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Health Care Landscape May Be Changing: Proposed Rules Modifying Federal Anti-Kickback and Physician Self-Referral (Stark) Regulations

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Whenever two massive proposed regulations are released on similar, but distinct health care laws, it is the right time to evaluate the changes occurring in the relationships and referrals of health care services. On Oct. 9, 2019, the Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) released two rules with a similar message: providers and plans should focus on innovating and moving more rapidly to value-based models.

With over 100 questions already raised for comment, all impacted stakeholders should evaluate what relationships may change as a result of this movement toward greater risk-sharing and utilization of new models of care. Comments on both rules are due **75** days from the date of publication in the Federal Register (to be determined, but a few days after Dec. 23, 2019).

In outlining these proposed changes, there are nuggets of information where comments may highlight other relevant issues raised.

Changes to the Federal Anti-Kickback Regulations

Background

The proposed rule was issued by the OIG with the Department of Health and Human Services' (HHS) Regulatory Sprint to Coordinated Care. The rule proposes to prospectively add (after completion of the final rule) certain safe harbor protections for value-based and care coordination arrangements among providers and suppliers. In addition, the rule looks to add a new safe harbor for donations of cybersecurity technology, and amends certain existing safe harbors for electronic health

records items and services and personal services and management contracts. Protections are added under the Anti-Kickback statute (AKS) and civil monetary penalty (CMP) laws for programs that promote consumer engagement.

The OIG adhered to the following guiding principles in developing the proposed rule: (1) to allow for beneficial innovations in health care delivery; (2) for the promulgated safe harbors and exceptions to reflect up-to-date understandings in medicine, science, and technology; and (3) to be useful for a range of individuals and entities engaged in the coordination and management of patient care. Thus, the draft regulations seek to strike the right balance between flexibility for innovation and safeguards to protect patients and the integrity of federal health care programs.

Overview of Proposed Changes

Notable changes in the proposed rule include:

- Three new safe harbors for certain remuneration (in-kind and monetary) exchanged for participants in value-based arrangements (VBA) that foster care coordination:
  - Care coordination arrangements to improve quality, health outcomes, and efficiency;
  - VBAs with substantial downside financial risk; and
  - VBAs with full financial risk.
- A new safe harbor for certain tools and supports furnished under patient engagement, and support arrangements to improve outcomes and efficiencies;
- A new safe harbor for certain remuneration provided about a CMS-sponsored model (thereby reducing OIG’s need to issue waivers);

- A new safe harbor for donations of cybersecurity technology and services;
- Proposed modifications to the existing safe harbor for electronic health records (EHR); adding protection for certain cybersecurity technology as part of EHR;
- Proposed modifications to the existing safe harbor for personal services and management contracts for flexibility with outcome-based payments and part-time arrangements;
- Proposed modifications to the existing safe harbor for warranties (definition and for one or more related services);
- Proposed modifications to the existing safe harbor for local transportation to expand and modify mileage limits for rural areas and transportation for discharged patients; and
- Codify the statutory exception to the definition of “remuneration” relating to accountable care organization (ACO) Beneficiary Incentive Programs for the Medicare Shared Savings Program.

The changes to the Civil Monetary Penalty statute include:

- Amending the definition of “remuneration” to add a new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients; and

- Clarifying that the new safe harbors would also become exceptions to the beneficiary inducements definition of remuneration.

OIG and HHS are seeking comments and specifically raise certain questions for the health care industry to consider and provide feedback. For example, they specifically want to know if the VBA safe harbors adequately address the identified undesired effects of such arrangements and other unintended consequences to the health care system, if “value” should be defined, if accountable bodies should be required to have more oversight of the VBA (e.g., related to utilization, quality, patient experience, and the privacy, integrity, and security of data), if VBEs should exclude pharmacy benefit managers (PBMs) and pharmacies, the definition for care coordination, and if VBEs should be imposed on to require independence or a duty of loyalty.

Changes to the Physician Self-Referral Regulations (Stark)

Background

Also on Oct. 9, 2019, CMS released the long-awaited proposed amendments to the regulations governing the Ethics in Patient Referrals Act (Stark), 42 U.S.C. 1395nn.

The proposed regulations are designed to address any undue regulatory impact of the physician self-referral law and adopt new exceptions to bolster the ability of physicians to engage in VBAs. The primary focus of the proposed regulations is the concern that because the consequences of noncompliance with the physician self-referral law are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow the rate of growth). In drafting the proposed changes, CMS notes that Stark was initially designed to combat potential overutilization caused by the referral of patients for services where the physician has a financial interest. A value-based model, however, greatly reduces these concerns by focusing on the value of the care provided while working to disincentive overutilization.

Overview of Proposed Changes

The central focus of the proposed regulations is the exception, to be codified as new section 411.357(aa), for value-based contracting. The proposal sets forth different requirements depending on the level of risk taken by the physician (from a full-risk model to no risk). The exceptions apply only to compensation interests, and apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.

Notable changes in the proposed rule include:

- Proposed new definitions that would be included in exceptions for compensation arrangements that satisfy specified

requirements based on the arrangement characteristics and level of financial risk. The new exceptions include the following:

– Detailed definitions of value-based activity; VBA; value-based enterprise (VBE); value-based purpose; VBE participant; and target patient population are proposed with an application of such definitions to certain exceptions;

– Concern is expressed about potentially abusive arrangements between certain types of entities that furnish designated health services; specifically, there is a concern about compensation arrangements between physicians and laboratories or suppliers of durable medical equipment, prosthetics, orthotics, and supplies that may improperly influence or capture referrals without improving the coordination of care. CMS is considering excluding from the definition of VBE laboratories, durable medical equipment (DMEs), pharmaceutical manufacturers, PBMs, wholesalers, and distributors.

• Clarification of commercial reasonableness, Fair Market Value, and “volume or value” requirement;

• Clarification on group practice requirements, including organizational changes to the group practice bonus and profit

share provisions;

- An exception for certain arrangements where a physician receives limited remuneration for items or services actually provided by the physician;
- An exception for the donation of cybersecurity technology and related services;
- An amendment to the existing exceptions relating to EHR items and services, as well as new requirements for interoperability.

As previously noted, the proposed regulations include a significant number of requests for comments from impacted stakeholders. For example, CMS specifically asks for feedback on whether additional interpretation in defining “value-based purpose” is necessary, which persons and entities should qualify as VBE participants, how CMS can best pursue price transparency objectives in the context of the self-referral law (in terms of a value-based care system and otherwise), and whether CMS should limit what it considers to be “remuneration related to the provision of designated health services” to remuneration paid explicitly for a physician’s provision of designated health services to a hospital’s patients.

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