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December 20, 2019

Ms. Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521
Cohen Building
330 Independence Avenue SW
Washington, DC 20201.

Re: Comments on OIG-0936-AA10-P, 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

Dear Acting Inspector General Chiedi,

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Office of Inspector General's (OIG's) above-captioned Proposed Revisions. AAHomecare members include a cross section of suppliers, manufacturers, and other industry stakeholders that assist, make or furnish Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) that Medicare beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost-effective, safe and reliable home care products and services. As such, our comments are primarily focused on the Proposed Revisions as they pertain to DMEPOS.

Importance of Coordination of Care

AAHomecare recognizes that the existing health care delivery model (Existing Model) needs to be improved. Under the Existing Model, a provider/supplier[1] is paid for the services/products it furnishes, regardless of their effectiveness in treating the patient. Further, the Existing Model does not encourage coordination among providers and suppliers. Essentially, each provider/supplier "operates in a silo." Too often, the provider/supplier

[1] Physicians, home health agencies, therapy clinics and other health care providers are commonly referred to as "providers." Durable medical equipment (DME) suppliers are commonly referred to as "suppliers." Throughout this letter, "providers" and "suppliers" will be used interchangeably.

does not have a stake in whether (i) the overall care to the patient is cost-effective and (ii) the care results in improvement to the patient's health.

AAHomecare agrees with the OIG that providers and suppliers need to be encouraged to coordinate with each other in providing care to patients covered by federal government health care programs (FGHCPs). Indeed, DME suppliers are central to such coordination. DME suppliers furnish equipment and products designed to (i) allow FGHCP patients to live independently in their homes (as opposed to living in more expensive facilities) and (ii) reduce the incidences of physician and hospital visits. Unlike most other providers, DME suppliers have regular communications with FGHCP patients and their caregivers. These communications allow DME suppliers to report to, and coordinate with, treating physicians and other clinicians.

Providers that should collaborate include hospitals, physicians, therapists (respiratory, physical and occupational), DME suppliers, home health agencies, pharmacies, labs and skilled nursing facilities. When such collaboration occurs, FGHCP patients are treated more cost-effectively, FGHCP patients avoid unnecessary physician and hospital visits, and FGHCPs save money.

Coordination of Care and its Relationship to Preventing Fraud

When providers and suppliers work together in delivering patient care, challenges arise. Specifically, any time one provider refers a FGHCP patient to another provider and there is a payment of compensation or sharing of reimbursement, then there is a risk of a kickback in violation of the federal anti-kickback statute (AKS).[2] Likewise, any time a provider works with and/or incentivizes a FGHCP patient with the goal of improving the FGHCP patient's health, then there is a risk of an inducement in violation of the beneficiary inducement statute (Inducement Statute).[3] And yet, referrals, sharing of compensation, and incentivizing FGHCP patients are necessary for there to be effective coordination of care. While it is important that FGHCPs encourage coordination, it is equally important that protection against fraud be maintained. This is a balancing act.

Impact of the AKS on Care Coordination

The AKS is designed to prevent a person or entity from receiving anything of value in exchange for referring (or arranging for the referral of) a FGHCP patient. The AKS has a number of safe harbors. A safe harbor is designed to permit an arrangement that will enhance treatment of a FGHCP patient but that, without the safe harbor, may violate the AKS. While the existing safe harbors have served FGHCPs well, they are proving to be inadequate as health care moves to a coordination of care model (New Model). As such, AAHomecare supports the goal of modifying and expanding the AKS safe harbors to facilitate coordination of care.

Impact of the Inducement Statute on Care Coordination

The Inducement Statute is designed to prevent a provider from offering anything of value to a FGHCP patient in order to induce the patient to purchase a good or service from the provider. The nominal value exception to the Inducement Statute allows a provider to give a gift of "nominal value" to the FGHCP patient.[4] Currently, a provider can offer one gift that has a retail value of $15 or less.[5] The provider can offer multiple gifts to a FGHCP patient so long as the gifts, in the aggregate, do not exceed $75 in retail value over a 12 month period.[6] These gifts cannot

[2] 42 U.S.C. § 1320a-7b(b).
[3] 42 U.S.C. § 1320a-7a(a)(5).
[4] Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting from Public Law 104-191, 65 FR 24410, 24411 (Apr. 26, 2000).
[5] U.S. Dep't. Health and Human Serv., Office of Inspector General, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.
[6] *Id.*

be in the form of money or money equivalents (such as gift cards).[7] While the existing nominal value exception has served FGHCPs well, it is proving to be inadequate as health care moves to the New Model. As such, AAHomecare supports the goal of modifying and expanding the nominal value exception to facilitate coordination of care.

Proposed Safe Harbor: Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (42 C.F.R.1001.952(ee))
AAHomecare (i) supports the goals of this proposed safe harbor and (ii) has no specific comments.

Proposed Safe Harbor: Value-Based Arrangement with Substantial Downside Financial Risk (42 C.F.R.1001.952(ff))
AAHomecare (i) supports the goals of this proposed safe harbor and (ii) has no specific comments.

Proposed Safe Harbor: Value-Based Arrangements with Full Financial Risk (42 C.F.R.1001.952(gg))
AAHomecare (i) supports the goals of this proposed safe harbor and (ii) has no specific comments.

Proposed Safe Harbor: Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency (42 C.F.R.1001.952(hh))
AAHomecare supports the goals of this proposed safe harbor. AAHomecare recommends that this safe harbor not be limited to Value-Based Enterprise (VBE) participants. Providers and suppliers, that do not fall into the category of VBE participants, provide patient engagement tools and support (PETS) that accomplish the same purpose as PETS provided by VBE participants. For example:

- DMEPOS suppliers can offer encounters between patients and one or more of the following employees or independent contractors of the DMEPOS supplier: respiratory therapist, physical therapist, or nurse. The encounters can be physical face-to-face (e.g., in the patient's home or at the DMEPOS supplier's facility) or via real time video conference.

As discussed later in these comments. AAHomecare urges the OIG not to exclude DMEPOS suppliers from the VBE participant category. Also as later discussed in these comments, DMEPOS suppliers have regular contact with patients, their caregivers, and their treating physician.

AAHomecare suggests that PETS include cash payments, gift cards, waiver or reduction of copayments, and other cash equivalents (collectively referred to as "cash equivalents"). It is in the best interest of the Medicare program for patients to engage in actions designed to keep the patients healthy and out of the hospital. Offering a cash equivalent as a reward for a particular action (e.g., keeping an appointment with a physician, taking medications as prescribed) will motivate a number of patients to take the appropriate actions.

AAHomecare shares the OIG's concern that offering cash equivalents not be a subterfuge designed to market the provider's/supplier's products and services. As such, AAHomecare suggests that the following protections be in place: (i) as suggested in the Proposed Regulations, the total cash equivalents provided to a patient cannot exceed $500 in a 12 month period, and (ii) the cash equivalent can be provided only after the patient has taken the required action.

Proposed Safe Harbor: CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (42 C.F.R.1001.952(ii))

[7] U.S. Dep't Health and Human Serv., Office of Inspector General, Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (Apr. 2002), https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

AAHomecare (i) supports the goals of this proposed safe harbor and (ii) has no specific comments.

Proposed Safe Harbor: Cybersecurity Technology and Services (42 C.F.R.1001.952(jj))
AAHomecare (i) supports the goals of this proposed safe harbor and (ii) has no specific comments.

Proposed Modification to Existing Safe Harbor: Electronic Health Records, Items and Services (42 C.F.R.1001.952(y))
The OIG proposes to update provisions regarding (i) interoperability, (ii) expanding the definition of a "protected donor," and (iii) elimination of the sunset provision. AAHomecare supports these proposed modifications and recommends that they be adopted.

Proposed Modification to Existing Safe Harbor: Personal Services and Management Contracts (42 C.F.R.1001.952(d))
To provide flexibility to undertake innovative arrangements, the OIG is proposing to (i) remove the requirement at 42 C.F.R. 1001.952(d)(5) that the aggregate amount of compensation paid over the term of the agreement be set in advance and (ii) add the requirement that the parties determine the arrangement's compensation methodology in advance of the initial payment under the arrangement.

The OIG further proposes to remove the requirement at 42 C.F.R. 1001.952(d)(3) that provides for services on a periodic, sporadic, or part-time basis to specify "exactly the schedule of such intervals, their precise length, and the exact charge for such intervals." According to the OIG, removing this requirement will afford parties additional flexibility in designing bona fide business arrangements, including care coordination and quality-based arrangement, where parties provide legitimate services.

AAHomecare agrees with the OIG that the proposed modifications (i) provide flexibility to providers and suppliers desiring to enter into innovative arrangements and (ii) more closely align themselves to the personal services exception to the Stark physician self-referral law (42 C.F.R. 411.357(d)). Accordingly, AAHomecare recommends that this proposed modification be adopted.

Proposed Modification to Existing Safe Harbor: Warranties (1001.952(g))
AAHomecare (i) supports the goals of this proposed modification and (ii) has no specific comments.

Proposed Modification to Existing Safe Harbor: Local Transportation (42 C.F.R. 1001.952(bb))
AAHomecare supports the goals of this proposed modification. DMEPOS suppliers in sparsely populated areas (e.g., South Dakota, North Dakota, Montana, parts of Texas, parts of California) service patients who reside greater than 75 miles from the DMEPOS supplier's facility. The same is true with other types of providers (e.g., hospitals, home health agencies, respiratory/physical therapists). Accordingly, AAHomecare recommends that the mileage restriction be expanded to 100 miles. AAHomecare further recommends that safe harbor protection be expanded to transportation to non-health venues that nevertheless (i) benefit the patient's health outcomes and (ii) address social determinants of health.

Proposed Codification of Statutory Exception: Accountable Care Organization (ACO) Beneficiary Incentive Programs (42 C.F.R. 1001.952(kk))
AAHomecare (i) supports the goals of this proposed codification and (ii) has no specific comments.

Proposed Amendment to Definition: Telehealth for In-Home Dialysis (42 C.F.R. 1003.110)
AAHomecare (i) supports the goals of this proposed amendment and (ii) has no specific comments.

Exclusion of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers from the Definition of Value-Based Enterprise (VBE) Participant

The OIG proposes to use the term VBE to describe the network of individuals and entities that collaborate together to achieve one or more value-based purposes as defined in 42 U.S.C. 1001.952(ee)). The OIG further proposes to define "VBE participant" as "an individual or entity that engages in at least one value-based arrangement." The OIG cites the following as examples: (i) performing an action to achieve certain quality or outcome metrics and the providing or receiving of payment for such achievement and/or (ii) coordinating care to achieve better outcomes or efficiencies (e.g., sharing staff or infrastructure to improve the discharge planning and care follow-up process between two VBE participants).

As a limitation, however, the "VBE participant" definition excludes certain providers/suppliers, including DMEPOS suppliers. As its basis for such exclusion, the OIG expresses its concern that DMEPOS suppliers and other providers/suppliers, that are dependent on practitioner prescriptions, might misuse the proposed safe harbors for value-based arrangements to market their products, rather than as a means to create value for patients and third party payors. The OIG further states that DMEPOS suppliers and other providers/suppliers are less likely to be on the front line of care coordination and treatment decisions in the same way as other types of proposed VBE entities, such as hospitals, physicians, and remote monitoring companies that provide care coordination and management tools and services directly to patients.

AAHomecare disagrees with the exclusion of DMEPOS suppliers from the definition of "VBE participant." In particular, AAHomecare disagrees with the OIG statement that DMEPOS suppliers are less likely to be on the front line of care coordination and treatment decisions. Unlike most providers, DMEPOS suppliers (i) visit the patient in his/her home and (ii) communicate regularly with the patient, the patient's caregiver (e.g., adult child), and the patient's physician. The DMEPOS supplier is responsible for the equipment that allows the patient to breathe (oxygen concentrator, nebulizer, ventilator, CPAP), ambulate (walker, wheelchair), walk without pain (diabetic shoes), control chronic diseases (diabetic meter and strips), and deal with daily challenges (catheters, urological supplies, incontinence supplies, and wound care supplies). When one of these items malfunction or are just simply not working to the patient's expectation, then the first call that the patient/caregiver usually makes is to the DMEPOS supplier. It is the DMEPOS supplier that goes to the patient's home at 3:00 a.m. or on Saturday afternoon.

The care coordination provided by DMEPOS suppliers is being enhanced by technological advances that result in "smart" equipment that, in turn, allows remote monitoring by the treating physician and the DMEPOS supplier. The smart equipment (i) will allow the DMEPOS supplier to be made aware that a piece of equipment is malfunctioning and (ii) notify both the treating physician and the DMEPOS supplier when a patient's health signs do not fall within an acceptable range. Often, it is the DMEPOS supplier on its own, or as directed by the treating physician, that responds when the patient's health signs are "off."

With the foregoing in mind, AAHomecare strongly believes that DMEPOS suppliers are on the frontline of care coordination. Accordingly, AAHomecare urges the OIG to include DMEPOS suppliers in the definition of "VBE participant." The safeguards are in place to reduce the risk that DMEPOS suppliers will misuse the safe harbor for marketing purposes. These safeguards include:

- The prohibitions/restrictions set out in the federal anti-kickback statute (AKS).
- The prohibitions/restrictions set out in the federal Stark physician self-referral law (Stark).

- The prohibitions/restrictions set out in the federal beneficiary inducement statute (Inducement Statute).
- State anti-fraud laws that mirror federal anti-fraud laws.
- DMEPOS supplier standards that state that a DMEPOS supplier must adhere to the law.

AAHomecare sincerely appreciates the opportunity to provide the OIG with these comments. We are available to discuss them in greater detail at your convenience.

Sincerely,

Tom Ryan
President & CEO
American Association for Homecare