan requires the parties to rely upon the most recent utilization projections. COMAR § 10.24.17.05A(1). Yet, the Reviewer relied upon utilization projections for CY 2020, an analysis the parties have no ability to replicate, even applying the assumptions from the State Health Plan chapter methodology, because CY 2020 projected population data is also not entered into the record.
- Additional data that would allow UM BWMC to replicate the Reviewer's methodology is also missing, but it is not readily apparent what it is because it has not been disclosed. For example, when UM BWMC attempted to recreate the Recommended Decision's definition of AAMC's 85% MSGA service area, it came up with a total of 41 Zip Codes within the service area. The Recommended

Decision refers to only 39. It is not clear why, what data was used to arrive at 39, or which Zip Codes included in UM BWMC's attempt to recreate the analysis were excluded by the Reviewer.

Because the Recommended Decision relies upon newly entered and undisclosed data, UM BWMC has been unable to fully analyze and recreate the Reviewer's conclusions.

B. The Recommended Decision relies upon an alternative method to analyze minimum volume without fully disclosing the assumptions or methodology underlying the method.

In addition to relying upon data newly entered into the record and data not disclosed at all, the Recommended Decision relies upon a new, alternative model to analyze minimum volume and, further, uses the results of that model as the sole basis for finding that UM BWMC did not meet the minimum volume of the requirement of the applicable State Health Plan chapter and thus that its program was not entitled to a comparative review with AAMC's proposed program. The Recommended Decision, however, does not fully disclose the assumptions and methodology of the alternative model it relies upon. For example, the latest cardiac surgery use rate published by the Commission is for FY 2019, yet the Recommended Decision projects cardiac surgery cases in CY 2020 without disclosing not only the use rate, but also what assumptions inform it. The Recommended Decision also fails to adequately explain the assumptions used to define the Zip codes that account for 85% of AAMC's MSGA service area discharges, as UM BWMC's attempt to recreate the service area based on the data disclosed yielded a different result than the Recommended Decision.

In order for UM BWMC to have an opportunity to consider, and potentially oppose, the entry of supposed facts into the record that result from the application of assumptions and a methodology not contained within the State Health Plan chapter, the Reviewer must fully disclose each assumption and each step of the methodology applied.

C. The Recommended Decision's reliance upon data newly entered into the record and missing data deprives UM BWMC of an opportunity to meaningfully contest that data.

Parties to a contested review under the Administrative Procedures Act, Md. Code, State Government, § 10-201 et seq., are entitled to a meaningful opportunity to contest any fact entered into the record. The Act provides, "[f]indings of fact must be based exclusively on the evidence of record in the contested case proceeding and on matters officially noticed in that proceeding." Id., § 10-214(a). "If the agency has any evidence that the agency wishes to use in adjudicating the contested case, the agency shall make the evidence part of the record." Id., § 10-213(b). In order to enter new evidence into the record, the agency "may take official notice of [certain] facts." Id., § 10-214(h)(1). "Before taking official notice of a fact, the presiding officer . . . shall give each party an opportunity to contest the fact." Id., § 10-214(h)(2).

Under the express language of the APA, a party is entitled to an opportunity to contest a fact <u>before</u> it is entered into the record. There is no dispute that the parties were given no such an opportunity here.

In addition, exceptions to a recommended decision do not constitute a meaningful opportunity to contest a fact. <u>In re Clarksburg Community Hospital</u> (Balt. City Cir. Ct,

No. 24-C-11-001046 (Pierson, J.) (Feb 21, 2012), attached as **Exhibit 1**. The Commission encountered this very issue in in the comparative review of the applications of Holy Cross Hospital Silver Spring and Clarksburg Community Hospital, Inc. to develop a new acute care general hospital. In that review, a recommended decision issued that relied upon historical, current, and projected population data and that D.C. Discharge database/Data Set. <u>Id</u>. at 2. The Court held on appeal that an agency must provide an opportunity to contest a fact before the agency takes official notice of it, and that exceptions filed in response to a recommended decision did not constitute a meaningful opportunity to contest a fact. <u>Id</u>. at 5. The Court reasoned as follows:

The explicit terms of the statute mandate that before an agency takes official notice of a fact it shall give each party an opportunity to contest that fact. Contrary to respondents' arguments, the court's review of the record convinces it that petitioners were not presented with a meaningful opportunity to contest the data relied upon by the reviewer. The issues presented in this case are of great complexity, and the record, as the Commission notes, is measured in feet rather than inches. The Reviewer's analysis of the data required a 180 page decision. Following the service of the Recommended Decision, petitioners had twenty days to file exceptions, and were allotted twenty minutes at the exceptions hearing to present all of their objections to the Recommended Decision. It is unrealistic to state that petitioners had a meaningful opportunity to contest the use of this information.

<u>Id.</u> at 5. This holding is directly applicable here. UM BWMC's exceptions do not constitute a meaningful opportunity to contest the facts entered into the record on December 30, 2016, or the facts relied upon in the Recommended Decision but absent from the record.

Furthermore, because the Recommended Decision applies the facts under an alternative model without sufficiently disclosing the assumptions and methodology that inform that model, the parties have been deprived of an opportunity to independently analyze the assumptions and recreate the methodology. The application of a model of unknown accuracy and support to exclude UM BWMC from a comparative review denies UM BWMC its right to due process.

CONCLUSION

For the reasons set forth above, UM BWMC respectfully requests the Commission strike the Recommended Decision and the facts referenced in the December 30, 2016 ruling from the record.

REQUEST FOR ORAL ARGUMENT

Pursuant to COMAR § 10.24.01.10B(6), UM BWMC requests the opportunity to present oral argument on its Motion to Strike prior to the consideration of the Recommended Decision by the full Commission.

Respectfully submitted

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Baltimore MD 21201

(410) 727-7702

Attorneys for University of Maryland Baltimore Washington Medical Center

January 19, 2017

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of January 2017, a copy of UM BWMC's

Motion to Strike the Recommended Decision was sent via email and first-class mail to:

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Ella R. Aiken

EXHIBIT 1

IN THE MATTER OF THE * IN THE

PETITION OF * CIRCUIT COURT

CLARKSBURG COMMUNITY * FOR BALTIMORE CITY

HOSPITAL, INC. * Case No.: 24-C-11-001046

* * * * *

ORDER

For the reasons set forth in a Memorandum of even date, it is, this ______ day of February, 2012,

ORDERED that the Final Decision of the Maryland Health Care Commission in Docket Nos. 08-15-2286 and 09-15-2294 is reversed and the case remanded to the Commission with direction to comply with Md. Ann. Code State Government Article § 10-213(h)(2) as set forth in the Memorandum.

W. MICHEL PIERSON, Judge

Judge's signature appears on original document

Judge W. Michel Pierson

IN THE MATTER OF THE * IN THE

PETITION OF * CIRCUIT COURT

CLARKSBURG COMMUNITY * FOR BALTIMORE CITY

HOSPITAL, INC. * Case No.: 24-C-11-001046

ORDER

The court having read and considered the Motion to Correct Administrative Record (No. 12), along with the opposition and reply, it is, this ______ day of February, 2012,

ORDERED that the motion is GRANTED, and further

ORDERED that the documents attached to the motion shall be included in the record before this court.

W. MICHEL PIERSON, Judge
Judge's signature appears on original document

Judge W. Michel Pierson

IN THE MATTER OF THE * IN THE

PETITION OF * CIRCUIT COURT

CLARKSBURG COMMUNITY * FOR BALTIMORE CITY

HOSPITAL, INC. * Case No.: 24-C-11-001046

* * * * *

MEMORANDUM

Before the court is a petition for judicial review of a decision of the Maryland Health Care Commission relating to proposed new hospitals in Montgomery County. The decision in question is the Commission's Final Decision of January 20, 2011 approving the application of Holy Cross Hospital of Silver Spring for a Certificate of Need to establish a new 93 bed acute care general hospital in Germantown, Maryland and denying the application of Clarksburg Community Hospital, Inc. for a Certificate of Need to establish a new 86 bed acute care general hospital in Clarksburg, Maryland. The petitioners are Clarksburg Community Hospital, Inc. and Adventist Healthcare, Inc. d/b/a Shady Grove Adventist Hospital.¹

Participating in the proceedings before this court were the petitioners, as well as the Maryland Health Care Commission and Holy Cross Hospital. The parties all filed memoranda in accordance with Rule 7-207. In addition, the Commission filed a Motion to Correct Administrative Record, seeking to supplement the administrative record with certain documents that were not included in the record transmitted to this court. This motion was opposed by petitioners.

Petitioners present three questions. First, they argue that the Commission violated the

¹ CCH was an applicant before the Commission; it is a wholly owned affiliate of the other petitioners, who were interested parties.

Administrative Procedure Act and the parties' right to due process by relying on extra-record evidence to support its decision. Second, they assert that the Commission misapplied the law by disregarding the State Health Plan in determining to issue a Certificate of Need to Holy Cross. Finally, they contend that the Commission exceeded its statutory authority by approving the Holy Cross project without required input from the Health Services Cost Review Commission. Each of these arguments will be addressed in turn.

1. Reliance on Extra-Record Evidence

Marilyn Moon, Ph.D., the Chair of the Commission, acted as the Reviewer on the applications. Between October 2009 and August 23, 2010, an extensive administrative record was compiled, and numerous procedural rulings were made. The Reviewer determined that the record would be closed to further submissions on August 27, 2010, and that an evidentiary hearing would be held on certain specified issues. An evidentiary hearing was held from August 30, 2010 through September 16, 2010, culminating in closing arguments.

A Recommended Decision was issued by the Reviewer on December 17, 2010. In the Recommended Decision, the Reviewer relied upon several sources of data that are the subject of petitioners' argument. She cited population data from Spatial Insights, Inc.; historical population data, current population estimates and projected population for 2014 prepared by Applied Geographic Solutions, Inc.; and the "D.C. Discharge databases/Data Set."

The significance of this information relates to the bed need standard. That standard permits an applicant to justify an increase in beds by application of projection methodology, assumptions and targets. Data employed for this purpose include zip code population data sets. Each of the

applicants used zip code level data provided by Claritas in presenting their analysis of a need for their proposed hospitals in estimating the projected market share of the hospital. The Reviewer used zip code area population estimates and projections provided by another vendor. There is no dispute that the population data used by the Reviewer was not part of the administrative record compiled before September 16, 2010.

Petitioners filed exceptions to the Recommended Decision on January 6, 2011, the deadline imposed at the time the Recommended Decision was issued. In their exceptions petitioners protested the use of the data in question. An exceptions hearing was conducted on January 20, 2011, at which time the full Commission voted to adopt the Recommended Decision.

Petitioners rely on the provisions of the Administrative Procedure Act, specifically State Government Article § 10-213(h). That section states:

- (1) The agency . . . may take official notice of a fact that is:
- (i) judicially noticeable; or
- (ii) general, technical, or scientific and within the specialized knowledge of the agency.
- (2) Before taking official notice of a fact, the presiding officer:
- (i) before or during the hearing, by reference in a preliminary report, or otherwise, shall notify each party; and
- (ii) shall give each party an opportunity to contest the fact.

Section 10-214(a) provides that "[f]indings of fact must be based exclusively on the evidence of record in the contested case proceeding and on matters officially noticed in that proceeding." Petitioners contend that the Commission's action contravened the express terms of the statute.

Respondents make several arguments in response. They suggest that the Commission complied with the terms of the statute because it afforded an opportunity to contest the facts. To

Administrative Law (2011) at 89: "Official notice may even be taken for the first time in the proposed decision as long as the opportunity for objection is provided." They claim that petitioners were not surprised by the use of the data in the Recommended Decision and dispute the argument that petitioners had no meaningful opportunity to challenge the data. They also state that petitioners have failed to establish that any prejudice occurred as a result of the supposed violation.

In support of their position, respondents state that petitioners could have addressed any disparities in the data in their exceptions to the Recommended Decision or in a later filed request for reconsideration. They note that on December 21, 2010 counsel for petitioners informed counsel for the Commission that he would be requesting data used in the decision that was not in the record.² However, petitioners' counsel waited until January 26, 2011, after the exceptions hearing had taken place, to request the data. Commission staff sent the requested data in a serious of e-mails, ten of which were sent on January 28 and the eleventh on January 31, 2011.

Respondents point to COMAR § 10.24.01.19, which permits the filing of a motion for reconsideration of a Commission decision. They state that petitioners could have sought reconsideration based on an allegation that the data presented significant and relevant information which was not previously presented to the Commission or that the data demonstrated that there had been significant change in factors or circumstances relied upon by the Commission in reaching its

² This information is contained in the Motion to Correct Administrative Record. While the court is not convinced that this material properly forms a part of the administrative record as such, it deems it expeditious to grant the motion in order to consider the impact of this information on the contention that petitioners had an opportunity to contest the use of these facts.

decision.

As to prejudice, the Commission states that while CCH used zip code area population data sets "that could be expected to differ to some degree from that used by the Reviewer, given that the data were supplied by different vendors[,] ... [i]t is common sense that all zip code area population data sets will contain very similar estimates and projections because the universe of inputs and techniques used to develop these data sets is limited." The Commission argues that petitioners fail to allege any harm or substantive error in the use of the data by the Reviewer.

The court concludes that petitioners' position has merit. The explicit terms of the statute mandate that before an agency takes official notice of a fact it shall give each party an opportunity to contest that fact. Contrary to respondents' arguments, the court's review of the record convinces it that petitioners were not presented with a meaningful opportunity to contest the data relied upon by the reviewer. The issues presented in this case are of great complexity, and the record, as the Commission notes, is measured in feet rather than inches.³ The Reviewer's analysis of the data required a 180 page decision. Following the service of the Recommended Decision, petitioners had twenty days to file exceptions, and were allotted twenty minutes at the exceptions hearing to present all of their objections to the Recommended Decision. It is unrealistic to state that petitioners had a meaningful opportunity to contest the use of this information. And given the circumstances, the failure of petitioners' counsel to secure the data prior to the exceptions hearing does not militate against this conclusion. Finally, in the court's view, the right to file a request for reconsideration of a final decision is not an opportunity to contest a fact that the agency proposes to notice within

³ It probably could more readily be measured in yards.

the contemplation of section 10-213.

Respondents also argue that the case should not be remanded because petitioners have failed to establish that any prejudice occurred as a result of the violation. The court believes that this argument is misplaced. Whether petitioners were prejudiced by use of the information is ineluctably linked to an analysis of what part that information plays in the findings that were the foundation of the decision. To determine whether the data used by the Commission was equivalent to the data otherwise in the record and what part that information played in the Decision would require the court to undertake the weighing of the data. In seeking to place upon petitioners the burden to demonstrate to this court how the use of this data prejudiced them, respondents would have this court take on the functions of the administrative agency, whose role is to determine the weight to be accorded to evidence.

For this reason, the Decision must be reversed to permit petitioners the opportunity to contest the facts noticed by the Commission after the closing of the record. The Commission must comply with the provisions of section 10-213 by giving the parties a meaningful opportunity to contest the facts of which it took official notice.

2. Misapplication of the law

Petitioners' second argument asserts that the Commission disregarded the bed need standard embodied in the 2009 Acute Care Hospital State Health Plan, COMAR § 10.24.10.04B(2), by the manner in which it determined that Holy Cross had established a bed need at its new proposed location. Petitioners contend that the Commission allowed Holy Cross to relocate 39 beds currently licensed for use at its existing hospital to the new location. Petitioners argue that this contravenes

the provisions of the Plan because the Plan does not permit the shifting of licensed beds in order to make a showing of need.

This argument is founded entirely upon comments made on page 36 of the Decision. After careful consideration of those statements in the context of the entire passage relating to the analysis of the showing of bed need under section (c)(i)(iv), the court does not believe that petitioners' characterization is accurate. The Decision finds that there was an adequate demonstration of bed need based on a service area analysis. The comments on page 36 are not necessary to this analysis. Notably, petitioners seize upon a single statement and do not consider its relation to the entire text of the lengthy and closely-reasoned discussion of the bed need showing. Furthermore, if there were a showing of need, Holy Cross's decision not to use licensed beds at its existing location would not amount to a "shifting" of beds (although it might look like it). The court is convinced that this is an illusory issue.

3. Disregard of Health Services Cost Review Commission

The third argument is based on the provisions of Health-General Article §19-103(d), which provides that the Commission shall coordinate the exercise of its functions with the Health Services Cost Review Commission to ensure an integrated, effective health care policy for the State. Petitioners argue that in awarding a Certificate of Need to Holy Cross, the Commission disregarded the requirements of this section. They rely upon a memorandum from HRCRC provided in response to a request for that agency's input. That memorandum expressed the opinion of HRCRC staff that "neither [applicant] can prudently and successfully undertake the financing, construction and successful operation of a new facility at this time."

In its Decision, the Commission undertook a detailed discussion of the viability of each

proposal, which review included the availability of resources necessary to sustain the project. (Final

Decision at 148 - 163). Within that discussion, the Decision acknowledges the conclusions of the

Health Services Cost Review Commission. After that acknowledgement, the Decision integrates that

input with its findings on viability. In the court's view, the Commission's treatment of the HSCRC

input complies with the requirements of section 19-103(d).

The statute requires coordination of the Commission's functions with HRCRC. The

language does not vest HRCRC with veto power over the Commission decisions. Given the

deference that the court must extend to the agency, the weight to be given to HRCRC input should

be measured by the Commission, as long as it is cognizant of its statutory obligation to coordinate

its function. The Decision of the Commission adequately documents its compliance with this

standard.

4. Conclusion

Because the court has concluded that the only defect in the proceedings below was the use

of extra-record information in the Decision, that defect may be rectified by a remand for the purpose

of enabling petitioner to respond to the information in question. Accordingly, the decision will be

reversed and remanded for the purpose of permitting petitioner to comment on the information

employed in the Decision.

Dated: Lebruary 21, 2012

W. MICHEL PIERSON, Judge

Judge's signature appears on original document

Judge W. Michel Pierson