

ATTORNEY ANGLES

Proposed Rules For Stark, The Federal Anti-Kickback Statute & Civil Money Penalties Law

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On Oct. 9, 2019, the Department of Health and Human Services revealed its highly anticipated proposals to update the Physician Self-Referral Law (Stark), the Federal Anti-Kickback Statute (AKS), and the Beneficiary Inducements Civil Money Penalty (CMP) law as part of its Regulatory Sprint to Coordinated Care. The proposed regulations for Stark and the AKS (and the CMP law) were issued by Centers for Medicare and Medicaid Services and Office of Inspector General (OIG), respectively.¹ The proposed rules are intended to promote, and remove barriers to, value-based arrangements and care coordination, and ease compliance burdens associated with existing regulations.² These proposed rules are prospective and both agencies have stated that, unless finalized, the proposed changes to existing concepts are not applicable.

Stark Proposed Rule Overview

The proposed rule for Stark creates new exceptions for value-based compensation arrangements, donations of cybersecurity technology and related services, and a physician's receipt of limited remuneration for the provision of items or services. The proposed rule also revises existing Stark exceptions and definitions in an effort to provide guidance, address non-abusive relationships, and reduce the burden of compliance with Stark while balancing CMS' legitimate program integrity concerns.³

CMS proposes three new Stark exceptions for value-based compensation arrangements that satisfy certain requirements depending on the level of financial risk undertaken by the participating parties: (1) full financial risk, (2) value-based arrangements with meaningful downside financial risk, and (3) value-based arrangements. These exceptions apply regardless of whether care is provided to Medicare beneficiaries, non-Medicare patients, or both, and they are intended to protect CMS-sponsored models and eliminate the need for any new waivers of Section 1877 of the Social Security Act.⁴ Several new, highly technical definitions are proposed to provide context to these new exceptions, which exceptions generally only apply to protect remuneration paid under value-based arrangements between a value-based enterprise

(VBE) and one or more of its VBE participants, or between or among VBE participants within the same VBE, for the provision of at least one value-based activity that is reasonably designed to achieve at least one value-based purpose of the VBE for a target patient population.⁵ Notably, CMS is considering whether to exclude compensation arrangements between physicians and laboratories; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS); pharmaceutical manufacturers; pharmacy benefit managers; wholesalers; distributors; or health technology companies from the protection of the exceptions.⁶ In addition to the proposed value-based exceptions, CMS also proposes two additional new exceptions relating to limited remuneration to a physician of \$3,500 per calendar year, and cybersecurity technology and related services.

CMS also proposes various clarifications and revisions to existing regulatory requirements and definitions within Stark, including, without limitation, the "commercially reasonable" definition, the "volume or value" standard, the "other business generated" standard, the "fair market value" definition, and patient choice and directed referral requirements. Further, CMS proposes revisions to, and deletions of, certain regulatory requirements that it finds unnecessary at this time.

AKS and CMP Law Proposed Rule Overview

The AKS proposed rule creates new safe harbors for certain value-based arrangements, donations of cybersecurity technology and related services, and ACO beneficiary incentive programs. The proposed rule also revises existing AKS safe harbors for personal services and management contracts, warranties, EHR arrangements, and local transportation. In addition, the proposed rule would add a new safe harbor under the CMP law for certain telehealth technologies offered to patients who receive in-home dialysis. While the proposed new safe harbors for cybersecurity technology and services and modifications to the existing AKS safe harbor for EHR items

and services closely align with CMS' proposed Stark rule, OIG's proposed rules for value-based arrangements are more restrictive than CMS' comparable proposals due to the differences in statutory structures and penalties and the recognition that the AKS, as a criminal statute, should serve as a backstop protection for certain arrangements that may be permitted under Stark.⁷

Specifically, OIG proposes three new value-based safe harbors that operate similarly to their Stark counterparts. In addition, OIG is proposing a new value-based safe harbor to protect arrangements for patient engagement and support to improve quality, health outcomes, and efficiency and a safe harbor to protect CMS-sponsored model arrangements and patient incentives. OIG also proposes definitions to provide context to the new value-based safe harbors and while many terms are similar to the CMS proposed counterparts, there are key differences. For example, while CMS contemplates excluding

certain entities from the definition of a "VBE participant," OIG does, in fact, exclude pharmaceutical manufacturers; manufacturers, distributors, or suppliers of DMEPOS; and laboratories from the meaning of a "VBE participant."⁸ In addition, unlike CMS, OIG is considering precluding some or all of the protection under the proposed value-based safe harbors for value-based arrangements between commonly owned entities.⁹ OIG proposes various modifications to safe harbors within the proposed rule. For example, OIG proposes modifying the personal services and management contracts safe harbor at 42 C.F.R. § 1001.952(d) by removing the requirements pertaining to services provided on a part-time basis and that the "aggregate" compensation be paid over the term of the agreement be set in advance, and by expanding the safe harbor to apply to protect certain outcomes-based payments that meet various requirements.¹⁰

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Benkoff Health Law represents health care providers and entities on a national basis. Examples of providers and matters we assist with include:

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- **Corporate:** corporate structuring and documents, joint ventures, mergers, sales and acquisitions, and private equity investment and structures
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Conclusion

CMS and OIG have made extensive efforts to modernize Stark, the AKS and CMP laws to ease compliance burdens and promote value-based care. These proposed changes will affect how industry stakeholders approach Stark, the AKS and CMP law going forward and may affect recent and ongoing court cases. Interested parties should consider the impacts of these proposed rules and comment on issues relevant to their businesses by December 31, 2019. For additional information or assistance regarding Stark, the AKS, the CMP law, or the proposed rules, contact Reesa Benkoff, Esq. of Benkoff Health Law, PLLC at (248) 482-2780.

NOTES

- 1 See Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule (CMS-1720-P), Centers for Medicare and Medicaid Fact Sheet, October 9, 2019, available at: <https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule>; see also, HHS Office of Inspector General Fact Sheet: Notice of Proposed Rulemaking OIG-0936-AA10-P, October, 2019, available at: https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf.
- 2 HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care, U.S. Department of Health & Human Services Press Release, October 9, 2019, available at: <https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html>.
- 3 84 Fed. Reg. 55771-55772 (Oct. 7, 2019).
- 4 Id. at 55772-55773, 55778-55789.
- 5 Id. at 55773, 55775, and 55776.
- 6 Id. at 55775-55776.
- 7 Id. at 55696.
- 8 Id. at 55703-55704.
- 9 See id. at 55707.
- 10 Id. at 55744.



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Hematology/Oncology Fellowship Program Director
Ascension St. John Hospital, Detroit, MI

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MODERN TOOLS FOR INVESTIGATING BREAST MALIGNANCIES: ERA OF DIGITAL TECHNOLOGY

Anthony Hamame, MD

Diagnostic Radiology, Eastpointe Radiologist
Ascension St. John Hospital, Detroit, MI

OPIATE CRISIS: BY STANDARD OR NECESSITY?

Michael Stellini, MD

Clinical Professor, Karmanos Cancer Institute
Wayne State University Detroit, MI

NON-TRADITIONAL INDICATIONS FOR HIPEC SURGERY AND LIVER RESECTION

Richard Berri, MD

Chief of Surgical Oncology, Director of Peritoneal Malignancies Program
Ascension St. John Hospital, Detroit, MI

Attasit Chokechanachaisakul, MD

Director of Minimally Invasive Hepatobiliary and Pancreatic Surgery
Ascension St. John Hospital, Detroit, MI

TOXICITY FROM IMMUNE CHECKPOINT BLOCKADE FOR THE NON-ONCOLOGIST

Bryan Schneider, MD

Associate Professor, Rogel Cancer Center
University of Michigan, Ann Arbor, MI

CAR-T-CELL THERAPY

Dahlia Sano, MD

Assistant Professor, Lymphoma and Multiple Myeloma, Karmanos Cancer Institute
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