MARYLAND
Health Care
Commission

DATE: October 19, 2023

TO: Commission

FROM: Eileen Fleck, Chief Acute Care Policy and Planning

SUBJECT: Staff Recommendation for Proposed Permanent Regulations: State Health Plan for Acute Hospital Services (COMAR 10.24.10)

Maryland Health Care Commission (MHCC) staff received comments on the draft regulations posted for informal comment from one individual, James C. Buck, and three organizations, the Institute for Justice, the Maryland Hospital Association, and the University of Maryland Medical System. These comments are posted on MHCC's website.[1] The comments on each section of the draft regulations, and MHCC staff's response to each comment follows. In addition to the changes prompted by comments, staff made additional minor changes for consistency and clarity.

.03 Issues and Policies

Comment

James C. Buck commented that two corrections are needed on page 8 and page 9 of the draft regulations posted for informal comment. On page 8, under the title "The Maryland Hospital Payment Model," he suggested the second sentence should refer to "both private payors and government payors" or "both private and government payors." On page 9, in the last full paragraph, he noted an error in the second sentence. Instead of "model by considered," the sentence should refer to "model being considered."

Response

Staff agrees and the language has been corrected.

.04A General Standards

Comment

[1] https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

University of Maryland Medical System (UMMS) suggested that the language in the introductory paragraph should be revised because it refers to standards that are applicable to a Certificate of Need (CON) project for a CON applicant, but for exemption from CON requests, the language refers to an applicant demonstrating consistency with each general standard. UMMS suggested that an exemption is intended to be more streamlined and less burdensome, and the wording suggests a greater burden is placed on applicants for an exemption request. UMMS suggested that the wording in the regulations be modified so that applicants for a CON exemption request are only expected to address standards applicable to the proposed project.

Response

Staff revised the language to clarify that only applicable standards must be addressed.

.04A(1) Information Regarding Charges

Comment

The Maryland Hospital Association commented that MHCC should not verify compliance with state and federal price transparency policies; it should only be verified by those who enforce those policies.

Response

Staff verification of compliance is similar to the verification of licensure and accreditation. Staff will not be redoing work conducted by other state or federal agencies, rather, checking for documentation of compliance. This standard imposes a very minimal burden on CON applicants. Staff has revised the wording in this standard to clarify the approach of staff and expectations for an applicant.

Comment

The Maryland Hospital Association also questioned whether MHCC should deny an applicant a CON, if instances of non-compliance are later corrected, and whether MHCC has the authority to add a condition to a CON for non-compliance with state and federal price transparency and charity care policies.

Response

Including standards in the regulations that require compliance with federal and state policies is within the scope of MHCC authority in the review of a CON project. Staff recommends no changes.

Comment

UMMS suggested that only violations of price transparency laws as determined by the Health Education and Advocacy Unit of the Attorney General's Office should be considered and proposed modifying the standard in COMAR 10.24.10.04A(1)(c) to implement this suggestion. UMMS also suggested that there be a reasonable temporal limitation to substantiated violations that have been rectified by a hospital, a period of two years.

Response

Staff contacted the Health Education and Advocacy Unit (HEAU) in the Attorney General's Office regarding the comments from UMMS. Staff for HEAU noted that it does not determine violations. It acts as a mediator in disputes, and if it has concerns that a provider's practices violate the Consumer Protection Act, then it refers the case to the Consumer Protection Division's enforcement unit. Because HEAU does not determine violations, the proposed change by UMMS would not be appropriate. Staff has revised the language to refer to the Consumer Protection Division rather than HEAU. Staff concluded that limiting consideration of complaints or violation to the prior two years is too short and recommends no change to address this comment.

.04A (2) Charity Care and Financial Assistance Policy

Comment

UMMS noted that the timeline for responding to an applicant's request for financial assistance is 14 days after the patient applies for financial assistance in statute, and the draft regulations only allow for three days.

Response

Staff agrees that the regulations should be consistent with statute and revised the draft regulations as suggested.

.04A(3) Quality of Care

Comment

The Institute for Justice commented that the statement that a hospital shall provide high quality care is meaningless without specifying how MHCC measures quality.

Response

MHCC staff agree that specifying how MHCC measures quality of care is essential. MHCC has identified specific standards a hospital must meet to show a commitment to providing high quality care. A hospital must be licensed, in good standing, accredited by the

Joint Commission or other accreditation organizations, and in compliance with conditions of participation of the Medicare and Medicaid programs. Staff recommends no changes.

Comment

The Institute for Justice also cited the requirement that a hospital explain what steps it is taking to improve when it falls below average on Quality Measures in the Maryland Hospital Consumer Guide as an example of why the Quality of Care standards lack substance. The Institute for Justice stated that hospitals that have received CONs routinely perform below average on those performance metrics and concluded that because that is true, the CON process does not ensure that hospitals meet quality standards.

Response

Quality standards are a relevant component of CON review. The inclusion of quality standards is intended to also provide greater incentive for a hospital to meet quality standards. Staff recognizes the Maryland Consumer Guide for Hospitals is just one way to measure quality. An additional requirement was added to address the HSCRC quality measures to supplement and enhance the assessment of quality of care in hospitals. Staff continues to recommend that blocking approval of a hospital's project based on falling below average for any quality standard would be counterproductive to the larger goals of promoting access to health care, efficient delivery of care, and improving population health. Staff recommends no change.

.04B(1) Geographic Access

Comment

The University of Maryland Medical System commented that the objective criteria of travel time had been removed and suggested the first sentence reference travel time.

Response

Staff revised the standard to make it clear that optimal access is defined to be within 30 minutes travel time under normal driving conditions.

Comment

The Institute for Justice commented that by requiring that a new or relocated acute hospital services be situated so that 90 percent of the population in the health planning region are within 30 minutes under normal driving conditions encourages providers to be concentrated in one area instead of more evenly spread throughout the state.

Response

Staff notes that the requirement referenced by the Institute for Justice is not an absolute standard with no exceptions. The standard also states that a proposed location for a hospital is also acceptable, even if 90 percent of the population in the health planning region will not be within 30 minutes of the hospital, if the Commission determines that access will be substantially improved for the population in the applicant's service area through a reduction in travel time. Staff recommends no change.

Comment

James Buck noted that it appears "service area" is misspelled in this standard.

Response

Staff made the correction noted.

.04B(2)(a) Non-Geographic Barriers to Access

Comment

UMMS suggested that the language in this standard is unclear. UMMS asked whether the standard would require an emergency medical screening including active labor, regardless of an individual ability to pay, which would then be duplicative of the Emergency Medical Treatment & Labor Act of 1986, 42 U.S.C. §§139.dd. UMMS explained that the standard presents many concerns regarding hospital compliance, billing, and admission based on a patient's self-assessment.

Response

The standard refers to involuntary psychiatric patients. That is the only situation where the Commission has issued an exemption to allow the hospital to serve only voluntary psychiatric patients. Staff modified the standard to reference the State Health Plan chapter for acute psychiatric services, COMAR 10.24.21, to clarify the meaning of the standard. Staff also modified the standard to refer to an "exemption" rather than a "waiver" to be consistent with COMAR 10.24.21.

.04B(3) Identification of Bed Need and Addition of Beds

Comment

UMMS suggested that in some cases a lack of beds may be contributing to long emergency department wait times and patient boards. UMMS recommended that new language be added as follows:

"(d) The Commission shall prioritize a project involving an applicant's addition of MSGA bed capacity to reduce emergency department wait times and emergency department patient boarding where an applicant can demonstrate such metrics are negatively affected by a lack of bed capacity."

Response

Staff notes that the proposed draft regulations require an applicant to demonstrate the need for a proposed project and the standards for evaluating projects are broad. Staff recommends no change.

.04B(6) Cost-Effectiveness

Comments

UMMS suggested that an applicant should not be required to analyze alternatives to its proposed project, including detailed capital and operational cost estimates for such alternatives unless those projections can be done without undue burden, time, and expense. UMMS suggested modifying the standard in .04B(6)(a)(ii) to explicitly state this.

MHA suggested that instead of requiring an applicant to consider two alternatives to a proposed project, the Commission should allow an applicant to explain why fewer than two alternatives were considered.

Response

Staff has concluded that cost estimates are required in order to have a valid comparison of alternatives to the proposed project. Allowing an applicant to demonstrate that providing cost estimates is too burdensome and expensive would undermine the goal of obtaining useful information for analyzing an application while minimizing administrative burden. Staff recommends no change.

With respect to the comments from MHA, staff notes that the regulations already allow for an applicant proposing a project with limited objectives to demonstrate that there is only one practical approach to achieving the project's objectives. In other cases, the consideration of alternatives provides potentially valuable information and promotes the development of more cost-effective projects. Staff recommends no change.

Comment

UMMS suggested that the language in .04B(6)(c)(i) should be modified because it believes that there may not be one or even two alternative project sites to

serve the proposed populations within a Priority Funding Area as defined under the State Finance and Procurement Article, Title 5, Subtitle 7B.

Response

The standard requires that an applicant show it considered alternative project sites. An applicant can and should present information as to why alternative sites are not viable if applicable. The proposed change would not substantively reduce the burden on an applicant because an applicant would essentially still have to show that alternative locations were considered. Staff recommends no change.

.04B(11) Inpatient Nursing Unit Space

Comment

UMMS stated that this standard prohibits nursing units that exceed 500 square feet per bed from being recognized in rate adjustments to an applicant's global budget revenue and should be more flexible to allow for possible adjustments to a hospital's budget. UMMS explained that for community hospitals the smaller number of beds, with the same requirements for support space creates a much larger number of square feet per bed ratio. UMMS suggested modifying the language to state that for specialty units the allowed square feet per bed should be the standard required by licensure and design standards.

Response

Staff has revised the standard to allow for approval of additional space, if the applicant demonstrates that additional space is required to meet licensure and reasonable design standards.

.04B(14) Emergency Department Capacity and Space

Comment

UMMS commented that the standard should be modified to allow an applicant to demonstrate the need for additional treatment spaces or departmental space based on the population to be served or efforts to reduce emergency department wait times. UMMS included a quote from the ACEP Guidelines, which notes that the biggest impact on the space needed is the turnaround time for patients using examination spaces.

Response

Staff revised the standard to allow for greater flexibility. Specifically, if an applicant can demonstrate a need for additional treatment space above the benchmark

range, even with efficient operation of the emergency department, then additional treatment space may be considered.

.06 Definitions

Comment

UMMS requested that a definition of merger be included, the same one in the draft procedural regulations.

Response

The word merger does not appear in the regulations. For this reason, it is not included in the definitions. Staff recommends no change.

Comment

UMMS requested that the definition of "Threshold for capital expenditures" be changed to refer to the meaning set forth in statute which is consistent with draft procedural regulations. Staff also changed the defined term used for consistency, replacing "threshold for capital expenditures" with "hospital capital threshold."

Response

Staff revised the definition to reference the meaning set forth in Health-General Article §19-120(a)(4).

Comment

James C. Buck noted that on page 43, in the definition of "Inpatient Unit Program Space per bed" should refer to "HIPPA" should be to "HIPAA."

Response

Staff corrected this definition as suggested.

Other Comments

The Institute for Justice commented that CON laws harm patients. It cited sources that it believes support its statement that CON laws lead to higher costs for individual payers and government payers, and increased mortality rates for many common conditions, while failing to increase the quality of healthcare. The Institute for Justice suggested that reducing the burden of CON laws would address this issue based on broad generalizations about quality and access to health care in states with and without CON laws.

Response

Maryland is a unique state that maintains not only Certificate of Need laws but also regulation of hospitals' budgets through the Health Services Cost Review Commission. CON laws alone may not control health care costs, but Maryland has the ability to influence health care costs through regulation of hospitals' budgets, unlike most other states. Staff has strived to reduce the burden of CON regulations, including in draft COMAR 10.24.10. Staff recommends no changes.