



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

To: Commissioners

From: Eileen Fleck, Chief, Acute Care Policy and Planning

Date: May 20, 2021

Re: Staff Recommendation for Proposed Permanent Regulations, COMAR 10.24.11, State Health Plan for Facilities and Services: General Surgical Services

Maryland Health Care Commission (MHCC) staff is requesting that the Commission repeal and replace the regulations in COMAR 10.24.11, State Health Plan for Facilities and Services: General Surgical Services (“Surgical Services Chapter”). Several of the recommended changes in the replacement regulations stem from laws enacted during the 2019 and 2020 sessions of the Maryland General Assembly. Additional changes are based on internal review by staff and informal comments received in February 2021. Staff did not convene a workgroup because its primary intention was to update the Surgical Services Chapter to align with the laws enacted in 2019 and 2020 and make only minor additional changes. In response to a draft Surgical Services Chapter posted on February 16, 2021, staff received comments from three organizations, the Maryland Society of Anesthesiologists, the Maryland Ambulatory Surgery Association, and Johns Hopkins Health System.¹ The comments and staff’s analysis and recommendations are described below, as well as additional changes suggested by staff, in the order in which these changes appear in the draft Surgical Services Chapter.

.02B Legal Authority of the State Health Plan.

Staff added language stating that the State Health Plan shall be consistent with the All-Payer Model and made other minor changes. These changes were required for consistency with changes enacted in the 2019 legislative session (HB 646).

.03 Issues and Policies.

¹ The informal comments submitted are available on MHCC’s website:
https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

Staff substantially revised most of this section after posting a draft Surgical Services Chapter for informal comment. These changes included incorporating updated analysis of data and revising the text for clarity and accuracy. The Maryland Ambulatory Surgery Association (MASA) had two comments on this section. There were no comments from other organizations on this section.

Comment

MASA suggested that rather than stating that non-sterile procedure rooms may be used for certain types of procedures, the document should state that “general anesthesia can be used in procedure rooms “in certain clinical situations.”

Response

Staff added language that closely mirrors the language in statute. This language describes the specific procedures and circumstances when general anesthesia is not allowed in a procedure room.

.02D Chapter Content and Applicability.

This section of the Surgical Services Chapter was updated based on laws enacted in the 2019 and 2020 legislative sessions. Specifically, it states that the Surgical Services Chapter applies to the addition of one or more operating rooms (whether inpatient, outpatient, or mixed use) in a hospital, and it applies to the addition of one or more operating rooms in a freestanding medical facility. Staff did not receive any informal comments on these changes.

.03D Policy Statements.

Staff made minor changes to all policies, based on input received from Commissioners and internal review, except for Policy 6 and Policy 1. No changes have been made to Policy 6. Staff received one comment from MASA suggesting a change to Policy 1. The policies included in the draft Surgical Services Chapter are shown below with underlining of new text and strikethroughs for deletions of text.

Policy 1: Surgical services ~~will~~ should be provided in settings where patient safety will be assured by adherence to licensure and accreditation requirements for safety standards.

Policy 2: Surgical services, both inpatient and outpatient, should be provided in the most cost-effective manner ~~possible~~ for the health care delivery system that is consistent with safely and appropriately meeting the health care needs of patients.

Policy 3: The efficient use of resources for performing surgical services should be promoted. ~~;under-utilization of surgical capacity will be discouraged.~~

Policy 4: A provider of surgical services should participate in utilization review or a peer review programs for surgical services.

Policy 5: Surgical services, both inpatient and outpatient, in all settings, should be geographically and financially accessible ~~and should be accessible~~ regardless of a patient's ability to pay.

Policy 6: A provider of surgical services should consider smart and sustainable growth policies as well as green design principles in facility or center design choices.

Policy 7: A provider of surgical services ~~will~~ should continuously and systematically work to improve the quality and safety of patient care. This includes planning and implementing electronic health record systems that contribute to infection control, patient safety, and quality improvement and participation in quality performance initiatives.

Comment

MASA suggested that the standard refer to patient standards being met, rather than assuring patient safety because ASCs are held to standards rather than outcomes.

Response

Staff revised Policy 1 to refer specifically to adherence to licensure and accreditation requirements for safety standards. This change adds specificity and is consistent with the standard in the Surgical Services Chapter that requires, in .05A(4), that an ASF be accredited and meet or exceed minimum requirements for licensure in Maryland.

.04A Determination of Coverage.

Staff revised the description of who may apply for a determination of coverage, to be consistent with a law passed in the 2019 legislative session (SB 940). Previously, an ambulatory surgical facility was defined as having two or more operating rooms. The change in statute allows larger surgical facilities, those with two operating rooms, to be established through obtaining a determination of coverage, an abbreviated review process that requires the submission of information by proposed centers. In addition, SB 940 allows a hospital to establish a non-rate regulated ambulatory surgery center that has two or fewer operating rooms without a certificate of need (CON). Staff updated the Surgical Services Chapter to be consistent with these changes.

Staff reduced the amount of information required when there is a change in the principal owner or a change in a majority of the owners of an ASC. The revised draft Surgical Services Chapter provides that the notice may be limited to an affirmation that no changes are occurring in the physical facilities, physicians or other health care practitioners, staff, or surgical specialties provided at the ASC and that changes are limited to ownership.

Based on staff's knowledge of recent consumer complaints, staff added a requirement that an existing ASC shall certify that it is meeting a requirement to provide an estimate of out-of-pocket charges for each patient prior to arrival for surgery.

Staff also made minor changes to be consistent with new terminology for ASCs, which include ASC-P, ASC-1, and ASC-2. This terminology was adopted to distinguish ASCs based on the number of operating rooms, which is useful because an ASC-1 may add an operating room without CON review, but an ASC-2 seeking to add an operating room requires approval through the CON review process.

Comment

MASA suggested that item 12 on the list of information requested for a determination of coverage be revised to identify only the specialties for cases performed in an ASC, rather than specific procedures. MASA explained that a comprehensive list may not be known at the time of the application.

Staff Response

Staff requests that an applicant provide the specific procedures that will be performed in any sterile operating room and the types of anesthesia that will be used in the sterile operating room, and the specific procedures that will be performed in any non-sterile procedure room and the types of anesthesia that will be used in each non-sterile procedure room because this information is needed to determine if the room is appropriate for the surgical procedures proposed to be performed in it. This determination is relevant both to patient safety and to compliance with regulations for ASCs and ASFs. Staff recommends no change in response to MASA's comment.

.05A General Standards

.05A(1) Information Regarding Charges.

In the draft posted for informal comment, this standard remained unchanged compared to the current Surgical Services Chapter

Comment

MASA suggested that a general list of charges is misleading rather than informative, if a patient's insurance plan and co-pays are not taken into account. MASA suggested that, instead, a requirement that an ASC work with a patient to determine the anticipated charges is more reasonable.

Staff Response

Staff agrees that general charge information is less useful than an estimate based on the insurance plan of a patient. However, staff concludes that general charge information is still useful for potential patients who have not yet selected a location for treatment.

Other Staff Recommendations

Based on further internal review following posting of the draft Surgical Services Chapter for Informal public comment, staff revised standard .05A(1) to include a requirement for disclosure of health carrier network participation for the ASF and for each surgeon and health care provider. This information will be very helpful to consumers. The revised standard is shown below, with new text underlined and deletions shown with strikethroughs.

(1) *Information Regarding Charges and Network Participation.*

Information regarding charges for surgical services shall be available to the public.

(a) ~~A physician outpatient surgery center~~ Each ambulatory surgery center, ambulatory surgical facility, and hospital shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

(b) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry or as required by applicable regulations the names of the health carrier networks in which it currently participates.

(c) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry the names of the health carrier networks in which each surgeon and other health care practitioner that provides services at the facility currently participates.

(d) ~~(b)~~The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.

(e) ~~(c) Making this information available~~ Providing a patient with an estimate of out-of-pocket charges prior to arrival for surgery shall be a condition of any CON issued by the Commission.

.05A(3) Charity Care and Financial Assistance Policy.

Comment

MASA suggested the requirement that notice of the ASC's charity care policy be posted in the registration and business offices of an ASC is unreasonable because the policies are not easily explained in a short notice posted in a registration area. MASA suggested that instead a notice be posted stating that the information is available upon request.

Staff Response

Staff notes that the requirement for posting charity care policies is for ASFs and not both ASFs and ASCs. Staff concluded that adding specificity to the notice requirement would be helpful. Staff added a sentence to this standard to state that the notice of an ASF's charity care policy shall include general information about who qualifies and how to obtain a copy of the policy or may include a posted copy of the policy.

Comment

Johns Hopkins Health System (JHHS) suggested that additional clarification of the requirement that an applicant be able to demonstrate that its historic level of charity care or its projected level of charity care is appropriate. JHHS noted that the standard appeared to describe three distinct analytical approaches for how an applicant would demonstrate the appropriate level of charity care for a hospital's service area population. JHHS requested that the standard more clearly define what information is required.

Staff Response

Staff revised this standard to define more clearly the information requested, as suggested by JHHS. Staff added a sentence to state that the socio-economic indicators evaluated shall include median income and type of insurance by zip code area, when available. Staff also clarified that the analysis by an applicant must include a comparative analysis of charity care provision by the applicant hospital and other hospitals in Maryland. The current draft standard is shown below with new language underlined and deletions shown in strikethroughs.

~~(e) (b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent HSCRC Community Benefit Report, A hospital shall be able to demonstrate that its historic level of charity care or its projected level of charity care is appropriate to the needs of its actual or projected service area population. This demonstration shall include an analysis of the socio-economic conditions of the hospital's actual or projected service area population, a comparison of those conditions with those of Maryland's overall socio-economic indicators, and a comparative analysis of charity care provision by the applicant hospital and other hospitals in Maryland. The socio-economic indicators evaluated shall include median income and type of insurance by zip code area, when available. The analysis provided may also include an analysis of the social determinants of care affecting use of health care facilities and services and the health status of the actual or projected hospital service area population.~~

.05A(4) Quality of Care.

Staff revised .05A(4)(b) to provide that an applicant shall document that it is accredited by the Joint Commission or other accreditation organization recognized by the Centers for Medicare and Medicaid and the Maryland Department of Health as acceptable for obtaining Medicare

certification and Maryland licensure. In the current Surgical Services Chapter, the standard states only that a hospital shall document that it is accredited by the Joint Commission. The revisions to the standard provide for the potential for accreditation by another accrediting organization, if that organization is appropriately recognized. Staff received no comments on this change.

.05A(5) Transfer Agreements.

Staff revised this standard for consistency with the regulations of the Maryland Department of Health. Rather than requiring that an ASF have a written transfer agreement with a hospital for handling patients that exceed the capability of the ASF, the amended standard requires an ASF to have an arrangement that complies with the requirements of COMAR 10.05.05.09. These requirements include that a freestanding ambulatory surgical facility (FASF), a licensing term that includes both ASFs and ASCs, shall have either a written transfer agreement with a local Medicare participating hospital or require that all physicians, dentists, or podiatrists performing surgery at the FASF have admitting privileges at such a hospital. Staff did not receive any comments on this change.

.05B(7) Construction Costs.

Staff replaced the reference to any rate increase proposed by a hospital to an adjustment of the hospital's global budget revenue authorized for the hospital related to the capital cost of the project. This change makes the language consistent with how the Health Services Cost Review Commission now regulates revenue for Maryland hospitals. Staff did not receive any comments on this change.

After posting the draft Surgical Services Chapter staff changed the threshold for requiring an applicant to demonstrate the reasonableness of new construction costs from 15% over the Marshall Valuation Services (MVS) benchmark to 25% over the MVS benchmark. Staff concluded that an applicant for an ASF should not be required to justify the reasonableness of new construction costs until those costs exceed 25% of the MVS benchmark based on staff's assumption that construction costs will soon sharply increase.

.05B(10) Preference in Comparative Reviews.

Staff deleted this standard. This standard gave preference, in a comparative review, to the ambulatory surgical facility (ASF) that would provide a greater level of charity care. This standard was eliminated because it would rarely be the case that two ASFs are seeking to provide the same types of surgeries to the same service area population, and each project can be evaluated based on its own merits without this standard. Staff did not receive any comments on this change.

.06 Exemption from Certificate of Need Review for the Establishment of an ASF

This section was deleted because the law has changed to allow establishment of an ASC with two sterile operating rooms without CON review. This exemption process is no longer needed. Staff did not receive any comments on this change.

.07B Terms Defined

With the elimination of Regulation .06, Regulation .07 Definitions, became Section .06 Definitions. Staff added three definitions for clarity, and two other definitions as a result of the inclusion of a new standard requiring disclosure, upon public inquiry, of an ASF's participation in health carrier networks and each surgeon or other health care provider's participation in health carrier networks. The five definitions added are shown below.

“Ambulatory Surgery Center” or “ASC” means any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that has no more than two operating rooms, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services. Subcategories of ASCs include: an ASC-P, which has only procedure rooms; an ASC-1, which has one operating room; and an ASC-2, which has two operating rooms.

“FGI Guidelines” refers to the Facilities Guideline Institute’s Guidelines for Design and Construction of Outpatient Facilities or the Facilities Guideline Institute’s Guidelines for Design and Construction of Hospitals, as applicable.

“Health Carrier” means an insurer, non-profit health service plan, health maintenance organization, managed care organization, dental plan organization, employer, third party administrator, or any other entity that contracts to provide health care items or services to enrollees of the health carrier.

“Health Carrier Network” means a health carrier’s providers and facilities that contract directly or indirectly through a subcontracting entity with the health carrier to provide health care items or services to the carrier’s enrollees.

“Invasive procedure” is a procedure with high infection risk that penetrates the protective surfaces of a patient’s body, including skin and mucous membranes and generally requires entry into a body cavity or may involve insertion of an indwelling foreign body. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin are not included in this definition.

In addition to the five definitions added, staff revised the definition of ambulatory surgical facility for consistency with 2019 legislative changes. Staff also revised the definition of procedure room for consistency with the law enacted in 2020 (SB728/HB 935). The changes to the definition of procedure room are shown below, with new language underlined and deleted text shown through strikethroughs.

“Procedure room” means a non-sterile room in which minor surgical procedures are performed ~~under only topical, local, regional anesthesia or minimal intravenous sedation.~~ including endoscopy and endoscopic procedures requiring deep sedation. ~~A deeper level of intravenous sedation in a procedure room is only appropriate for a minor procedure, such as an endoscopy, that is minimally invasive. Minimal~~

intravenous sedation is a drug-induced state during which a patient responds normally to verbal commands, and the patient's airway reflexes, ventilator functions, and cardiovascular function are unaffected. A p-Procedure rooms shall only be accessed from a semi-restricted corridor or an unrestricted corridor. Procedure rooms shall not be used for open surgical procedures that enter the thorax, abdomen, pelvis, cranium, or spine, for procedures that routinely require induction of deep sedation or general anesthesia for the entirety of the surgical procedure, or for procedures that require a sterile environment. Deep sedation or general anesthesia may be induced if warranted by changes in a patient's clinical situation and the room is equipped to safely conduct the required level of anesthesia. An anesthesia practitioner is not precluded from providing the highest level of anesthesia support that may be required to safely treat patients undergoing procedures that are appropriate for the non-sterile environment of a procedure room, whether located in a hospital, a freestanding medical facility, an ambulatory surgical facility, or an ambulatory surgery center.

Staff deleted the definition of “Physician Outpatient Surgery Center” because this term is no longer consistent with who may establish an ambulatory surgery center through obtaining a determination of coverage. Staff received comments from one organization in response to the definitions included in the draft Surgical Services Chapter posted for informal comment.

Comment

The Maryland Society of Anesthesiologists expressed support for the proposed definitions of procedure room and special purpose operating room.

Staff Response

Staff recommends no change in response to this comment.