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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

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FEATURED ARTICLE

Medical Technology Company Arrangements and Opportunities for Participation in Value Based Care under AKS Final Rule

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The Health and Human Services (HHS) Office of Inspector General's (OIG) final rule amending the safe harbors to the federal Anti-Kickback Statute (AKS) recently took effect on January 19, 2021. The AKS final rule significantly changes the regulatory landscape, especially for value-based care arrangements, and provides new (although more limited than some had hoped) opportunities for medical technology company engagement and participation in value-based and other arrangements. The OIG issued the final rule on November 20, 2020, as part of HHS's Regulatory Sprint to Coordinated Care, which aims to advance the transition to value-based care and improve care coordination across settings, and in conjunction with the Centers for Medicare and Medicaid Services' final rule amending the Stark Law regulations.

Read more.

QUICK SHOTS

Stark and AKS Final Rules Effective January 19, 2021

On November 20, 2020, the U.S. Department of Health and Human Services (HHS) finalized reforms to the federal Anti-Kickback Statute and the Stark Law to reduce regulatory barriers to care coordination and accelerate the transformation of the healthcare system to promote payment for value and the delivery of coordinated care, which took effect on January 19, 2021 (except for a Stark law provision affecting group practice profit shares which becomes effective January 1, 2022). The final rules facilitate a range of arrangements to improve the coordination and management of patient care and the engagement

of patients in their treatment if all applicable regulatory conditions are met, including the following examples:

- To improve patient transitions from one care delivery point to the next, a hospital may wish to provide physician offices with care coordinators that furnish individually tailored case management services for patients requiring post-acute care.
- A hospital may wish to provide support and reward institutional post-acute providers for achieving outcome measures that effectively and efficiently coordinate care across care settings and reduce hospital readmissions. Such measures would be aligned with a patient's successful recovery and return to living in the community.
- A primary care physician or other provider may wish to furnish a smart tablet that is capable of two-way, real-time interactive communication between the patient and his or her physician. The patient's access to a smart tablet could facilitate communication through telehealth and the provision of in-home services.
- A health system furnishes cybersecurity technology to physician practices to reduce harm from cyber threats to all their systems.

See the Anti-Kickback Statute Final Rule, Stark Law Final Rule, and Press Release for more information.

HHS also issued a final rule on November 20, 2020 revising the discount safe harbor under the Anti-Kickback Statute to remove protection for rebates from a pharmaceutical manufacturer to plan sponsors under Medicare Part D or pharmacy benefit managers (PBMs) and creating new safe harbor protection for certain point-of-sale reductions in price on prescription pharmaceuticals and certain PBM service fees, with the changes taking effect on January 29, 2021, except for revisions removing safe harbor protection for rebates paid by drug manufacturers to PBMs, which would take effect January 1, 2022. This final rule is currently being challenged in litigation. See the Discount Final Rule and Press Release for more information.

5th Circuit Overturns $4.3 million HIPAA Penalty; HHS Settles Another HIPAA Data Breach for $5.1 million

On January 14, 2021, the U.S. Court of Appeals for the Fifth Circuit vacated a $4.3 million fine HHS levied against University of Texas MD Anderson Cancer Center in connection with alleged HIPAA violations related to three data breach incidents – a theft of an unencrypted laptop and losses of two unencrypted USB drives containing protected health information – finding the penalty "arbitrary, capricious and otherwise unlawful" under the Administrative Procedures Act.

On January 15, 2021, HHS announced that Excellus Health Plan, Inc. agreed to pay $5.1 million and implement a corrective action plan to settle potential HIPAA violations related to a breach affecting over 9.3 million people when hackers gained unauthorized access to its information technology systems. See the Press Release for more information.

HHS Proposes Modifications to HIPAA Privacy Rule

On December 10, 2020, the HHS Office for Civil Rights (OCR) announced proposed changes to the HIPAA Privacy Rule to support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the healthcare industry. The HIPAA proposed changes include:

- strengthening individuals' rights to access their own health information, including electronic information;
- improving information sharing for care coordination and case management for individuals;

- facilitating greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises;
- enhancing flexibilities for disclosures in emergency or threatening circumstances, such as the Opioid and COVID-19 public health emergencies; and
- reducing administrative burdens on HIPAA covered entities, while continuing to protect individuals' health information privacy interests.

This effort was made as part of HHS's Regulatory Sprint to Coordinated Care to promote value-based health care by examining federal regulations that impede efforts among healthcare providers and health plans to better coordinate care for patients. Public comments on the proposed rules will be due 60 days after publication of the Notice of Proposed Rulemaking (NPRM) in the Federal Register. See the NPRM and the Press Release for more information.

HHS Amends PREP Act Declaration

On December 3, 2020, HHS issued a fourth amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act). Among other changes, the Amendment:

- Authorizes certain out-of-state healthcare personnel using telehealth to order or administer Covered Countermeasures (such as a diagnostic test that has received Emergency Use Authorization from the FDA) for patients in a state. While many states have already permitted out-of-state practitioners to provide telehealth services to patients within their borders, not all states have done so and the Amendment preempts any state or local restrictions that prohibit (or effectively prohibit) such ordering or administration of Covered Countermeasures. Nothing in the Amendment preempts state laws that may allow for easier access to telehealth services.
- Explicitly expands liability protection of the PREP Act to not administering a Covered Countermeasure to an individual in certain situations.
- Expands PREP Act immunity to certain private distribution of Covered Countermeasures, effective December 3, 2020.

See the Amendment and the Press Release for more information.

FCA Working Group Announced

On December 4, 2020, HHS announced the creation of a False Claims Act Working Group that enhances its partnership with the Department of Justice (DOJ) and Office of Inspector General (OIG) to combat fraud and abuse. The Working Group seeks to protect government funds by identifying potential False Claims Act violations and referring them to DOJ and OIG. The Working Group will also aid DOJ and OIG in False Claims Act actions by providing HHS' views on the intricate legal frameworks of the agency's numerous funding programs. See the Press Release for more information.

Speaker Program Special Fraud Alert

On November 16, 2020, the OIG issued a Special Fraud Alert highlighting the fraud-and-abuse risks associated with exchanging remuneration in connection with Speaker Programs (i.e., "company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech . . . to other HCPs about a drug or device product or a disease state on behalf of [a pharmaceutical or medical device] company"). The Alert identified various characteristics of Speaker-Program arrangements that the OIG would find potentially suspect under the AKS, including, but not limited to, the following:

- Little or no substantive information is actually presented;
- Alcohol and/or meal(s) exceeding modest value is provided to attendees;
- Program held at location not conducive to the exchange of educational information;
- Company sponsors large number of programs on substantially the same topic, particularly if there has been recent change in relevant information regarding such topic;
- Program follows significant period of time without new medical/scientific information or new FDA-approved/cleared indication(s) for the product;
- HCPs attend programs on substantially the same topics more than once;
- Attendees include individuals who do not have a legitimate business reason for attending;
- Company's sales/marketing departments influence the selection of speakers; or
- Company pays HCP speakers more than fair market value for the speaking service.

The OIG concluded by explaining that the risks associated with speaker programs will become more pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs. The OIG advised companies to assess the need for in-person programs given the risks associated with offering or paying remuneration for such services and to consider less-risky alternatives for conveying information to HCPs. See the Alert for more information.

HHS Regulatory Reform Through Retrospective Review

On January 8, 2021, HHS issued a final rule requiring HHS to assess its regulations (subject to certain exceptions) every ten years to determine whether they are subject to review under the Regulatory Flexibility Act (RFA), which requires regular review of significant regulations. If a regulation is subject to the RFA, HHS must review the regulation every ten years to determine whether the regulations is still needed and whether it is having appropriate impacts. Regulations will expire if HHS does not assess, and, if required, review them in a timely manner. The deadline for assessing and reviewing HHS regulations that are more than ten years old is five calendar years from the effective date of the final rule. See the Final Rule for more information.

No Surprises Act

On December 27, 2020, the No Surprises Act was signed into law as part of the Consolidated Appropriations Act, 2021. The federal law restricts providers from balance billing patients for non-emergency services provided by out-of-network providers at in-network facilities, emergency services provided by out-of-network providers and facilities, and air ambulance services, and does not allow patients to be charged more than the in-network cost-sharing amount, subject to certain exceptions. The law also creates a dispute resolution process for out-of-network healthcare providers to use if they can't resolve payment issues with health plans. The law is effective January 1, 2022. See the Bill for more information.

ICYMI

On Tuesday, December 8, 2020, Suzie Trigg interviewed Joseph Franklin, Policy Director for the Principal Deputy Commissioner, FDA as part of FDLI's virtual event "Legal and Practical Issues in the Evolving World of Cannabis Regulation."

On Wednesday, January 20, 2021, Bill Morrison, Taryn McDonald, and Neil Issar presented The False Claims Act: 2020 Year in Review to the Dallas Bar Association Health Law Section virtual CLE.

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We'd like to hear your feedback and suggestions for future newsletters. Please contact:

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