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Compliance Today - February 2020
OIG proposed rule revises federal Anti-Kickback Statute and CMP Law

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In 2018, the United States Department of Health and Human Services (HHS) launched the Regulatory Sprint to Coordinated Care initiative (the initiative) to align existing regulations with and remove regulatory impediments to the healthcare industry's shift toward value-based and coordinated care payment models. The initiative covered the regulations implementing the Stark Law,[1] federal Anti-Kickback Statute (AKS),[2] and Civil Monetary Penalty Law (CMPL).[3] In furtherance of the initiative, on August 27, 2018, HHS's Office of Inspector General (OIG) issued a Request for Information seeking recommendations from the public regarding modifying or adding safe harbors to the AKS and exceptions to the CMPL's definition of "remuneration."[4] After receiving 359 responses from various stakeholders, on October 9, 2019, OIG issued a Notice of Proposed Rulemaking, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" (the proposed rule).[5] A high-level summary of this proposed rule follows.

On the same day, the Centers for Medicare & Medicaid Services (CMS) issued its proposed rule addressing the regulations implementing the Stark Law, which is summarized in "CMS issues long-awaited Stark proposed rulemaking" (also in this issue of *Compliance Today*).

Proposed revisions to the AKS, generally

The AKS prohibits anyone (which includes an individual or a corporation) from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration to a person in return for referring, or to induce such person to refer, an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program.[6]

However, the AKS regulations carve out certain types of payment arrangements from the definition of the "remuneration" that would otherwise potentially be prohibited (the safe harbors).[7]

In the proposed rule, OIG proposed five new safe harbors, as well as revisions to four existing safe harbors, intended to "foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse,"[8] as well as to protect certain incentives offered to beneficiaries to encourage patient engagement, which would otherwise be prohibited.

Definitions

Value-based arrangement: An "arrangement for the provision of at least one value-based activity for a target

patient population between or among: (A) the value-based enterprise (VBE) and one or more of its VBE participants;[9] or (B) VBE participants in the same VBE.[10] A VBE is defined as a "network of individuals and entities that collaborate together to achieve one or more value-based purposes."[11] VBE participants would not include pharmaceutical manufacturers; manufacturers, distributions or suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); or laboratories.

Value-based purposes: Coordinating, managing, and improving the quality of care of a target patient population, reducing the costs to payers without reducing the quality of care for a target patient population, and "transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population."[12]

Target patient population: The "identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the VBE's purpose(s)."[13]

Value-based activity: "Any of the following activities, provided the activity is reasonably designed to achieve at least one value-based purpose of the VBE: (A) the provision of an item or service; (B) the taking of an action; or (C) the refraining from taking an action." Value-based activities do not include the making of a referral.[14]

Substantial downside financial risk: Only specific methodologies qualify as substantial downside financial risk. For example, OIG proposes that a VBE is at a substantial downside risk if it is subject to shared savings with a repayment obligation to the payer of at least 40% of any shared losses.

Full financial risk: Similar to the definition of substantial downside financial risk, only certain methodologies qualify as full financial risk. For example, OIG would consider a VBE at full financial risk if it received a "prospective, capitated payment for all items and services covered by Medicare Parts A and B for a target patient population."[15]

Proposed new safe harbors: Value-based arrangements

OIG proposed three new safe harbors intended to protect arrangements under which remuneration is exchanged between or among eligible participants in a value-based arrangement involving both publicly and privately insured patients.

Care Coordination Arrangements safe harbor

The first value-based arrangement-related safe harbor proposed by OIG, the Care Coordination Arrangements safe harbor,[16] would cover certain in-kind, non-monetary remuneration, including services and infrastructure, exchanged between qualifying VBE participants with value-based arrangements, to be used primarily to engage in value-based activities, as long as all requirements of the safe harbor are met.[17] These requirements include, for instance, that the value-based arrangement be commercially reasonable, are set forth in writing, and have a direct connection to the coordination and management of care for the target patient population.[18] The proposed rule sets forth additional proposed elements for this safe harbor that are not described in this article, which highlights only some of the key elements discussed in the proposed rule.

The offeror of the remuneration is prohibited from "taking into account the volume or value of, or conditioning an offer of remuneration on, (i) referrals of patients that are not part of the value-based arrangement's target

patient population; or (ii) business not covered under the value-based arrangement."[19] The value-based arrangement must not contain restrictions on directing or restricting referrals, and may not include marketing items or services to patients or patient recruitment activities.[20] OIG is also seeking feedback regarding its proposed requirement that the safe harbor protection is conditioned on the recipient's payment of at least 15% of the offeror's cost for the in-kind remuneration, as well as whether a fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement should be imposed.[21]

Substantial Downside Financial Risk safe harbor

The second proposed value-based arrangement safe harbor, the Substantial Downside Financial Risk safe harbor,[22] would cover both in-kind and monetary remuneration and offer greater flexibility than the Care Coordination Arrangements safe harbor "in recognition of the VBE's assumption of substantial downside financial risk."[23] The safe harbor elements are similar to those proposed for the Care Coordination Arrangements safe harbor. In addition, the remuneration "must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk."[24]

The Full Financial Risk safe harbor

The third value-based arrangement safe harbor is the Value-Based Arrangements with Full Financial Risk safe harbor.[25] OIG sought public comment as to its proposed definition of "full financial risk," but the comment period closed December 31, 2019.[26] This safe harbor is intended to offer VBEs the "greatest ability to innovate with respect to coordinate care arrangements in light of their assumption of the highest level of risk."[27] Note that this safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment approach.[28] This safe harbor requires, among other elements, that the arrangement to be set forth in writing, be for a period of at least one year, and must not take into account referrals of patients who are not part of the target population or business not covered under the value-based arrangement.[29]

Additional, proposed new AKS safe harbors

The Patient Engagement and Support safe harbor[30] would protect certain in-kind patient engagement tools or support furnished by VBE participants to patients in a target patient population to improve quality, health outcomes, and efficiency, as long as the requirements of the safe harbor are met.[31] Significantly, because a practice permissible under the AKS is also exempted from the CMPL, this safe harbor would also remove certain barriers presented by the CMPL.[32]

For purposes of this safe harbor, "tools or support" are limited to "in-kind, preventive items, goods, or services, or items, goods, or services such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the target patient population," with an annual, aggregate retail value cap at $500 per patient.[33] The safe harbor currently excludes gift cards, cash, and any cash equivalent,[34] but OIG sought comment on whether to protect patient incentives and support provided in these forms in certain circumstances.[35] Irrespective of the type of in-kind remuneration, however, no item, good, or service may be used for patient recruitment or marketing of items or services to patients.[36]

The CMS Sponsored Models safe harbor[37] would protect remuneration distributed between and among parties of arrangements established pursuant to CMS-sponsored models, including Innovation Center models, provided certain conditions are met.[38] This safe harbor is intended to simplify and standardize CMS's current process of issuing specific AKS and CMPL waivers tailored to its sponsored model arrangements.[39]

The Cybersecurity Technology and Services safe harbor[40] would protect non-monetary remuneration in the form of donations of certain cybersecurity technology and related services when the donations meet five specific conditions.[41] For example, the safe harbor would only apply to technology and services that are necessary and used predominantly to implement and maintain effective cybersecurity.[42] The donor may not take into account the volume or value of referrals or other business between the parties when determining the eligibility of a potential recipient for the technology or services, nor may the donation be conditioned on future referrals.[43] Additionally, the safe harbor requires the recipient and the donor to enter into a signed, written agreement.[44]

Finally, OIG proposes to add the **Accountable Care Organization (ACO) Beneficiary Incentive Programs safe harbor**,[45] which would permit ACOs that apply to operate an ACO Beneficiary Incentive Program to provide incentive payments to assigned, Medicare fee-for-service beneficiaries.[46] This would only be permitted if the payment is made in accordance with the requirements set forth in Section 1899(m) of the Social Security Act.

Proposed revisions to existing AKS Safe Harbors

OIG also proposes certain revisions to existing safe harbors. For example, OIG proposes to revise the **Electronic Health Records Items and Services safe harbor**,[47] which protects certain arrangements involving the donation of interoperable electronic health records software or information technology and training services.[48] This safe harbor was initially scheduled to expire on December 31, 2013, but was extended through December 31, 2021, pursuant to previous rulemaking.[49] OIG sought comments on whether to make this safe harbor permanent or to further extend its expiration date. The Proposed Rule would also significantly revise many of the definitions applicable to this safe harbor.

OIG proposes to modify the existing **Personal Services and Management Contracts safe harbor**[50] to replace the requirement that aggregate compensation under these agreements be set in advance with a requirement that the methodology for determining compensation be set in advance.[51] The Proposed Rule would also eliminate the requirement that, if an agreement provides for the services of an agent on a periodic, part-time basis, the agreement must specify the schedule, length, and exact charge for such intervals.[52] OIG states that removing this requirement would "afford parties additional flexibility in designing bona fide business arrangements, including care coordination and quality-based arrangements, where parties provide legitimate services as needed."[53]

OIG also proposes to revise this safe harbor to protect "outcome-based payment" arrangements, which it defines "as payments from a principal to an agent that: (i) reward the agent for improving or maintaining improvement in patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintain the improved, quality of care for patients."[54] These payment arrangements may include shared savings or loss payments, gainsharing payments, or episodic or bundled payments.[55]

The Warranties safe harbor[56] would be revised to promote higher-value items covered by such warranties, including bundled warranties for one or more items and related services, if certain conditions are met.[57] For instance, OIG proposes to impose requirements that "[a]ll federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same federal health care program and in the same payment," and that "manufacturers and suppliers cannot condition bundled warranties on the exclusive use of one or more items or services or impose minimum-purchase requirements of any items or services."[58] OIG also proposes to modify the definition of "warranty" as that phrase is used in the safe harbor to eliminate an unintentional ambiguity as to whether the safe harbor covers warranties for drugs and devices regulated under the Federal Food, Drug and Cosmetic Act.[59]

Finally, OIG proposes to revise the **Local Transportation safe harbor**[60] to expand the distance to which residents of rural areas may be transported from 50 to 75 miles,[61] and to remove any mileage limit on transportation of a patient from a health care facility from which a patient has been discharged to the patient's residence.[62] OIG also seeks public comment on whether it should expand this safe harbor to include transportation for non-medical purposes that may improve or maintain health for certain populations, such as chronically ill patients, or for patients who are being discharged from a hospital or other facility.[63] However, OIG noted that its proposed, new Patient Engagement and Support safe harbor could include transportation for health-related, non-medical purposes.[64] Finally, OIG clarified that although it does not believe the existing Local Transportation safe harbor prohibits the use of ride-sharing services (as long as all elements of the safe harbor are met), it is soliciting comments as to whether this safe harbor should be modified to explicitly protect transportation offered through ridesharing services.[65]

Proposed revisions to the Civil Monetary Penalty Law

The CMPL beneficiary inducement provisions prohibit any person from offering or transferring any remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services.[66] In 2000[67] and in 2016,[68] OIG codified final rules amending the term "remuneration" to exclude from its definition certain payment arrangements under the CMP beneficiary inducement provisions (the CMPL exceptions).[69]

This proposed rule would amend the CMPL exceptions to codify amendments that were enacted in the Budget Act of 2018.[70] Specifically, OIG proposes to add an additional CMPL exception by amending the definition of "remuneration" to further exclude the provision of certain telehealth technologies related to in-home dialysis services.[71] This CMPL exception would only be available for telehealth technologies furnished by the provider of services or a renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other end-stage renal disease services to the patient.[72] The intent of this limitation is to "prevent arrangements where providers and suppliers offer telehealth technologies to patients with whom they do not have a prior clinical relationship in an attempt to steer patients to a particular provider or supplier."[73]

Conclusion

Although the proposed rule is intended to strike a balance between "flexibility for beneficial innovation and safeguards to protect patients and Federal health care programs," OIG acknowledges that it is not yet clear if these proposals succeed in doing so. As a result, OIG's solicitations for public comment requested that commenters opine as to whether or not they believe these proposed safe harbors should be protected from

criminal liability under the AKS.

OIG accepted public comments through December 31, 2019, which it will consider when preparing the final rule. The OIG's goal is to issue the final rule regarding the AKS and CMPL in 2020.

Takeaways

• OIG accepted public comments regarding a proposed rule modifying or adding safe harbors to the federal Anti-Kickback Statute (AKS) and exceptions to the Civil Monetary Penalty Law's (CMPL) definition of "remuneration."

• The proposed rule adds OIG's proposed three new federal AKS safe harbors intended to protect arrangements under which remuneration is exchanged between or among eligible participants in value-based arrangements.

• The proposed rule revises existing federal AKS safe harbors, such as the Personal Services and Management Contracts safe harbor, the Warranties safe harbor, and the Local Transportation safe harbor.

• The proposed rule adds an additional CMPL exception by amending the definition of "remuneration" to further exclude the provision of certain telehealth technologies related to in-home dialysis services.

• OIG intends to issue a final rule in 2020.

142 U.S.C. § 1395nn.
242 U.S.C. § 1320a-7b(b).
342 U.S.C. § 1320a–7a.
483 Fed. Reg. 43,607 (Aug. 27, 2018) Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP.
584 Fed. Reg. 55,694 (Oct. 17, 2019) Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Rules Regarding Beneficiary Inducements.
642 U.S.C. §§ 1320a-7b(b)(1)-(2).
742 C.F.R. § 1001.952.
884 Fed. Reg. at 55,695.
984 Fed. Reg. at 55,703, 55,722.
1084 Fed. Reg. at 55,702.
1184 Fed. Reg. at 55,700-01.
1284 Fed. Reg. 55,706-07.
1384 Fed. Reg. at 55,702.
1484 Fed. Reg. at 55,703.
1584 Fed. Reg. at 55,719.
1642 C.F.R. § 1001.952(ee).
1784 Fed. Reg. at 55,708.
1884 Fed. Reg. at 55,709-12.
1984 Fed. Reg. at 55,711.
2084 Fed. Reg. at 55,712.
2184 Fed. Reg. at 55,711, 55,714.
2242 C.F.R. § 1001.952(ff).
2384 Fed. Reg. at 55,716.
2484 Fed. Reg. at 55,718.
2542 C.F.R. § 1001.952(gg).
26 HHS Proposed Rule comment period, https://bit.ly/2KMMv4S.

27 84 Fed. Reg. at 55,719.
28 84 Fed. Reg. at 55,719.
29 84 Fed. Reg. at 55,719.
30 42 C.F.R. § 1001.952(hh).
31 84 Fed. Reg. at 55,721-722.
32 42 U.S.C. § 1320a-7a(i)(6)(B).
33 84 Fed. Reg. at 55,723, 55,728.
34 84 Fed. Reg. at 55,723
35 84 Fed. Reg. at 55,725, 55,726.
36 84 Fed. Reg.at 55,727.
37 42 C.F.R. § 1001.952(ii).
38 84 Fed. Reg. at 55,730.
39 84 Fed. Reg. at 55,730.
40 42 C.F.R. § 1001.952(jj).
41 84 Fed. Reg. at 55,733, 55,735.
42 84 Fed. Reg. at 55,735.
43 84 Fed. Reg. at 55,736.
44 84 Fed. Reg. at 55,738.
45 42 C.F.R. § 1001.952(kk).
46 84 Fed. Reg. at 55,752-53.
47 42 C.F.R. § 1001.952(y).
48 84 Fed. Reg. at 55,739.
49 84 Fed. Reg. at 55,739.
50 42 C.F.R. § 1001.952(d).
51 84 Fed. Reg. at 55,744.
52 84 Fed. Reg. at 55,744.
53 84 Fed. Reg. at 55,744.
54 84 Fed. Reg. at 55,745.
55 84 Fed. Reg. at 55,745.
56 42 C.F.R. § 1001.952(g).
57 84 Fed. Reg. at 55,748.
58 84 Fed. Reg. at 55,749.
59 84 Fed. Reg. at 55,750.
60 42 C.F.R. § 1001.952(bb).
61 84 Fed. Reg. at 55,750-51.
62 84 Fed. Reg. at 55,751.
63 84 Fed. Reg. at 55,751.
64 84 Fed. Reg. at 55,751 (referring to 42 C.F.R. § 1001.952(hh)).
65 84 Fed. Reg. at 55,752.
66 42 U.S.C. § 1320a-7a(a)(5).
67 Health Care Programs: Fraud and Abuse; Revised OIG Civil Monetary Penalties Resulting from Public Law 104-191, 65 Fed. Reg. 24,400, 24,409 (Apr. 26, 2000).
68 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368 (Dec. 7, 2016).
69 *See* the CMP Exceptions at 42 C.F.R. § 1003.100.
70 84 Fed. Reg. at 55,753.

[71]84 Fed. Reg. at 55,753.
[72]84 Fed. Reg. at 55,754.
[73]84 Fed. Reg. at 55,754.