



Submitted electronically via: www.regulations.gov

December 20, 2019

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on CMS-1720-P, “Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations”

Dear Administrator Verma:

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services’ (CMS’) above captioned Proposed Rule. 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 focused on the Proposed Rule as it pertains to DMEPOS.

Importance of Coordination of Care

AAHomecare recognizes that the standard fee-for-service (FFS) compensation methodology for health care providers is outdated and inefficient. Under the FFS model, a provider is paid for the services/products it furnishes regardless of their effectiveness in treating the beneficiary. Further, the FFS model does not encourage coordination among providers. Essentially, each provider “operates in a silo.” Too often, the provider does not have a stake in whether (i) the overall care to the beneficiary is cost effective and (ii) the care results in improvement to the beneficiary’s health.

AAHomecare agrees with CMS that health care providers need to be encouraged to coordinate with each other in providing care to beneficiaries. Indeed, suppliers of DMEPOS (DME suppliers) are central to such coordination. DME suppliers furnish equipment and products designed to (i) allow beneficiaries 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 health care providers, DME suppliers have regular communications with beneficiaries and their caregivers. These communications allow DME suppliers to report to, and coordinate with, treating physicians.

Health care providers that should collaborate include: physicians, therapists (respiratory, physical and occupational), DME suppliers, home health agencies and pharmacies. When such collaboration occurs, beneficiaries are treated more cost effectively, beneficiaries avoid unnecessary physician and hospital visits, and the Medicare program saves money.

Coordination of Care and its Relationship to Preventing Fraud

When health care providers work together in delivering patient care, challenges arise. Specifically, any time one provider refers a beneficiary to another provider and there is a sharing of reimbursement, then there is a risk of (i) a kickback in violation of the federal anti-kickback statute and/or (ii) a physician self-referral in violation of Stark. And yet, referrals and sharing of compensation are necessary for there to be effective coordination of care. While it is important that the Medicare program encourage coordination, it is equally important that protection against fraud be maintained.

Impact of Stark on Care Coordination

Stark is designed to prevent physicians from ordering services and products for beneficiaries when the motivation is for the physicians to profit as opposed to the motivation being the effective treatment of the beneficiaries. Stark provides several exceptions. An exception is designed to permit an arrangement that will enhance treatment of a beneficiary but that, without the exception, may violate the language of the statute. While the existing exceptions have served the Medicare program well, they are proving to be inadequate as health care moves to a coordination of care model. As such, AAHomecare supports the goal of modifying and expanding the Stark exceptions to facilitate coordination of care.

Proposed New Exception: Arrangements That Facilitate Value-Based Health Care Delivery and Payment (42 C.F.R. 411.357(aa))

CMS is seeking comments on whether physicians' arrangements with DMEPOS suppliers should be ineligible as Value-Based Arrangements (VBAs) because DMEPOS suppliers ostensibly have a lack of direct patient contact. AAHomecare disagrees that DMEPOS suppliers have a lack of direct patient contact. 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 malfunctions, or just simply does not work 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) allows the DMEPOS supplier to be made aware that a piece of equipment is malfunctioning and (ii) notifies 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 do not fall within an acceptable range.

AAHomecare strongly believes that DMEPOS suppliers are on the frontline of care coordination. Accordingly, AAHomecare urges CMS to include physicians' arrangements with DMEPOS suppliers in VBAs.

Proposed New Definition: Commercially Reasonable (42 C.F.R. 411.351)

CMS proposes to define "commercially reasonable" to mean that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

AAHomecare agrees with the deletion of the requirement that the arrangement result in profit. AAHomecare suggests that the following phrase be deleted: "and is on similar terms and conditions as like arrangements." If a particular arrangement is designed to achieve the goal of care coordination and positive patient outcome, then it is irrelevant as to whether the arrangement is similar to other arrangements. In fact, requiring that the arrangement be similar to other arrangements can have an adverse effect on the parties to the arrangement: they may be restricted from entering into an otherwise effective arrangement.

Proposed Revised Definition: Fair Market Value (42 C.F.R. 411.351)

AAHomecare supports this proposed revised definition and has no specific comments.

Proposed New Special Rules: Compensation That Takes Into Account the Volume or Value of Referrals or Other Business Generated (42 C.F.R. 411.354(d)(5)(6))

AAHomecare supports these proposed new special rules and has no specific comments.

Proposed Addition to Carve-Out From Definition: Designated Health Services (42 C.F.R. 411.351)

AAHomecare supports this proposed addition and has no specific comments.

Proposed Revisions to Special Rules: Group Practices' Distributions of Profit Shares and Productivity Bonuses (42 C.F.R. 411.352)

AAHomecare has no specific comments.

Proposed Elimination of Provision: Outer Limits on Period of Disallowance (42 C.F.R. 411.353)

AAHomecare has no specific comments.

Proposed New Special Rule: Grace Periods for Temporary Noncompliance with Writing and Signature Requirements (42 C.F.R. 411.354(e)(3))

AAHomecare supports this proposed new special rule and has no specific comments.

Proposed Additional Exception: Ownership and Investment Interests (42 U.S.C. 411.354(b)(3))

AAHomecare supports this proposed additional exception and has no specific comments.

Proposed New Provision: Exceptions Applicable to Indirect Compensation Arrangements (42 C.F.R. 411.354(c)(4))

AAHomecare supports this proposed new provision and has no specific comments.

Proposed Removal of Requirements Not to Violate the Federal Anti-Kickback Statute

AAHomecare has no specific comments.

Proposed Provisions: Required Referrals (42 C.F.R. 411.354(d)(4))

AAHomecare has no specific comments.

Proposed Changes to Exceptions: Direct Compensation Arrangements (42 C.F.R. 411.357(a)(3))

AAHomecare supports this proposed change and has no specific comments.

Proposed Changes to Exception: Physician Recruitment (42 C.F.R. 411.357(e)(4)(i))

AAHomecare has no specific comments.

Proposed Replacement of Exception: Certain Arrangements With Hospitals (42 C.F.R. 411.357(g))

AAHomecare has no specific comments.

Proposed Narrowing of Exception: Isolated Transactions (42 C.F.R. 411.351)

AAHomecare has no specific comments.

Proposed Expansion of Exception: Payments by a Physician (42 C.F.R. 411.357(i)(2))

AAHomecare supports this proposed expansion of the exception and has no specific comments.

Proposed Expansion of Exception: Fair Market Value Compensation (42 C.F.R. 411.357(l))

AAHomecare supports this proposed expansion of the exception and has no specific comments.

Proposed Expansion of Exception: Electronic Health Records Items and Services (42 C.F.R. 411.357(w))

AAHomecare supports this proposed expansion of the exception and has no specific comments.

Proposed Revisions to Exception: Assistance to Compensate a Non-Physician Practitioner (42 C.F.R. 411.357(x))

AAHomecare has no specific comments.

Proposed New Exception: Limited Remuneration to a Physician (42 C.F.R. 411.357(z))
AAHomecare supports this proposed new exception and has no specific comments.

Proposed New Exception: Cybersecurity Technology and Related Services (42 C.F.R. 411.357(bb))
AAHomecare supports this proposed new exception and has no specific comments.

Stark and DMEPOS

Under the in-office ancillary services exception, a physician can self-refer patients for an array of services that the physician provides.¹ For example, a physician can own and operate an ambulatory surgery center (ASC) and if certain requirements are met, the physician can refer Medicare beneficiaries to the ASC.² The in-office ancillary services exception allows, under certain conditions, for a physician to provide the following products to beneficiaries who are the physician's patients: canes, crutches, walkers, folding manual wheelchairs, blood glucose monitors, and certain types of infusion pumps (collectively referred to as "Allowed Products").³ On the other hand, the exception does not allow the physician to provide durable medical equipment not listed in the Allowed Product category (collectively referred to as "Disallowed Products") to the beneficiaries who are the physician's patients.⁴ For the following reasons, AAHomecare recommends that this prohibition remain in place:

- **Lack of Infrastructure to Service Beneficiaries** – Furnishing the product is only one component of what a DME supplier does for the beneficiary. The DME supplier furnishes a continuum of care to the beneficiary: (i) the DME supplier sets the beneficiary up on the product and educates the beneficiary on how to use, clean and maintain the product; (ii) the DME supplier proactively communicates with the beneficiary (and/or his caregiver) on a regular basis to ensure that the beneficiary is properly using the product; and (iii) the DME supplier maintains and repairs the product and, as necessary, replaces the product. To provide these "after sale" services requires a large investment in employees, equipment and technology. It is doubtful that a physician will invest in such an infrastructure.
- **Lack of Product Selection** – In order to successfully service beneficiaries, the DME supplier needs to offer multiple brands of products in a particular product category. While these brands will have varying costs to the DME supplier, Medicare reimbursement is the same. It is doubtful that a physician will spend the money to purchase multiple brands of products in a particular product category. In order to limit the cost of providing durable medical equipment, it is likely that most physicians will purchase the least expensive products that will be of the lowest quality. Low quality products will result in (i) non-usage by beneficiaries, (ii) malfunctions, (iii) inadequate treatment results, and (iv) greater chances of the beneficiaries needing to return to the physician and/or hospital.

¹ See 42. U.S.C. § 1395nn(b).

² *Id.*

³ 42 C.F.R. § 411.355(b)(4).

⁴ *Id.* § 411.355(b).

- **Lack of Accreditation** – One of the requirements for a DME supplier to be issued a Medicare Part B supplier number (PTAN) is for the supplier to be accredited and adhere to quality standards. No such requirement is imposed on physicians who sell DME. If the Stark in-office ancillary services exception is relaxed to allow physicians to provide Disallowed Products, then the safeguards afforded by accreditation and the quality standards will be absent.

These concerns are consistent with the June 2018 MedPAC report (Report) to Congress that addresses physician owned distributorships (PODs).⁵ The Report says, in part:

*Physician-owned distributors (PODs) allow physicians to profit from the sale of medical devices they use. Specifically, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. The primary concern with PODs is that such entities create an incentive for physicians to base their preferences, such as whether to operate on a patient and which instrumentation to use, on financial rather than clinical considerations...PODs raise several concerns for the Medicare program and beneficiaries: **Increased volume.** Physicians who own PODs have an incentive to refer more patients for surgery because more surgeries result in more devices used...**Increased intensity.** Physicians who own PODs have an incentive to use more devices in a given case or refer patients for more intense procedures that require more devices. **Inappropriate care.** PODs' financial incentives could encourage physicians to refer patients for surgery inappropriately, and, because they have a financial interest in choosing devices that their PODs sell, to use devices of inferior quality or that are not best suited for a procedure....⁶*

The Report discusses PODs in the context of implantable medical devices, which do not fall under the Stark definition of “designated health services.” Nevertheless, the concerns raised by the Report apply to the scenario in which the Stark in-office ancillary services exception is expanded to include Disallowed Products.

Conclusion

AAHomecare agrees with the July 17, 2018 comments by Deputy Secretary Eric D. Hagan, before the U.S. House Ways and Means Committee/Subcommittee on Health, entitled “Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program.”⁷ In particular, AAHomecare agrees with Deputy Secretary Hagan’s statement that:

⁵ Medicare Payment advisory Comm’n, Report to the Congress: Medicare and the Health Care Delivery System 133 (June 2018).

⁶ *Id.* at 158.

⁷ Eric D. Hagan, Deputy Sec’y, U.S. Dep’t of Health and Human Servs., Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program, Testimony Before the U.S. House Ways and Means Comm., Subcomm. on Health (July 17, 2018).

When enacted in 1989, the Stark Law rightfully addressed the concern that inappropriate motives could distort decision-making in healthcare....But what made sense for the healthcare system in the 1980s does not necessarily translate to the modern healthcare system...The Stark Law, which as I noted, is designed for a fee-for-service model, is not one that always works in a system transitioning and moving to value-based payments for healthcare. The Stark Law may unduly limit ways that physicians and healthcare providers can coordinate patient care by restricting ways physicians can organize and work together and with others....⁸

As the Stark restrictions are modified or eliminated to facilitate the shift to a collaborative/value-based model, we encourage CMS to keep in mind that certain prohibitions need to be kept in place, including the one that states that Disallowed Products are not covered by the in-office ancillary services exception.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Ryan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Tom Ryan
President & CEO
American Association for Homecare

⁸ Eric D. Hargan, Deputy Sec'y, U.S. Dep't of Health and Human Servs., Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program, Testimony Before the U.S. House Ways and Means Comm., Subcomm. on Health (July 17, 2018).