



Maryland Health Care Commission

Thursday, June 15, 2017

1:00 p.m.



AGENDA

1. **APPROVAL OF MINUTES**
2. UPDATE OF ACTIVITIES
3. **ACTION:** Cardiac Services Advisory Committee Membership Change
4. **ACTION:** Certificate of Need – Columbia Surgical Institute, L.L.C. (Docket No. 17-13-2391)
5. **ACTION:** Certificate of Need – Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center (Docket No. 16-03-2360)
6. **ACTION:** COMAR 10.25.19 – State Recognition of an Electronic Advance Directives Service – Proposed Permanent Regulations
7. **PRESENTATION:** Health Care Data Breaches: A Changing Landscape
8. Overview of Upcoming Initiatives
9. ADJOURNMENT



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ACTION:

Cardiac Services Advisory Committee Membership Change

(Agenda Item #3)



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ACTION:

**Certificate of Need – Columbia Surgical Institute, L.L.C.
(Docket No. 17-13-2391)**

(Agenda Item #4)



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Certificate of Need – Franklin Square Hospital Center d/b/a
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(Agenda Item #5)



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ACTION:

COMAR 10.25.19 – State Recognition of an Electronic Advance Directives Service – Proposed Permanent Regulations

(Agenda Item #6)

Proposed Regulations

COMAR 10.25.19

*State Recognition of an
Electronic Advance Directives Service*

June 15, 2017



The MARYLAND HEALTH CARE COMMISSION

Overview

- Proposed regulations developed the following two pieces of legislation passed by the General Assembly:
 - House Bill 1385, *Procedures, Information Sheet, and Use of Electronic Advance Directives* (2016)
 - House Bill 188, *Public Health - Advance Directives - Witness Requirements, Advance Directives Services, and Fund* (2017)
- In general, the laws require the development of a statewide Advance Directives Program with the aim of facilitating diffusion of cloud-based technology to support the use of electronic advance directives

Proposed Regulations

- In the fall of 2016, staff collaborated with stakeholders on electronic advance directives
- Stakeholder feedback was used to develop draft regulations
- In general, the regulations detail the process for developing criteria for State Recognition of an electronic advance directives service and application processes to be awarded State Recognition from MHCC

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

Key Components *(continued...)*

- Provisions on the non-transferability 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

Informal Comment

- Draft regulations were posted to MHCC's website for an informal comment period from May 19th – June 2nd
- Comments were received from the Attorney General's Health Education Advocacy Unit; suggested enhancements include:
 - Clarifying language to align definitions and provisions with current law;
 - Additions to affirm a qualified entity; and
 - Additional notice provisions

Requested Commission Action & Next Steps

- Staff recommends that the Commission adopt the regulations as proposed permanent
- The following timeline details next steps if the proposed regulations are approved by the Commission:
 - July-August – Publication in Maryland Register/public comment
 - September 21st – Request final action from the Commission
 - October 23rd – Effective date of regulations



Questions?



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PRESENTATION:

Health Care Data Breaches: A Changing Landscape

(Agenda Item #7)

Health Care Data Breaches:

A Changing Landscape

An Information Brief

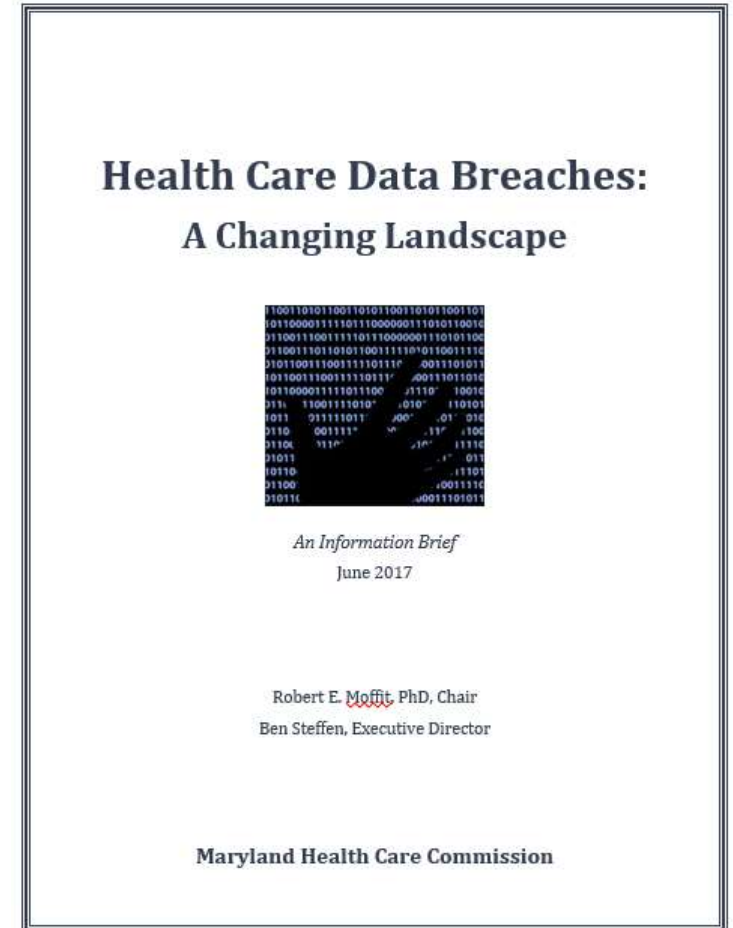
June 15, 2017



The MARYLAND HEALTH CARE COMMISSION

Framing the Discussion

- Expanded use of electronic health information, and a surge in hacking related incidents is contributing to the increase in breaches
- Industry experts see persistent cyber-attacks as the single greatest threat to the protection of health care data
 - Impact critical health care operations and patients' wellbeing



Background

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established national standards for confidentiality of protected health information (PHI)
- The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 made changes to HIPAA, such as broadening the definition of a breach and notification requirements
 - HITECH defines a breach as the unauthorized acquisition, use, or disclosure of PHI which compromises the security or privacy of PHI

About the Assessment

- Staff analyzed data searchable through the Office of Civil Rights (OCR) breach portal
 - Data from 2010 through 2016
 - Reportable breaches affecting 500 or more individuals
- Recommendations for enhancing security processes to prepare for and mitigate the effects of evolving cyber threats
- Findings aimed to build stakeholder awareness about the increasing prevalence of breaches and inform program development activities for security education and awareness

Breaches by Covered Entity Type

- Between 2010-2016, providers experienced more than half of all breaches
- Greater reliance on business associates (BAs) by providers increases their cybersecurity risk
 - Small and midsized BAs can be more vulnerable due to their lower budgets for privacy and security and less formal monitoring and auditing programs
- Health plans locally and nationally experienced an uptick in breaches in recent years

Frequency and Impact

- Risk of a breach continues to amplify as adoption of health information technology increases
- 2015 stands out for both Maryland and the nation given the number of records that were exposed or stolen collectively affecting over 114M individuals
 - In comparison, an estimated 41M records were compromised between 2010 through 2014

Common Types of Breaches

- Within the past three years, there has been a significant shift in the way PHI has been breached

Table 1: Percent Growth - Top Three Breach Types

Type of Breach	2010	2011	2012	2013	2014	2015	2016	Growth Rate 2010-2016	Growth Rate 2014-2016
Hacking/IT Incident	3	6	4	9	12	23	44	55	92
Theft	18	16	16	17	15	11	8	-12	-24
Unauthorized Access/ Disclosure	2	6	6	15	17	24	30	59	32

Note: Information above represents compound annual growth rate.

Assessing the Impact

- Effects of a breach or cyber-attack include financial and reputational harm
 - Loss of sensitive and proprietary information
 - Cost to address security gaps and implement corrective actions
 - Disruption to operations
 - Impact on consumer trust, confidence, and loyalty
- Response and recovery efforts in the hours and days that follow is crucial to remediating risk

Minimizing Risk

- Hacking incidents prompting new awareness in Maryland about the adequacy of incident response planning
 - Should include breach response protocols as well as rapid response protocols to try and avoid a breach
- Importance of understanding the issue of human error
 - Phishing, hacking, and malware were leading causes of security incidents in 2016; yet the underlying cause was often attributed to human error

Regulatory Considerations

- Fines for non-compliance are based on level of negligence and can range from \$100 to \$50,000 per violation (or record)
 - Critical to prepare for responding to an OCR investigation by undertaking corrective actions to resolve an investigation quickly
- Covered entities and BAs can anticipate an increase in the volume of enforcement actions triggered by OCR for small-scale breaches fewer than 500 individuals

Regulatory Considerations *(continued...)*

- Security incidents involving a non-breach of PHI pose significant threats to patient health
 - Evident from the rise in ransomware where hackers deny access to data
- Federal and Maryland laws lack clarity regarding notification requirements to the public when data is locked by a hacker but not stolen
 - Impact on health care operations can be substantial, forcing care delivery techniques to be redirected until systems are able to be brought back online

Third Party Reviews

- Third party reviews provide an extra level of independent examination of risk management plans and procedures
 - Enable corrective actions to be deployed more quickly
 - Aligned with key industry standards
- Approximately 80 percent of breaches are discovered by independent third party review as compared to internal discovery of threats that stands at a mere 10 percent

Next Steps

- Analyze the OCR breach data to determine how Maryland ranks in comparison with other states
- Use the findings to inform stakeholders and build awareness about breaches and cyber-attacks
- Work with stakeholders to develop initiatives aimed at enhancing IT risk management and organizational readiness
- Facilitate provider association peer learning sessions focused on increasing situation awareness

Thank You!



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Overview of Upcoming Initiatives

(Agenda Item #8)



ENJOY THE REST OF
YOUR DAY