



# **Maryland Health Care Commission**

Thursday, March 23, 2017

1:00 p.m.



MARYLAND  
HEALTH CARE  
COMMISSION

# AGENDA

## 1. APPROVAL OF MINUTES

## 2. UPDATE OF ACTIVITIES

3. [ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center \(Docket No. 15-02-2360\) and University of Maryland Baltimore Washington Medical Center \(Docket No. 15-02-2361\)](#)

4. [ACTION: Changes in Membership of the Cardiac Services Advisory Committee](#)

5. [PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11](#)

6. [Overview of Upcoming Initiatives](#)

7. [ADJOURNMENT](#)



MARYLAND  
HEALTH CARE  
COMMISSION

# AGENDA

1. APPROVAL OF MINUTES

## 2. UPDATE OF ACTIVITIES

3. [ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center \(Docket No. 15-02-2360\) and University of Maryland Baltimore Washington Medical Center \(Docket No. 15-02-2361\)](#)

4. [ACTION: Changes in Membership of the Cardiac Services Advisory Committee](#)

5. [PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11](#)

6. [Overview of Upcoming Initiatives](#)

7. [ADJOURNMENT](#)

1. APPROVAL OF MINUTES
2. UPDATE OF ACTIVITIES
3. **ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center (Docket No. 15-02-2360) and University of Maryland Baltimore Washington Medical Center (Docket No. 15-02-2361)**
4. ACTION: Changes in Membership of the Cardiac Services Advisory Committee
5. PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11
6. Overview of Upcoming Initiatives
7. ADJOURNMENT



## **ACTION:**

Certificate of Need – Exceptions Hearing on Revised  
Recommended Decision – Baltimore/Upper Shore Cardiac Surgery  
Review – Anne Arundel Medical Center (Docket No. 15-02-2360)  
and University of Maryland Baltimore Washington Medical Center  
(Docket No. 15-02-2361)

(Agenda Item #3)



MARYLAND  
HEALTH CARE  
COMMISSION

# AGENDA

1. APPROVAL OF MINUTES
2. **UPDATE OF ACTIVITIES**
3. [ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center \(Docket No. 15-02-2360\) and University of Maryland Baltimore Washington Medical Center \(Docket No. 15-02-2361\)](#)
4. [ACTION: Changes in Membership of the Cardiac Services Advisory Committee](#)
5. [PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11](#)
6. [Overview of Upcoming Initiatives](#)
7. [ADJOURNMENT](#)



# **ACTION:**

## **Changes in Membership of the Cardiac Services Advisory Committee**

(Agenda Item #4)



MARYLAND  
HEALTH CARE  
COMMISSION

# AGENDA

1. APPROVAL OF MINUTES
2. **UPDATE OF ACTIVITIES**
3. [ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center \(Docket No. 15-02-2360\) and University of Maryland Baltimore Washington Medical Center \(Docket No. 15-02-2361\)](#)
4. [ACTION: Changes in Membership of the Cardiac Services Advisory Committee](#)
5. [PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11](#)
6. [Overview of Upcoming Initiatives](#)
7. [ADJOURNMENT](#)





# **PRESENTATION:**

Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11

(Agenda Item #5)



# Update on Revisions to the State Health Plan Chapter for General Surgical Services (COMAR 10.24.11)

Maryland Health Care Commission Meeting  
March 23, 2016



- Provide an overview of the current regulations for general surgical services.
- Explain proposed changes and feedback from work group meetings.
- Obtain feedback from the Commission prior to asking the Commission to consider draft proposed regulations.



- Commission staff were asked to develop regulations for an exemption process for a provider of ambulatory surgical services to add a second operating room.
- The authority for MHCC to develop an exemption process for establishing an ambulatory surgical facility with two operating rooms is stated in Health General 19-114(b)(1).
- MHCC has not previously implemented regulations to allow for this exemption process.
- This SHP Chapter needs to be updated to account for potential changes to regulations for freestanding medical facilities (FMFs).

# Background: Authority to Establish an Exemption Process

Health General 19-114(b)(1) states:

The office of one or more health care provider or a group practice performing ambulatory surgical services with two operating rooms may be exempt from Certificate of Need (CON) requirements if the Commission, in its sole discretion, determines that:

- (a) A second operating room is necessary to promote the efficiency, safety, and quality of the surgical services offered; and
- (b) The office meets the criteria for exemption from CON review as an ambulatory surgical facility set forth in the SHP under COMAR 10.24.11

# Background: Authority to Establish an Exemption Process

Health General 19-120(k) states:

(9) Nothing in this subsection may be construed to permit a hospital to build or expand its ambulatory surgical capacity in any setting owned or controlled by the hospital without obtaining a certificate of need from the Commission if the building or expansion would increase the surgical capacity of the State's health care system.

# Background: Current Regulations



- Currently, CON approval is required to establish a facility with two or more operating rooms.
- Alternatively, an entity may request a determination of coverage to establish a physician outpatient surgery center (POSC) with no more than one sterile operating room.
- The limit on the scope of CON regulation has resulted in a proliferation of ambulatory surgical providers with one operating room or only procedure rooms.

# Exemption Process for Establishing an ASF with Two ORs

## Applicability:

- An existing POSC with one OR that has operated for a minimum of one year.
- Two existing POSCs that both operate no more than one OR and that have both operated for a minimum of one year.
- A general hospital seeking an exemption from CON to convert to an FMF and establish an ambulatory surgical facility with two operating rooms on the same campus as the FMF.



# Exemption Process for Establishing an ASF with Two ORs

- The General Standards that apply to CON reviews would also apply to requests for an Exemption.
- The General Standards include the following:
  - Information Regarding Charges
  - Information Regarding Procedure Volume
  - Charity Care
  - Quality of Care
  - Transfer Agreements

## General Standard: Information Regarding Charges

- The Director from the Consumer Protection Division of the Maryland Attorney General participated in the work group and expressed concerns about consumers being surprised by bills from providers of ambulatory surgical services, such as POSCs and ASFs.
- MHCC staff has proposed modifying the current standard to specifically note that complaints against a POSC, ASF, or hospital regarding a failure to disclose charge information will be a factor in determining compliance with this standard.

# General Standard: Information Regarding Charges

- Although a POSC cannot be held accountable by MHCC if an affiliated provider, such as an anesthesia group, fails to provide transparent billing information, and existing POSCs cannot be forced by MHCC to provide transparent charge information, the revised standard provides an opportunity to consider this factor in making decisions on CONs and exemption requests.
- The work group supports this approach.
- In addition to the revised standard that applies to CONs and exemption requests, MHCC staff have proposed revising the information requested for determinations of coverage to make it clear that POSCs are required to provide estimates of out-of-pocket charges for patients.

# General Standard: Information Regarding Procedure Volume

- MHCC staff concluded that procedure volume is relevant to an individual's decision on where to have surgery because of the relationship between quality and volume for many surgical procedures.
- MHCC staff received feedback following the final work group meeting that greater reporting of volume information should be required.
- The work group did not specifically consider this proposed change.

# General Standard: Information Regarding Procedure Volume

- Upon inquiry, ASFs, POSCs, and hospitals will be required to provide information on volume for specific surgical procedures for the most recent 12 months available, updated on at least a quarterly basis.
- Existing POSCs cannot be required to provide this information. However, for future POSCs, the request for a determination of coverage shall include a statement attesting that the center or facility shall provide volume information for specific surgical procedures for the most recent 12 months available, updated on at least a quarterly basis.

# General Standard: Charity Care



- This standard was revised in the last update of this SHP chapter to promote greater provision of charity care by ASFs and POSCs that seek to become ASFs.
- There are no proposed changes to this standard.
- The consensus of the work group was that the current standards are acceptable.

# General Standard: Quality of Care



- Under the current regulations, an existing ASF must:
  - Document that it is licensed, in good standing, by DHMH
  - In compliance with conditions of participation for Medicare and Medicaid program.
  - Accredited by one of several agencies.
- An applicant proposing an ASF must demonstrate that the ASF will meet the above standards.
- A hospital must be accredited by the Joint Commission.

# General Standard: Quality of Care



- MHCC staff has proposed an addition to the current criterion for the Quality standard.
- An applicant shall provide information on how its existing POSC or ASF has performed on quality measures adopted by CMS.
- The work group discussed this proposed change and reached consensus on taking this approach.





## ● Exemption Requests

- Need
- Design Requirements
- Location
- Efficiency
- Construction Costs

## ● CON Reviews

- Service Area
- Need
- Design Requirements
- Support Services
- Patient Safety
- Construction Costs
- Financial Feasibility
- Impact
- Preference in Comparative Reviews



- For both a CON and an exemption request to establish an ASF with two ORs, the need standards are very similar.
- The proposed operating rooms are likely to be utilized at or above optimal capacity within three years of beginning to use the new or replacement surgical capacity.
- The optimal capacity assumptions have not changed.



- A POSC seeking to add a second OR through an exemption must demonstrate that the existing OR was utilized at or above optimal capacity in the most recent 12 month period for which data has been reported to the Commission.
- If two POSCs are seeking to combine and establish an ASF with two ORs, each must have reported data to the Commission for at least 12 months, but each is not required to have operated its OR at or above optimal capacity for this period.



- MHCC staff discussed with the work group how much flexibility should be allowed in the choice of location for an ASF established through an exemption.
- The consensus of the work group was that some flexibility is acceptable. However, there was no consensus on a specific proposed approach.
- The standard proposed by MHCC allows an applicant to locate a proposed ASF at a nearby site, under certain circumstances.



- An applicant must demonstrate that the proposed ASF cannot be located at the current location or an immediately adjacent location, before an alternative nearby site may be considered for approval.
- Nearby is defined as a site that can be reached from the reference site by crossing no more than one public thoroughfare.



- An applicant must demonstrate how its project will result in more efficient and effective delivery of surgical services.
- This is consistent with the statute that authorizes MHCC to develop an exemption process for the addition of a second OR.

# Next Steps



- Staff will review the informal feedback received and consider additional revisions to the draft SHP chapter for surgical services.
- Staff will ask the Commission to consider adopting a replacement proposed SHP chapter for surgical services after considering Staff's analysis of the informal feedback.



MARYLAND  
HEALTH CARE  
COMMISSION

# AGENDA

1. APPROVAL OF MINUTES
2. **UPDATE OF ACTIVITIES**
3. [ACTION: Certificate of Need – Exceptions Hearing on Revised Recommended Decision – Baltimore/Upper Shore Cardiac Surgery Review – Anne Arundel Medical Center \(Docket No. 15-02-2360\) and University of Maryland Baltimore Washington Medical Center \(Docket No. 15-02-2361\)](#)
4. [ACTION: Changes in Membership of the Cardiac Services Advisory Committee](#)
5. [PRESENTATION: Update of State Health Plan Regulations for General Surgical Services, COMAR 10.24.11](#)
6. [Overview of Upcoming Initiatives](#)
7. [ADJOURNMENT](#)





# **Overview of Upcoming Initiatives**

(Agenda Item #6)



ENJOY THE REST OF  
YOUR DAY