IN THE MATTER OF	*	
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BALTIMORE / UPPER SHORE CARDIAC	*	BEFORE THE
	*	
SURGERY REVIEW	*	MARYLAND HEALTH
	*	
Anne Arundel Medical Center	*	CARE COMMISSION
Docket No. 15-02-2360	*	
	*	
University of Maryland	*	
Baltimore Washington Medical Center	*	
Docket No. 15-02-2361	*	
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UNIVERSITY OF MARYLAND
BALTIMORE WASHINGTON MEDICAL CENTER'S
COMMENTS IN RESPONSE TO THE JANUARY 23, 2017 RULING

University of Maryland Baltimore Washington Medical Center ("UM BWMC"), by its undersigned counsel and pursuant to COMAR § 10.24.01.10B, submits these comments in response to the January 3, 2017 ruling (the "Ruling"). As described more fully below, UM BWMC objects to the admissibility of the data for the purpose of assessing minimum volume because it is not relevant to the parties' compliance with that standard, and objects to the admissibility of the data because it is not reliable.

COMMENTS

I. The data should not have been admitted for the purpose of assessing minimum volume because it is not relevant to that analysis.

A. Evidence not relevant to a disputed issue is not admissible.

The data should not have been admitted for its intended purpose because it was used to determine the applicants' compliance with the minimum volume standard under

an "alternative forecast model" that was constructed entirely by the Reviewer, has no demonstrated ability to project a hospital's cardiac surgery volume, and is not scientific.

Under the Administrative Procedure Act ("APA"), the Reviewer may exclude evidence that is irrelevant. MD. CODE ANN., STATE GOV'T § 10-213(d)(2). The Maryland Rules define "relevant evidence" to mean "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Maryland Rule 5-401. In other words, relevant evidence tends to either establish or disprove issues in a case. Parker v. State, 156 Md. App. 252, 268, cert. denied, 383 Md. 347 (2004). Evidence that is not relevant is not admissible. Maryland Rule 5-402. It is not possible to determine the relevance and admissibility of evidence without assessing the purpose for which it is offered, because one could not determine that the evidence tends to prove or disprove an issue in the case.

Moreover, upon request, evidence may be found to be admissible for one purpose but not for another purpose. Maryland Rule 5-105; St. James Const. Co. v. Morlock, 89 Md. App. 217, 226-27 (1991) (the court concluded that evidence of the projected cost of restoring brick veneer was admissible only for purpose of showing the reasonableness of the cost of repairs and not for other purposes). In these circumstances, the tribunal should restrict the evidence and find that it has limited admissibility.

On October 5, 2016, the Reviewer stated that he intended "to use information beginning with Calendar Year 2009 to the most recent quarter of information available

from the HSCRC Discharge Database and from the District of Columbia Database in this review." (DI #74GF, p. 4). Also, immediately before issuing the Recommended Decision on December 30, 2016, the Reviewer stated that certain Nielson Claritas population data had been entered into the record. (December 30, 2016 Letter to Parties). However, the Reviewer did not identify, much less explain, the relevance of admitting these data into the record. At that time, UM BWMC could not have known that the Reviewer had admitted the discharge data and the population data for the purpose of supporting the alternative forecast model in assessing the applicants' compliance with the minimum volume standard, COMAR § 10.24.17.05A(1). Indeed, until after the Recommended Decision was released and reviewed, no party was even aware of the existence of the alternative forecast model. Thus, at the time the data were admitted, there was no meaningful opportunity for the parties to contest admissibility on relevance grounds because the Reviewer did not identify any intended uses of the data.[1]

The Reviewer's Ruling, which permits the parties to file comments regarding only the 13 Virginia cardiac surgery cases from the VHI data set and the 2020 population projections, does not remedy the error of previously admitting additional data that was later used for the purpose of supporting the alternative forecast model. These limited data constitute only a small portion of the evidence that should not have been admitted

[1] In his January 25, 2017 Letter Ruling, the Reviewer notes that UM BWMC actually used the D.C. Discharge Database in the development of its case volume projections. Presumably, the Reviewer makes this observation in support of the relevance of the data. However, as discussed above, evidence may be admitted for one purpose but not for another.

for this purpose. The Reviewer should restrict the admissibility of all of the discharge data and the population projection data. Specifically, the Reviewer should exclude the use of this evidence to support the alternative forecast model, because that model is not relevant.

B. The alternative forecast model is unsupportable and is inconsistent with the regulations governing this review.

The alternative forecast model is severely flawed. As a result, no data admitted into the record for the purpose of analyzing minimum volume pursuant to the alternative forecast model can be relevant to this review. The alternative forecast model relies upon an unsupportable premise that there is a correlation between the population size of a hospital's MSGA service area, and the hospital's case volume from all geographic locations. Thus, it relies on a comparison based on two distinctly different service lines and two different geographic regions. There is no evidence in the record that there is any correlation between these concepts, and indeed there is no evidence or article cited in the record in this review that support would support the theory on which the alternative model relies.

In addition, the alternative forecast model is flawed because it is plainly inconsistent with the state health plan chapter applicable to this review, as demonstrated by the following examples:

- The alternative forecast model considers volume in CY 2020. The parties each anticipate that their projects will be implemented within months of CON approval: 8 months for AAMC, 7 months for UM BWMC. (UM BWMC Appl., 29; AAMC Appl., 22). The minimum volume standard refers to the *second* full year of operation. Thus, the applicable year is 2019, not 2020.

- The alternative forecast model applies an adjustment to reduce cardiac surgery cases to open heart surgery cases. In doing so, the model relies on the incorrect version of the applicable State Health Plan chapter. The applicable chapter for this review is the version in effect as of August 18, 2014, which requires that an applicant document the ability to perform 200 cardiac surgery cases. COMAR § 10.24.17.05A(1) (Aug. 18, 2014). The November 9, 2015 version was amended to require an applicant to perform 200 *open heart* cardiac surgery cases. COMAR § 10.24.17.05(A)(1). The 2015 chapter is not applicable to this review. COMAR § 10.24.17.02E (Nov. 9, 2015) ("An application or letter of intent submitted after the effective date of these regulations is subject to the provisions of this chapter.")

- The alternative forecast model appears to use an incorrect definition of cardiac surgery. The Recommended Decision, which introduces the alternative forecast model, applies the November 9, 2015 version of the applicable State Health Plan chapter, based both on the discrepancy noted under the bullet point above, and that noted in footnote 2 of UM BWMC's Exceptions to the Recommended Decision. Cardiac surgery is defined differently in that version than in the version that applies to this review. The August 18, 2014, version contains 48 ICD-9 codes that are not included in the definition of cardiac surgery included in the version that went into effect just 14 months later, on November 9, 2015. Also, the November 9, 2015 version contains 25 ICD-9 codes that are not included in the earlier version. *Compare* COMAR § 10.24.17.09 (Aug. 18, 2014) with COMAR § 10.24.17.11(8) (Nov. 9, 2015).

The alternative forecast model is also flawed for the reasons described in UM BWMC's January 11, 2017 Exceptions to the Recommended Decision.

Because the alternative forecast model is flawed, no data that will be input into the alternative forecast model to assess minimum volume is relevant or admissible for the purpose of considering the parties' compliance with the minimum volume standard.

C. The parties lack sufficient information to independently recreate the results of the alternative forecast model.

The parties lack sufficient information to recreate the alternative forecast model. As a result, it cannot be deemed reliable, and no data should be entered into the record for the purposes of assessing minimum volume under the alternative forecast model.

While the January 23, 2017 Ruling provides some detail that previously prevented the parties from recreating the alternative forecast model, additional information is still lacking. For example, COMAR § 10.24.17 specifies that utilization should be trended forward by Health Planning Region. The alternative forecast model projects utilization based on the "hospital service area level, the age-adjusted use rate trend for the Zip Code areas constituting the AAMC and BWMC 85% relevance MSGA service area." (January 23, 2017 Ruling). The Recommended Decision does not indicate whether the alternate methodology projects utilization (i) by individual Zip Code for all Zip Codes within the service area, or (ii) by the service area as a whole. These two approaches could result in the same data being input into the model with different final results.

Based on the results described in the Recommended Decision, it appears most likely that the alternative forecast model projects utilization based on trends for the service area as a whole. In that case, however, the model does not identify clearly how the discharges from overlapping Zip Codes were calculated. Utilization in the AAMC service area as a whole trends differently than the BWMC service area as a whole, but there is no method described to projected discharges for a Zip Code in both service areas.

Because the record in this review does not contain sufficient information to independently recreate the alternative forecast model, it is not reliable, and no data should be admitted for the purpose of assessing minimum volume pursuant to the model.

II. The Virginia Dataset should not have been admitted for any purpose because it lacks sufficient information to be reliable.

The State Health Plan chapter applicable to this review contains a definition of "Cardiac Surgery" that is based on International Classification of Disease (9^{th} Revision) procedure codes ("ICD-9 codes"). COMAR § 10.24.17.09 (Aug. 18, 2014). The data provided from Virginia hospitals does not indicate how cardiac surgery is defined. Thus, there is no way, from the available record, to determine whether the cases reported as cardiac surgeries would meet the definition of cardiac surgery that applies to this review.

This distinction is important to the reliability and accuracy of the Virginia data. As this Commission's regulatory history demonstrates, ICD-9 codes that are considered cardiac surgery can change over time. Cardiac surgery, as defined in the version of the applicable State Health Plan chapter that became effective on August 18, 2014, and governs this review, contains 48 ICD-9 codes that are not included in the definition of cardiac surgery included in the version that went into effect just 14 months later, on November 9, 2015. Also, the November 9, 2015 version contains 25 ICD-9 codes that are not included in the earlier version. *Compare* COMAR § 10.24.17.09 (Aug. 18, 2014) with COMAR § 10.24.17.11(8) (Nov. 9, 2015). There is not sufficient evidence in the record for the parties to determine whether the cases identified as cardiac surgery cases in the VHI dataset meet the definition of cardiac surgery that applies to this review.

In addition, even if the Reviewer obtained the Virginia dataset with a request based on only specific ICD-9 codes, the data may still be inaccurate. The Recommended Decision cites and quotes the later version of COMAR § 10.24.17 in the discussion of minimum volume. Recommended Decision, 15-16. If the Reviewer similarly relied upon the ICD-9 codes set forth in the later version in requesting the VHI dataset, the results would not be consistent with the definition of cardiac surgery that governs this review.

III. UM BWMC objects to the entry of additional data into the record because it was not given a meaningful opportunity to object, and the data is inaccurate, unreliable, or not relevant.

The Ruling concedes that the Recommended Decision relies upon facts and data entered into this review for the purpose of inputting it into a "alternative forecast model"[2] to assess minimum volume, without providing the parties an opportunity to comment in advance on the proposed entry of that data, and indeed without even entering some of the data into the record until after the issuance of the Recommended Decision. Yet, the Ruling denies the motion to strike the Recommended Decision. As described more fully in UM BWMC's January 19, 2017 motion to strike the Recommended Decision, the APA requires that parties be given the opportunity to comment on data *before* it is entered into the record.[3] MD. CODE, STATE GOVERNMENT, § 10-214(h)(2). Under the

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[2] Recommended Decision, 27.

[3] AAMC's attempt to distinguish In re Clarksburg Community Hospital is misplaced. First, AAMC's argument is inconsistent with the plain text of the APA, which states: "Before taking official notice of a fact, the presiding officer . . . shall give each party an opportunity to

APA, the Reviewer should have followed the following steps: (1) give notice of intent to enter data into the record; (2) provide an opportunity to comment; (3) if appropriate, make a ruling to enter the data into the record; and (4) rely upon the data in rendering a decision. Id.; see also In re Clarksburg Community Hospital (Balt. City Cir. Crt., Feb 21, 2012) No. 24-C-11-001046 (Pierson, J.) (attached as Exhibit 3 to UM BWMC January 11, 2017 Exceptions). The table below demonstrates that a meaningful opportunity was not provided.

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contest the fact." MD. CODE, STATE GOVERNMENT, § 10-214(h)(2). Second, the case AAMC cites in support, Mehrling v. Nationwide Ins. Co., is distinguishable: it considers whether parties to a review may enter new evidence when filing exceptions. Mehrling v. Nationwide Ins. Co., 371 Md. 40, 58-60 (2002) It makes no finding regarding the entry of facts into the record by an agency or person acting in the capacity of an Administrative Law Judge. The distinction is important because an Administrative Law Judge's decisions regarding evidence admitted into the record are restricted by the parties' rights to due process. Third, AAMC provides no support for its conclusion that the decision in In re Clarksburg Community Hospital, which considered a factually analogous case before the Maryland Health Care Commission, is incorrect. To the contrary, that decision is directly on point and expressly finds that the Reviewer may not do what occurred in this review. In re Clarksburg Community Hospital (Balt. City Cir. Crt., Feb 21, 2012) No. 24-C-11-001046 (Pierson, J.), p. 5 ("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.").

Data / Facts	(1) Disclosure of reliance on data / disclosure of purpose for which data would be used (if different)	(2) Opportunity to comment[1]	(3) Entry of Data into the Record	(4) Reliance on Data / Facts by Reviewer
VHI data set	January 23, 2017	Feb. 3, 2017[2]	Jan. 23, 2017[3]	Dec. 30, 2016
CY 2020 population projections	December 30, 2016	Feb 3, 2017[2]	Dec. 30, 2016[4]	Dec. 30, 2016
CY 2020 use rates	December 30, 2016	None	Dec. 30, 2016[4]	Dec. 30, 2016
HSCRC discharge database	October 5, 2016 / December 30, 2016	None	October 5, 2016.[5]	Dec. 30, 2016
DC discharge database	October 5, 2016 / January 23, 2017	None	October 5, 2016.[5]	Dec. 30, 2016

Note 1: Exceptions filing not included as opportunity to comment. *See* In re Clarksburg Community Hospital (Balt. City Cir. Crt., Feb 21, 2012) No. 24-C-11-001046 (Pierson, J.).

Note 2: As discussed below, the opportunity to comment was insufficient to comply with APA.

Note 3: Information sufficient to analyze relevance of data still missing.

Note 4: Information sufficient to analyze data not provided until 1/23/2017.

Note 5: Reviewer gave notice of reliance on October 5, 2016. However, data has not been entered into record in this review.

The Reviewer's determination to allow the parties to comment *post hoc*, and only on certain data sets in isolation, both on its own and when combined with the Reviewer's decision not to strike the Recommended Decision, demonstrates that this is not a meaningful opportunity to comment that the data is inaccurate, unreliable, or irrelevant for its intended purpose, and as a result should not be entered into the record. Under the APA, the parties should be given an opportunity to persuade the Reviewer that the data is not accurate, not reliable, or not relevant for the purpose for which the Reviewer intends to use it (and in fact already has). That opportunity has not been provided.

The only way to remedy this procedural flaw is to strike the Recommended Decision and data from this review, and provide the parties the opportunity to comment on *all* data, in combination with the proposed purpose/use of the data to assess minimum

volume under the alternative forecast model, in advance of any ruling by the Reviewer. Any other procedure violates both the intent and plain meaning of the APA.

CONCLUSION

For the reasons set forth above, UM BWMC respectfully requests the Commission strike the data admitted into the record pursuant to the January 23, 2017 ruling in the December 30, 2016 ruling from the record.

Respectfully submitted,

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February 3, 2017

CERTIFICATE OF SERVICE

I hereby certify that on the 3rd day of February 2017, a copy of UM BWMC's Comments in Response to January 23, 2017 Ruling was sent via email and first-class mail to:

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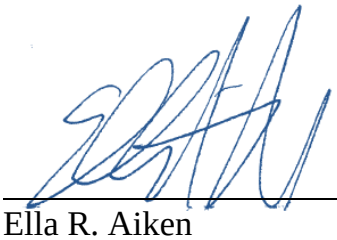

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