

HIPAA COMPLIANCE STRATEGIES FOR DISEASE MANAGEMENT AND E-HEALTH

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Overview

- **Issues that Won't Be Discussed:**
 - **NO HIPAPOTAMUSES**
 - Mudslinging at Congress OK
 - **NO "FUZZY MATH"**
 - Outrageous Cost of HIPAA Compliance OK
 - **NO LEGALESE**
 - Lawyers' HIPAA Fees OK (+ liability costs)
 - **NO GEEK SPEAK**
 - Consultants' Even Higher HIPAA Fees OK (+ IT costs)

Overview

- **ISSUES THAT WILL BE DISCUSSED:**
 - **WHAT'S AT STAKE FOR DM UNDER HIPAA?**
 - **HOW IS DM COVERED BY HIPAA?**
 - **WHAT ARE THE HIPAA COMPLIANCE REQUIREMENTS FOR DM PROGRAMS?**
 - **WHAT STATE LAWS STILL APPLY?**
 - **WHAT IS DMAA DOING ABOUT ALL THIS?**

WHAT'S AT STAKE FOR DISEASE MANAGEMENT?

- **HEALTH PLANS/ OTHER PAYORS**
 - **ABILITY TO ACCESS CLAIMS AND OTHER DATA TO IDENTIFY ELIGIBLE PATIENTS**
 - **ABILITY TO ENROLL/ ENGAGE ELIGIBLE PATIENTS**
- **PATIENTS**
 - **ABILITY TO COMMUNICATE WITH PATIENTS TO PROVIDE DM SERVICES**
- **PHYSICIANS**
 - **ABILITY TO COMMUNICATE WITH PHYSICIANS RE: THEIR PATIENTS DM PROGRAM**
 - **ABILITY TO PROVIDE PHYSICIANS WITH BEST PRACTICES DATA RE: THEIR PATIENTS**

WHAT'S AT STAKE FOR DISEASE MANAGEMENT?

EVERYTHING!!!

DISEASE MANAGEMENT: COVERED ENTITIES?

- APPLIES TO:

- Health Plans

- Insurers/ HMOs/PPOs
- ERISA Plans/ Govt. HPs

- Health Care Providers

- MDs, RNs, hospitals, etc.
- Care managers, if licensed as health care providers
- EAPs, On-site clinics
- Other person or org. who furnishes, bills, or is paid for h/c services or supplies (e.g., group practice, on-line pharmacy) (INCLUDE DMOs?)

- Clearinghouses

- Billing agencies

- WHENEVER THEY:

- Transmit or maintain Protected Health Information (PHI) Electronically

- Even if PHI is later reduced to paper form (but may change to include original paper)

- PHI is: health information which identifies or could lead to ID of the patient
- HEALTH INFO is: information created or received by a CE, ER, etc. that relates to past, present, or future health care services or payment therefore

DISEASE MANAGEMENT: BUSINESS PARTNERS?

- **BP DEFINITION:**
 - “A person to whom the CE discloses PHI so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the CE.”
- **YES:** if receive PHI from CEs
- **NO:** if receive PHI only from patients
- **MAYBE:** what happens if MDs/ RNs or other health care providers employed by DMO receive data from patient and provide to DMO?

HIPAA PRIVACY RULES: COMPLIANCE BY COVERED ENTITIES

- **Comply With Use And Disclosure Rules**
- **Comply with Administrative Rules**
 - **Permit patient access, amendment, and limitation to PHI**
 - **Notice of info practices: disclose/ maintain/ amend policies**
 - **Account for disclosures**
 - **Designate privacy official**
 - **Train workforce**
 - **Maintain complaint process**
- **Comply with Security Rules**
- **Subject to Civil and Criminal Penalties**
- **Liable for Private Right of Action Under State Law?**
- **Liable for Business Partner Violations**
 - **if the covered entity knew or reasonably should have known of such breach and failed to take reasonable steps to cure the breach or terminate the contract.**

HIPAA PRIVACY RULES: COMPLIANCE BY BUSINESS PARTNERS

- **Comply With Use And Disclosure Rules - YES, contractual**
- **Comply with Administrative Rules - SOME, contractual**
 - **Permit patient access, amendment, and limitation to PHI - YES**
 - **Notice of info practices: disclose/maintain/amend policies - NO**
 - **Account for disclosures - NO**
 - **Designate privacy official - NO**
 - **Train workforce - NO**
 - **Maintain Complaint process - NO**
- **Comply with Security Rules - YES, by contract only**
- **Subject to Civil and Criminal Penalties - NO**
- **Liable for Private Right of Action Under State Law? - NO**
- **Liable for Business Partner Violations - NO, unless contract**

HIPAA PRIVACY RULES: USE AND DISCLOSURE REQUIREMENTS

- **PROBLEM AREAS FOR ALL BPs:**
 - **Minimum Necessary Rule**
 - **De-identification Rule**
 - **Destruction of Data Rule**
 - **Health Care Component CE Rule**
 - Health plans
 - Health care services
 - **CE Liability for Your Violations**
 - Duty to Monitor
 - Duty to Mitigate

HIPAA PRIVACY RULES: USE AND DISCLOSURE REQUIREMENTS

- **PROBLEM AREAS FOR ALL BPs:**
 - **OBTAIN DETAILED PATIENT AUTHORIZATION *UNLESS FOR:***
 - Treatment
 - Payment
 - Health Care Operations
 - Enumerated Exceptions (e.g., public health, research)
 - **WITHOUT PREEMPTION, SUBJECT TO ALL MORE STRINGENT STATE AUTH. FORMS (e.g., bigger font?)**

HIPAA PRIVACY RULES: SPECIAL ISSUES FOR DM

- **TREATMENT EXCEPTION TO PATIENT AUTHORIZATION**

- “The provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) among, health care providers; the referral of a patient from one provider to another; or the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual.”

HIPAA PRIVACY RULES: SPECIAL ISSUES FOR DM

- **DEFINITIONAL ISSUE**
 - **"The definition of 'treatment' includes' [disease] management as an included function. DM is not a defined term, and this creates one of the biggest loopholes in the rule. Protected health information could be disclosed to virtually anyone--including marketers and employers ... it is essential that this loophole be closed."**
 - **Robert Gellman, Member, National Committee on Vital and Health Statistics.**

HIPAA PRIVACY RULES: SPECIAL ISSUES FOR DM

- **POPULATION MANAGEMENT**

- **HHS**

- “Our definition is intended to relate only to services provided to an individual and not to an entire enrolled population.”

- **NCQA**

- “[T]he definition . . . in the proposed rule is limited to a range of services provided to individuals and not to enrolled population groups. This limited definition of what constitutes health care operations conflicts with NCQA requirements for managed care plans.”
 - “NCQA expects accredited health plans to institute population-based management of care programs ... and generally be responsible for improving the outcomes of enrolled populations.”

HIPAA PRIVACY RULES: SPECIAL ISSUES FOR DM

- **PHARMA-PBM-MARKETING: PHYSICIAN PERSPECTIVE**
 - “The danger of equating information disclosures for DM with disclosures for treatment is not a theoretical one, as anyone knows who has received mailings at home for an alternate, competing medication after having filled a prescription at the pharmacy.”
 - “If the true motive of its proponents is to improve individuals’ care, then they should not object to coordinating all DM activities through the individual’s physician. If, however, the purpose is ...to market protected health information to commercial entities or employers, then the proponents will eschew physician participation and seek to directly influence the patient.”
 - The AMA opposes any “disease management” language in the proposed rule that is not qualified by requiring the coordination and cooperation of the individual’s physician.”

PREEMPTION/ STATE LAW ISSUES: CALIFORNIA

- **The Law:**
 - “No provider of healthcare or Health Care Service Plan or contractor shall disclose medical information regarding a patient of the provider of healthcare or an enrollee or subscriber of a Health Care Service Plan without first obtaining an authorization, except . . .”
- **The Exception:**
 - “For purposes of chronic disease management programs, information may be disclosed to any entity contracting with a Health Care Service Plan to monitor or administer care of enrollees for a covered benefit. . .”
- **The Exception to the Exception:**
 - “. . . provided that the disease management services and care are authorized by a treating physician.”

PREEMPTION/ STATE LAW ISSUES: CALIFORNIA

- **FIREBAUGH AMENDMENT: ADVANTAGES**

- **(1) No need for physician authorization if:**

- entity is a DMO, as defined in new Section 1399.900 of the Health and Safety Code, provided that the health care service plan or its contractor provides a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians.

- **(2) Uses DMAA definition of DMO and “DM services”**

- **(3) DMAA compromise with CMA**

- **(4) Probably will avoid similar problems in other states**

PREEMPTION/ STATE LAW ISSUES: CALIFORNIA

- **FIREBAUGH AMENDMENT: TRADE-OFFS**

- (1) **DMOs must still obtain physician authorization prior to the time that the DMO, its employees, or its independent contractors do either of the following:**
 - Provide home health care services. (Home health visits made solely for patient assessment, monitoring, or education are not subject to the physician authorization requirement).
 - Dispense, administer, or prescribe a prescription medication. (A valid prescription written by a treating physician is adequate authorization).
- (2) **DMOs are now subject to the other provisions of the California Confidentiality law, including penalties for violations.**
- (3) **DMOs may not use medical information to solicit or to offer for sale to a health care service plan enrollee any products or services in the provision of DM services to the enrollee.**
 - Enrollee may elect to use a DMO to obtain information about health care products and services and then the DMO may offer to the enrollee health care products or services that are directly related to enrollee's condition.

PREEMPTION/ STATE LAW ISSUES: TEXAS

- **TEXAS HOUSE: MAXEY BILL**
 - **MORE STRINGENT THAN HIPAA OR ANY OTHER STATE LAW**
 - **PRIVATE RIGHT OF ACTION WITH PUNITIVES**
 - **DMOs MAY BE COVERED ENTITIES?**
 - **MUST COMPLY WITH ALL ADMIN/ POLICY REQUIREMENTS**
 - **MUST GET PATIENT “INFORMED CONSENT” FOR ANY USE OF DATA**
 - **ONLY EXCEPTION IS FOR “DELIVERY OF HEALTH CARE”**
 - **PAYER/ER MAY NOT REQUIRE PARTICIPATION IN A DM PROGRAM**

PREEMPTION/ STATE LAW ISSUES: TEXAS

- **TEXAS HOUSE: MAXEY BILL**
 - **“A HEALTH CARE PAYOR MAY NOT INITIATE CONTACT WITH THE SUBJECT OF SENSITIVE HEALTH INFO RE: ANY DM PROGRAM . . . PERTAINING TO THE SENSITIVE HEALTH INFO. THE HEALTH CARE PAYER SHALL INITIATE COMMUNICATION THROUGH A HEALTH CARE PRACTITIONER.”**
 - **“A HEALTH CARE PAYER MAY SEND MAIL ADDRESSED TO AN INDIVIDUAL RE: ANY HEALTH TOPIC, INCLUDING GENERIC MATERIAL RE: SENSITIVE HEALTH INFO., IF THE MATERIAL DOES NOT NAME OR O/W IDENTIFY THE INDIVIDUAL WITHIN THE MATERIAL SENT”**

PREEMPTION/ STATE LAW ISSUES: TEXAS

- **TEXAS SENATE: PRIVACY WORK GROUP**
 - **“Recently, the California Health Care Foundation released a poll..., which found that 70 percent of polled adults do not want drug companies to review their medical record for the purpose of marketing new drugs and products. This overwhelming result points to the challenge in developing a Disease Management program that provides educational benefit to patients while respecting their medical privacy [AND] preventing any data from being used for unwarranted marketing purposes. There is a need to develop a coherent federal and state privacy policy that clearly establishes the definition of legitimate disease management and overt commercialization of direct marketing to a sometimes vulnerable patient population.”**