HHS Publishes Proposed Changes to the Stark Law and Anti-Kickback Statute

SUMMARY

On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) and Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), each issued a proposed rule to amend respectively the regulations governing the Self-Referral Law (commonly known as the Stark Law) and the Anti-Kickback Statute (AKS). The stated purpose of the proposed regulations is to reduce unnecessary regulatory burdens and provide new ways for physicians and other providers to coordinate care as part of CMS’ Patients over Paperwork initiative and HHS’ Regulatory Sprint to Coordinated Care.

The proposed rules are scheduled to be published in the Federal Register on October 17, 2019. Individuals and organizations subject to the Stark Law or the AKS should review the proposed rules to determine if they present new opportunities or raise new questions or challenges. HHS has solicited questions and comments on the proposed rules, which must be received within seventy-five (75) days of the date published in the Federal Register, or December 31, 2019 if the regulations are published on schedule.

The intent of the proposed rules is largely to encourage value-based reimbursement for care. The proposed rules are quite broad in scope, clarifying and changing much of the guidance previously provided by CMS and OIG. The following is a selection of topics discussed in the proposals to give a sense of their breath.

Proposed Changes to the Stark Law Exceptions

The Stark Law prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician or the physician's immediate family member has a financial relationship, unless an exception applies. Financial relationship is defined broadly and includes ownership, investment, and compensation arrangements. The Stark Law also prohibits that entity from presenting or causing to be presented claims to Medicare for those referred services.

In the proposed rule, CMS creates new exceptions to the Stark Law:

1. Value-based arrangements where a value-based enterprise has assumed full financial risk for patient care services for a target patient population;
2. Value-based arrangements under which a physician is at a meaningful downside financial risk for failure to achieve the value-based purpose of the arrangement;
3. Other value-based arrangements where neither party has undertaken any downside financial risk provided several enumerated safeguards are satisfied;
4. Indirect compensation arrangements that involve a value-based arrangement;
5. A new exception for limited remuneration to a physician not exceeding $3,500; and
6. A new exception related to cybersecurity technology and services.

Additionally, the proposed rule includes supplementary guidance and clarification with respect to critical Stark defined terms and requirements, including the definitions for commercial reasonableness, the volume or value standard, and fair market value. The definition of “designated health services” is being amended to exclude services provided by a hospital to an inpatient if the service does not affect the amount of Medicare’s payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System. CMS also seeks to bring additional clarity to the rules addressing profit shares and productivity bonuses. CMS is also proposing two helpful changes for when a financial relationship no longer meets a Stark Law exception. Under the proposed rule, the rule on the period of disallowance would be deleted to provide more flexibility. And, perhaps most importantly, CMS is proposing to allow participants to fix a financial relationship to bring it back into compliance as long as the financial relationship is still active.

Finally, CMS is soliciting comments on price transparency, specifically to help it develop regulations giving patients access to price and out-of-pocket cost information prior to the rendering of service or provision of goods and the burdens imposed by requiring such access.

**AKS and Civil Monetary Penalty Law**

The AKS makes it a crime to knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward business reimbursable under Medicare, Medicaid, and other federal health care programs. The OIG created AKS Safe Harbors that protect certain arrangements from prosecution if each of the elements of the Safe Harbor is satisfied. Because the scope of the AKS is broad, and the penalties for non-compliance are significant, structuring an arrangement that fits within a Safe Harbor is the preferred means for any commercial arrangement to ensure AKS compliance. An arrangement that does not fit squarely within an AKS Safe Harbor is not necessarily illegal.

**New Proposed Safe Harbors: Value-Based Arrangements and Patient Support Tools and Cybersecurity Donations**

The OIG is proposing the following new AKS safe harbors:

1. Three new safe harbors related to remuneration exchanged between participants in value-based arrangements that foster better coordinated and managed patient care;
2. A safe harbor for tools and support provided to patients to improve quality, health outcomes and efficiency;
3. A safe harbor for remuneration provided in connection with CMS-sponsored models; and
4. A new safe harbor related to cybersecurity technology and services.

**Changes to Existing Safe Harbors: EHR, Personal Services, Warranty and Transportation**

In an effort to reduce the regulatory burdens associated with AKS, the OIG proposes the following modifications to existing safe harbors:

1. Protections for certain cybersecurity technology, updating provisions regarding interoperability, and removing the existing sunset date in the safe harbor for electronic health records items and services;
2. Adding flexibility with respect to outcomes-based payments and part-time arrangements in the personal services and management contracts safe harbor;

3. Under the warranty safe harbor, revising the definition of “warranty” and providing protection for warranties for one or more items;

4. Expanding the mileage limits for rural areas and for transportation for discharged patients under the local transportation safe harbor; and

5. Codification of the statutory exceptions for the ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program. Three new safe harbors related to remuneration exchanged between participants in value-based arrangements that foster better coordinated and managed patient care.

**Beneficiary Inducement Protection for Telehealth Technologies**

The Civil Monetary Penalty Law permits the HHS Secretary to impose penalties on individuals who defraud Medicare or Medicaid or engage in certain other unlawful conduct, including providing remuneration to beneficiaries that a provider knows or should know will likely influence the beneficiary to receive services from a particular provider, practitioner or supplier.

The rule proposes an amended definition of “remuneration” in the Civil Monetary Penalty Law rules regarding beneficiary inducement for telehealth technologies furnished to certain in-home dialysis patients. Earlier this year, the Trump Administration announced a proposed rule affecting dialysis care.

**Next Steps**

Organizations which may be impacted by these proposed regulations should review the proposed rule and provide comments to ensure CMS understands the impact – pro and con – of the proposed rulemaking. Proposed rules are often amended in response to comments and this 75-day window of opportunity presents a valuable opportunity to healthcare providers to shape regulatory policy. It is important to note that these are proposed rules and may not be relied upon until finalized.

Saul Ewing Arnstein & Lehr attorneys are experienced in counseling clients with respect to the AKS and Stark Law and can assist interested parties in providing comments to these proposed regulatory changes. For more information on these matters, please contact the authors or the attorney at the firm with whom you are regularly in contact.

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