



HIPAA RFI Breakfast

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Agenda

- + **About Us**
- + **HIPAA Overview**
- + **RFI Context**
- + **Congressional Actions**
- + **Proposals in the RFI**
- + **Comments**

+ About Us



Health policy, advocacy and data analytics services to health industry clients

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Affiliation with McDermott Will & Emery offers seamless, one-stop shopping across clients' lobbying, analytics, policy and legal needs



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120+ dedicated health care attorneys

Tier 1 National Health Rankings in all of the industry's top legal directories

Health Care Practice Group of the Year *Law360* (2018) and *Chambers USA* (2010, 2013, 2017)

+ Administration Priorities

- + HHS Secretary Alex Azar has identified four priority areas:
 - Health Reform
 - Drug Pricing Reform
 - Opioids and Mental Health
 - Value-Based Transformation and Innovation
 - Parallel tracks of model development/modification and regulatory relief

+ Value Movement

- + The basic premise – if providers take more financial risk, the administration will remove regulatory burdens and barriers
- + Dep. Secretary Eric Hargan Announces #RS2CC
 - Stark Law RFI
 - AKS RFI
 - HIPAA RFI
 - 42 CFR 2 RFI
- + Innovation Center activity
- + Medicare Shared Savings Program final rule

+ H e a l t h I n s u r a n c e P o r t a b i l i t y a n d A c c o u n t a b i l i t y A c t o f 1 9 9 6

- + The U.S. Department of Health and Human Services (HHS) published:
 - Original HIPAA Privacy Rule Final Rule in December **2000**
 - Original HIPAA Security Rule Final Rule in February **2003**
- + Applies to **Covered Entities** and **Business Associates**
 - Covered Entities include: health plans, health care clearinghouses, and health care providers who engage in electronic transactions (i.e., bill Medicare or private health insurance)
- + Generally prohibits use and disclosure of Protected Health Information (PHI) unless a permissible pathway applies
- + HIPAA Omnibus Final Rulemaking in January 2013 updated portions of the Privacy Rule, gave the Office for Civil Rights the authority to enforce HIPAA directly against Business Associates, and finalized a new Breach Notification Rule
- + Despite Omnibus Rulemaking, portions of the HIPAA Privacy and Security Rules may warrant updating
- + RFI motivated in part by recognition from OCR that change or further guidance/education needed to accommodate efforts to deliver value-based health care, and form new innovative models of care coordination and case management

+ Proposals Discussed in the RFI

- + Requirement to respond to requests for PHI from other health care providers for treatment, care coordination or case management
- + Excepting care coordination and case management disclosures from the minimum necessary requirement
- + Express permission to disclose PHI to social service agencies or community-based support programs
- + Revisiting the status of health care clearinghouses as Business Associates
- + Establishing new disclosure pathways for Covered Entities to share PHI with family members, caregivers, and others, including potential changes to the personal representative pathway
- + Expanding the HIPAA Privacy Rule's accounting of disclosures requirement to include disclosures through an Electronic Health Record (EHR) for treatment, payment and health care operations
- + Eliminating or modifying the obligation for health care providers to obtain an acknowledgment of the receipt of the provider's Notice of Privacy Practices upon the individual's first visit
- + Requesting public input on other ways to modify HIPAA to remove regulatory obstacles and decrease regulatory burdens

+ RFI and Congressional Action

- + HIPAA is not the only regulatory mechanism for the Administration to address access to and sharing of protected personal health information:
 - Implementation of Cures
 - Information blocking
 - Implementation of opioids legislation
 - Patients over Paperwork and Meaningful Measures embedded into payment rules

- + Congress works around the edges and falls short on larger changes to HIPAA
 - Mental health reform
 - Cures
 - Opioids

- + HIPAA RFI may lead to legislative changes

+ Tips for Drafting Comments

General v. Specific

Comprehensive v. Targeted

Permissive v. Required

Regulatory v. Statutory

CAUTION Watch for:

- ✓ Solutions in search of problems
- ✓ State and other federal law
- ✓ Prohibitions
- ✓ Ambiguity: Moving to red or green light

+ Questions?



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Scott provides legal counsel on health care regulatory compliance, contracting and transactional due diligence, with a focus on health information privacy and security, Medicare and Medicaid's health information technology and quality reporting requirements, and clinical research regulations. Scott additionally provides legal counsel on federal and state privacy and data protection laws.