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## Proposed Changes to Stark and Anti-Kickback Regulations May Provide New Flexibility for Healthcare Providers

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On October 9, 2019, the Department of Health and Human Services (HHS) announced proposals for a number of new and revised exceptions to the Stark Law and safe harbors for the Anti-Kickback Statute (AKS) that are intended to allow greater coordination and innovation among healthcare professionals and entities. The new exceptions and safe harbors are designed to encourage a transition from the traditional fee-for-service healthcare model to more value-based care in which compensation is based on quality of care, health outcomes, and efficiency. For example, providers working in conjunction as part of newly defined “value-based enterprises” will be allowed greater flexibility in their arrangements, particularly as they assume more financial risk. The preference for a more collaborative approach is reflected in proposed new and expanded exceptions and safe harbors allowing providers to share the costs of technology services related to cybersecurity and electronic health records.

Additional proposed changes to the Stark law also seek to provide greater clarity on three key terms used through the regulations:

- What it means for an arrangement to be “commercially reasonable”;
- When compensation “takes into account the volume or value of referrals or other business”; and
- The definition of “fair market value.”

Other proposed changes to the Stark Law seek to ease certain requirements and allow greater flexibility, including:

- Eliminating the rules defining the time period when referrals are prohibited due to a noncompliant relationship in order to allow more case-by-case flexibility;
- Excluding titular ownership and employee stock ownership programs from ownership or investment interests;
- Creating a 90-day grace period to satisfy the signature and writing requirements of the exceptions;
- Eliminating the requirement that physician practices sign three-party relocation agreements in certain circumstances;

- Expanding the exception for remuneration unrelated to designated health services to include remuneration “not related to patient care services” (i.e., for services performed by a physician that could be performed by someone who is not a medical professional);
- Expanding the fair market value exception to cover leases, including those for less than a year that would otherwise not qualify for the office space rental exception;
- Allowing physicians to be paid up to \$3,500 per year for items and services even in the absence of documentation, provided other requirements are met.

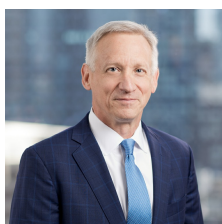
Finally, proposed changes to the AKS rules include revisions to a number of existing safe harbors:

- The personal services and management safe harbor would be modified to allow for outcomes-based payments and to eliminate the requirements that the aggregate amount of compensation and exact schedule for the services be set in advance;
- The warranties safe harbor would be modified to allow coverage of bundled items and services, to impose additional safeguards, and to provide a written definition of “warranty”; and
- The local transportation safe harbor would be modified to expand the distance residents of rural areas may be transported and to remove any mileage limit on transporting discharged patients.

Both the Stark and AKS rules are scheduled to be published in the Federal Register on October 17, 2019, after which comments will be accepted until December 31, 2019. The proposed changes follow Requests for Information from the Centers for Medicare & Medicaid Services and Office of the Inspector General, published in the summer of 2018 as part of HHS’s Regulatory Sprint to Coordinated Care, which received over 700 comments from industry stakeholders.

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