OCTOBER 17, 2019

Long-awaited proposed revisions to Stark Law, Anti-Kickback Statute and Civil Monetary Penalties tackle roadblocks to care coordination and value-based care

By Megan McGovern, Harsh P. Parikh and Jennifer Greco

Today, on October 17, 2019, the U.S. Department of Health and Human Services (HHS) published two proposed rules in the Federal Register that could transform key federal laws restricting health care arrangements. The revised rules address perceived or actual barriers to care coordination and value-based care under the federal physician self-referral law (Stark Law), the federal health care program Anti-Kickback Statute (AKS), and the federal beneficiary inducements Civil Monetary Penalty law (CMP). In promulgating the proposals, HHS intends to "modernize and clarify" the regulations that implement and interpret these laws to drive innovation and move towards a more affordable health care delivery and payment system, while still maintaining guardrails to prevent overutilization and fraud and abuse. HHS recognizes that the broad reach of the current Stark law, AKS, and CMP framework potentially inhibit arrangements in the health care industry that advance the transition to value-based care, enhance care coordination, improve quality, and reduce waste.

The proposals—the Stark proposed rule issued by the Centers for Medicare & Medicaid Services (CMS)[1] and the AKS/CMP proposed rule issued by the Department of Health and Human Services, Office of Inspector General (OIG)[2]—incorporate voluminous public comments that HHS received in response to its requests for information (RFI) last summer.[3] The RFIs sought stakeholder input on how to address regulations that may act as barriers to coordinated care or value-based care.

---

[1] CMS, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (Oct, 17, 2019), available here.

[2] OIG, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (Oct. 17, 2019), available here.

[3] CMS, Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29524 (Jun. 25, 2018); OIG, Medicare and State Healthcare Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43607 (Aug. 27, 2018).

This newsletter is intended as an information source for the clients and friends of Nixon Peabody LLP. The content should not be construed as legal advice, and readers should not act upon information in the publication without professional counsel. This material may be considered advertising under certain rules of professional conduct. Copyright © 2019 Nixon Peabody LLP. All rights reserved.

The HHS Deputy Secretary, Eric Hargan, who is leading the agency's "Regulatory Sprint to Coordinated Care," envisions that the proposed rules will improve outcomes by "mov[ing] away from the old modes of inpatient hospitalizations, the most expensive type of care being immediately resorted to by the public." The HHS press release regarding the proposed rules includes the following examples, amongst others, that, depending on the facts, may not fit under existing Stark Law, AKS, or CMP protections, but would be permissible if the proposed rules are adopted:

- Hospitals and physicians could work together in new ways to coordinate care for patients being discharged from the hospital. The hospital might provide the discharged patients' physicians with care coordinators to ensure patients receive appropriate follow-up care, data analytics systems to ensure that their patients are achieving better health outcomes, and remote monitoring technology to alert physicians or caregivers when a patient needs health care interventions to prevent unnecessary emergency room visits and readmissions.
- To improve health outcomes for patients with end-stage kidney disease, a nephrologist, dialysis facility, or another provider could furnish the patients with technology capable of monitoring the patient's health and two-way, real-time interactive communication between the patient, facility, and physician. In addition, the facility could equip the physicians with data analytics software to help them monitor patients' health outcomes.
- A physician practice could provide smart pillboxes to patients without charge to help them remember to take their medication on time. The practice could also provide a home health aide to teach the patient and the patient's caregiver how to use the pillbox. The pillbox could automatically alert the physician practice and caregiver when a patient misses a dose so they could follow-up promptly with the patient.

Each of the proposed rules employs various methods in an effort to reform the Stark Law, the AKS, and the CMP. The revisions include new exceptions and safe harbors, modify or remove existing outdated regulations, and modernize language and terms within the current regulations. As arrangements between and amongst stakeholders in the health care industry can often implicate both the Stark Law and AKS, CMS and OIG worked together to ensure that the Stark Law exceptions and AKS safe harbors, as well as any clarification or modification under either law, are consistent. HHS is open to engaging with the industry on these proposed changes and requests comments from all interested parties.

Background on the Stark Law and AKS

The federal Stark Law has two basic prohibitions: a referral prohibition and a billing prohibition. Pursuant to the referral prohibition, absent an applicable statutory or regulatory exception, a physician who has a financial relationship with an entity (either directly or through an immediate family member) may not make a referral to that entity to furnish "designated health services" (DHS) for which payment may be made by the Medicare program. Pursuant to the billing prohibition, absent an applicable exception, a health care provider may not bill for improperly referred DHS.

The Stark Law prohibition restricts various arrangements aimed to provide support for patients and physicians. For instance, in the first example above, the hospital's provision of in-kind goods (such as the care coordinator, data analytics, and remote monitoring technology) creates a financial relationship between the physician and the hospital. Under the Stark Law, the physician may not refer any Medicare patients to the hospital for the furnishing of DHS, and the hospital may not bill for any of the improperly referred DHS unless an exception applies. Unlike the AKS, the Stark Law is a "strict liability" statute—whether or not the referring physician and the DHS entity with which

the physician has a financial relationship intended to enter into such an arrangement in order to induce referrals does not matter. The mere existence of a financial relationship, absent an applicable exception, triggers the referral and billing prohibitions under the Stark Law.

The AKS broadly applies to any relationship, including those that do not involve physicians. Under the federal AKS, a person is prohibited from "knowingly and willfully" giving (or offering to give) remuneration to another person if the payment is intended to induce the recipient to (i) refer an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under a federal health care program (i.e., a "covered item or service"); (ii) purchase, order, or lease any covered item or service; (iii) arrange for the purchase, order, or lease of any covered item or service; or (iv) recommend the purchase, order, or lease of any covered item or service. The AKS also prohibits the solicitation or receipt of remuneration for any of these purposes. The AKS is an intent-based statute (i.e., the "knowingly and willfully" element), but some courts have held that as long as "one purpose" of the payment at issue is intended to induce referrals, an arrangement may implicate the AKS. Accordingly, an arrangement may implicate the AKS even if inducing referrals is not the primary purpose of the payment and even where there are other, legitimate reasons for the arrangement. OIG established a number of statutory and regulatory exceptions, "safe harbors," to the AKS. An arrangement that fits squarely into a safe harbor is immune from prosecution under the AKS. But, the fact that a particular arrangement does not fit within a safe harbor does not mean that the arrangement implicates the AKS. Providers often voluntarily seek to comply with AKS safe harbors so that they have assurances that their business practices will not be subject to any AKS enforcement action.

Stark and AKS protections to facilitate value-based arrangements

With the big push towards moving to a system of value-based care, both CMS and OIG propose to add new protections to facilitate this shift. CMS proposes three new Stark Law exceptions that will apply broadly to all patients, not just Medicare or Medicaid beneficiaries, and will protect compensation arrangements between physicians and hospitals, other health care providers and/or payors that qualify as value-based enterprise (VBE) participants. OIG also proposes three new safe harbors for value-based arrangements.

The concept behind the proposed Stark Law and AKS protections is that greater flexibility can be offered to such arrangements where these VBEs are assuming financial risk. Simply put, the more financial risk an enterprise takes on, the fewer the requirements to satisfy the exceptions and vice versa.

Notably, the proposed AKS safe harbors *exclude* pharmaceutical manufacturers, durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) manufacturers, distributors, suppliers and laboratories. OIG is concerned that these types of entities might misuse the proposed safe harbors "primarily as a means of offering remuneration to practitioners and patients to market their products." For similar reasons, OIG also considers excluding pharmacies, pharmacy benefit managers and pharmaceutical wholesalers and distributors from the definition of VBE participants. If the proposed exclusions are adopted in the final rule, these categories of providers and suppliers would not be afforded the protections proposed under the new AKS safe harbors. While the Stark Law exceptions do not include the same restrictions related to VBE participants, CMS asks for comment as to whether or not the agency should adopt the same exclusions as proposed by OIG in order to more closely align with the AKS safe harbors.

Under the Stark Law, these new value-based exceptions will be known as (i) the "full financial risk" exception; (ii) the "meaningful downside financial risk" exception; and (ii) the "value-based

arrangement exception" (regardless of the level of risk). Recognizing the link between value-based arrangements and the likely possibility that such arrangements may not be able to satisfy the existing direct and/or indirect compensation exceptions to the Stark Law, CMS proposes to identify circumstances where these value-based exceptions apply to compensation arrangements. It is important to note that the three proposed exceptions do not include any requirements related to fair market value (FMV), commercial reasonableness or that the remuneration not be determined in a manner that takes into account the volume or value of referrals between the parties, conditions found throughout many of the existing Stark Law exceptions that constitute significant barriers to value-based payment arrangements.

Under the AKS, analogous safe harbors include (i) the "care coordination arrangements" safe harbor; (ii) the "value-based arrangements with substantial downside financial risk" safe harbor; and (iii) the "value-based arrangements with full financial risk" safe harbor. The care coordination arrangements safe harbor proposes to protect "in-kind remuneration," such as services and infrastructure, between the parties in VBEs if the arrangement meets the requirements of the safe harbor.

Protections for cybersecurity and electronic health records under both Stark and AKS

The proposed rules both include proposals for new exceptions related to "non-abusive business practices" related to donations of cybersecurity technology and related services that "safeguard the integrity of the healthcare ecosystem." Under the proposed exception and safe harbor, donations of software and other information technology, but not hardware, would be permitted, based on the rationale that donations of "valuable, multifunctional hardware" pose a higher risk of improper referrals, compared to software.

The proposed rules also include updates to the existing protections for donations of electronic health record (EHR) items and services, including removing the sunset provision and modifying the definition of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act. Consistent with the Stark exception, OIG proposes to modify the safe harbor to prevent arrangements that lead to information blocking and referral lock-in. The proposal adds language to mandate that the donor of the EHR items and services cannot engage in information blocking with regard to the donated items and services.

Narrowing the Stark Law

CMS proposes several modifications and clarifications to existing exceptions under the Stark Law. Many of the Stark Law exceptions related to direct and indirect compensation relationships with physicians require one, two or all of the following: (1) the compensation arrangement itself is commercially reasonable; (ii) the amount of the compensation is FMV; and (iii) the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. In response to commenters' requests for clearer guidance on these esoteric terms, the proposal includes CMS's effort to establish "clear, bright-line rules" regarding these fundamental terms. Specifically:

Commercially reasonable

CMS proposes two alternative definitions for "commercially reasonable." Under the first definition, "commercially reasonable" means "that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." In the alternative, CMS is proposing to define the term to mean "the arrangement makes commercial

sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty." CMS is seeking comments regarding each of the proposed definitions and other possible definitions that would provide clear guidance. CMS is also proposing to clarify that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Fair market value

The proposed rule includes a general definition of "fair market value," as it appears in a number of compensation arrangements exceptions, as well as a similar, but slightly more specific, definition of "fair market value," as it applies to the rental of equipment and space lease arrangements. CMS proposes to generally define FMV as the "value in an arm's-length transaction with like parties under like circumstances, of assets or services, consistent with the general market value of the subject transaction."

Volume or value of referrals

CMS proposes an "objective test for determining whether the compensation [under an arrangement] is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties." Specifically, under the CMS proposal, compensation will be considered to be based on the volume or value of referrals or to take into account the other business generated between the parties if: (i) it uses a mathematical formula that includes referrals or other business generated as a variable; and (ii) the compensation amount correlates with the number or value of a physician's referrals to an entity.

In addition to the modifications above, CMS also proposes to:

- Clarify the definition of "**group practices**" with respect to the "volume or value standard" and the distribution of profit shares, productivity bonuses, and revenue associated with participation in a VBE. For example, under the CMS proposal, a group practice could distribute directly to a "physician in the group" the profits from DHS services furnished by the group that are derived from the physician's participation in a VBE, including profits from DHS referred by the physician. Such distribution would be deemed not to directly take into account the volume or value of the physician's referrals.
- Establish a 90-day grace period for non-compliance for compensation arrangements that are missing a **signature** or are not in **writing**. An arrangement would be deemed to meet the signature and writing requirement if the arrangement meets all other requirements under the Stark Law exception, and the writing and/or signature deficiency is cured within 90 days of the date the arrangement failed to satisfy such requirements.
- Include the removal of certain provisions that CMS determined as unnecessary or duplicative. For example, CMS proposed to remove the requirement under various compensation arrangement exceptions that the arrangement complies with the AKS or any federal or state law governing billing or claims submissions.
- Remove bright-line rule regarding the "**period of disallowance**"—the period of time during which a physician may not make referrals for DHS to an entity and the entity may not bill Medicare for the referred DHS, which currently begins on the date on which an arrangement failed to satisfy the requirements of any applicable exception and ends on the date the financial relationship ends or is brought back into compliance. Because it is not always clear when a financial relationship ends, CMS instead proposes a case-by-case analysis, taking into account the unique facts and circumstances of each financial relationship, in order to determine when a financial relationship ends and the duration of

the period of disallowance.

- Exclude limited remuneration through the addition of a new limited exception for non-abusive business practices. In a similar way to donations of cybersecurity technology and other related services, CMS views certain limited remuneration to a physician as a non-abusive business practice that poses little risk of program or patient abuse. In addition to the existing non-monetary benefits exception and the medical staff incidental benefits exception, which cover *de minimus* remuneration to physicians, CMS proposes a new exception related to limited remuneration from an entity to a physician "even in the absence of documentation regarding the arrangement and where the amount of or a formula for calculating the remuneration is not set in advance of the provision of the items or services" if: (ii) the arrangement is for items or services actually provided by the physician; (ii) the amount of the remuneration to the physician is limited; (iii) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit for either or both parties; (iv) the remuneration is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician; and (v) the remuneration does not exceed the FMV for the items or services. CMS is proposing that the exception would only apply to remuneration that does not exceed an aggregate $3,500 per calendar year, which would be adjusted annually for inflation.

Expansion of the Anti-Kickback Statute safe harbor protections

OIG contends that the addition of three new safe harbors related to value-based arrangements, as well as other amendments to the AKS regulations, will encourage providers and managed care organizations to transition to more value-based care and improve the coordination of patient care amongst providers and across care settings. In response to 359 comments it received from stakeholders following the RFI, OIG proposes several modifications to existing safe harbors and introduces new protections to encourage coordinated care amongst various stakeholders, including providers, suppliers, payors, and networks. While OIG seeks to encourage flexibility and promote innovation, the agency proceeds with caution, including considerable safeguards to "strike the right balance."

The agency proposes the following key changes:

Patient engagement and support

OIG proposes an additional AKS safe harbor to promote value-based arrangements, which will be known as the "patient engagement and support" safe harbor. OIG appreciates that patients' involvement in their care is necessary to improve value and achieve well-coordinated care. Therefore, the patient engagement and support safe harbor seeks to remove barriers that are preventing providers from entering into arrangements that offer patients tools and support that promote patient engagement in their care, and in turn, improves quality, health outcomes, and efficiency. The proposed safe harbor will be available only to VBE participants and, so long as all conditions of the safe harbor are met, the proposed safe harbor would exclude from remuneration in-kind patient engagement tools and supports used for the coordination and management of care that are furnished to patients in a defined target population.

Personal services and management contracts

The proposed rule provides expanded safe harbor protections for commonly used personal service and management contracts. Specifically, OIG offers to remove the requirement that the "aggregate"

compensation be set in advance. In its place, the revised safe harbor rules require only that the method for computing compensation be established in advance. To increase flexibility in designing periodic business arrangements, the agency also proposes to eliminate the requirement that parties specify the timing or duration of part-time arrangements. OIG also proposes to utilize the personal services safe harbor to enact certain value-based arrangements flexibilities.

CMS-sponsored model arrangements and patient incentives

Currently, participants in CMS-sponsored demonstration programs and other value-based models, have had to rely on program-specific waivers of the AKS, which are of limited-duration, to protect the arrangements permitted under the program. OIG proposes to "standardize and simplify" AKS (and CMP) compliance for certain models with a new safe harbor. Participants of these CMS-sponsored arrangements will have the choice of (i) relying on program-specific waivers for protection or (ii) structuring arrangements to comply with the new AKS safe harbor. Like current waiver protections, safe harbor protection will be limited to the period of participation in the CMS-sponsored model.

Under the proposed safe harbor, remuneration between parties participating in CMS-sponsored model arrangements will be permitted. In addition, remuneration in the form of incentives and supports to patients covered by the CMS-sponsored model will be permitted. CMS may set programmatic requirements (i.e., limiting participation to certain providers or entities, or limiting the scope of incentives that are protected) that participants will be required to meet for remuneration under these arrangements to be protected by the safe harbor.

Unlike some other proposed safe harbors, OIG has not excluded pharmaceutical manufacturers, DME distributors, or laboratories under this proposed safe harbor. However, the CMS-sponsored model arrangement safe harbor does not extend to commercial and private insurance arrangements as CMS does not have the ability to oversee and monitor the insurers as they do with other model participants.

Outcome-based payments for services

OIG adds to the personal services and management contracts safe harbor by including flexibility on outcome-based payment arrangements. With the understanding that outcome-based payment models encourage the coordination of care, OIG proposes to protect payments from shared savings, shared losses payments, pay-for-performance, or episodic or bundle payment programs. To qualify, such payments must be based on outcome measures that are evidence-based or have credible medical support. The measures must improve the quality of care or reduce costs while maintaining or improving the quality of patient care. The new safe harbor includes the usual contract requirements (i.e., a signed, written agreement with a term of at least one year, and compensation methodology set in advance and consistent with FMV), but also includes additional requirements that the parties regularly monitor and assess performance and periodically rebase the measures used for outcome-based payments.

But, once again, the draft regulations exclude outcome-based payments from pharmaceutical manufacturers, DME distributors, and laboratories from protection, which OIG believes are heavily dependent on prescriptions and referrals. The draft only allows protection for outcome-based payments that are used across care settings. Payments from arrangements that relate "solely to internal cost savings," such as savings from one of the Medicare prospective payment reimbursement systems (i.e., inpatient hospital, outpatient hospital, inpatient psych, etc.), are excluded under the proposal.

Bundled warranties

OIG proposes to expand the warranties safe harbor to cover bundled warranties and support for related services if certain conditions are met. The expansive modification could potentially protect a device manufacturer and distributor's warranty that certain procedures performed in combination with one or more devices will result in a particular clinical outcome or level of performance. The modified bundled warranties safe harbor imposes several restrictive conditions, including that items be reimbursed by the same federal health care program payment and that the warranty cannot be conditioned on exclusive use or minimum-purchase of certain items or services. The safe harbor prohibits manufacturers from paying for any medical, surgical, or hospital expenses outside of the warranty. Warranties for services must be tied to a related item under the proposed rule. But OIG is considering, and seeks comments on, giving manufacturers the ability to remedy unsatisfactory outcomes or extend safe harbor protections to warranties only for services with sufficient safeguards.

Local transportation

OIG proposes to extend the local transportation safe harbor by (i) expanding to 75 miles the distance which rural area residents may be transported, and (ii) removing mileage limits on patient discharge. In potentially opening health care to the floodgates of ride-share technology platforms, OIG explicitly acknowledges the use of ride-sharing services for transporting patients within parameters of the safe harbor.

Other notable changes for accountable care organizations (ACOs) and telehealth

The OIG proposed rule codifies the statutory exception for incentive payments made under the ACO Beneficiary Incentive Program, with minor additions. In addition to the statutory requirements, OIG would clarify that an ACO may furnish incentive payments only to assigned beneficiaries.

OIG also proposes to amend the CMP law for the provision of telehealth technologies for in-home dialysis services. The CMP law prohibits offering inducements to Medicare or Medicaid beneficiaries that the offeror knows or should know is likely to influence the selection of particular providers. The proposed rule imposes four conditions on the appropriate technology: (i) that the telehealth is furnished by the current provider of dialysis services; (ii) the technology is not offered as part of any advertisement or solicitation; (iii) the telehealth technology contributes substantially to the provision of telehealth services related to an individual's end-stage renal disease is not of excessive value and is not duplicative of the beneficiary's technology; and (iv) it does not shift the costs of the technology to federal health care programs, other payors, or individuals.

Conclusions and takeaways

HHS hopes that these proposed rules will provide greater flexibility to providers and certainty that they are complying with the federal laws in order to facilitate the coordination of care and a shift towards a more affordable, high-quality, value-based health care system. These changes intend to lead to greater patient autonomy and an increase in access to various sites of care, including the patient's home. The HHS Deputy Secretary describes the agency's vision: "we are going to see the healthcare sector move away from [hospital care] and into wider and a greater number of sites of care . . . we are going to see patients get more and more care for themselves . . . they are going to be able to care for themselves at home and their loved ones at home."

At the same time, it is imperative to remember that the government's publication of these potential changes does not offer protection to or materially modify compliance risk for current arrangements that run afoul of Stark Law, AKS, and CMP law. The proposed rules are subject to change and seek to offer prospective protections—meaning the protection will only apply to arrangements after the final rules are developed and implemented. Current arrangements and arrangements entered into prior to implementation are subject to existing regulations governing Stark Law, AKS, and CMP as they stand today.

The proposed Stark Law and AKS rules were issued on October 9, 2019, and published in the Federal Register today, October 17, 2019. In light of the significant impact that these changes may have on the industry, the agency is extending its normal 60-day comment period to 75 days. Stakeholders and interested parties must submit comments by December 31, 2019. Given the significant opportunities that these changes may bring, if finalized, providers and managed care organizations should pay close attention to these proposals and actively participate in the rulemaking process. To that end, Nixon Peabody attorneys can assist with comment submissions. Health care industry leaders should also consider how these changes may impact their organizations going forward.

HHS Regulatory Sprint

Launched by the Deputy Secretary of HHS in 2018, the "Regulatory Sprint to Coordinated Care" aims to remove potential regulatory barriers to care coordination and value-based care created by four key federal health care laws and associated regulations. First, the rules under 42 C.F.R. Part 2 facilitate and enhance coordination of care for substance use disorder treatment that HHS published on August 26 (and our team covered here). These highly anticipated proposed rules that narrow Stark law's application and expand AKS protections across the continuum of care followed. Up next on HHS's plate is the health data law that is often the biggest roadblock to digital care coordination—HIPAA.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

- Megan McGovern at **mmcgovern@nixonpeabody.com** or 617-345-1179
- Harsh P. Parikh at **hparikh@nixonpeabody.com** or 213-629-6108
- Jennifer Greco at **jgreco@nixonpeabody.com** or 516-832-7641
- Peter Egan at **pegan@nixonpeabody.com** or 516-832-7633
- Jill Gordon at **jgordon@nixonpeabody.com** or 213-629-6175
- Valerie Breslin Montague at **vbmontague@nixonpeabody.com** or 312-977-4485
- Rebecca Simone at **rsimone@nixonpeabody.com** or 516-832-7524
- Philip Rosenberg at **prosenberg@nixonpeabody.com** or 518-427-2709
- Stephen Zubiago at **szubiago@nixonpeabody.com** or 401-454-1017