Maryland Health Care Commission

Thursday, February 18, 2016

1:00 p.m.

MARYLAND HEALTH CARE COMMISSION

AGENDA

1. **APPROVAL OF MINUTES**
2. **UPDATE OF ACTIVITIES**
3. **ACTION**: COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information, Proposed Amendments
4. **ACTION:** Certificate of Need/Change in Approved Project: Prince George's Post Acute, LLC (Docket No. 13-14-2347)
5. **UPDATE:** Development of a State Health Plan Chapter for Freestanding Medical Facilities
6. **ACTION:** Proposed Legislation
7. **OVERVIEW OF UPCOMING INITIATIVES**
8. **ADJOURNMENT**

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MARYLAND HEALTH CARE COMMISSION

ACTION:

COMAR 10.25.18

COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information, Proposed Amendments

(Agenda Item #3)

Health Information Exchange

Privacy and Security

Draft Amendments

COMAR 10.25.18

February 18, 2016

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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
- Collaborative Process
  - The HIE Policy Board, a staff advisory workgroup that consists of a diverse group of stakeholders, advises staff on HIE privacy and security policies
  - Developed privacy and security policies that became the framework for the initial draft HIE regulations

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

Amendments

- 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

SDU for Population Care Management

- Allows an HIE to disclose data to care management organizations for population care management
- Population-based activities relating to improving patient and population health or reducing health care costs where no treatment relationship exists
- Identifiable data 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 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 pertaining to 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, an HIE shall provide a health care consumer an accounting of any disclosures made to an entity for SDU purposes

Emergency Access

- An HIE must clearly communicate its emergency access policy to consumers
- 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; and
  - Information available through the HIE may be relevant to the specific emergency treatment;
- An HIE must implement technical procedures to document and audit emergency access

Other Draft Amendments

- Electronic Health Record System definition broadened to apply to all EHR technology (.02B(#))
- More specific information within patient notice from participating organization and HIE (.03G(c))
- Audit requirements strengthened to identify potential inappropriate access (.06A(1))

Next Steps

– The following timeline details next steps if proposed amendments are approved by the Commission:
  - April 1, 2016 – Publication date
  - May 1, 2016–Public comment period ends
  - May 19, 2016 – Staff presentation to the Commission for final action
  - June 20, 2016 – Effective final date of amendments

Thank You!

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Certificate of Need/Change in Approved Project
Prince George's Post Acute, LLC
(Docket No. 13-14-2347)

(Agenda Item #4)

MARYLAND HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

UPDATE:

Development of a State Health Plan Chapter for Freestanding Medical Facilities

(Agenda Item #5)

MARYLAND HEALTH CARE COMMISSION

Development of a State Health Plan Chapter for Freestanding Medical Facilities

An Update

Center for Health Care Facilities Planning and Development

February 18, 2016

MARYLAND HEALTH CARE COMMISSION

Overview

- Freestanding Medical Facilities
- The December, 2015 Draft State Health Plan (for Informal Comment)
- Informal Comments Received
- 2016 FMF Legislation
- Next Steps

Freestanding Medical Facilities (FMFs)

- Maryland's version of the freestanding emergency center – a category of licensed health care facility established in 2005
- Operated as a satellite hospital outpatient department – but a separately & distinctly licensed health care facility
- Provides unscheduled outpatient services
- Open 24 hours per day / seven days a week
- Subject to EMTALA
- Required Services, Staffing, & Equipment

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Freestanding Medical Facilities

- **Bowie Health Center** – not a pilot but licensed as an FMF – formerly operated under license of its parent, Prince George's Hospital Center – operational since 1979
- **Germantown Emergency Center -** established by Adventist HealthCare's Shady Grove Medical Center in 2006 – first pilot
- **Queen Anne's Emergency Center** – established by the University of Maryland Medical System's Shore Medical Center at Easton in 2010 – second pilot
- MHCC reported to the General Assembly on the operations, utilization, & financial performance of FMFs in 2009 and 2015

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Draft State Health Plan (SHP) December 2015

http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.axpx

Inputs

- The statute
- Licensure regulations
- Mandated studies of the pilot projects
- Literature review
- Policies & standards developed by national bodies and other states
- An Advisory Committee

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Draft State Health Plan December 2015

Policy Framework

- Emergency medical services shall be financially & geographically accessible to Maryland's population.
- Emergency medical services shall be provided in the most cost-effective manner possible.
  - Safe & effective care
- Resources shall be used efficiently in producing emergency medical services.
  - Avoid excess capacity & match capacity development to need

MARYLAND HEALTH CARE COMMISSION

Draft State Health Plan December 2015

Policy Framework

- An FMF shall provide high quality care.
  - Performance measurement
  - Continuous quality improvement
- An acute care general hospital operating an FMF
  - Shall assess the primary care needs of its service area population & maximize the number of people in its service area who have a regular source of primary care.
  - Shall continuously & systematically improve the quality & safety of patient care.

MARYLAND HEALTH CARE COMMISSION

Draft State Health Plan December 2015

Standards

Need

- Must be established in 85% relevance service area of parent hospital consistent with CMS limitations for provider-based status.
- Need demonstration based on overcrowding at parent hospital ER and/or inadequate access & availability of emergency medical services.
- ACEP ED design guidelines incorporated by reference for space & treatment capacity.

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Draft State Health Plan December 2015

Standards

Access

- Must demonstrate improvement of access as a result of the FMF project.
- Must identify access problems of underserved & present plan for overcoming access barriers for each underserved group.
- Must locate FMF to optimize access based on consultation with each emergency medical system in the area to be served by the FMF.

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Draft State Health Plan December 2015

Standards

Cost and Effectiveness

- Comparison with at least two alternative approaches for achieving project objectives required for demonstration that the proposed project is the most cost effective.
- CEA must identify why less expensive models of unscheduled service cannot meet population's needs.
- Must describe measures taken to comply with MSHIP & the plan for coordination of care with primary care providers with emphasis on management of chronic disease & mental health conditions.

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Draft State Health Plan December 2015

Standards

Efficiency

- Must demonstrate improvement in efficiency of emergency service delivery as a result of project.
- Demonstration must encompass emergency transport, hospital ED, & FMF operations. Provided to EMS system in area for review & comment.
- Must address how process improvement will be accomplished & how it will affect per visit cost.
- Must address integration of care to reduce episodic visit volume for chronic medical conditions.

MARYLAND HEALTH CARE COMMISSION

Draft State Health Plan December 2015

Standards

Construction Costs

- Cap on recognition of construction cost in GBR based on MVS benchmark costs.

Financial Feasibility/Viability

- No undue negative effect on parent hospital viability.
- Positive net operating income for combined hospital & FMF operations within three years.
- Must address workforce shortages – emergency trained physicians, nurses, and ancillary staff – with recruitment plan.

MARYLAND HEALTH CARE COMMISSION

Draft State Health Plan December 2015

Standards

Impact

- No undue negative effect on existing hospitals or FMFs.
- Impact analysis covering parent hospital & all other hospitals/FMFs in existing or projected service area. Impact on payer mix, CMI, volume, & cost of services.

Quality Improvement

- QI plan with performance measures & performance targets. Six mandated measures.

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Draft State Health Plan December 2015

Standards

Preferences in Comparative Reviews

- Cost effectiveness.
- Proven ability to reduce low acuity visits & inappropriate use of the parent hospital ED.
- Effective outreach to minority, indigent, & underserved.
- Research, training, & educational components meeting regional needs.
- Ability to integrate FMF with primary care delivery linking FMF patients to appropriate primary care.

Informal Comments Received, January 2016

http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs-shp.aspx

- Recognize that FMFs can provide a wider range of outpatient services beyond unscheduled emergent & urgent care.
- Limit location of FMFs to primary service area (60% relevance) of parent hospital – effectively reducing overlap of service area with other hospitals.
- Elevate community need & limited access as basis for need over ED overcrowding.
- Impact of long-term volume shifts on hospital GBRs is key impact.
- More clarity needed in a number of areas & for a number of terms– primary care needs assessment, integration with primary care delivery, undue negative effect, inadequate access, access barriers, severe adverse impact.

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2016 FMF Legislation

Senate Bill 707

- Allows general hospital transition to FMF through exemption from CON review - substitutes the FMF, a known and well-defined entity, for a "limited service hospital," an untried and less defined entity, as a hospital transition option.
- Requirements for planning (transitioning acute care delivery, addressing health care needs retraining & placing displaced employees, the hospital physical plant & site), timelines, public informational hearings (in counties with less than three hospitals), & preparation and distribution of hearing summaries.

2016 FMF Legislation

Senate Bill 707

- FMF site must be within 5-mile radius of general hospital being replaced.
- Definition of "hospital services" expanded to include outpatient services, as specified by HSCRC in regulation, provided at an FMF.
- Definition of "FMF" modified to require ability to meet CMS requirements for "provider-based status."
- MHCC must find maintenance of adequate & appropriate delivery of emergency care as determined by MIEMSS

MARYLAND HEALTH CARE COMMISSION

Next Steps

Options

- Commission could proceed with current SHP development process based on current law & revisit Plan if new law is established affecting regulation of FMFs.
- However, 2016 legislation & the level of interest in this legislation suggests that the SHP development process be paused to incorporate new law into the work already done
- The community concerns surrounding transition of general hospitals to outpatient care campuses warrants development of more explicit guidance for this type of exemption review, if it is established.

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Next Steps

- SHP would provide guidance to the Commission & to hospitals, in the case of a hospital to FMF conversion, on:
  - The public interest concerns to be considered.
  - The planning & plan content requirements to be addressed by a hospital or hospital system.
  - The meaning of "improved effectiveness and efficiency" in health service delivery.
  - The meaning of "adequate" & "appropriate" emergency care (with MIEMSS input)

QUESTIONS AND DISCUSSION

MARYLAND HEALTH CARE COMMISSION

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MARYLAND HEALTH CARE COMMISSION

ACTION:

Proposed Legislation

(Agenda Item #6)

Legislative Update

Erin Dorrien

Chief, Government and Public Affairs

February 18, 2016

MHCC | MARYLAND HEALTH CARE COMMISSION

Hospital Conversion

- SB 707/ HB 1350 Freestanding Medical Facilities- Certificate of Need, Rates and Definitions
  - Establishes a process for a licensed general hospital to convert to a freestanding medical facility through a CON exemption.
  - Expands the scope of services that can be offered at the FMF to observation stays and outpatient services authorized by HSCRC.
  - Expands public notification requirements for closure or conversion.

Bills Related to CON/ Health Planning

- SB 12/HB 1121 Health Care Facilities- Closures or Partial Closures of Hospitals- County Board of Health Approval
- HB 1018 Prince George's County- Closures or Partial Closures of Hospitals- Board of Health Approval PG 406-16
- SB 352 Maryland Health Care Commission- Certificate of Need Review- Interested Party

Bills Related to Maryland Patient Referral Law

- MHCC convened a workgroup to develop a consensus on changes to the law
- HB 929 Health Occupations- Prohibited Patient Referrals- Exceptions -- offered by MPCAC
- SB 739/HB 1422 Integrated Community Oncology Reporting Program – offered by medical oncology
- SB 886 Health- Collaborations to Promote Provider Alignment offered by MHA

On the Horizon

- SB 857/ HB 1265 MHCC- Hospital and Physician Financial Arrangement Disclosure- Requirements
  - Requires hospitals and physicians to disclose financial arrangements with pharmaceutical and medical device manufacturers to MHCC
  - Requires MHCC to establish and maintain a searchable database of disclosure forms

On the Horizon

- HB 1385 Public Health- Electronic Advance Directives- Witness Requirements, Information Sheet, and Repository
  - Requires MHCC and DHMH to approve an electronic advanced directive service that will connect with CRISP
  - Requires CRISP to make paper advanced directives available through the approved electronic advanced directive service
  - Requires payers and MCO's to notify enrollees of the electronic advanced directive service

Other Legislation of Interest

- SB 242 HB 886 Maryland Medical Assistance Program- Telemedicine- Modifications
- SB 324/ HB 309 Prince George's County Regional Medical Center Act of 2016
- SB 335/HB 1505 Health Insurance Assignment of Benefits and Reimbursement of Nonpreferred Providers- Modifications
- SB 382/ HB 456 Prescription Drug Monitoring program- Revision

Other Legislation of Interest

- SB 537/ HB 437 DHMH- Prescription Drug Monitoring Program Modifications
- HB 908 Hospitals- Establishment of Substance Use Treatment Programs- Requirements
- HB 1103 Health Care Practitioners- Use of Teletherapy

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MARYLAND HEALTH CARE COMMISSION

Overview of Upcoming Initiatives

(Agenda Item #7)


ENJOY THE REST OF
YOUR DAY