Maryland Health Care Commission

Thursday, February 18, 2016
1:00 p.m.
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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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

The MARYLAND HEALTH CARE COMMISSION
• 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!

The MARYLAND HEALTH CARE COMMISSION
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8. **ADJOURNMENT**
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(Agenda Item #4)
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UPDATE:
Development of a State Health Plan Chapter for Freestanding Medical Facilities

(Agenda Item #5)
Development of a State Health Plan Chapter for Freestanding Medical Facilities

An Update

Center for Health Care Facilities Planning and Development

February 18, 2016
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
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
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
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
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.
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.
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.
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.
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.
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.
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.
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

- 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.
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
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.
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)
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(Agenda Item #6)
Legislative Update

Erin Dorrien
Chief, Government and Public Affairs
February 18, 2016
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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Overview of Upcoming Initiatives

(Agenda Item #7)
ENJOY THE REST OF YOUR DAY