Maryland Health Care Commission

Thursday, May 19, 2016

1:00 p.m.

MARYLAND HEALTH CARE COMMISSION

AGENDA

1. **APPROVAL OF MINUTES**
2. UPDATE OF ACTIVITIES
3. **ACTION:** Certificate of Need: Suburban Hospital – Docket No. 15-15-2368
4. **ACTION:** Approval of Release of MCDB Data
   - The Lewin Group
5. **ACTION:** Privately Insured Spending Report for 2014
6. **ACTION**: COMAR 10.25.18 – Health Information Exchanges: Privacy and Security of Protected Health Information – Final Regulation
7. **PRESENTATION:** Maryland Healthcare Quality Report Website: 2015 HAI Results and Plans for Promotion
8. **PRESENTATION:** COMAR 10.24.15 - State Health Plan Chapter Update for Organ Transplant
9. Overview of Upcoming Initiatives
10. ADJOURNMENT

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Certificate of Need: Suburban Hospital - Docket No. 15-15-2368

(Agenda Item #3)

MARYLAND HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Approval of Release of MCDB Data

* The Lewin Group

(Agenda Item #4)

MARYLAND HEALTH CARE COMMISSION

MCDB Data Release and IRB Review –Lewin

COMMISSION MEETING

NOVEMBER 19, 2015

Overview

- Goal: Review and vote on application for MCDB Data by Lewin
- Framework for evaluation of applications
- Lewin application details
- Recognition of IRB

Framework for Evaluation

- Appropriate use of data
  - Is it a permitted use?
  - Is the data appropriate for the project?
- Qualified user
  - Does the applicant have expertise with this type of data?
  - Does applicant have expertise with the specified analyses/projects
- Data Security / Data Management Plan
  - Is there an appropriate plan for securing the data?
  - Is access restricted to qualified users?
  - Adherence to limitations on re-release and reporting of data

Lewin Application

- Appropriate Use
  - Lewin has been contracted by the CMS Innovation Center (CMMI) provide a variety of supportive functions in conjunction with the Maryland All-Payer Model and the agreement between CMS and the State of Maryland.
  - The broad scope of the contract with Lewin (and their affiliated sub-contractors) includes specific tasks related to analytics, assessment, monitoring, evaluation support, quality, and other various functions for all payers and all care settings within the State of Maryland.
- Qualified User
  - Lewin has extensive experience with these types of analyses and is a leading consultant nationally to federal and state agencies.
  - The project team has specific expertise in similar evaluations using claims data, such as for the State Innovation Model program.
- Data Security / Data Management Plan
  - Lewin has provided appropriate documentation of its data management plan to secure MCDB Data
  - Access to MCDB data will be restricted to project staff, who will be identified to MHCC in DUA

Lewin Application

- Data request is for Commercial Data for CY 2010-2018
- MCDB includes eligibility records and claims files (professional, institutional, and pharmacy)
  - No direct identifiers in the data, such as name, address, SSN, etc.
  - Indirect identifiers include gender, age, zip code of residence, dates of service.
  - Member ID's will be masked to permit linking across MCDB files.
    - DUA will prohibit linking beyond MCDB files at the member level
    - DUA will prohibit efforts to re-identify members
  - No individual payor identification

IRB Review

- Lewin's application was reviewed by Chesapeake IRB, the MHCC recognized IRB
- Chesapeake IRB determined that this study meets the regulatory requirements found at 45 CFR 46.116(d) for a Waiver of Informed Consent/Assent. The IRB also determined that this study meets the regulatory requirements found at 45 CFR 164.512(i)(2) for a Waiver of Authorization.
- Chesapeake IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects. The IRB determined that the research study meets the criteria found in the risk category described as follows: 45 CFR 46.404: *"Research not involving greater than minimal risk." Parental permission waived in accordance with 45 CFR 46.116(d).*

Next Steps

- If approved by Commissioners, MHCC staff will execute a DUA with Lewin and release data.
- Ongoing compliance review under DUA

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Privately Insured Spending Report for 2014

(Agenda Item #5)

Privately Fully-Insured Report

Commission Meeting

May 19, 2016

MHCC | MARYLAND HEALTH CARE COMMISSION

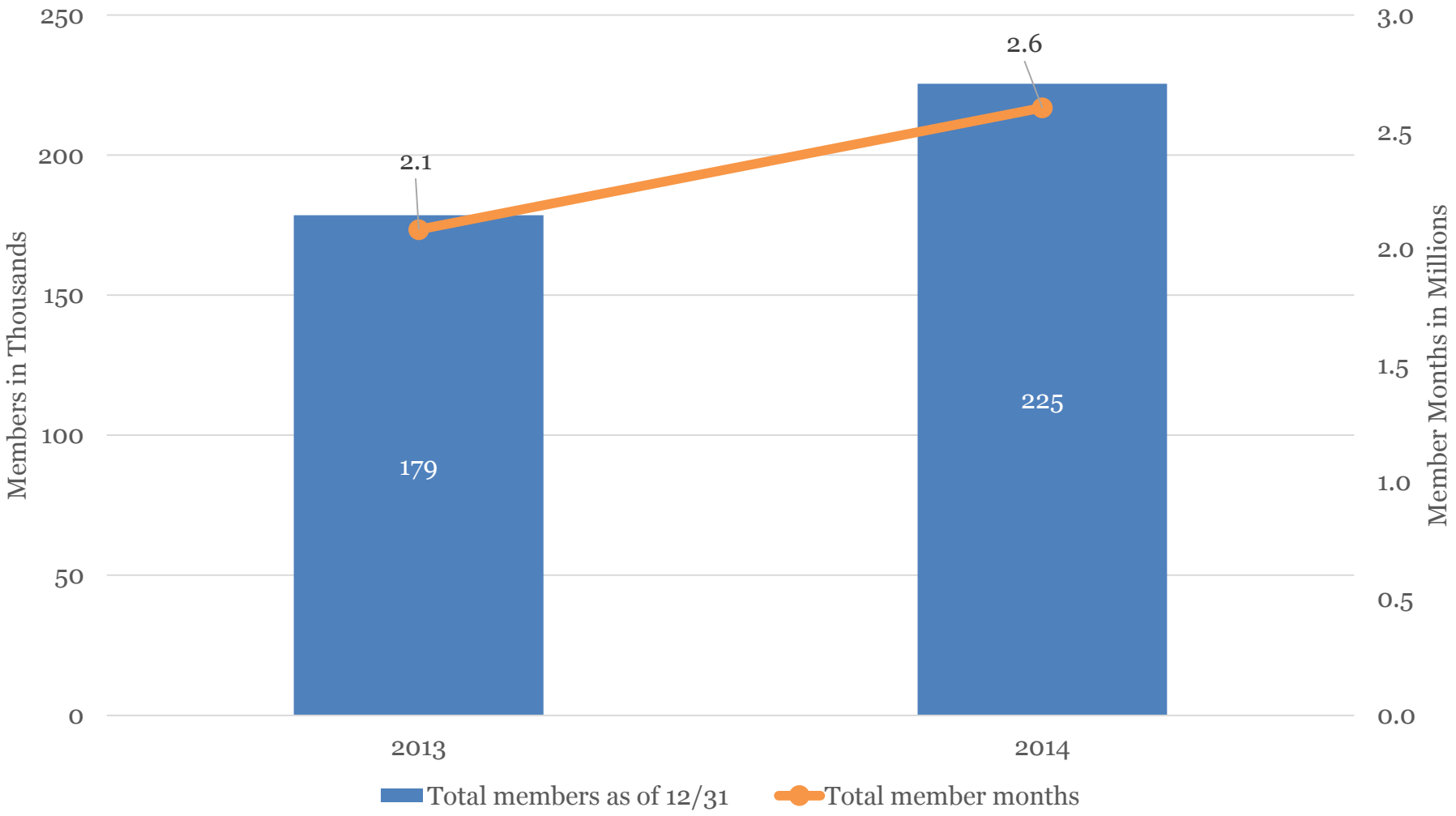
Takeaways

- Total Per Member Per Month (PMPM) spending across all market segments and service categories increase by about 3% from 2013 to 2014
- Total members as of 12/31/2014 in the Individual Market increased by about 26% over a year ago
- Total PMPM spending in the Individual Market for all services combined increased over 30% from 2013 to 2014
- Utilization per 1,000 members increased in the Individual Market for all service categories from 2013 to 2014, ranging from about 16% for professional services to about 51% for prescription drugs.
- Unit Costs for all service categories increased in 2014, except for inpatient facility services, where unit costs declined across all markets.
- PMPM spending for inpatient facility services decreased in both Small Employer and Large Employer markets, but increased in the Individual Market.

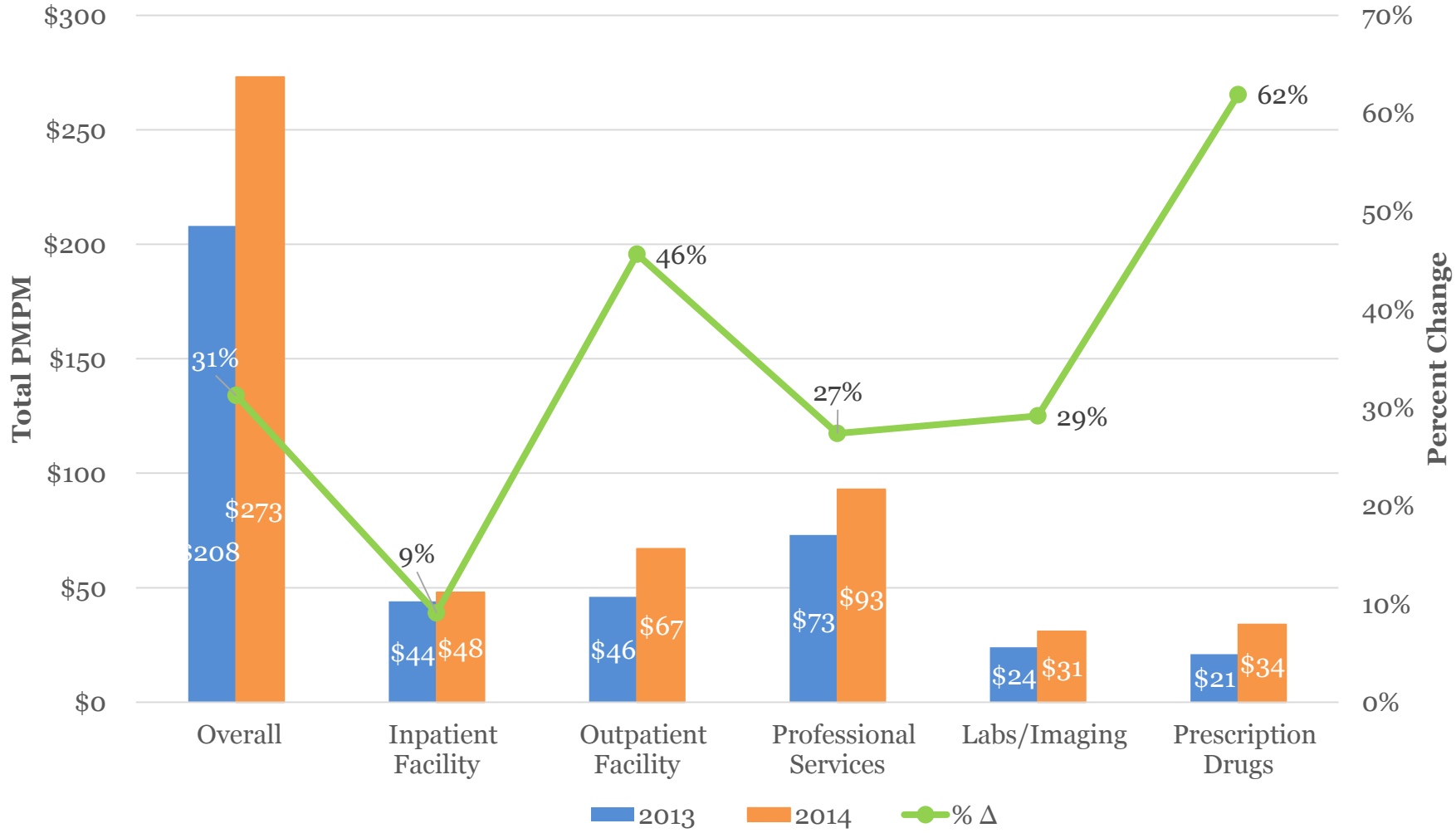
Background

- MHCC is required to report annually on healthcare spending and utilization
  - Source: Medical Care Data Base (2013 and 2014 data)
  - Fully-insured private plans, Maryland residents
  - Study variation by market segment, geography, age, and service category
- Special focus on the Individual Market
  - Many individuals with significant medical conditions who had previously been covered through the state-based "high-risk" pool (MHIP) have transitioned into the Individual Market since the ACA went into effect on 1/1/2014.
  - Many individuals who did not have health insurance prior to 2014 have also entered the Individual Market since ACA enactment.

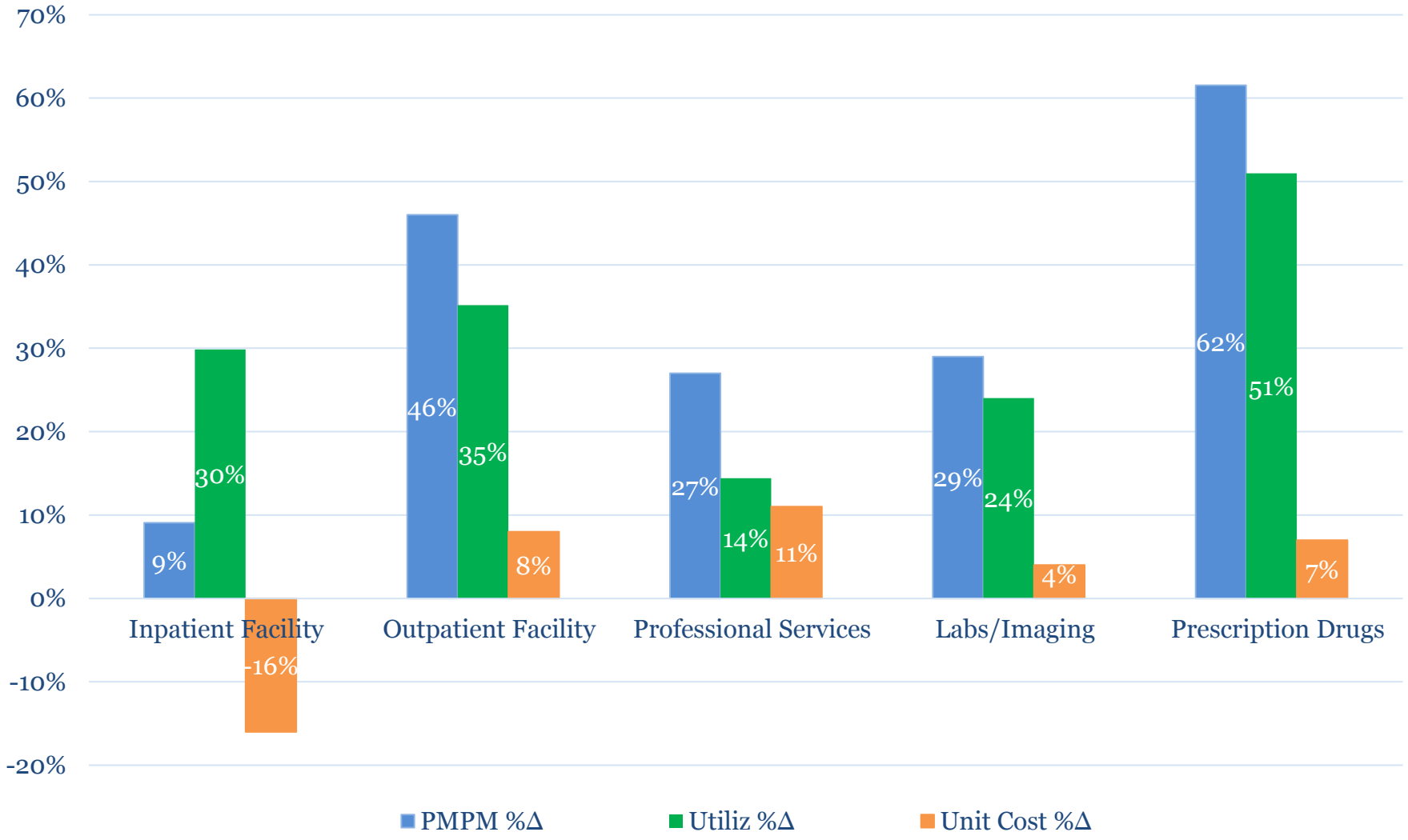
Members as of 12/31 and Member Months, Individual Market (2013 vs. 2014)



Total PMPM Changes by Service Category, Individual Market (2013 vs. 2014)

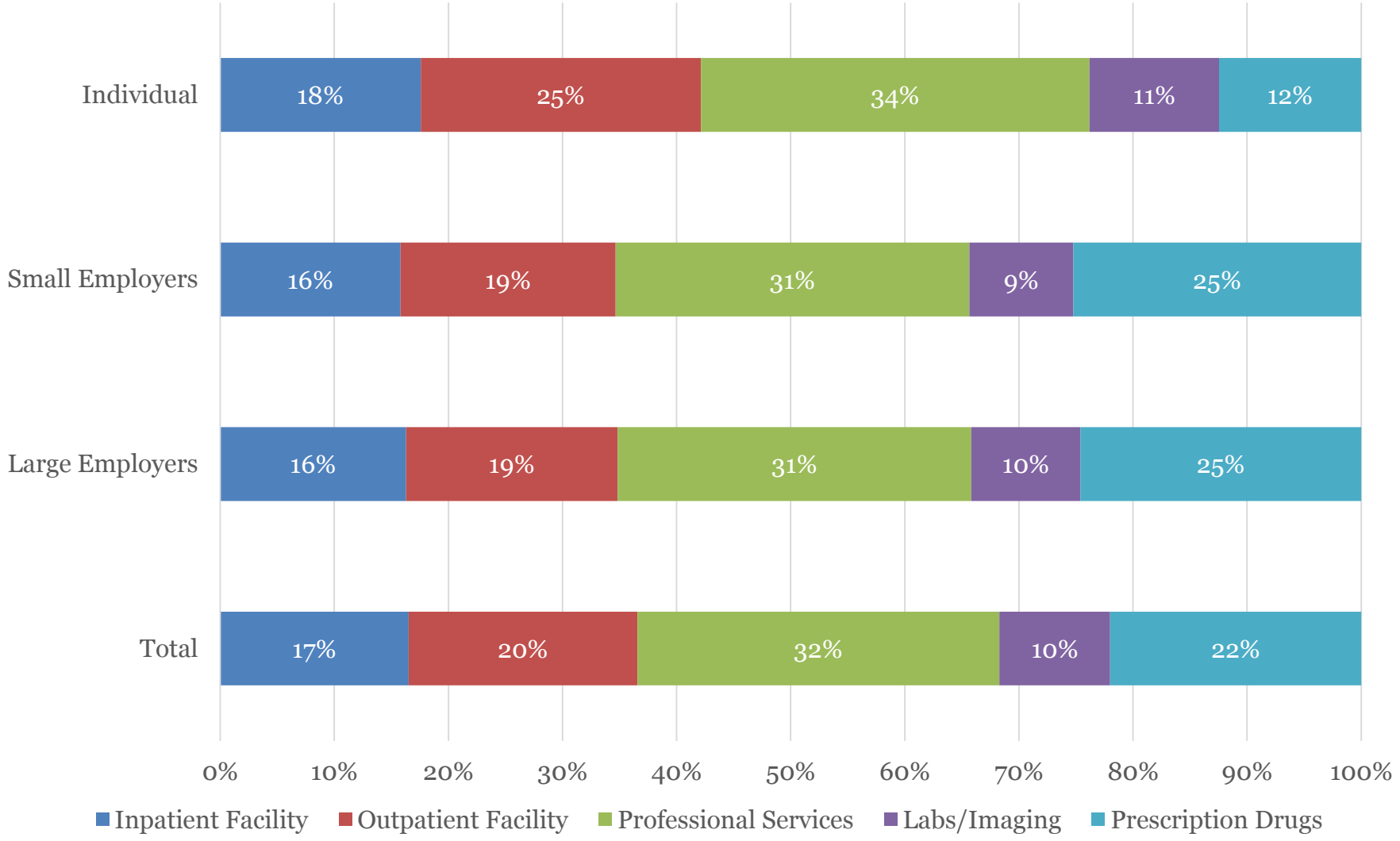


PMPM, Utilization Per 1,000 Members and Cost Per Unit Changes (12-Mo Trends) by Service Category, Individual Market (2014 over 2013)

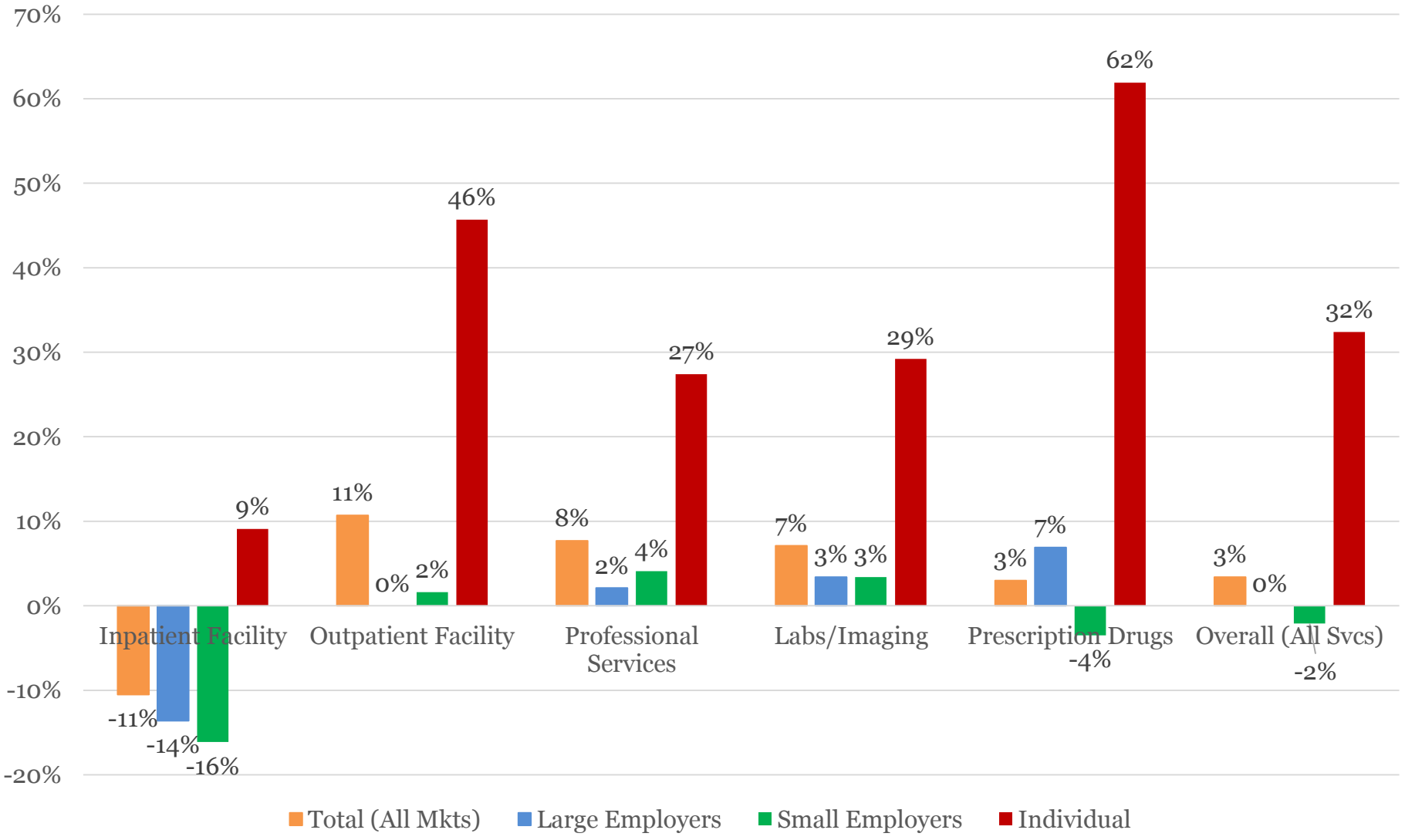


PMPM SPENDING BY MARKET AND SERVICE CATEGORY (2014)

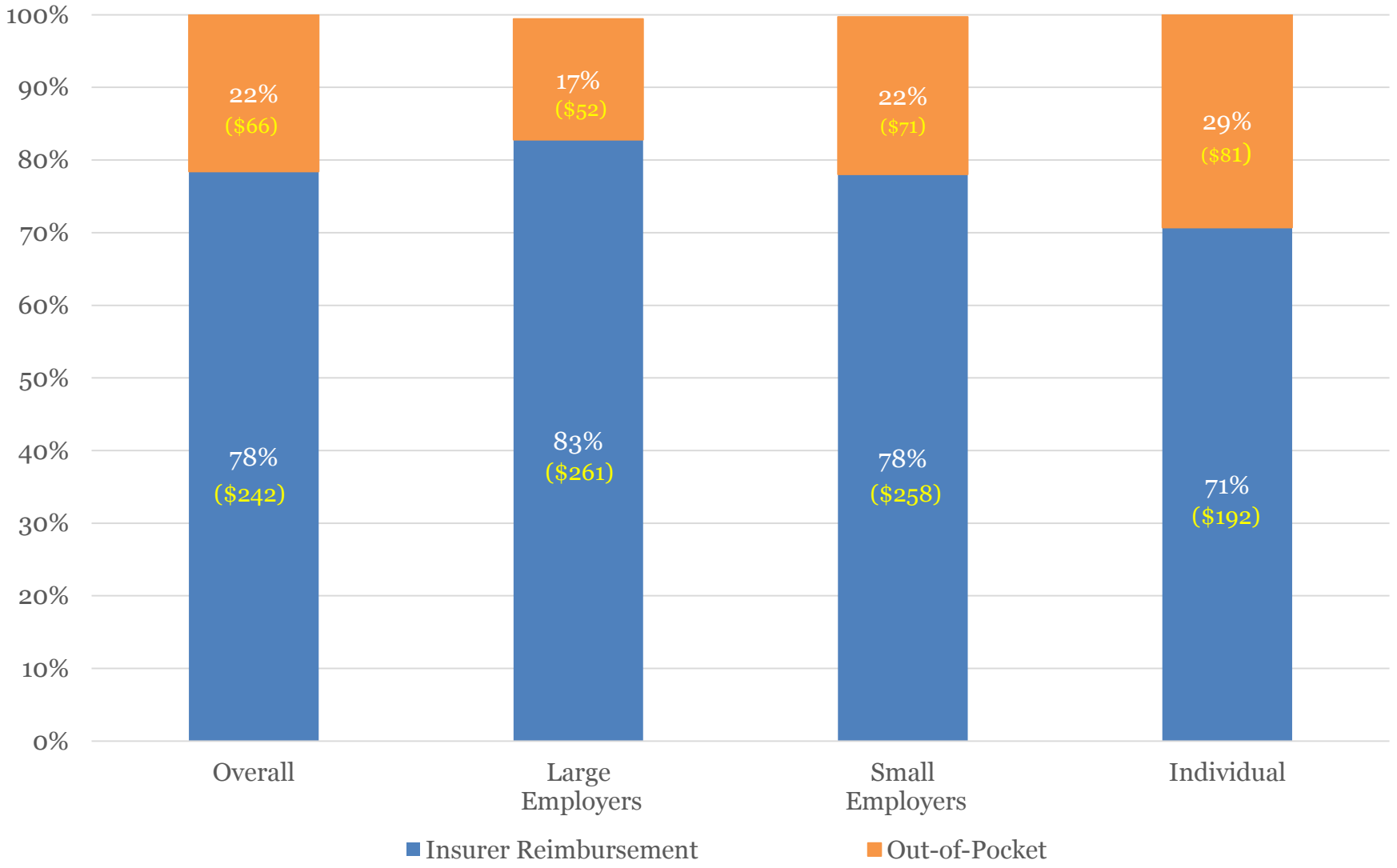
Distribution of PMPM Spending by Service Category and Market (2014)



PMPM Spending Changes by Market and Service Category (2014 over 2013)



Out-of-Pocket and Reimbursed Shares of Total Spending by Market (2014)



Questions?

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COMAR 10.25.18 – Health Information Exchanges: Privacy and Security of Protected Health Information – Final Regulation

(Agenda Item #6)

Health Information Exchange Privacy and Security

Draft Amendments – Final Action

COMAR 10.25.18

May 19, 2016

The MARYLAND
HEALTH CARE COMMISSION

Background

- Legislative Authority
  - A 2011 law requires MHCC to adopt regulations for the privacy and security of protected health information (PHI) exchanged through a health information exchange (HIE)
- The Need for HIE Regulations
  - National concerns exist about the sufficiency of HIPAA; the regulations help to ensure that consumers' information is protected
  - Initial regulations went into effect on March 17, 2014
- Collaborative Process
  - The HIE Policy Board (Board) consists of a diverse group of stakeholders that advises staff on HIE privacy and security policies
  - The Board developed privacy and security policies that became the framework for the initial draft HIE regulations

Amendments – Development Process

- Over the past year, the HIE Policy Board worked to develop the following policies:
  - Secondary Data Use (SDU) for Population Care Management
  - SDU for Research
  - Emergency Access for Participating Organizations
- Staff considered the above policies in the development of the draft amendments released on October 16, 2015
  - Six comment letters were received; staff worked with stakeholders to incorporate the changes to the draft amendments
- Staff proposed the amendments to the Commission on February 18, 2016

SDU for Population Care Management

- Allows an HIE to disclose data to care management organizations for population care management purposes
- Population care management includes population-based activities relating to improving patient and population health or reducing health care costs where no treatment relationship exists
- Personally identifiable information may only be disclosed after:
  - Appropriate notice has been provided to consumers whose information is to be disclosed; and
  - The consumer has authorized the release of their information
- An external and independent review committee of the requesting entity may approve an authorization waiver request if certain conditions are met

SDU for Research

- HIE may disclose data to a qualified research organization for research purposes
  - Disclosure of de-identified data must be approved by a Privacy Board
  - Disclosure of identifiable data must be approved by an Institutional Review Board or Privacy Board, including documentation of approved waiver or alteration of authorization requirement
  - An HIE may charge a reasonable fee reflective of the direct and indirect cost associated with preparing and disclosing the data

SDU – Enforcement and Reporting

- An HIE will make summary reports available to the public quarterly about the release of data for secondary purposes
- An HIE shall report at least annually to the Commission certain information about the release of information for population care management
- Commission staff may require an HIE to conduct an audit of SDU disclosures, using a third-party auditor
- Upon request by a health care consumer, an HIE shall provide an accounting of any disclosures made to an entity for SDU purposes

Emergency Access

- An HIE must establish and clearly communicate its emergency access policy to health care consumers
- If an HIE allows for emergency access, an HIE shall only disclose information to the requesting health care provider under certain circumstances; e.g.,
  - In the professional opinion of the requesting health care provider, an emergency exists
  - The consumer's condition precludes the ability for the participating organization to obtain consumer consent
  - Information available through the HIE may be relevant to the specific emergency treatment
- An HIE must implement a technical process to document and audit emergency access

Other Proposed Amendments

- Electronic Health Record System definition broadened to apply to all EHR technology and not just certified EHR technology (.02B(18))

- More specific information within patient notice from a participating organization and an HIE (.03G(c))

- Audit requirements strengthened to identify potential inappropriate access (.06A(1))

Comments Received

- Organizations
  - CareFirst Blue Cross Blue Shield *(six items)*
  - Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. *(seven items)*
- General Observations
  - Clarification requested to specify circumstances where secondary data use is applicable
  - Proposed changes to existing language in the regulations; staff plans to consider including proposed changes in future revisions of the regulations

Non-Substantive Changes Recommended

- CareFirst recommends adding language to the definition of "appropriate notice" in Section .02B(2) to clarify that the notice applies for secondary use
    - Staff recommends the addition of clarifying language stating that the notice applies for secondary use in Section .02B(2)
- CareFirst recommends adding language to the definition of "research" in Section .02B(52) to clarify that the term "research" applies only to secondary use
    - Staff recommends the addition of clarifying language stating that "research" applies only to secondary use in Section .02B(52)

Requested Commission Action

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

Thank You!

The MARYLAND
HEALTH CARE COMMISSION

Appendix

Summary of Comments Received and Staff Recommendations

- CareFirst recommends deleting language to the definition of "care management organization" in Section .02B(10)(d) that specifies that a "care management organization" does not include an organization that provides care management as part of a treatment relationship; i.e., primary use.

  - Staff action – No change: Staff believes this language provides clarification as to the activities that are not applicable under this definition. This language was added in response to questions raised during the informal comment period.

- CareFirst noted that the amendments made to the definition of "electronic health record system" in Section .02B(18) unnecessarily broadens the scope of what may be considered an electronic health record.

  - Staff action – No change: The definition is meant to define a system that supports an "electronic health record" that is defined in Section .02B(17).

Summary of Comments Received and Staff Recommendations (cont.)

- CareFirst recommends deleting language in Section .03G(1)(c) to remove "treatment, payment, health care operation and" as the purpose of the regulations is solely to focus on secondary use

  - Staff action – No change: The language is intended to ensure that health care consumers are provided with information regarding the reasons in which an organization participating in an HIE may access their electronic health information

- CareFirst recommends deleting language in Section .05F(3). CareFirst notes that each participating organization should have the autonomy to administer the participating organization's access, unless that access goes beyond the scope of the use within the contract

  - Staff action – No change: Coordination with HIE is necessary to ensure that appropriate access levels are established for authorized users

Summary of Comments Received and Staff Recommendations (cont.)

- CareFirst noted that the non-amended language in Section .05F(5) may not be practical for an HIE to implement
  - Staff action – No change: The language in Section .05F(5) is not included in the proposed amendments to the regulation
- CareFirst recommended the term "non-HIPAA violation," as amended in Section .08, is clarified
  - Staff action – No change: The language in Section .02B(34) defines a "non-HIPAA violation"

Summary of Comments Received and Staff Recommendations (cont.)

- Kaiser stated that the non-amended requirement in Section .03G(1) that participating organizations provide both written and oral notice to the health care consumer regarding the organization's participation in the HIE and the patient's right to opt-out, is overly burdensome
  - Staff action – No change: The language in Section .03G(1) is not included in the proposed amendments to the regulation
- Kaiser noted that amended language under Section .11B(1), regarding access to information during an emergency, includes requirements that are overly burdensome on the provider
  - Staff action – No change: The requirements under Section .11B(2)(a) require an HIE to implement technological procedures to allow for the requesting provider to attest that the provisions in Section .11B(1) are met. This section should limit burden's imposed on providers related to access to information during an emergency

Summary of Comments Received and Staff Recommendations (cont.)

- Kaiser recommended to omit references to "opt-in" within Section .11A(2)(b)
  - Staff action – No change: The language applies to HIEs that implement an opt-in or opt-out model for sharing of electronic health records, and for HIEs that enable consumers to control provider access to their electronic health information
- Kaiser noted that the requirement that providers discontinue query of the patient's record after an emergency encounter ends, in Section .11B(2)(e)(ii), does not take into account that, even after the emergency encounter has ended, access to the patient's information will still be necessary for post-emergency follow-up and treatment
  - Staff action – No change: The requirement is limited to the emergency encounter. Appropriately authorized and authenticated providers participating in an HIE have access to a patient's electronic health information for treatment, payment, and operations in situations where the consumer has not opted out

Summary of Comments Received and Staff Recommendations (cont.)

- Kaiser noted that access to a patients information through the HIE, by an appropriately authorized provider, is not prohibited when that patient has not opted out for routine care. Kaiser recommended that the requirements outlined under Section .11B(1), should only apply when a patient has opted out of an HIE
  - Staff action – No change: The requirement is limited to the emergency encounter. Appropriately authorized and authenticated providers participating in an HIE have access to a patient's electronic health information for treatment, payment, and operations in situations where the consumer has not opted out
- Kaiser recommended that clarification be made to the consumer notification requirement as detailed in Section .11B(2)(e)(iv)
  - Staff action – No change: The requirements are for HIEs to implement a health care consumer notification process when electronic health information is accessed during an emergency

Summary of Comments Received and Staff Recommendations (cont.)

- Kaiser suggested the modification of the non-amended language in the definition of "disclosure" in Section .02B(16) be removed to permit an HIE to acknowledge the existence of a record even when a patient has opted-out

  - Staff action – No change: The language in Section .02B(16) is not included in the proposed amendments to the regulation

Key Provisions of the Current Regulations

- Health care consumer rights
  - An opportunity to opt-out of allowing the exchange of their health information
  - Information concerning who has accessed their health information
  - Accurate and current information about their rights
- Access, use, or disclosure of PHI
  - Procedural and technical controls that must be in place, including authorization and authentication
  - Use of data is only permitted for treatment, payment, certain health care operations, reporting to public health authorities, and some secondary uses

Key Provisions of the Current Regulations (Continued)

- Access, use, or disclosure of sensitive health information
  - Sensitive health information may only be exchanged electronically using a secure message or email through an HIE
- Auditing requirements
  - At least monthly, an HIE must conduct random audits of user access to the HIE, and promptly investigate any unusual findings identified
  - Conduct an annual privacy and security audit

Key Provisions of the Current Regulations (Continued)

- Remedial actions to be taken by an HIE
  - Immediately suspend access rights when it is necessary to avoid serious harm to the privacy and security of health information available through an HIE
- Notice of breach or violation
  - Participating organizations and consumers must be notified regarding any violation of the privacy and security of PHI through and HIE
  - Notification must be provided no later than 60 days from the time of the breach or violation and include certain information
- Registration and enforcement
  - HIEs must register and annually renew registration with MHCC to operate in the State

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MARYLAND HEALTH CARE COMMISSION

PRESENTATION:

Maryland Healthcare Quality Report Website: 2015 HAI Results and Plans for Promotion

(Agenda Item #7)

The Maryland Health Care Quality Reports

Staff Update on Improvements to the Consumer Website

Theressa Lee, Director, Center for Quality Measurement and Reporting
Eileen Witherspoon, Chief, Hospital Quality Initiatives

May 19, 2016

The Mission

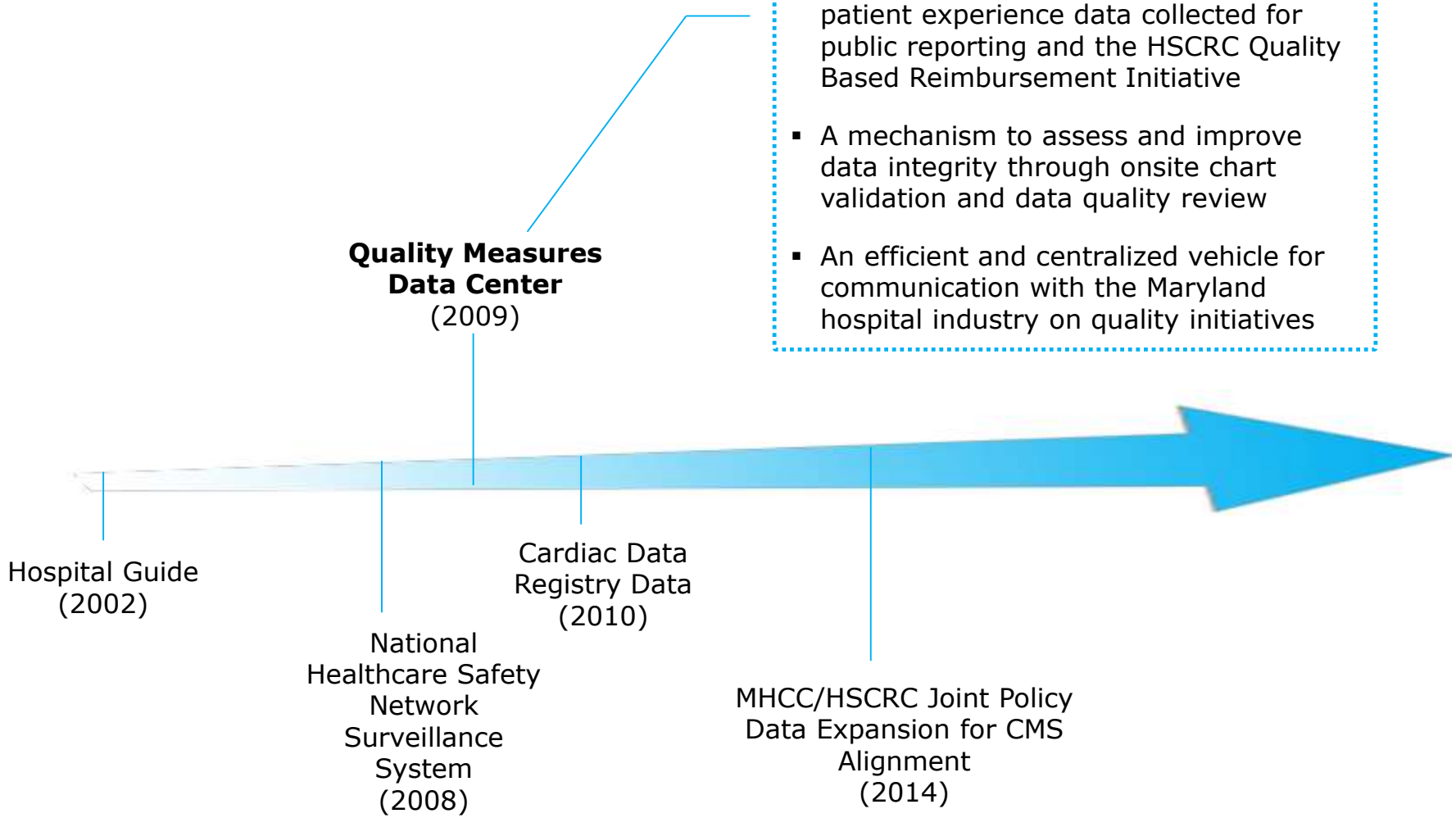
Establish a comprehensive, integrated online resource that enables consumers to access meaningful, timely, and accurate healthcare information reported by healthcare providers and payers in Maryland

Presentation Outline

- Background: The Hospital Performance Evaluation System
- The *new* Maryland Health Care Quality Reports website
- Transforming the MHCC System for Quality Data Reporting
  - Collaboration
  - Consumer Outreach
- Update to the website: April 2016 Release
  - New Healthcare Associated Infections (HAI) Data
  - Enhanced Information Resource for Hospital Industry
  - CY2015 Medical Conditions & Charges
- Promoting Consumer Awareness and Engagement

The Hospital Performance Evaluation System

- A web-based tool for hospitals to report and preview quality measures and patient experience data collected for public reporting and the HSCRC Quality Based Reimbursement Initiative
- A mechanism to assess and improve data integrity through onsite chart validation and data quality review
- An efficient and centralized vehicle for communication with the Maryland hospital industry on quality initiatives



The Hospital Performance Evaluation System

Existing ("old") System

Hospital Guide

Quality Measures Data Center

Maryland Health Care Quality Reports

A Single Point of Access to Information About Health Care Quality ("new" system)

One platform to …

- Eliminate parallel processing system for measures calculation
- Address the evolving data needs of the HSCRC / Medicare Waiver Modernization Project
- Strengthen the role of the Consumer
- Enhance communication with hospitals
- Utilize current technology
- Integrate other data sets
- Create the framework to include additional provider settings – "The Maryland Health Care Quality Reports"

The Maryland Health Care Quality Reports

- Lays the foundation for a more integrated and interactive public reporting system focusing on information for the consumer audience
- Establishes a platform and infrastructure for expansion to other provider settings and Health Plan information
- Includes new updated hospital performance and pricing data
- Supports flexible content management -- the system can evolve over time

Collaboration and Consumer Engagement

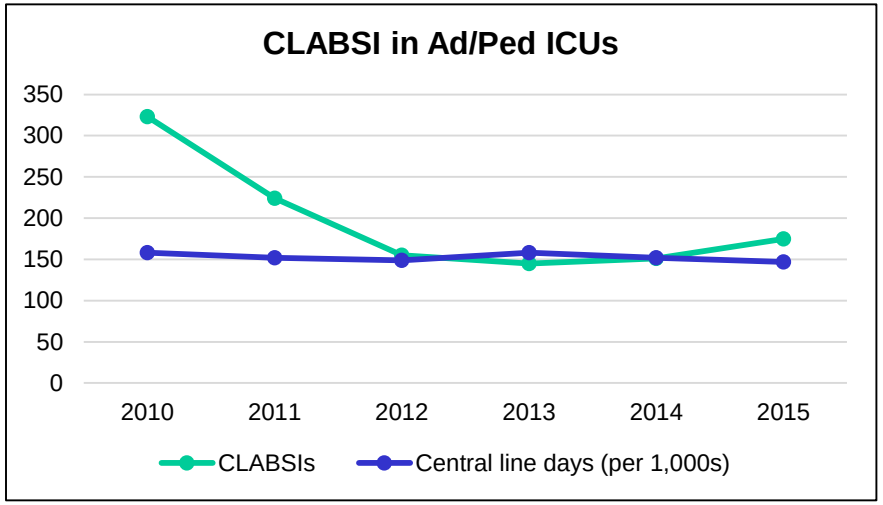
- Health Services Cost Review Commission
  - Support for streamlined quality measures data processing
  - Sharing of Price transparency methodology
  - Quality measures align with new hospital payment model
- CMS -- Approval of data sharing protocol
- Agency for Healthcare Research and Quality (AHRQ) – integration of MONAHRQ quality reporting software
- Consumer Engagement
  - Consumer involvement throughout the development process
  - Ongoing review of content, new design, format and functionality

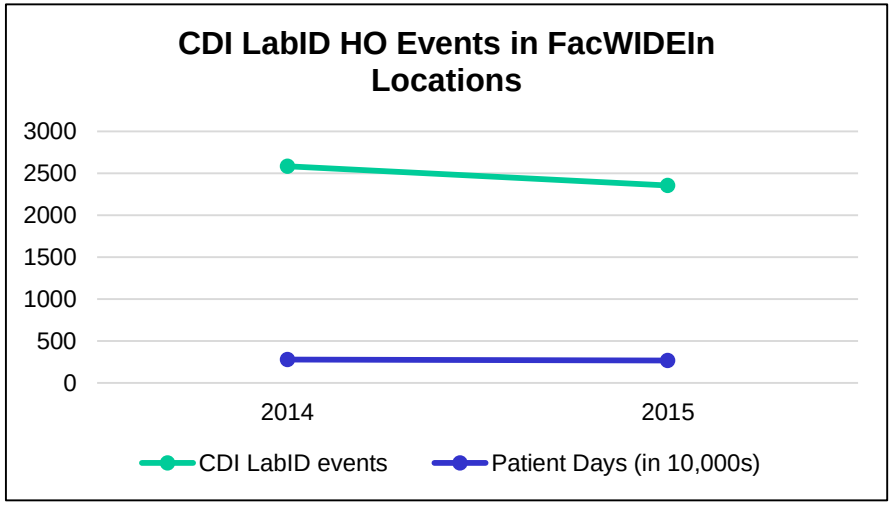
Update to the Consumer Website: April 2016 Release

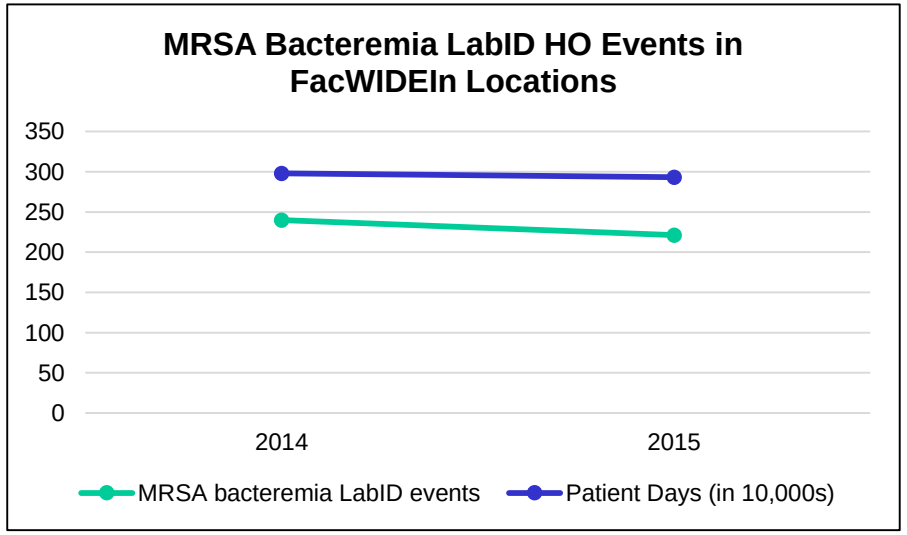
New Hospital Healthcare Associated Infections (HAI) Data

- CLABSI for ICU and Med/Surg Wards (CY2015)
  - 175 infections reported statewide
  - Statewide performance better than national experience
  - Performance consistent with previous years
  - 1st year reporting for Medical, Surgical and Med/Surg Wards
- *Clostridium difficile* Infections (CY2015)
  - 2,355 infections reported
  - Statewide performance worse than national experience
  - Slight improvement over CY2014
- MRSA Infections (CY2015)
  - 221 infections reported
  - Statewide performance worse than national experience
  - No measurable improvement over CY2014

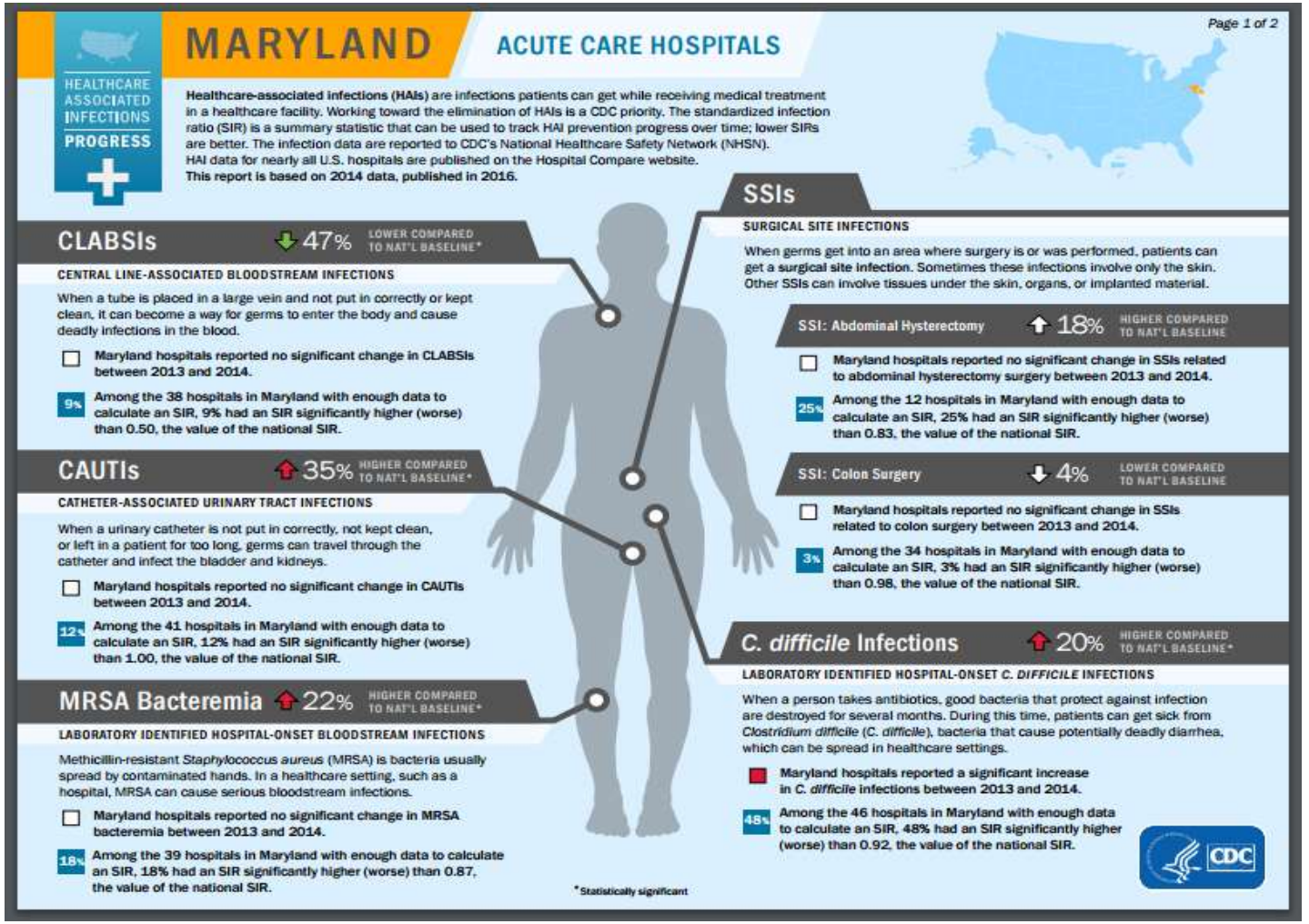
HAI Data Trending







CDC's 2016 Maryland HAI Progress Report (2014 Data)



Staff Efforts to Facilitate HAI Improvement

- Hold quarterly HAI Advisory Committee meetings of experts and stakeholders
- Support statewide antimicrobial stewardship workgroup led by DHMH with monthly meetings at MHCC
- Perform targeted onsite audits of HAI data to assess data quality
- Provide ongoing education and outreach to hospitals
- Partner with VHQC for hospital onsite data reviews
- Researching use of CDC tools and resources including Targeted Assessment for Prevention (TAP) Reports
- Support hospital participation in statewide collaboratives

Update to the Consumer Website: April 2016 Release

Hospital Medical Conditions & Charges

- Inpatient Quality Indicators updated thru Sept 2015
  (e.g., ER throughput (wait times);Heart Attack, Heart Failure)
- Hospital Volume, Ave Length of Stay & Charges
  (updated thru CY2015)

Creating Information Resource/Communication Tool Professionals

- Access thru Provider Log In Area
- Focus on Hospitals – Cardiac Coordinators, Infection Preventionists

Promoting Consumer Awareness and Engagement

- Google Analytics: About 700 users of website per month
- Recognized need to promote website
- Released Request for Information (RFI) Feb 18th
- RFI Purpose: to obtain access to marketing/consumer engagement expertise to inform promotion plan and next steps
- RFI requested Information packet and invitation for brief discussion
- Received over 20 responses from interested vendors and held 20 individual meetings to review ideas
- April 20th Released Bid Board Notice
- 14 proposals received by May 4th
- Vendor selected and contract start this week
- Project will focus on digital and social media promotion

http://healthcarequality.mhcc.maryland.gov/

MARYLAND HEALTH CARE COMMISSION

AGENDA

1. APPROVAL OF MINUTES

2. UPDATE OF ACTIVITIES

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4. **ACTION:** Approval of Release of MCDB Data
   - The Lewin Group

5. **ACTION:** Privately Insured Spending Report for 2014

6. **ACTION**: COMAR 10.25.18 – Health Information Exchanges: Privacy and Security of Protected Health Information – Final Regulation

7. **PRESENTATION:** Maryland Healthcare Quality Report Website: 2015 HAI Results and Plans for Promotion

8. **PRESENTATION: COMAR 10.24.15 - State Health Plan Chapter Update for Organ Transplant**

9. Overview of Upcoming Initiatives

10. ADJOURNMENT

MARYLAND HEALTH CARE COMMISSION

PRESENTATION:

COMAR 10.24.15 – State Health Plan Chapter Update for Organ Transplant

(Agenda Item #8)

Draft Regulations for Organ Transplantation Services
COMAR 10.24.15

May 19, 2016

Overview

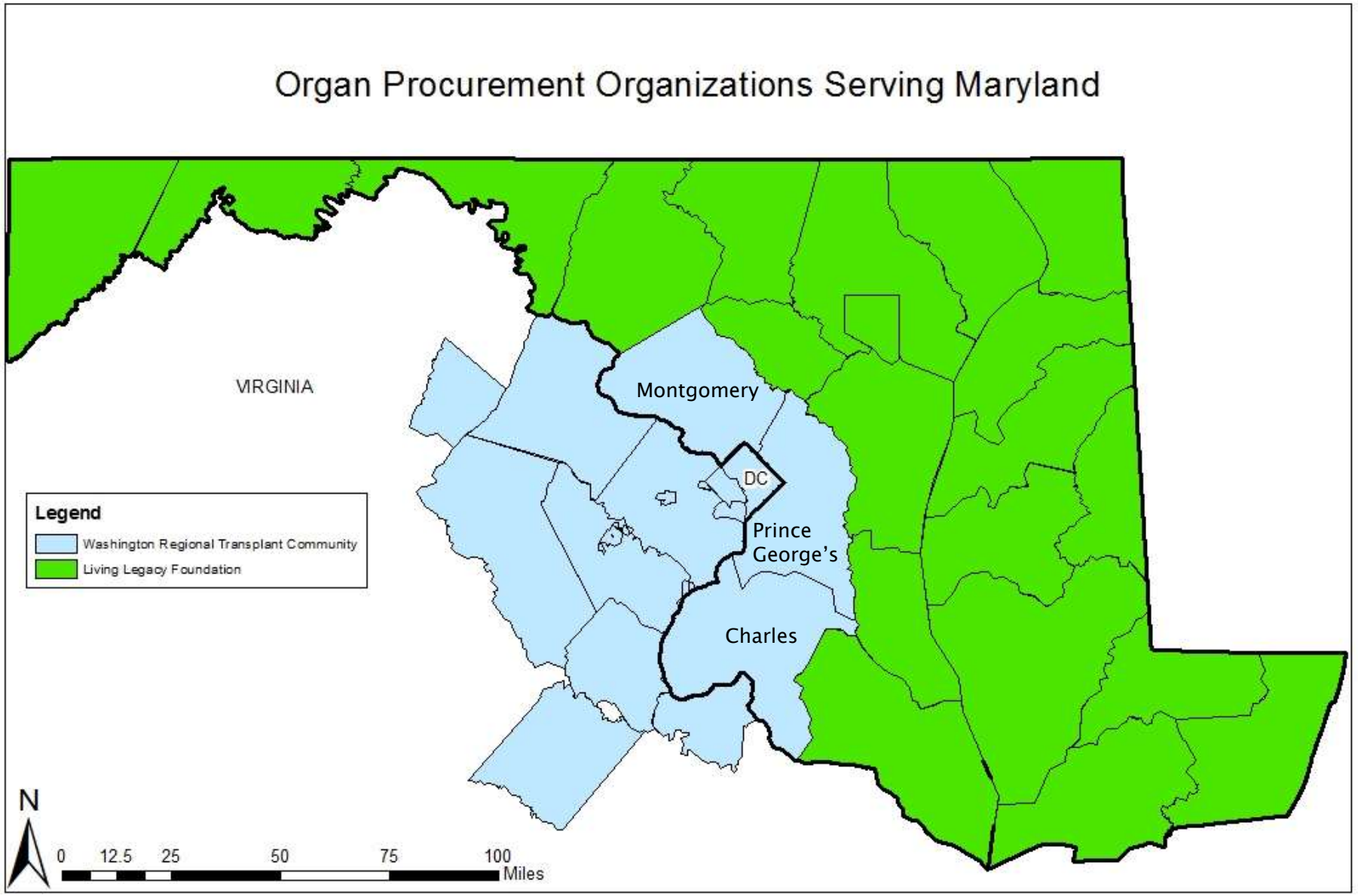
- Background
- Policies
- Evaluation of Need for Additional Programs
- Docketing Rules
- Project Review Standards
- Next Steps

Regulation of Organ Transplant Services

- National Organ Transplant Act of 1984 provided for the establishment of the national Organ Procurement and Transplantation Network (OPTN).
- The primary goals of the OPTN are to increase organ sharing effectiveness, efficiency, and equity.
- The Department of Health and Human Services awarded the OPTN contract to the United Network for Organ Sharing (UNOS) in 1986.

Regulation of Organ Transplant Services

- UNOS develops, monitors, and enforces the rules governing allocation, procurement, and transplantation of all organs, except bone marrow transplants.
- UNOS divides the U.S. into 11 regions. Within regions, Organ Procurement Organizations (OPOs) are designated by the Centers for Medicare & Medicaid Services.
- Two OPOs serve Maryland jurisdictions.


Organ Procurement Organizations Serving Maryland
VIRGINIA
Montgomery
DC
Prince George's
Charles
Legend
Washington Regional Transplant Community
Living Legacy Foundation
N
0 12.5 25 50 75 100
Miles

Policies

- Cost Effectiveness
- Quality of Care
- Access to Care

Evaluation of Need for Additional Organ Transplant Programs

- The current SHP chapter contains a need projection methodology.
- There is no need projection in the draft SHP chapter for organ transplant services.
  - MHCC staff raised concerns about the methodology.
  - Work group members raised additional concerns.
  - Work group members recommended taking a different approach to evaluating the need for additional organ transplant programs.

Current Need Projection Methodology

- Defines the need for two regions
- Relies on historic case volume at transplant centers in the prior three-year period for use rate calculations.
- Includes all age groups and pediatric hospitals.
- Includes deceased and living donor organs.
- Incorporates historic migration trends.

Current Evaluation of Need

- Need for additional transplant program exists if the net need for transplants in a region is greater that the threshold volume standard for that organ type.

- Threshold volume standards in the current SHP chapter are used as guide for measuring adverse impact on existing programs and do not refer to optimal volumes or efficient utilization.

Threshold Volume Standards

Type of Organ	Current Annual Threshold Volume Requirement	Proposed Annual Threshold Volume Requirement
Kidney		
Adult	50	50
Pediatric	Not applicable*	10
Liver	20	20
Pancreas	20	No requirement
Heart	20	20
Lung	20	20
Heart Lung	20	No requirement
Hematopoietic Stem Cell:		
Autologous	10	10
Allogeneic	40	40
Intestine/Small Bowel, Islet Cells, Hepatocytes, and Others, to be determined by the Commission as needed.	No requirement	No requirement
Vascular Composite Allograft	Not applicable**	No requirement

*Pediatric kidney transplant programs did not have a different standard than adult programs.
**Vascular composite allografts are a newer category of transplants that was not specifically regulated by UNOS at the time of the last update to this SHP chapter.

Organ Transplant Volume by Type and Location, CY 2015

Hospital	Organ Type	Number of Transplants
The Johns Hopkins Hospital	Heart	17
University of Maryland Medical Center	Heart	24
The Johns Hopkins Hospital	Kidney	254
University of Maryland Medical Center	Kidney	264
The Johns Hopkins Hospital	Liver	100
University of Maryland Medical Center	Liver	147
The Johns Hopkins Hospital	Lung	19
University of Maryland Medical Center	Lung	43
The Johns Hopkins Hospital	Pancreas	0
University of Maryland Medical Center	Pancreas	6
The Johns Hopkins Hospital	Heart/Lung	0
University of Maryland Medical Center	Heart/Lung	1

Source: https://optn.transplant.hrsa.gov/data/viewdata-reports/center-data/

Proposed Evaluation of Need

- Docketing Rules
  - All existing non-federal organ transplant programs must have been operating at the annual threshold case volume for at least three years prior to the filing of the application, unless an organ transplant program in the health planning region has been designated as a member not in good standing by the OPTN.
  - All of the existing non-federal organ transplant programs in the health planning region engaged in transplantation of the same organ type as the proposed program have been in operation at least three years.

Need Standard

- An applicant must demonstrate that a new or relocated organ transplant center is needed.
- An applicant must address:
  - The ability to increase the supply or use of donor organs for patients served in Maryland.
  - Projected volume shifts from programs in the two OPOs that serve Maryland residents.
  - Utilization trends in the health planning region for the proposed program and the jurisdictions in which the population to be served resides.

Minimum Volume Standard

- An applicant shall demonstrate that the proposed organ transplantation service can generate the minimum annual case volume as defined in the SHP chapter within the first three years of operation.

- Approval of a new program is conditional on meeting the minimum volume requirements.

Access Standard

- Each type of organ transplant service should be accessible within a three-hour one-way drive time for at least 95% of Maryland residents.
- Requirements:
  - Present evidence to demonstrate that barriers to access exist.
  - Present a credible plan to address barriers identified.
- Closure of an existing service or travel to another health planning region do not necessarily indicate a barrier to access.

Cost Effectiveness Standard

- Requirements for Applicants:
  - Analyze why existing programs cannot meet the need for organ transplants for the proposed population to be served.
  - Analyze how the proposed program will benefit the population to be served, quantifying the benefits to the extent feasible and documenting the projected annual costs over a period of at least five years.
  - Provide estimates of the costs and benefits to the health care system as a whole over a period of five years.

Impact Standard

- A proposed program shall not interfere with the ability of existing programs to maintain at least the annual threshold volumes.

- It shall also not have an unwarranted adverse impact on the financial viability of another hospital's organ transplant program, the quality of services provided, or patient outcomes following organ transplantation.

Other Project Review Standards

- Certification and Accreditation
- Health Promotion and Disease Prevention
- Comparative Reviews

Next Steps

- Review the informal comments received
- Revise the draft regulations
- Present proposed regulations for consideration by the Commission

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MARYLAND HEALTH CARE COMMISSION

Overview of Upcoming Initiatives

(Agenda Item #9)


ENJOY THE REST OF
YOUR DAY