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Health Care

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ACA: The Supreme Court to Decide

- The Case: *King v. Burwell*
- The Issue: Can Federal Govt. provide ACA Tax Subsidies to People on Federal Exchanges?
- The Four Words: "Established by the State"
- The Timing of a Decision: June/July 2015
- The Likely Result: The Government wins & ACA subsidies for federal exchanges upheld

ACA: The Supreme Court to Decide

- Why Does the Government Likely Win?
- Solid Votes for the Government: 4 votes – Justices Sotomayor/Breyer/Kagan/Ginsburg
- Solid Votes for the Plaintiff: 3 votes – Justices Scalia/Thomas/Alito
- Swing Votes: Justices Roberts & Kennedy
- Justice Kennedy as Swing Vote Likely to Back the Government which is 5/9 votes for ACA

The Congressional Response

- What Does Congress Do if Plaintiff Wins?
- Option # 1 – Nothing – "Let Them Eat Cake"

  But leave 5-8 million people w/o coverage
- Option # 2 – Pass New Law to Kill ACA

  But Lack Senate Democratic Votes & Veto
- Option # 3 – Pass New ACA Temporary Fix
- Likely Bi-partisan Support for Temporary Fix through 2015 & maybe 2016 elections

How does King impact California

- California operates a state exchange, called Covered California, that will not be impacted by an adverse decision in *King v. Burwell*
- Covered California enrollees will continue to be eligible for federal subsidies

ACA Impacts on the Health Care Industry

- 16.9 million new enrollees for health insurers
  - 11.2 Million in Exchanges
  - 12.6 Million in Medicaid Expansion
  - 5.9 lost coverage
- Medicaid expansion beneficiaries are often covered by managed care contracts between state agencies and health plans, including in California

Changes in Provider Delivery System

- Medicare ACOs have spurred significant changes in the health care delivery system
- Private insurers have adopted ACO-like models to deliver health care on a more efficient basis with incentives for quality of care

Changes in Provider Delivery Systems

- Providers obtaining insurance/health plan licenses
- Payers acquire providers
- Providers integrate with other providers
- Risk-based payment arrangements
- Payer/Provider affiliations

Hospitals

- Establishing MA Plans by obtaining state managed care or insurance licenses and contracting with CMS
- Obtaining licenses to directly compete in the commercial market
- Obtaining licenses to assume financial risk under managed care contracts
- Entering into ventures with insurers involving profit sharing

Health Plans

- Health Plan acquisition and development of physician practices
- Health Plan acquisition of care management entities
- Establishment of private ACOs with willing provider participants
- Narrow network products with provider partners

Physician Groups

- Obtaining risk-bearing licenses and other authority to assume financial risk
- Participants in ACO MSSPs, Pioneer ACOs and private payor ACOs
- Targets for hospitals, health plans and other larger providers

Legal Challenges for Providers and Payers

- Corporate Practice of Medicine
- Insurance/Risk-Bearing Entity Licensing
- Physician Incentive Plan Regulations
- Fraud and Abuse
- Antitrust
- Flow down requirements from government contracts

HEALTHCARE – ENHANCED FOCUS ON INFORMATION/DATA SECURITY

Healthcare Entities' Obligations for Protecting Patient Privacy

- HIPAA
- California Laws

Evolving Healthcare IT Environment

HIPAA – WHO IS REGULATED?

- Covered Entities: health plans, providers, clearinghouses
- Business Associates: anyone else who has access to PHI from a CE, including subcontractors
  - Includes vendors, cloud providers, contractors
  - "Conduit" exception very narrow

WHAT INFORMATION IS PROTECTED?

HIPAA: Information that relates to:

- an individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,
- and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

WHAT INFORMATION IS PROTECTED?

CALIFORNIA CIVIL CODE SECTION 1798.82:

- “Personal information" means an individual's first name or first initial and last name in combination with any one or more of the following data elements, when either the name or the data elements are not encrypted:
  (1) Social security number
  (2) Driver's license number or California Identification Card number
  (3) Account number, credit or debit card number, in combination with any required security code, access code, or password that would permit access to an individual's financial account
  (4) Medical information
  (5) Health insurance information

HIPAA

Privacy Rule

- Defines what has to be protected and how it may be used within an organization and disclosed to third parties

HIPAA

Security Rule

- Establishes parameters for how electronic protected health information must be protected from unauthorized disclosure

HIPAA

Security Rule

- Three kinds of safeguards:
  - Administrative (e.g., security awareness and training)
  - Physical (e.g., secure location of servers)
  - Technical (e.g., access control (passwords) and transmission (secure e-mail))

HIPAA

Breach Notification Rule

- Requires a covered entity to notify specified individuals/entities of a breach
- Common breaches:
  - Employee/Vendor Negligence
  - Lost laptop or hard drive
  - Inadvertent transmission

HIPAA

Breach Notification Requirements

- Presumption is that impermissible use or disclosure is a breach requiring notification
- Requires written notification to affected individuals without unreasonable delay but *no later than 60 days from discovery*
- Content Requirements
- Notification to HHS/Media

HIPAA

- The Secretary of HHS has authority to audit covered entities and business associates, investigate complaints and impose penalties
- The Breach Notification Rule makes it easier for the Secretary to learn of potentially non-compliant activities and conduct targeted audits
- The Secretary is now all but required to impose fines and penalties for anything but the least culpable violations
- States' attorneys general have authority to bring actions on behalf of state residents to enjoin unlawful practices and obtain some measure of damages

CALIFORNIA LAWS

- Confidentiality of Medical Information Act (Civil Code Section 56 et seq.)
- Insurance Information and Privacy Protection Act (Insurance Code Section 791 et seq.)
- California Customer Records Act (Civil Code Sections 1798.80 – 1798.84)

Confidentiality of Medical Information Act (CMIA) (Civil Code § 56.36)

- Prohibits "disclosure" of "medical information" regarding a patient without authorization.
- Mandatory and permissive exceptions.
- Requires covered entities that create, maintain, preserve, store, abandon, destroy or dispose of medical records to do so in a manner that preserves confidentiality.

California Insurance Information and Privacy Protection Act (California Insurance Code Sections 791-791.28)

- Sets standards for use and disclosure of information including, but not limited to, medical records and "personal information" broadly defined
- Prohibits disclosure without authorization
- Exceptions to rule requiring authorization exist for agents, fraud detection and law enforcement
- Insurance Commissioner can bring enforcement action and affected persons can sue

CALIFORNIA CUSTOMER RECORDS ACT (Civil Code Sections 1798.80 – 1798.84)

- Requires disclosure of "any breach of the security of the system" to any California resident whose "personal information" was acquired by an unauthorized person.

CALIFORNIA BREACH NOTIFICATION LAW

- If personal information is potentially comprised, must comply with California breach notification law
  - CA Attorney General has enforcement authority
  - Timing: "in the most expedient time possible," "without unreasonable delay"
  - Personal notice, letter or electronic, is required when the identities of the affected individuals are known
  - Substitute notice is required in all other instances meaning posting on the business web site, and notice to "major statewide media" meaning print, television and radio and the Office of Privacy Protection
  - Notify CA Attorney General > 500 persons affected

EVOLVING HEALTHCARE IT ENVIRONMENT

- Electronic Health Records
- Cloud Solutions

ACA Changes to FCA

- Claims submitted under a relationship that violates the AKS now also constitute false claims. *Id.*(f)(1); 42 U.S.C. § 1320a-7b(g).
- Knowledge standard was expanded to include reckless disregard and willful ignorance. *Id.*
- Affects defense based on *Hansleter v. Shalala*, 51 F.3d 1390 (9th Cir. 1995) that AKS required proof of specific knowledge of law and intent to violate it.

Implications of Changes to Plans

- Focus of FCA enforcement in health arena has traditionally been on providers that submit claims for services under federal health programs.
- Changes bring plans into FCA cross-hairs.
- Any false claim, record or statement resulting in receipt of any federal funds can expose plan to FCA liability.
  - Federal Employees Health Benefits Program (*e.g.*, certification of community rate);
  - Medicare Advantage (*e.g.*, plan rate bid certs.);
  - Contractor performance (*e.g.*, claims payment timeliness, claims denials, reconsiderations and appeals, marketing, utilization and accessibility of services).

Implications

- Falsification of Reports / Certifications (*e.g.*, encounter data, quality-of-care review, enrollee health status reports, or data required to be submitted to the government and used in rate setting).
- "Red-lining" (*e.g.*, insurers that provide Medicare supplemental insurance and paid on per patient basis, improperly discourage enrollment by persons they deem to be sicker or at higher risk for serious illness, to decrease risk and increase profits).
- Medicare Part D Fraud.
- Intermediary Services (*e.g.*, failure to properly monitor downstream provider quality and detect provider fraud).

U.S. ex rel. Kester v. Novartis Pharm. Corp., 43 F.Supp.3d 332 (S.D.N.Y. 2014)

- Relator brought FCA and AKS action on behalf of the U.S. and 26 states and D.C. against Novartis and CVS Caremark, Accredo and Curascript alleging Novartis conducted illegal kick-back schemes involving 5 of its specialty drugs covered by federal programs.
- Relator was a former Novartis sales employee who alleged Novartis gave volume-based rebates and performance payments based on volume or market share and patient referrals.
- Relator alleged Novartis steered new patients to the co-defendant pharmacies in exchange for rebates and performance payments.

Kester v. Novartis

- Government intervened in the action and had previously filed an FCA action against Novartis.
- Caremark contended the allegations were substantially similar to accusations against it in state court actions dating back to 2008 including attempting to persuade physicians and patients to switch to drugs to maximize rebate payments from drug manufacturers.
- Caremark entered into a nationwide settlement of the various state lawsuits which received attention from national news media.
- Defendants sought dismissal based on the public disclosures.

Kester v. Novartis

- Government contended that the publicly disclosed allegations were not "substantially similar" enough.
- The district court found that the essential elements of the fraud in the state actions was substantially similar to current allegations.
- But the court found that the allegations that Caremark continued the fraudulent practices after the state settlements was new information.
- The court set 3/23/10 as the date the claim accrued because that was the date the ACA was enacted and the state complaints ceased to qualify as public disclosures. 29 U.S.C. § 3730(e)(4)(A)(2010).

Questions?

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