

**Staff Recommended Changes and Discussion Questions
For Surgical Services Work Group Meeting, February 14, 2017**

.02D Plan Content and Applicability

MHCC staff recommends adding language to note that the SHP chapter for surgical services is applicable in part to requests for an exemption from CON review for a general hospital seeking to convert to a freestanding medical facility, pursuant to COMAR 10.24.19.04C, that includes surgical capacity. MHCC staff plans to reference only the design requirements in .05B (4) and the operating room capacity and needs assessment standards in .06A.

MHCC staff notes that the SHP chapter for freestanding medical facilities will be a new chapter and draft regulations will be considered for adoption as proposed regulations by the Commission on February 16, 2017. In addition, MHCC staff anticipates that the licensure regulations for FMFs will likely be updated, and currently an FMF may not include surgical services. However, MHCC staff believes that covering the potential inclusion of surgical services at an FMF is appropriate in order to allow flexibility in future decisions made by other State agencies that regulate FMFs.

1. Are the proposed requirements for surgical capacity at a freestanding medical facility appropriate? Should additional requirements be included?

.04 Procedural Rules

Staff plans to add to .04A, which describes the requirements for a Determination of Coverage for a physician outpatient surgery center (POSC), the other questions that have been part of MHCC staff's review of a Determination of Coverage request for over a decade. Only about half the questions are currently included in the SHP chapter. Staff will also include a statement regarding participation in data collection necessary for MHCC to carry out its responsibilities for health care planning. Currently, data collection from physician outpatient surgery centers and ambulatory surgical facilities is primarily through an annual survey, and the requirement to participate in the annual survey is not specifically mentioned in the regulations. However, MHCC's authority for data collection from these facilities is established in statute. MHCC staff have provided a copy of the information currently requested for a Determination of Coverage.

Staff plans to update .04B, which describes the design requirements for POSCs, based on the most recent Facility Guidelines Institute's *Guidelines for Design and Construction of Hospitals and Outpatient Facilities* ("FGI Guidelines"). In the most recent FGI Guidelines, the former terminology of "Class A, B, and C operating rooms" has been replaced with the terms operating room and procedure room. Staff recommends that the SHP chapter for surgical services also use this terminology.

.03 Issues and Polices

MHCC staff plans to update some of the discussion and statistics included in this section. MHCC staff is not recommending changes to the list of seven policies included on page 6 of the current SHP chapter for surgical services.

1. A concern has been raised regarding access to care and the higher, sometimes unexpected cost of care for patients who have surgery at ambulatory surgery centers that are out of network. Should a discussion of this issue be included in the SHP chapter? Should policies or standards be modified to address this issue?
2. Are there other issues that have been missed that should be included in this section?
3. Does anyone want to propose changes to the existing policies?

.05A General Standards

For the standards on Information Regarding Charges and Charity Care Policy, MHCC staff recommends no changes. For the standard on Quality of Care, MHCC staff recommends adding language to state that an applicant shall provide information on how its existing POSC(s) or ambulatory surgical facility (ASF) performed on any quality measures adopted by the Centers for Medicare and Medicaid Services (CMS) that are publicly reported and explain how its POSC(s) or ASF compares on these quality measures to other facilities that provide the same type of specialized services in Maryland that are included in public reports, if applicable. MHCC staff also recommends that an applicant share also provide information on how it compares to national or regional benchmarks calculated by CMS for these quality measures, if applicable. Although there is not currently mandatory participation in CMS's data collection pertaining to quality measures, there is a financial penalty for not participating and participation is high nationally. In addition, while public reporting on these measures has not been implemented yet, MHCC staff anticipates that this reporting will likely be implemented soon.

1. At the previous Surgical Services Work Group meeting, a change to the charity care policy standard was suggested. Specifically, it was proposed that the standard for hospitals refer only to compliance with HSCRC policies. However, the Work Group only spent a short time discussing this standard. What do work group member think about this proposed change?
2. Are there any concerns about MHCC's staff's suggested modification of the Quality standard?
3. Are there other changes to the Quality standard or other general standards that anyone wants to discuss?

.05 Project Review Standards

MHCC staff plans to update the standard for Construction Costs to refer to global budgets rather than rate increases. MHCC staff also wants to reconsider whether ambulatory surgical facilities that exceed the Marshall Valuation Service benchmark by 15% or more have been approved or would potentially be approved in the future. MHCC staff has concluded that the impact standard currently included in .06C should be included as project review standard, but otherwise is not proposing changes to the assessment of impact on a hospital.

1. Are there changes to the project review standards that anyone wants to propose?
2. Is it acceptable that the impact of additional surgical capacity on hospitals is referenced and appears to be a consideration, but not the impact of additional surgical capacity on other ambulatory surgical facilities?

Exemptions from CON Review to Establish an ASF with Two Operating Rooms

MHCC staff proposes that there be an opportunity to establish an ASF with two operating rooms through an exemption from CON review in three circumstances.

- An existing physician office surgery center with one sterile operating room that has operated for a minimum of two years that seeks to add one operating room.
 - Two existing physician office surgery centers that both operate no more than one sterile operating room and that have both operated for a minimum of two years that seek to establish an ASF through consolidation of their operations to create a single ASF with two operating rooms.
 - A general hospital seeking an exemption from Certificate of Need to convert to a freestanding medical facility with two operating rooms on the same campus as the freestanding medical facility, if it seeks such an exemption in conjunction with an exemption to convert to a freestanding medical facility.
1. Is it reasonable to require that a POSC be operation two years prior to an applicant being eligible for an exemption from CON to establish an ASF? Is there a different time period that should be used, or both a time period and completion of at least one of MHCC's staff's annual surveys?
 2. Are there are circumstances when an exemption from CON to establish an ASF with two operating rooms should be allowed? Hospitals not converting to FMFs but seeking to establish ASFs outside the scope of hospital rate regulation through exemption from CON review were proposed at the first Work Group meeting.

MHCC staff proposes that the same general standards for CON reviews, pertaining to Information Regarding Charges, Charity Care Policy, and Quality of Care apply to exemptions from CON review to establish an ASF with two operating rooms. MHCC staff proposes that an applicant be required to also meet specific project review standards for Need, Design Requirements, Efficiency, Construction Costs, and Transfer Agreements. MHCC staff has concluded that the standards for Design Requirements, Transfer Agreements, and Construction Costs should be the same standards that apply to CON applications.

For the Need standard, MHCC staff proposes:

- That an applicant seeking to add an operating room to its existing POSC shall demonstrate that its existing sterile operating room was utilized at or above optimal capacity in the most recent two 12- month periods for which data has been reported to the Commission;
 - Similarly, for two applicants seeking to combine operations, the applicants would have to demonstrate that on a combined basis, their two sterile operating room were utilized at or above optimal capacity for one operating room in the most recent two 12- month periods for which data has been reported to the Commission; and
 - For an applicant proposing to establish a two-operating room ambulatory surgical facility in conjunction with establishment of a freestanding medical facility through conversion of a general hospital, the applicant would need to demonstrate that, in the most recent two 12-month periods for which data is available, the converting hospital performed sufficient outpatient surgery to demonstrate that more than one operating room is needed, based on the optimal capacity standards for operating rooms included in the SHP chapter for surgical services.
1. Is two years of data sufficient for evaluating the need for a second operating room? Should only one year of data be required?
 2. Should alternative ways to demonstrate need be included?

MHCC staff proposes that an applicant in an exemption from CON review shall demonstrate how its project will result in the more efficient and effective delivery of surgical services, consistent with the established criteria for exemption reviews. When the applicant proposes to add an OR to the existing POSC, the required demonstration will be more efficient and effective delivery of surgical services will result from establishment of the proposed ASF as compared to the continued operation of the applicant's POSC. When two applicants propose to combine their existing POSCs together to establish the proposed ASF, they will have to demonstrate that the proposed ASF will result in more efficient and effective delivery of surgical services as compared to the continued operation of the applicants' two POSCs. For a hospital seeking to convert to an FMF, the applicant will be required to demonstrate that more efficient and effective delivery of services is possible through establishing the ASF rather than through establishment of a POSC.

1. Is the proposed approach to consideration of improved efficiency and effectiveness appropriate? Are there changes anyone wants to propose?

MHCC staff plans to explicitly state that exemption from CON to establish an ASF with two operating rooms will be considered by the Commission within 45 days of receipt of complete information addressing all of the applicable standards and criteria in the SHP chapter for surgical services. This approach is consistent with State statute.

1. Are the proposed requirements reasonable? Are there any changes that anyone wants to propose?

.07 Definitions

MHCC staff proposes deleting the definitions for Class A, B, and C operating rooms and modifying the definition of operating room and procedure room.

1. Are there other changes to definitions that anyone wants to propose?