PRIVATE PRACTICE SECTION, APTA

APTA
American Physical Therapy Association

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October 26, 2018

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Room 5513 Attention: OIG-0803-N
Cohen Building
330 Independence Ave, SW
Washington, DC 20201

Submitted electronically

RE: Medicare and State Health Programs; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

On behalf of the over 4,200 members of the Private Practice Section (PPS) of the 100,000 member American Physical Therapy Association (APTA), I write to provide input and feedback on the Department of Health and Human Services Office of Inspector General (OIG) request for information (RFI) regarding the Anti-Kickback Statute and Beneficiary Inducements CMP that was published in the Federal Register on August 27, 2018.

PPS is an organization of physical therapists in private practice who use their expertise to restore function, improve mobility, relieve pain, and prevent or limit permanent physical disabilities in patients with injury or disease. The rehabilitative and habilitative care they provide restores, maintains, and promotes overall fitness and health. In representing independent, small business owners we are interested in policies that will allow our patients who are Medicare beneficiaries the ability to choose for themselves which clinician and type of practice through which to access affordable, high-quality physical therapy.

While the OIG's RFI is clearly focused on physician providers, value-based care and bundled-payment arrangements are also relevant to other Medicare enrolled providers and suppliers, including physical therapists. PPS encourages the OIG to also consider how modernizations explored would impact the care Medicare beneficiaries receive from other non-physician health care providers and suppliers. The goal of balancing the anti-kickback law's restrictions while modernizing the regulations to support value-based reimbursement can be met while also protecting a Medicare beneficiary's right to receive quality care from the provider of their choice—in many cases that will be from independent, private practice physical therapy practitioners.

PPS strongly urges the OIG to consider the following recommendations when deciding how to use its regulatory authority to modernize and reform the anti-kickback statute. Below please find our perspective for the questions to which PPS members have relevant experience and expertise to share. For your convenience, I have noted the question posed in the RFI.

Section 1: Promoting Care Coordination and Value-Based Care

Question A: Please tell us about either potential arrangements that the industry is interesting in pursuing, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements that may implicate the anti-kickback statute or beneficiary inducements CMP.

The RFI expresses a strong interest in modernizing the anti-kickback statute in order to facilitate and support the increased use of bundled payment and shared savings/risk models; PPS recommends that the OIG provide flexibility in the anti-kickback statute that would facilitate the participation of suppliers of ancillary services, such as physical therapy, in such models. This could be achieved by modeling financial arrangements that would likely occur under an Alternative Payment Model (APM) that involves rehabilitation ancillary services. Here are a few suggestions:

1. Allow physical therapists to participate in an APM on a risk sharing basis. The participating physical therapist should be able to receive a proportional share of capitation and episodic payments related to savings for the management of a specified patient population. Physical therapists traditionally have been paid reduced fee-for-service rates in an Accountable Care Organization (ACO) model. While physical therapists are not excluded from participation, when payment occurs under an episodic or capitated model there is no mandate that the physical therapy provider receives a proportional share of the savings. Physical therapists should have access to reward and risk opportunities like other participating providers.
2. When a medical group is paid under an APM there should be an opportunity for providers *not employed by that medical group under the In-Office Ancillary Services (IOAS) exception* to participate in a fair bidding process to participate in the APM. PPS recommends that OIG establish criteria to qualify for bidding eligibility. If the IOAS exception is to continue then it is only appropriate to empower non-owned entities to prove their value via outcomes, provider interoperability, and cost.
3. The IOAS exception inherently restricts patient choice as there is an incentive to refer in-house; however, under an APM an objective criteria is used to evaluate the participants providing the care. At minimum, providers who participate in the Quality Payment Program (QPP) and score above the performance threshold (proposed to be 30 for 2019) should be eligible to bid and participate in local ACOs and APMs that are controlled by health systems and medical groups. PPS suggests this with the goal of leveling the playing field. The QPP is intended to provide an assessment of value across all settings. Facilitating this change would allow physical therapy providers to participate on a contractual basis regardless of their practice type or employment relationships with a group functioning under an APM.

Question D: Please share thoughts on definitions for critical terminology
PPS suggests that the OIG establish definitions for "outcomes-based care," and "value-based care" to aid in the assessment of value-based care models and ensure that stakeholders, providers, and patients have a clear understanding of terms which are essential in measuring quality of care as well as the success of models which seek to promote and reward care coordination.

We recommend that the OIG define "health outcomes" using the construct described by the World Health Organization (WHO). WHO defines health as "the state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[1] To achieve this, a healthy society must establish and sustain conditions, including a healthful natural and constructed environment, as well as equitable social and economic policies and institutions, that ensure the "happiness, harmonious relations, and security of all [its] peoples."[2] Positive health outcomes for people include not only being alive but also functioning well mentally, physically, and socially, and having a sense of well-being. "Outcomes-based care" should follow these principles to measure whether or not health outcomes have been achieved.

We recommend that the OIG define "value-based care" as it is most typically described in health care as the health outcomes achieved per dollar spent.[3]

Section 2: Beneficiary Engagement

A: Beneficiary Incentives

Question A(i): Please provide feedback regarding the types of incentive providers, suppliers, and other are interested in providing to beneficiaries, how providing such incentives would contribute to or improve the quality of care, care coordination, and patient engagement…
As small business owners of outpatient therapy clinics who rely upon our reputation for providing high quality care in order to insure a thriving business, PPS appreciates that the OIG is concerned about the types of incentives which could be provided to beneficiaries and the implications of such. We are concerned that the use of beneficiary inducements could create a considerable imbalance where the largess of corporate entities could enable them to unduly influence patient choice.

Instead, PPS suggests that OIG could work with CMS to objectively identify high performing providers who have demonstrated superior outcomes and cost savings, and then publish a list of those "preferred providers" online. CMS could produce this objective standard by using its

[1] Preamble to the constitution of the World Health Organization. Geneva (CH): World Health Organization; 1946.
[2] Stiglitz JE, Sen A, Fitoussi J-P. Report by the Commission on the Measurement of Economic Performance and Social Progress. Paris (FR): Commission on the Measurement of Economic Performance and Social Progress; 2009.
[3] Porter M. What is Value in Health Care? N Engl J Med 2010; 363:2477-2481

Common Working File data to study injuries by diagnosis and payment by Employer Identification Numbers. While data mining can be flawed, one thing that could positively impact Medicare's bottom line would be the ability to sort average costs of treating types of injuries. This should be less challenging to achieve with ICD-10 in place. For example, using a diagnosis like Lumbago-M54.15, data could be mined by market areas. Using statistical data, CMS could determine a bell-shaped curve for how many visits were used during an episode of care and the total cost of treatment. If a particular therapy provider is able to demonstrate the ability to achieve consistent results at a lower cost than the average, CMS could identify them as a "preferred provider". Preferred providers could then be allowed the special privilege of offering beneficiary incentives—within the existing limits OIG General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries.[4]

The providers highlighted as "preferred" would be those who are saving taxpayer money, providing positive outcomes and, reducing avoidable readmissions. CMS would publish the information, but not mandate that patients receive care at one of the highlighted clinics. This kind of transparency would increase the quality of information by which a patient could make an educated choice about where to seek care. An additional benefit would be that if other facilities notice that their number of Medicare beneficiary patients was dropping, it would encourage them to learn why and take action to change their care in a positive way.

Should the described tool be available, beneficiaries could then search for and learn why clinicians in their area are receiving a "preferred provider" certification from CMS. Using a system like this, Medicare could ensure beneficiaries' free choice to receive their care where they see fit, while simultaneously inducing patients to choose treatment with objectively identified "preferred providers" by reducing or eliminating the beneficiary's coinsurance, deductible, and copay amounts. This would provide patients with incentive to use a provider that is demonstrating care that is consistently cost effective and of high quality. Additionally, the Medicare program could elect to remove (from the program) or scrutinize providers that are consistently performing well below these episodic averages.

Furthermore, CMS could also make this information available to providers so that they may research their competition. For example, if treatment costs are varying significantly in a particular market area, providers might target growth into those areas where they think they can beat the competition by providing a better service at a lower cost. Providers would assess their competitive advantages and disadvantages and continually evaluate their businesses; they would learn, develop, grow, and improve in order to maintain or improve market share. This would be the case in rural, suburban, and urban communities.

[4] OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), available at https://oig.hhs.gov/fraud/docs/alertsandbullitens/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf

Question A(i)(a): What, if any, restrictions should OIG place on the sources, types, or frequency of beneficiary incentives that could be provided to reduce the risk of fraud and abuse?

PPS strongly suggests that steps be taken to ensure patients are fully aware of both the limitations and benefits they will have agreed to upon accepting a beneficiary incentive. We suggest that OIG and CMS create a standard disclosure form, written in plain language, that is fully explained to the beneficiary before they accept an incentive in exchange for seeking treatment with a specific provider or at a specific facility.

PPS urges caution when creating a model which would allow companies, hospitals, or clinics to incentivize potential patients to choose one provider over another. PPS believes it is paramount that providers not be allowed to offer incentives to beneficiaries that can induce patients to obtain their rehabilitation therapy from a participant practice or other specific suppliers and providers. An entities' ability to provide incentives would clearly reflect their ability to spend money to increase patient volume but would not necessarily have any correlation with the quality of care the patients would receive. Furthermore, were incentives to be allowed it would certainly favor larger companies and practices over smaller or independent providers who don't have the extra funds available for incentives such as nominal cash incentives or gift cards.

Question A(i)(a): What, if any, disclosures should the OIG require the offeror to make to beneficiaries regarding an incentive?

PPS recommends that OIG establish policies to increase transparency in all aspects of physician referrals and patient choice. At minimum, physicians should be required to provide beneficiaries a written list of the local providers from whom they can choose to receive their rehabilitation therapy. Physicians and other health care professionals should be required to hold face-to-face-discussions with patients on their options for how and where to receive ancillary services such as physical therapy. Additionally, PPS requests that OIG ensure that physicians disclose to the patient, in clear terms, their financial interest in the service for which the patient is being referred and incentivized to utilize. Patients should receive written notification of their beneficiary rights under Medicare, including their right to refuse self-referred services and select an alternative provider, as well as the benefit that the provider acquires upon increasing their patient volume (through the offering of incentives).

As OIG formulates how best to achieve responsible transparency, the Agency should evaluate what data and disclosures may be necessary to help patients make an informed decision about why they might be offered an incentive and from whom they wish to receive their physical therapy, including:

1. The cost of the service to the Medicare program and to the patient (comparing self-referred, incentive-giving, and providers independently chosen by the beneficiary);
2. The amount the provider is earning for providing the service (comparing self-referred, incentive-giving, and providers independently chosen by the beneficiary);
3. How soon the service commenced post-referral (comparing self-referred, incentive-giving, and providers independently chosen by the beneficiary);
4. Utilization (on average, how many visits did the patient require);
5. Patient outcomes (how did the therapy impact the patient's function);

6. Patient satisfaction (comparing self-referred, incentive-giving, and providers independently chosen by the beneficiary).

B: Cost-Sharing Obligations

Question B(ii): Please describe the financial impact on providers, suppliers, and other entities, as well as the frauds and abuse risks, if cost-sharing amounts could be waived.

Instead of empowering the provider to shoulder the cost-sharing amounts, OIG should empower CMS to be the entity which would provide incentives for patients to choose high quality care that is provided at a lower cost. Patient incentives could be in the form of reduced or waived deductibles, coinsurance, and copays when they obtain care from those facilities who have demonstrated the ability to provide quality care at a lower cost. However, should a model allow for beneficiary incentives in the form of reduced financial obligations, it would need to simultaneously ensure that participating providers were provided with an assured income stream that would not result in a net loss. Without that assurance, it would be difficult to find providers willing to participate.

Section 4: Intersection of Physician Self-Referral Law and Anti-Kickback Statute

Question: Please share any feedback regarding specific circumstances in which (i) exceptions to the physician self-referral law and safe harbors to the anti-kickback statute should align for the purposes of the goals of this RFI; and (ii) exceptions to the physician self-referral law in furtherance of care coordination or value-based care should not have a corresponding safe harbor to the anti-kickback statute.

As the Administration seeks to modernize the anti-kickback statute, PPS recommends OIG revisit the In-Office Ancillary Services (IOAS) exception found at 42 CFR 411.355(b). The IOAS exception allows physicians to self-refer patients to care provided by a clinician who is who is employed by and is providing care within that physician group practice—this includes physical therapy provided by a physical therapist. The IOAS exception includes a number of designated health services (DHS) and was intended to improve coordination of care by allowing physicians to self-refer for DHS which are integral to primary care.

However, the IOAS exception has been broadly applied and poses risks of abuse and waste for the Medicare program. Noting the rapid growth of services covered by the exception and evidence that these services are sometimes furnished inappropriately by referring physicians, the Medicare Payment Advisory Commission (MedPAC) stated that physician self-referral of ancillary services creates incentives to increase volume under Medicare's fee-for-service payment systems and the rapid volume growth contributes to Medicare's rising financial burden on taxpayers and beneficiaries.

Another rationale for including physical therapy in the IOAS exception list was to offer convenience to patients. However, a patient rarely receives physical therapy services during a regularly scheduled physician visit. MedPAC's *Report to the Congress: Aligning Incentives in*

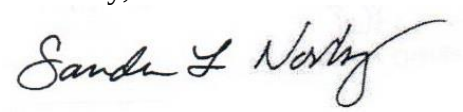
Medicare[5] determined that only 3 percent of outpatient physical therapy services were provided on the same day as an office visit, only 9 percent within 7 days of an office visit, and only 14 percent within 14 days of an office visit. These services are not integral to the physician's initial diagnosis and do not improve patient convenience because patients must return (and not necessarily to the same location) for physical therapy treatments. The misapplication of this exception to self-refer patients to physical therapy has led to the overutilization of physical therapy services by physicians with ownership interests in physical therapy practices, which in-turn negatively impacts the quality of care furnished to patients when that care is self-referred. These unintended consequences pose an ongoing risk to the quality of patient care and the financial security of the Medicare program.

PPS requests that OIG support and work internally at the Department of Health and Human Services as well as with Congress with the goal of revising the IOAS policy so that physical therapy is removed from the exception and is thereby subject to the anti-kickback prohibitions as well as Stark Law's prohibitions on provider self-referral. PPS further suggests that OIG should clarify in future rulemaking that physical therapy does not qualify as a designated health service and the IOAS exception should only apply to those services (such as diagnostic services and specific durable medical equipment use) which are truly begun and completed the same day as the physician visit.

Conclusion

PPS appreciates the opportunity to respond to OIG's request for information about factors to consider when deliberating how to modernize the anti-kickback statute. We hope our insight and perspective on how these policies impact patients as well as program integrity will be helpful as the OIG considers making changes which will support the increased utilization of value-based payment models while improving patient outcomes. Additionally, while OIG might not have been considering how the anti-kickback statute applies to rehabilitation therapy, we hope that our comments were able illustrate how the IOAS impacts Medicare beneficiaries, our members, and their outpatient physical therapy clinics. We look forward to future conversations about how to balance the integration necessary for bundled payment programs with self-referral prohibitions that protect patients as well as the financial integrity of the Medicare program.

Sincerely,



Sandra Norby, PT, DPT
President, Private Practice Section of APTA

[5] Report to the Congress: Aligning Incentives in Medicare, Chapter 8 "Addressing the Growth of Ancillary Services in Physician's Offices", *MedPAC*, June 2010, https://www.aacom.org/docs/default-source/grad-medical-education/jun10_entirereport.pdf?sfvrsn=2.