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Recent Updates in Legal Medicine: Federal Court Ruling

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This presentation and outline are limited to a discussion of general principles and Should not be interpreted to express legal advice applicable in specific circumstances.

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RECENT UPDATES IN LEGAL MEDICINE: FEDERAL COURT RULINGS

Navigating and keeping updated on recent federal court rulings is a challenge for most health care professionals and health care attorneys. Given the increasingly complex judicial, legislative, and regulatory environments in which physicians practice, this presentation will provide an overview and summary of recent federal court rulings which impact physicians and practice groups. This presentation will focus on key federal court rulings, and provide a summary of certain issues and decisions that physicians should keep on their radar for 2015.

2

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RECENT DEVELOPMENTS IN LEGAL MEDICINE

Status of Affordable Care Act

- **In November 2014, the U.S. Supreme Court agreed to hear a challenge to the Affordable Care Act (ACA)**

3

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King v. Burwell

- According to the challengers in King v. Burwell, the subsidies are being provided illegally in states that have decided not to run the marketplaces ⟶ 36 states
  - In these states, only individuals with their own exchanges can get subsidies.
  - IRS issued a regulation stating that subsidies are allowed whether the exchange is run by a state or by the federal government.
  - In July 2014, the Court of Appeals for the Fourth Circuit ruled against the challengers. On the same day, the Court of Appeals for the District of Columbia agreed with the challengers and this decision was vacated in September 2014.
  - The case will be argued before the U.S. Supreme Court on March 4, 2015, and a decision will probably be published in June 2015.

4

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REPRODUCTIVE HEALTH

Burwell v. Hobby Lobby Stores, Inc. et al.

- In 2014, U.S. Supreme Court held that some closely held for-profit corporate employers do not have to comply with the ACA requirement to include coverage of contraception in their employee health plans.
- In a 5-4 decision, the U.S. Supreme Court held that the Religious Freedom Restoration Act (RFRA) allowed corporate employers to deny their employees the mandated contraceptive coverage because the ACA's requirement to provide insurance coverage of contraception was not the least restrictive means of guaranteeing such coverage.

5

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THE PHYSICIAN PAYMENTS SUNSHINE ACT

- Under the Sunshine Act, aka "Open Payments" program, CMS released data on payments and items of value given to physicians and teaching hospitals for the first time on September 30, 2014.
- Manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal health care programs track and report this information to CMS on an annual basis.
- Physicians have the right to review these reports and to challenge reports that are false, inaccurate or misleading.
- Major exclusions include:
  1) certified and accredited CME;
  2) buffet meals, snacks, drinks generally available to all participants of large-scale conference or similar large-scale events;
  3) product samples not intended to be sold and are intended for patient use;
  4) discounts including rebates; and
  5) in-kind items used for the provision of charity cases.

6

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LARGEST HIPAA SETTLEMENT

- New York Presbyterian Hospital and Columbia University paid a combined $4.8 million to the office of Civil Rights (OCR) to settle a HIPAA violation that occurred in 2010.
- Both institutions filed a joint report with HHS, as required by the HITECH Act, regarding a data breach.
- The institutions have a joint agreement in which Columbia University faculty members serve as attending physicians of the hospital and there is a shared data network and firewall.
- The breach occurred when a physician tried to deactivate a personal computer that contained electronic PHI which led to the PHI of 6,800 patients becoming accessible on Internet search engines, including vital signs, medication and lab test results.

LARGEST HIPAA SETTLEMENT

- OCR's investigation found that neither institution had:
  - conducted an adequate risk assessment of their systems;
  - neither institution had a risk management plan addressing potential hazards and threats to the security of PHI; and
  - New York Presbyterian Hospital did not have appropriate policies and procedures for authorizing access to its database, and did not follow its own implemented information access policies.

FRAUD AND ABUSE RECORD FINES

- On November 20, 2014, the Department of Justice (DOJ) announced that the U.S. had recovered almost $6 billion from False Claims Act litigation in 2014.
- This is the first time the DOJ has recovered more than $5 billion in a single year. This is the third consecutive year that the DOJ has announced record recoveries.
- There were over 700 whistleblower lawsuits filed on the government's behalf in 2014.

STARK LAW AND MEDICAID

Stark Law and Medicaid

- A significant development in Fraud and Abuse was a federal court ruling in April 2014, which held that the Stark Law applies to Medicaid claims.
- This April 2014 ruling approved a $7 million settlement of a State and federal FCA Qui Tam filed by a whistleblower who alleged that a children's hospital violated the Stark Law by overcompensating referring physicians. In 2010, more than 70% of patient care at this hospital was paid by the Medicaid program.

STARK LAW AND MEDICAID

- The whistleblower alleged that as the children's hospital began to lose market share, the hospital embarked on an aggressive recruitment campaign and paid compensation in excess of fair market value.
- The Federal Court relied on language in recent decisions and ruled that the Stark Law applies to Medicaid claims even though CMS never implemented a 1993 amendment to the Stark Law through rulemaking which extends aspects of the Medicare prohibition on physician self-referral to Medicaid.
- The DOJ did not intervene in this case; however, the DOJ submitted a Statement of Interest regarding its position that the Stark Law applies to Medicaid claims.

MEDICAL MALPRACTICE CAPS

- In March 2014, the Florida Supreme Court declared its State's medical malpractice cap unconstitutional in Estate of McCall v. U.S.
- In a 5-2 decision, the Florida Supreme Court ruled that the caps violate the equal protection guarantee in the State's Constitution.
- 35 states have some type of cap on medical malpractice awards. With this decision, Florida became at least the 7th state to declare medical malpractice award limits unconstitutional.
- This Florida case involved a lawsuit filed against the federal government by the parents of Michelle McCall who died after giving birth in 2006 while being treated by U.S. Air Force doctors at Fort Walton Beach Medical Center.
- A jury awarded her parents and son $2 million, but a federal court lowered the award to $1 million citing the State cap that limited physician liability for non-economic damages to $1 million in cases involving deaths.

RECENT FEDERAL CASE

U.S. v. Patel

On February 10, 2015, the Seventh Circuit held in U.S. v. Patel that even if a patient receives no influence from the physician in selecting a provider of additional services, and all the services the patient receives are medically necessary, the physician still commits a felony if the physician receives remuneration in exchange for signing a truthful recertification that the services continue to be medically necessary.

* U.S. v. Patel significantly increases the definition of "referral" under the Anti-Kickback Statute.

* The impact of this ruling exposes health care providers to civil and criminal penalties, even if the provider never directs patients to another provider.

13

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14

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