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CURRENT LEGAL ISSUES IN HEALTH CARE

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INTRODUCTION

- No shortage of important topics this year
- Major changes in the health care legal landscape
- Can’t cover all current legal issues today
- Presentation for approximately 45 minutes – time for questions and discussion
- Remain flexible

TOPICS

- Patient Protection and Affordable Care Act (“PPACA”) and Health Care and Education Reconciliation Act (“HCERA”) Highlights
- HIPAA after the Health Information Technology for Economic and Clinical Health Act (“HITECH”)
- Electronic Health Records Update
- Health Care Enforcement Developments

PATIENT PROTECTION AND AFFORDABLE CARE ACT ("PPACA") AND HEALTH CARE AND EDUCATION RECONCILIATION ACT ("HCERA") HIGHLIGHTS

- Why healthcare reform?
  1. Large number of Americans are uninsured (some by choice)
  2. Increases in insurance premiums and out-of-pocket costs for those who have insurance
  3. U.S. spends more money per person on health care than any other nation
  4. Preventive care is under-utilized
  5. Chronic diseases and conditions (hypertension, diabetes, obesity, etc.) burden system
  6. Gaps in quality and efficiency of care
  7. Failure to detect and reduce errors
  8. "Defensive medicine" increases costs

PPACA/HCERA HIGHLIGHTS

- What did Congress do?
  1. House passed Senate health care reform bill, H.R. 3590 (P.L. 111-148), Patient Protection and Affordable Care Act ("PPACA") on Sunday, March 21, 2010 at 10:45pm
  2. House passed reconciliation bill, H.R. 4872, Health Care and Education Reconciliation Act ("HCERA") on Sunday, March 21, 2010 at 11:45pm
  3. PPACA signed into law by President on Tuesday, March 23, 2010
  4. Senate passed H.R. 4872 on Thursday, March 25, 2010
  5. Minor changes – H.R. 4872 returned to House for final vote on Thursday, March 25, 2010 at 9:00pm
  6. President signed HCERA into law at Northern Virginia Community College on Tuesday, March 30, 2010
  7. 2,559 pages
  8. No Republican votes in favor

PPACA/HCERA HIGHLIGHTS

- Significance?
  1. Has been compared to Medicare, Social Security and Civil Rights Act of 1964
  2. Death threats, vandalism, protests, legal challenges, possible impact on mid-term Congressional elections
  3. Medicare Modernization Act of 2003 (Medicare prescription drug benefit – Part D) – Cost of $400 billion over 10 years, affected primarily Medicare beneficiaries and pharmaceutical and insurance industry
  4. PPACA/HCERA - $940 billion over 10 years, affects 32 million uninsured persons and every stakeholder in the health system

PPACA/HCERA HIGHLIGHTS

- PPACA/HCERA objectives:
  1. Ensure all (94+%) have access to quality, affordable health care
  2. Create necessary transformation within health care system to contain costs
  3. Congressional Budget Office determined that PPACA and HCERA fully paid for – and will actually reduce federal deficit by $143 billion over next 10 years

PPACA/HCERA HIGHLIGHTS

- PPACA/HCERA breakdown – Ten Titles
  1. Coverage expansion – Titles I and II (25%)
  2. Quality improvement/cost efficiency – Titles III-VIII (more than 50%)
  3. Revenue enhancements – Title IX
  4. Title X – improvements to preceding nine Titles and additional changes
  5. Will take more than four years to fully implement. For a good detailed implementation timeline, go to the Henry J. Kaiser Family Foundation website, http://www.kff.org/healthreform/8060.cfm

PPACA/HCERA HIGHLIGHTS

- Breakdown of PPACA/HCERA provisions
  1. Coverage expansion
     - Title I: “Quality, Affordable Health Care for All Americans” (private insurance coverage reforms and improvements – already had issue on pre-existing exemptions for children – tax credits for individuals, families and small businesses, exchanges, availability of coverage, insurance, required coverage for most individuals)
     - Title II, “The Role of Public Programs” (no “public option,” includes significant Medicaid expansion – beginning in 2014, Children’s Health Insurance Program (“CHIP”) extension, Coordination of care under Medicare and Medicaid).

PPACA/HCERA HIGHLIGHTS

2. Quality improvement/cost efficiency
   - Title III, “Improving the Quality and Efficiency of Health Care” (Medicare payments linked to better quality outcomes, national strategy to improve quality and general population health, beneficiary access to care, improving payment accuracy, Medicare Part D enhancements)
   - Title IV, “Prevention of Chronic Disease and Improving Public Health” (modernizing disease prevention and public health systems, increased access to clinical preventive services, creating healthier communities, support for public health innovation)
   - Title V, “Health Care Workforce” (innovations in health care workforce, increased supply of workers, enhanced workforce education and training, strengthening primary care)

PPACA/HCERA HIGHLIGHTS

- Title VI, “Transparency and Program Integrity” (fraud and abuse, transparency requirements for physicians, nurses, nursing homes, Medicare, Medicaid and CHIP enrollment screening, enhanced Medicare and Medicaid program integrity provisions, med mal “sense of the Senate”)
- Title VII, “Improving Access to Innovative Medical Therapies” (biologics price competition and innovation, more affordable medications for children and underserved communities)
- Title VIII, “Community Living Assistance Services and Supports” (new, voluntary, self-funded long term care insurance program, the CLASS Independence Benefit Plan for purchase by functionally limited persons of community living assistance services and support – no taxpayer funds used to pay benefits)

PPACA/HCERA HIGHLIGHTS

3. Revenue Enhancements
   - Title IX, “Revenue Provisions” (additional requirements – including periodic community needs assessment – on charitable hospitals (effective 2010), 10% tax on indoor tanning services payments (effective 2010), limitations on health flexible spending/health savings account arrangements (effective 2011), annual fee on branded prescription pharmaceutical manufacturers and importers (effective 2011), increase in Medicare Part A hospital insurance – tax on wages and certain unearned income and increase medical expense itemized deduction requirement from 7.5% to 10% (effective 2013), eliminate tax deduction for employers receiving Medicare Part D retiree drug subsidy payments (effective 2013), excise tax on medical devices (effective 2013), annual fee on health insurance sector (effective 2014), excise tax on “Cadillac Plans” (effective in 2018), etc. - also includes study and report by VA on veterans’ health care cost and access to medical devices and branded drugs)

PPACA/HCERA HIGHLIGHTS

4. Improvements to previous nine Titles and additional changes

   – Title X “Strengthening Quality, Affordable Care” (improvements to: coverage, role of public programs, Indian health care, Medicare, public health programs, workforce, and transparency and program integrity)

PPACA/HCERA HIGHLIGHTS

- Closing PPACA/HCERA comments:
  1. Laws create new boards (i.e., Independent Payment Advisory Board), new "working groups" (i.e., Interagency Working Group on Health Care Quality), new funds (i.e., Prevention and Public Health Investment Fund), new commissions (i.e., National Health Workforce Commission), and new institutes (i.e., Institute of Medicine Conference on Pain Care) – much work to implement
  2. When will guidance come?
     - By July 1, 2010, HHS must establish website where people can identify "affordable health insurance coverage options"
     - Look for guidance on defining the "essential health benefits" that must be offered by all insurers and which dependants are entitled to stay on their parents' insurance.

HIPAA AFTER THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC CLINICAL HEALTH ACT ("HITECH")

- Privacy and Security changes – most significant since initial adoption of HIPAA Privacy Rule (most provisions effective on February 17, 2010)
- Changes approved as part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), the "stimulus bill" – signed into law on February 17, 2009.
- Title XIII of Division A and Title IV of Division B of ARRA collectively referred to as HITECH.
- Emphasis in today's presentation on most significant HITECH HIPAA substantive changes:
  1. Breach prevention and notification requirements
  2. Business Associate requirements contract changes
- HIPAA-related policies and procedures changes are required

HIPAA AFTER HITECH

- Major Themes of HIPAA

  1. Promote electronic health care transactions

  2. Patient access to information

  3. Privacy and security of information

  4. HIPAA major themes echoed in HITECH

HIPAA AFTER HITECH

- Significant HIPAA/HITECH Changes – Breach Notification

1. Breach Notification Requirements and Prevention

— Breach notification required

a. Effective September 23, 2009

b. Enforcement delayed until February 22, 2010 (but, compliance still expected)

c. Basic rule

i. Breach of patient's protected health information ("PHI")

ii. Must notify patient in writing promptly

iii. Must notify HHS in writing (annually/promptly)

iv. May need to notify media (promptly)

v. "Unsecured" PHI – not encrypted or shredded

HIPAA AFTER HITECH

— Determining a Breach

a. "Breach" is "unauthorized acquisition, access, use, or disclosure of PHI which compromises the security or privacy of the PHI."

b. Risk Assessment – Required

i. Fact-specific – Will the disclosure pose "significant risk of financial, reputational, or other harm to the individual"?

ii. Focus on:

Who acquired/to whom was the PHI disclosed?

Mitigation that may have occurred immediately?

Type and amount of PHI involved?

Example: forensic proof that laptop was not accessed?

iii. Document the risk assessment

HIPAA AFTER HITECH

— Exceptions from "breach" definition

a. "Unintentional" use by covered entity's workforce member – provided no further disclosure
b. "Inadvertent" disclosure between two similarly situated individuals at a covered entity, if both have authority to access PHI (although perhaps different aspects) – provided no further disclosure
c. "Good faith belief" that unauthorized recipient would not reasonably been able to retain the information (e.g., wrong discharge instructions quickly retrieved)
d. Limited data set – minus date of birth and zip code (narrow exception defined out via risk assessment)
e. Note: no exception for redacted information
f. Note: "incidental disclosure" is not a violation of the Privacy Rule

HIPAA AFTER HITECH

— "Unsecured" PHI

a. Breach notification applies to "unsecured" PHI only
b. "Unsecured" PHI is not secured through a technology that makes it "unusable, unreadable, or indecipherable to unauthorized individuals"
c. Guidance from HHS – encryption or destruction (shredding). 74 Fed. Reg. 42740 (Aug. 24, 2009)
d. www.hhs.gov/ocr/privacy - will have updates on identified methodologies
e. Cheapest method to comply – encrypt and shred
f. Especially: laptops, thumb drives, portable media
g. Note: "unsecured" PHI can be in any form – electronic, paper, or oral

HIPAA AFTER HITECH

— Specific notifications required

a. Breach discovered – workforce member knows, or should have known, of breach (other than the person who caused the breach)

b. Timeliness – "without unreasonable delay," but in no event more than 60 days after discovery (law enforcement exception)

c. Content of notice:

i. Description of what happened, including date of breach and date of discovery

ii. Description of types of information involved

HIPAA AFTER HITECH

i. Any steps the individual should take to protect himself or herself

iii. Description of what covered entity is doing to investigate, mitigate harm, and protect against further breaches

iv. Contact procedures to ask questions

d. Manner of notice

i. First class mail (unless agreed to email notice)

ii. Insufficient information – substitute notice (e.g., phone), unless more than 10 people, then: prominently on web-page for 90 days (or major print or broadcast media) and toll-free number for more information

iii. Exceptions for urgent notification needed

HIPAA AFTER HITECH

iv. Notification to media – more than 500 individuals requires notice to "prominent media outlets"

v. Notification to HHS – more than 500 individuals requires contemporaneous notice to HHS; otherwise, annual log.

e. Notification by Business Associate – BAs must provide notice to CE "without unreasonable delay" and no event more than 60 days. The BA must identify each individual whose PHI was compromised by the breach. [Note: BA contract should address timing, costs, and responsibility for notification]

HIPAA AFTER HITECH

f. Administrative requirements for breach notification
   i. Policies and Procedures, e.g., identification of breach, notification, reporting, and "securing"
   ii. Train work force members and have sanctions for failure to comply with policies and procedures
   iii. Permit individuals to file complaints regarding policies and procedures or failure to comply
   iv. Refrain from intimidating or retaliatory acts
   v. Retain documentation to prove compliance with required notifications (and to show no breach because of risk assessment or exception).

NOTE: In addition to federal requirements, health care providers and organizations are potentially subject to applicable state breach notification laws

HIPAA AFTER HITECH

2. Business Associate Contract ("BAC") changes

   — Current law – Business Associates are not directly regulated by HIPAA

   — Covered Entities are required to enter BACs to disclose PHI. This is a "back door" to impose some HIPAA requirements on BAs

HIPAA AFTER HITECH

— Under HITECH, Business Associates:

a. Required to notify covered entities of breach
b. Security: directly required to comply with Security Rule (administrative, physical, technical, documentation)
c. Privacy: use or disclose PHI only if such use/disclosure complies with privacy provisions of BAC

HIPAA AFTER HITECH

- BACs
  a. HITECH privacy and security requirements “shall be incorporated into business associate agreement”
  b. Interpretation – incorporated by application of law, or requirement to amend?
- BA responsibility to terminate or report
  a. Knows of pattern of activity that is a breach of BAC by covered entity
  b. Must terminate BAC or report CE to HHS
- BA directly subject to civil and criminal penalties
  a. BA must have security compliance process
  b. Review BACs for amendments
- CEs – review BAC for amendments
- CEs and BAs in more adversarial relationship under HITECH

ELECTRONIC HEALTH RECORDS ("EHR") UPDATE

- Health information technology ("HIT") remains a top health care legal issue
- Passage of ARRA (the "stimulus bill" previously referenced), signed into law on February 17, 2009, introduced radical changes to the government's HIT programs.
- Government's intent is to significantly expand electronic health record ("EHR") implementation
- Approximately $36 billion of ARRA stimulus funds allocated to investment in HIT-related programs
- Bulk of $36 billion allocated to incentives for hospitals and health care professionals to encourage widespread adoption of EHRs

EHR UPDATE

- A portion of the HITECH Act (Title XIII of Division A) deals with HIT-related matters

- HITECH includes HIT provisions that:

    1. Create committees to establish and test standardized health information technology; and
    2. Provide grants for enhanced use of health information technology

EHR UPDATE

- HIT structure under HITECH
  1. Office of National Coordinator for Health Information Technology ("ONC") made permanent
  2. Development of national HIT infrastructure
  3. HIT Policy Committee and HIT Standards Committee advise ONC
  4. Certified EHR technologies are EHR systems that have received certification
     - ONC announced on March 2, 2010 proposed new federal rule creating temporary (would expire in 1st Q 2012) and permanent certification programs
     - Could permit certification of EHR component parts or modules by as early as summer of 2010

EHR UPDATE

5. Only “qualified electronic health record” can be certified

6. Qualified electronic health record must:

   — include patient demographic and clinical health information
   — have following functionality: provides clinical decision support; supports physician order entry; captures health care quality information; exchanges electronic health information with other sources

EHR UPDATE

- Hospitals and physicians can qualify for supplemental Medicare and Medicaid payments and separate incentive payments by adopting and "meaningfully" using certified EHR technology
- After 2014, physicians and hospitals will incur payment reductions if not "meaningfully" using certified EHR
- "Meaningful use" definition is the subject of proposed rule announced on December 20, 2009
    1. CMS goal for "meaningful use" definition to be consistent with Medicare and Medicaid requirements while continually advancing contributions of certified EHR technology
    2. Proposed rule would phase in "more robust" criteria in three stages
- Implementation of EHR presents monumental challenges, including eliminating EHR "silos," and protecting privacy and security of EHRs (releases of government and private personal information are a significant problem)

EHR UPDATE

- Department of Veterans Affairs ("VA") and Department of Defense ("DOD") working on exchanging patient information online for a number of years
  1. VA and DOD are ahead of private facilities in implementation of facility-based integrated electronic medical records
  2. In January, 2010, VA and Kaiser Permanente announced formation of pilot program to exchange electronic health record information using Nationwide Health Information Network created by HHS
  3. Pilot program connects Kaiser Permanente HealthConnect and the VA's EHR system, VistA
  4. No information currently to be shared without "explicit permission" of the patient
  5. Program to be expanded from San Diego to three communities "to be selected" during 2010

HEALTH CARE ENFORCEMENT DEVELOPMENTS

- Background
  1. Passage of the PPACA increases government health care spending significantly, and requires increased revenue production.
  2. Fraudulent and other improper activity in health care have been a problem for some years, and need to be addressed more aggressively for deterrence as well as revenue production.
  3. Government funds to fight health care fraud and other improper conduct are more plentiful (includes significant PPACA appropriations).
  4. With increased emphasis on EHRs and electronic communications in health care, more aggressive pursuit of patient privacy and security violations is necessary.
  5. Recent legislative developments enhance government's ability to pursue those attempting to misuse taxpayer funds.

HEALTH CARE ENFORCEMENT DEVELOPMENTS

6. Significant settlements and judgments encourage government enforcement officials
   - U.S. secured $2.4 billion in cases of health care fraud against government during fiscal year ended September 30, 2009
   - Largest health care recoveries from pharmaceuticals and medical devices (Aventics, Eli Lilly, Quest Diagnostics)
   - In October, 2009, the Department of Justice (DOJ) announced largest health care fraud settlement in history against Pfizer ($2.3 billion)
7. In 2009, largest Medicaid settlement ever ($540 million from New York State and New York City).
8. Medicare program integrity auditors are increasing their activities.
9. HHS and DOJ both involved.

HEALTH CARE ENFORCEMENT DEVELOPMENTS

- Specific developments
  1. In 2009, Congress amended the False Claims Act ("FCA") as part of the Fraud Enforcement and Recovery Act of 2009 ("FERA")
     - Significant modifications to FCA's liability provisions enhance government's ability to pursue violators
  2. Recovery Audit Contractors ("RACs") will begin operating in all 50 states during 2010
     - RACs will likely increase visibility by more unscheduled onsite visits to provider locations, and more widespread Medicare audits
     - Contractors receive percentage of amounts recovered
     - "Probe" audits and more complex audits will increase

HEALTH CARE ENFORCEMENT DEVELOPMENTS

3. In addition to financial appropriations, PPACA contains provisions to enhance the government's enforcement capabilities, including:
   - administrative penalties for beneficiaries knowingly participating in health care fraud
   - civil monetary penalties for false statements or misrepresentations by federal program providers or suppliers in applications and agreements
   - "intent" clarification stating that actual knowledge or specific intent re: kickback violation is unnecessary

HEALTH CARE ENFORCEMENT DEVELOPMENTS

4. In May, 2009, Attorney General Holder announced creation of Health Care Fraud Prevention and Enforcement Action Team ("HEAT"), making battle against health care fraud a cabinet-level priority for DOJ and HHS
   - Key component of HEAT initiative is DOJ Civil Division's efforts to enforce False Claims Act against health care providers, as well as pharmaceutical and medical device manufacturers.
5. State Medicaid fraud enforcement becoming increasingly aggressive
   - States stepping-up efforts to detect, prevent and recover improper Medicaid payments
   - State Medicaid Fraud Control Units ("MFCUs") – present in 49 states and D.C. – recovered more than $1.3 billion in FY 2008
   - In view of significant Medicaid expansion under PPACA, greater Medicaid scrutiny at federal and state levels is inevitable.

HEALTH CARE ENFORCEMENT DEVELOPMENTS

6. Increased HIPAA enforcement, audits and penalties under HITECH

— Enforcement

a. Criminal penalties apply to individual(s) violating HIPAA (whether or not employee of HIPAA covered entity – "CE") who obtains or discloses information without authorization

b. HHS may bring criminal cases (previously, just DOJ)

c. State attorneys' general may bring civil actions for criminal violations

d. Civil money penalties will go to Office of Civil Rights ("OCR") to promote more HIPAA enforcement

e. A portion of civil money penalties will go to harmed individuals (after February, 2012)

f. OCR now enforces Privacy and Security Rule; "vigorous enforcement" promised

HEALTH CARE ENFORCEMENT DEVELOPMENTS

— Audits

a. Periodic audits of CEs and Business Associates ("BAs") are required concerning Privacy and Security Rules

b. Audits begin in 2010, with required report to Congress

c. Audits to be posed on HHS website

d. May be conducted without cause

HEALTH CARE ENFORCEMENT DEVELOPMENTS

— Penalties

a. "Does not know" of violation - **$100/violation** (cap of $25,000 for violations of identical requirement/calendar year)

b. "Reasonable cause" to have known - **$1,000/violation** (cap of $100,000 for violations of identical requirement/calendar year)

c. "Willful neglect" – Two levels:

   i. Corrected within 30 days - **$10,000/violation** (cap of $250,000 for violations of identical requirement/calendar year; cap of $1.5 million for all violations of this type)

   ii. Not corrected - **$50,000/violation**, up to $1.5 million for all identical or non-identical violations/calendar year

d. Investigation must occur and penalty must be imposed for willful neglect.

CONCLUSION

- New health care landscape created by PPACA and HCERA
- Health care legal requirements of critical importance - stakes are high
- Complexities and compliance rules continue to increase
- Need to focus on recognizing legal issues and seeking necessary help early
- Effective electronic technology in health care –tough to get there
- Heightened enforcement challenges
- Waiting for guidance and implementation