Maryland Health Care Commission

Thursday, May 18, 2017

1:00 p.m.

MARYLAND HEALTH CARE COMMISSION

AGENDA

1. **APPROVAL OF MINUTES**
2. UPDATE OF ACTIVITIES
3. ACTION: Certificate of Need – Stella Maris, Inc. (Docket No. 16-03-2375)
4. ACTION: COMAR 10.24.19 – State Health Plan for Facilities and Services: Freestanding Medical Facilities – Final Regulations
5. ACTION: COMAR 10.25.18 – Health Information Exchanges: Privacy and Security – Final Regulations
6. ACTION: COMAR 10.25.19 – State Recognition of Electronic Advance Directive Service Provider – Release for Informal Public Comment
7. UPDATE: COMAR 10.24.11 - State Health Plan for Facilities and Services: General Surgical Services
8. Overview of Upcoming Initiatives
9. ADJOURNMENT

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Certificate of Need – Stella Maris, Inc.
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(Agenda Item #3)

MARYLAND HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

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COMAR 10.24.19 – State Health Plan for Facilities and Services: Freestanding Medical Facilities – Final Regulations

(Agenda Item #4)

MARYLAND HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

ACTION:

COMAR 10.25.18 – Health Information Exchanges: Privacy and Security – Final Regulations

(Agenda Item #5)

Health Information Exchange Privacy and Security

Amendments – Final Action

COMAR 10.25.18

May 18, 2017

The MARYLAND
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Summary

- Legislative Authority - A 2011 law requires MHCC to adopt regulations for the privacy and security of protected health information exchanged through a health information exchange (HIE)
- Staff seeks Commission action in adopting the proposed amendments to COMAR 10.25.18 *Health Information Exchanges: Privacy and Security of Protected Health Information,* as final amendments
- Overview:
  - Applies to HIEs that choose to provide consumers with electronic access to their information
  - Ensures that HIEs that offer access do so in a way that safeguards the patient's health information
  - Addresses electronic consumer access, including: view, download, transfer, control, and submit
  - Requires HIEs to provide consumers with access to an electronic disclosure report

Background

- The need for HIE regulations - National concerns exist about the sufficiency of HIPAA/HITECH as the floor for privacy and security

- Regulations went into effect on March 17, 2014 and were amended on June 20, 2016

- HIEs currently operating in Maryland:

  - Calvert Memorial Hospital
  - Chesapeake Regional Information System for our Patients (CRISP)
  - Children's IQ Network
  - Frederick Memorial Hospital
  - Peninsula Regional Medical Center
  - Prince George's County Public Health Information Network
  - Western Maryland Health Systems
  - Surescripts

Developing the Amendments

- Staff worked with the HIE Policy Board, a staff advisory group, to develop consumer access policies
  - In general, consumers want access to their electronic health information
  - Consumer engagement increases awareness and often results in more active health care management for the individual and their family
  - Informal comments were sought in December (stakeholders were notified on November 23, 2016); comments were considered in finalizing the proposed amendments
- Approximately 13 organizations provided informal comments to the draft amendments; three letters of support were received
- Staff proposed the amendments to the Commission on January 26, 2017

Proposed Amendments

Access

- HIEs must appropriately verify the identity of the health care consumer requesting electronic access
- HIEs must allow the consumer to authorize another person to have access to their health information, such as a family member or caregiver
- An HIE may charge a reasonable cost-based published fee for providing electronic access

View Access

- Patient's information available for view, must be equivalent to what is made available to health care providers using the HIE
  - Certain attributes about their health information must be made available, such as date of treatment and source of the information
- An HIE must provide information to consumers that will assist them if they have any questions about their electronic health information
- Patient's electronic information must be presented in a way that is easy to navigate and can be easily printed

Download, Transfer, or Control Access

- HIEs that offer consumers the ability to control how their information is released must implement technology processes that meet generally accepted industry processes and practices

- HIEs that offer consumers the ability to download or transmit their health information shall provide the patient's information in a readily available industry standard format, standards that are typically used in other online applications

The Ability to Submit

- An HIE that offers health care consumers the ability to submit information to the HIE, shall:
  - Identify the source of the information, such as, patient, payor, health care provider, etc., when presented to the provider using the HIE
  - Not use patient submitted health information to override or replace health information submitted from other sources, such as providers or payors

Consumer Education

- An HIE must provide information to consumers regarding electronic access, including:
  - What information the consumer must provide as part of patient identity proofing
  - The right to authorize another individual to also have access to their electronic health information
  - The right to request review of a denial of access
  - What level of consumer control they may have over their health information
  - Advice concerning safeguarding their health information obtained from the HIE

Disclosure Report

- Within six months of the regulation effective date, an HIE must establish and maintain an online process that allows consumers to obtain an electronic report detailing any disclosures of their information through the HIE

- An HIE must comply with certain security provisions such as, identity proofing, authentication, audits, etc.

Exemption

- An HIE may request a one-year exemption from certain requirements in the regulation, when certain conditions are met
- An HIE may not be exempted from any provisions of the regulation that is in current federal law or other State law
- An exemption request must specify the reason for the exemption and the time period requested for the exemption if applicable
- The MHCC may choose to issue the exemption, request additional information, or deny the request

Comments Received

- Two letters from:
  - Ms. J. Sarah Posner, J.D., Consumer advocate, HIE Policy Board member
  - Maryland's Office of the Attorney General's Health Education and Advocacy Unit (HEAU)
- General Observations
  - Support for the provisions, where enhancements provide better clarity and are appropriately balanced
  - Recommended changes that would align the provisions with current consumer rights laws
  - Suggestions for additional clarification or regulatory framework on HIEs

Non-Substantive Changes Recommended

- HEAU recommends adding language in subsection .12A(1) to clarify that an HIE must meet the requirements under the subsection when accepting patient health information in addition to disclosing their information
  - Staff action – Clarification recommended: Staff agrees with the addition of clarifying language under subsection 12A(1) as recommended
- HEAU recommended that “cost-based” be added following the word reasonable in subsection .12B(1) to align with language in current law
  - Staff action – Clarification recommended: The word “cost-based” should be added in subsection .12B(1) as recommended
- HEAU noted that the provision in subsection .12E are slightly inconsistent with the proposed definition of “download” in subsection .02B(18)(a).
  - Staff action – Clarification recommended: The definition of “download” should be amended to align with subsection .12E.

Requested Commission Action

Staff recommends that the Commission adopt the proposed amendments as final with three non-substantive changes

Thank You!

The MARYLAND
HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

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COMAR 10.25.19 – State Recognition of Electronic Advance Directive Service Provider – Release for Informal Public Comment

(Agenda Item #6)

Regulations – DRAFT

COMAR 10.25.19

State Recognition of an

Electronic Advance Directives Service

Recommendation to Release for Informal Public Comment

May 18, 2017

MARYLAND

The MARYLAND HEALTH CARE COMMISSION

Background

- 2011 – The Maryland Health Care Commission (MHCC) awarded roughly $1.6M by the Office of the National Coordinator for Health Information Technology (ONC) to pilot the exchange of electronic advance directives

- 2012 – The Secretary of the Department of Health and Mental Hygiene (DHMH) provided MHCC with additional startup funding to support a pilot that would enable statewide exchange of electronic advance directives through the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP)

Background *(continued…)*

- 2013 – The MHCC issued a Request for Proposals to identify a vendor to implement a statewide electronic advance directives system that health care providers could access through CRISP; ADVault (dba MyDirectives.com) was competitively selected

- 2014 – Interface between the MyDirectives.com repository and CRISP was launched; remains operational today absent funding

House Bill 1106

- *Public Health – Electronic Advance Directives – Witness Requirements* passed during 2015 legislative session

- Key elements of the law:
  - Requires two witnesses for electronic signature on an advance directive outside the personal presence of the declarant who signed the advance directive if it was created in compliance with electronic witness protocols of DHMH

House Bill 1385

- *Public Health – Advance Directives – Procedures, Information Sheet, and Use of Electronic Advance Directives* passed during 2016 legislative session

- Key elements of the law:
  - Alters witness requirements for electronic advance directives
  - Expands scope of education and outreach efforts, including required contents of a specified advance directive information sheet and the distribution process
  - Requires MHCC to develop a State Recognition program for electronic advance directive services in order to connect to CRISP

House Bill 188

- *Public Health – Advance Directives – Witness Requirements, Advance Directives Services, and Fund* passed during 2017 legislative session

- Key elements of the law:
  - Clarifies definition of an advance directive
  - Clarifies that DHMH may contract with one or more electronic advance directives services
  - Establishes an advance directives program fund (nonlapsing)

Regulations Development

- The MHCC and DHMH developed two workgroups:
  - Criteria and Connectivity
  - Engagement and Special Issues
- Workgroups met during the fall of 2016 to consider various policy issues related to electronic advance directives
- Output from workgroup meetings used to develop draft regulations

Draft Regulations

- Key Components:
  - Process for developing criteria for State Recognition of an electronic advance directives service
  - MHCC procedures for State Recognition of an electronic advance directives service – initial and renewal
  - Procedure to contest a denial of State Recognition

Draft Regulations *(continued…)*

- Key Components:
  - Provisions on the nontransferability of State Recognition including the closure, sale, merger, lease, assignment or transfer of all or part of a State Recognized electronic advance directives service
  - MHCC oversight, including the process to investigate and revoke State Recognition from an electronic advance directives service

Next Steps

- Staff seeks Commission support to release the draft regulations for informal public comment
  - May 19th – Publish draft regulations on MHCC website for informal public comment
  - June 2nd – Evaluate stakeholder comments and make changes to the draft regulations as needed
  - June 15th – Bring the regulations back to the Commission as proposed permanent
  - September 21st – Request final action from the Commission
  - October 23rd – Effective date of regulations

Questions?

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UPDATE:

COMAR 10.24.11 - State Health Plan for Facilities and Services: General Surgical Services

(Agenda Item #7)

Further Development of State Health Plan Standards for General Surgical Services: COMAR 10.24.11

May 18, 2017

MHCC | MARYLAND HEALTH CARE COMMISSION

- Where We Are
- Questions from April 20, 2017 Meeting
- Commissioner Preferences
- Policy Changes and Implications
- Process Going Forward

Where We Are Currently

CON required to establish any ambulatory surgical facility or ASF (2+ operating rooms)

CON required to add operating rooms (ORs) in any setting

In either case, finding a need for the project is based on OR capacity assumptions

- **Achieve a specified OR hour volume level to get consideration**
- **Demonstrate an ability to reach specified OR hour volume within a specified time**

Where We Are with Draft Changes – April 2017

CON exemption to establish an ASF through the addition of a second OR or the consolidation of two one-OR centers

CON exemption to establish two-OR ASF by a hospital converting to a freestanding medical facility

Finding a need for a second OR requires achievement of a specified OR hour volume level to get consideration

In all exemption cases, a demonstration of an ability to reach specified OR hour volume within a specified time is required

Questions from April 21, 2017 Commission Discussion

- How are ORs used in Maryland with reference to the SHP's current capacity assumptions?
- How does Maryland compare with other states with respect to use of hospital and non-hospital settings for outpatient surgery?
- How does payer mix differ by surgery setting? Can Medicaid MCOs increase use of non-hospital settings?
- What is the geographic distribution of ASFs and POSCs?
- What is the likely impact of shifting outpatient surgery to ASFs from hospitals and the implications for total cost of care and system savings?
- What are the implications of policy changes on regulatory oversight of dedicated inpatient ORs?

Questions from April 21, 2017 Commission Discussion

- What, if any, limitations on location of expanded or new ASFs relative to the current location of the ASF(s) or the hospital should be established?
- How do MHCC charity care requirements overlap with HSCRC requirements and are such requirements consistent across regulated services?

How are ORs used in Maryland with reference to the SHP's current capacity assumptions?

Average OR Hours per OR per Year, Hospital Mixed-Use Operating Rooms, 2008 - 2015

Average OR Hours per OR	2008	2009	2010	2011	2012	2013	2014	2015
Under 500	3	2	3	2	2	2	3	4
500 - 699	2	1	2	2	1	4	2	2
700 - 899	1	1	1	3	2	1	3	4
900 - 1,099	0	1	2	3	4	4	3	4
1,100 - 1,299	4	7	7	8	9	7	5	8
1,300 - 1,499	11	11	9	5	11	10	11	10
1,500 - 1,699	11	9	9	10	6	5	9	7
1,700 - 1,899	8	7	6	6	6	8	5	4
1,900 - 2,375 *	4	6	6	6	5	2	5	3
2,376 or higher	0	0	0	0	0	2	0	1
Total Number of Reported Hospitals	44	45	45	45	46	45	46	47

Source: MHCC Annual Hospital Supplemental Survey Note: Assumes 25 min. turnaround time for OR cases.

* According to SHP, a hospital mixed-use OR is assumed to have full capacity use of 2,375 hours per year and an optimal capacity of 80% of full capacity, which is 1,900 hours per year.

How are ORs used in Maryland with reference to the SHP's current capacity assumptions?

Average OR Hours per OR per Year, Non-Hospital Operating Rooms, 2008 - 2015

[Includes only facilities open for full year]

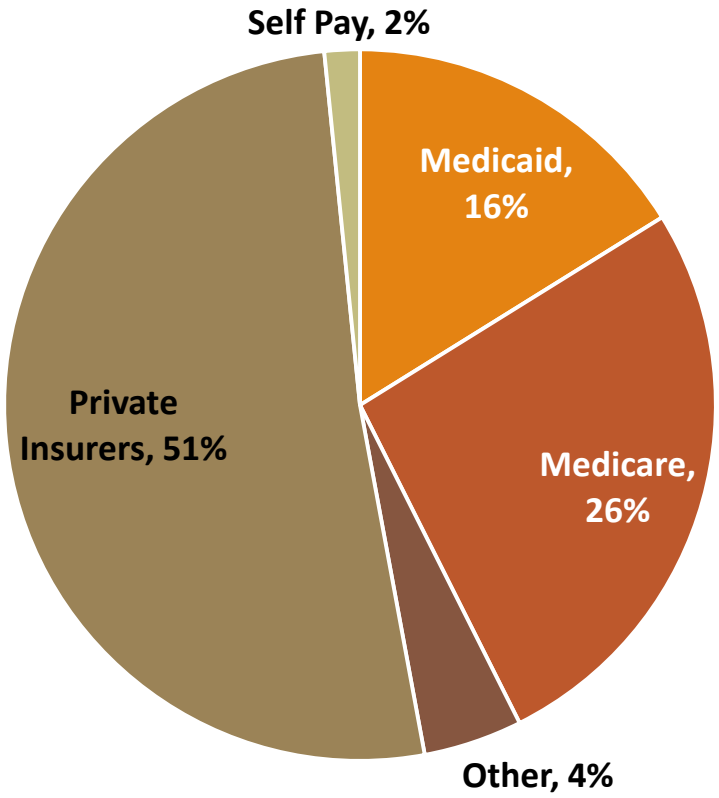
Average OR Hours per OR	2008	2009	2010	2011	2012	2013	2014	2015
Below 100	29	25	26	23	24	26	24	24
100 - 299	44	34	30	30	29	23	31	27
300 - 499	19	20	22	30	23	17	10	13
500 - 699	13	25	15	12	18	24	15	15
700 - 899	19	12	19	24	16	11	22	20
900 - 1,099	14	15	20	16	17	18	13	17
1,100 - 1,299	15	17	15	12	12	12	18	12
1,300 - 1,499	13	13	10	14	13	19	15	17
1500 - 1631	11	6	4	7	6	8	9	7
1632 - 2040 *	11	11	13	10	17	19	24	21
2041 or higher	13	22	20	21	25	24	24	27
Total Number of Reported Non-Hospital Surgical Facilities	201	200	194	199	200	201	205	200

Source: MHCC Annual Ambulatory Surgery Survey Note: Assumes 25 min. turnaround for OR cases.

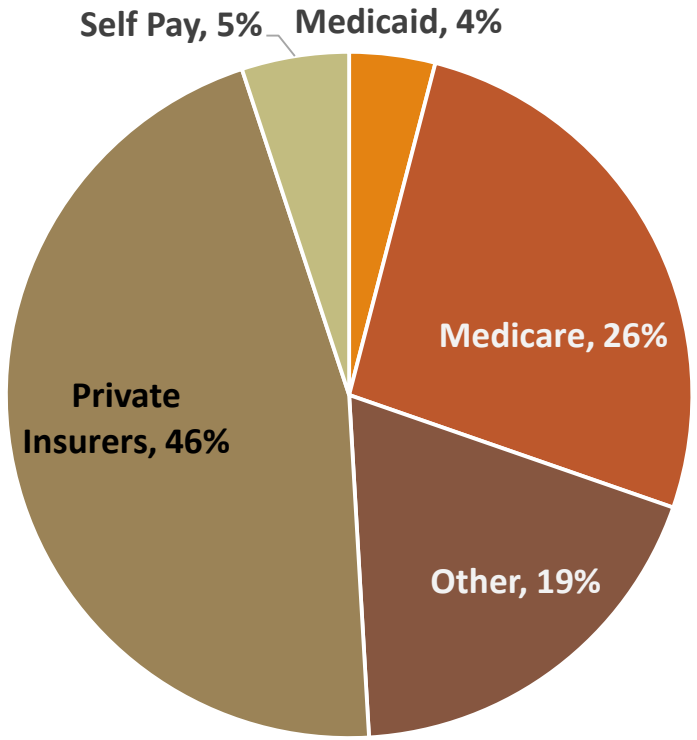
According to SHP, a dedicated outpatient OR is assumed to have full capacity use of 2,040 hours per year and an optimal capacity of 80% of full capacity, which is 1,632 hours per year.

How does payer mix differ by surgery setting?

Percent of Total Surgery Charges at Hospital Outpatient, CY 2015



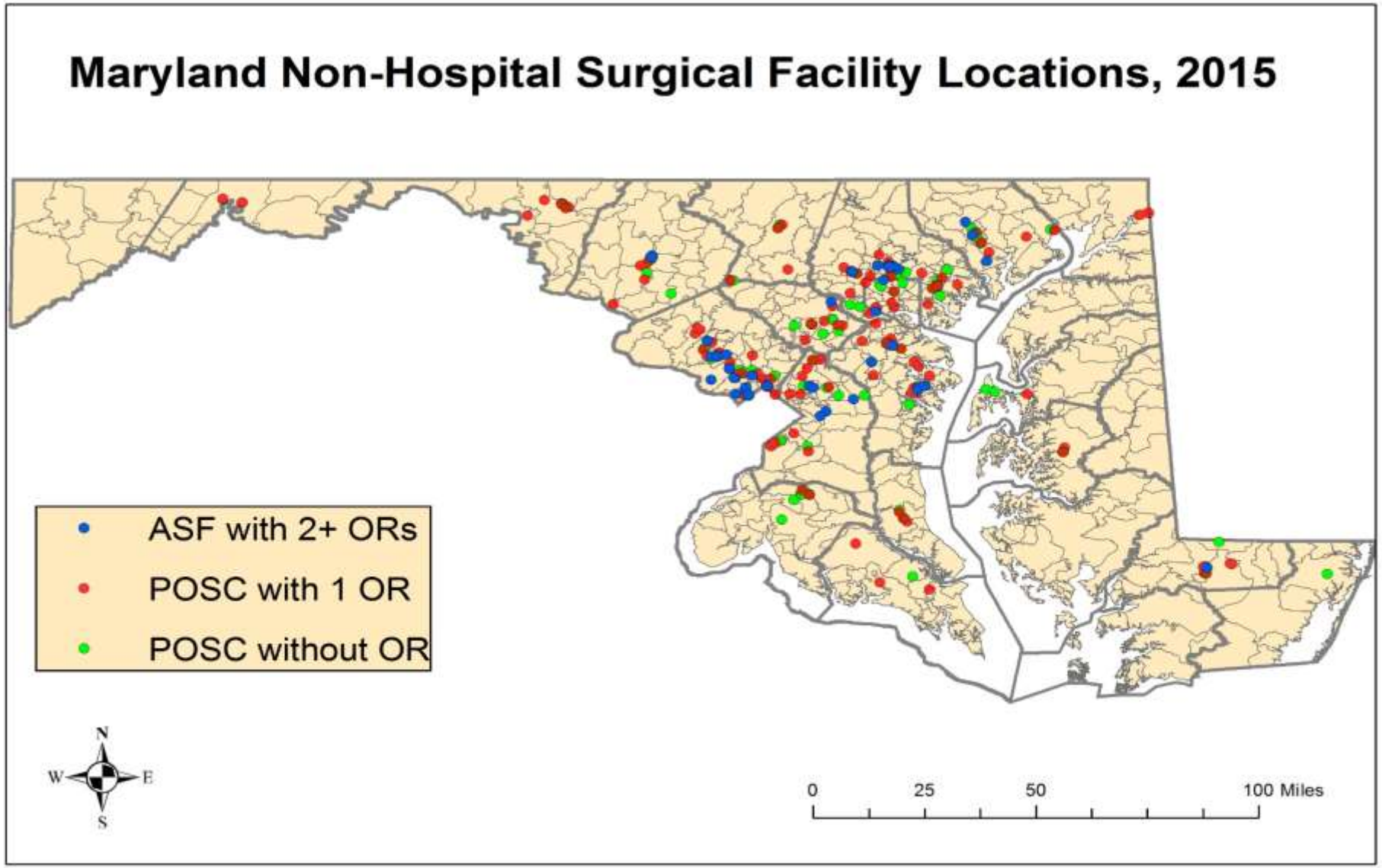
Percent of Total Net Revenue at Non-Hospital Surgical Facilities, CY 2015



Includes all facilities, with and without operating rooms

Note: For Hospital, 'Other' includes Government program, Worker's compensation, Charity and others;
For Non-Hospital, 'Other' also includes some plans that are not clarified in the survey.

What is the geographic distribution of ASFs and POSCs?



Data Source: MHCC Annual Ambulatory Survey, 2015

Commissioner Preferences

Minimize regulatory barriers for development of surgical capacity in the non-hospital setting for all persons, including hospitals, consistent with existing statute

- **Reconsider use of capacity assumptions in need determination**
- **Facilitate ability of hospitals to establish ASFs**

Policy Priority: Maximize ability to perform outpatient surgery in the lowest charge setting, the ASF. Hours of time in which ORs are used should be, at best, a secondary consideration

Policy Changes Reflecting Commissioner Preferences

1. Eliminate use of OR capacity assumptions in consideration of need for ASF projects for CON and exemption reviews. Require demonstration of efficiency by applicant.

2. Retain exemption reviews as proposed in the April, 2017 draft – expansion of POSCs, consolidation of POSCs, and ASFs for FMFs – without use of OR capacity assumption

3. Add a exemption review process allowing for hospitals to establish ASFs without increasing overall OR capacity they operate.

Policy Implications of Changes

Maryland may see growth in proportional use of non-hospital setting for outpatient surgery and in number two-OR ASFs and hospital-owned or controlled ASFs

Shifting OR capacity and use from hospitals to hospital ASFs is likely to reduce charges paid for outpatient surgery. It may not result in significant system savings. Hospitals will still need to retain revenue in GBR for fixed costs and overhead associated with surgical facilities in place. The SHP could require a showing of system savings as a requirement for project approval.

Hospital ASFs are unlikely to have the same payer mix as the hospital. They will be incentivized to minimize surgery for Medicaid and uninsured patients.

Process Going Forward

Review Commission preferences, policy options, and implications with surgical services Work Group. Continue to dialogue with HSCRC staff on policy implications. WG will meet June 1, 2017.

Develop new draft proposed SHP chapter for consideration by Commission at July 2017 meeting.

Consider desired legislative changes related to CON regulation of surgery.

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Overview of Upcoming Initiatives

(Agenda Item #8)


ENJOY THE REST OF
YOUR DAY