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Healthcare Legal Update

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AGENDA

- Explore various legal updates from 2015 and into 2016. We will cover a variety of topics.

HIPAA

- September 2015: OIG issued report “OCR Should Strengthen Its Oversight of Covered Entities’ Compliance with HIPAA Privacy Standards.”
- In letter dated September 23, 2015, OCR concurred with each of the recommendations and noted that it “will launch Phase 2 of our audit program in early 2016.”

HIPAA

- February 3, 2016, for only the second time in history, OCR imposed a civil money penalty on a covered entity for allegedly violating the HIPAA Privacy Rule.
- Expect increased audits in 2016.
- Look-back at some of the enforcement actions of 2015.

EHR MEANINGFUL USE

- Recent remarks made by the CMS Acting Administrator Andy Slavitt at a healthcare conference in San Francisco indicated that CMS will be ending the “meaningful use” electronic health record (“EHR”) Incentive Program in 2016, five years ahead of its original final end date of 2021.
- January 19 Mr. Slavitt posted on the CMS Blog.
- What will replace meaningful use?

MACRA AND SUSTAINABLE GROWTH RATE

- On April 16, 2015, President Obama signed the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), which included:
 - Repeal of the sustainable growth rate (SGR)
 - Significant changes to the Medicare physician payment methodology
- New regulations may be coming in 2016.

OVERPAYMENTS FINAL RULE

- On February 11, 2016 the CMS published its final rule regarding reporting and returning Medicare overpayments.
- The final rule takes effect March 14, 2016.
- Summary of the final rule

MEDICAID EXPANSION

- Gov. John Bel Edwards signed an executive order Jan. 19, 2016, to make Louisiana the 32nd state to adopt Medicaid expansion under the Affordable Care Act. Montana's Medicaid expansion became effective Jan. 1.
- South Dakota, Virginia and Wyoming are including Medicaid expansion in upcoming state budget proposals.
- Washington and Alaska Medicaid expansion

MANDATORY EPISODE-BASED BUNDLED PAYMENT PROGRAM

- CMS issued its Final Rule on Nov. 16 for the Comprehensive Care for Joint Replacement (“CJR”) model, which mandates that CMS pay providers a bundled payment per episode of care for a Medicare beneficiary undergoing a hip or knee replacement.
- First mandated episode-based bundled payment
- The CJR model will require hospitals in 67 markets to participate in the program initially.

NEW TIMESHARE EXCEPTION TO STARK LAW

- CMS published and finalized the Stark timeshare exception rules on November 16, 2015.
- Initial publication of the proposed rules on July 15, 2015.
- CMS adopted the proposed rule, except for 3 modifications.

OIG FRAUD ALERT: COMPENSATION AGREEMENT FOR PHYSICIANS

- On June 9, 2015, the OIG issued a Fraud Alert targeting physician compensation agreements that potentially violate the federal Anti-Kickback Statute.
- While the OIG fraud alert provides no additional Anti-Kickback guidance, it does signal increased federal scrutiny and enforcement activity directed at physicians.

HUMAN SUBJECTS RESEARCH: COMMON RULE

- September 8, 2015, HHS and 15 other federal departments and agencies released a Notice of Proposed Rulemaking to amend the Federal Policy for the Protection of Human Subjects, which was originally promulgated as the Common Rule in 1991.

CONTRACEPTION COVERAGE

- ACA requires that employer-sponsored health plans include, without cost-sharing, preventive services including all FDA-approved contraceptives.
- On November 16, 2015, the U.S. Supreme Court agreed to hear the challenges of seven religious nonprofit organizations seeking a decision to overturn the requirement that nonprofit organizations have to take action to opt out.

QUESTIONS?

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