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August 24, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Attention: CMS–1720–NC

***Submitted electronically***

RE: Medicare Program; Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

On behalf of the nearly 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 Center for Medicare & Medicaid Services (CMS) request for information (RFI) regarding the Physician Self-Referral Law that was published in the Federal Register on June 25, 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 RFI published by CMS 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 CMS 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 physician self-referral law's restrictions while modernizing the regulations to support value-based reimbursement can be met while also protecting a Medicare beneficiary 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 CMS to consider the following recommendations when deciding how to use its regulatory authority to modernize and reform physician self-referral limitations. 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.

**Question 1: Please tell us about either existing or potential arrangements that involve designated health service (DHS) entities and referring physicians that participate in alternative payment models or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS.**

As CMS has expressed a strong interest in modernizing the physician self-referral restrictions in order to facilitate and support increased use of bundled payment and shared savings/risk models, PPS recommends that CMS facilitate the participation of ancillary services such as physical therapy in such models. The Agency could do so 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 CMS 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 6: Please share your thoughts on possible approaches to address the application of the physician self-referral law to financial arrangements among participants in alternative payment models and other novel financial arrangements.**

Please see the answer to question 1 where PPS suggests how CMS could implement incentives for physical therapy providers to participate in APMs and how participation in shared-risk financial arrangements could address disparities that otherwise exist because of the IOAS exception.

**Question 15: Please identify any provisions, definitions, and/or exceptions in the regulations at 42 CFR 411.351 through 411.357 for which additional clarification would be useful.**

As CMS seeks to modernize the physician self-referral law, PPS recommends that the Agency 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 physical therapy provided by a physical therapist who is employed by and is providing care within that physician group practice. The IOAS exception includes a number of designated health services (DHS) and was intended to improve coordination of care and promote patient convenience by allowing physicians to self-refer for DHS which are integral to primary care.

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.

The 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. Furthermore, MedPAC's *Report to the Congress: Aligning Incentives in Medicare*[1] 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 CMS support and work 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 Stark Law's prohibitions on provider self-referral. PPS further suggests that CMS should clarify in

[1] 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.

future rulemaking that physical therapy does not qualify as a designated health service and the Agency should tailor the IOAS exception to apply to only 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.

**Question 16: Please share your thoughts on the role of transparency in the context of the physician self-referral law.**

Because of the IOAS exception, a physician is allowed to self-refer physical therapy patients to providers with which he/she has a financial interest. Furthermore, because of this permission, a physician has no real incentive to refer patients out-of-system to independent rehabilitation professionals who have clinical expertise specific to the outcome desired for their patients or may be more cost-effective and achieve higher functional outcomes for their patient populations. Medicare beneficiaries are also negatively impacted. At one end of the spectrum, patients are often unaware that they have full freedom to choose where to receive their follow-on care; more egregiously, patients are often instructed by their physician that if they didn't go to their in-house physical therapist they would have to find another physician. Therefore, PPS believes that greater emphasis must be placed on ensuring that patients are made aware not only of their options, but of the financial interest their physician may have in the referral. When patients receive sufficient information to make an informed decision about their care this greater transparency in the physician-referral process can also reduce the risk of waste and abuse.

PPS therefore recommends that CMS establish policies to increase transparency in physician referrals. 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 and 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 CMS ensure that physicians disclose to the patient, in clear terms, their financial interest in the service for which the patient is being referred and 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 CMS formulates how best to achieve responsible transparency, the Agency should evaluate what data may be necessary to help patients make an informed decision about from whom they wish to receive their physical therapy, including:

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

Finally, PPS recommends that CMS consider mechanisms through which it can better monitor physical therapy services furnished by a physical therapist in a physician-owned physical therapy

practice versus those provided in a physical therapist private practice (PTPP). Frequently, it is not possible to discern these differentiations in billing locations, thus skewing the data and seemingly inflating the number of PTPPs. One such option would be to require the use of a place of service code, such as 49 indicating an independent clinic, to designate where the referred patients received care. This data is necessary to monitor utilization of self-referred physical therapy services, aberrant billing patterns, and impact of self-referred services on patient outcomes. It is imperative that CMS expand its capability to collect patient outcomes data for self-referred services.

**Question 19: Please identify any recent studies assessing the positive or negative effects of the physician self-referral law on the healthcare industry.**

The following four studies have found that physician self-referral of certain designated health services such as physical therapy led to overutilization and reduced quality of care:

1. A *Forum for Health Economics and Policies* study found that non-self-referred episodes of care were far more likely to provide "active," or hands-on services (such as evaluation, therapeutic exercise, and gait training) than self-referral episodes—52% compared with 36%.[2] According to the study's authors, this suggests the care delivered by physical therapists in non-self-referred episodes is more tailored to promote patient independence and a return to performing routine activities without pain. The study also highlights the difference in overall expenditures for episodes of care between self-referring and non-self-referring physicians. For example, the study examines the total insurer-allowed amounts for low back pain episodes of care and parses out expenditures on physical therapy only; on average, spending for services by self-referring providers was $144 as opposed to only $73 for services by non-self-referring providers. This is a significant difference for a common episode of care.

2. *Health Services Research* published a study examining the use of physical therapy following total knee replacement surgery.[3] This study also showed that patients treated by physicians with a financial self-interest in follow-up therapy received less hands-on, active, and one-on-one care than patients who were treated by physicians who have no financial interest in the follow-up therapy; these self-referral patients received more palliative modalities such as ultrasound, electrical stimulation, and massage. The IOAS exception provides an incentive to extend care for more visits while billing less-intensive therapy codes that do not necessarily expedite patient recovery.

3. The *Government Accountability Office*'s June 2014 "Medicare Physical Therapy: Self-Referring Providers Generally Referred More Beneficiaries but Fewer Services per

[2] Mitchell J. Physician Self-Referral of Physical Therapy Services for Patients with Low Back Pain: Implications for Use, Types of Treatments Received and Expenditures. *Forum for Health Economics and Policies*. 2015; 19(2): 179-199.
[3] Mitchell J. Use of Physical Therapy Following Total Knee Replacement Surgery: Implications of Orthopedic Surgeons' Ownership of Physical Therapy Services. *Health Services Research*. 2016; 51(5): 1883-1857.

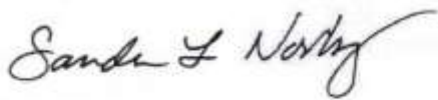
Beneficiary" (GAO-14-270)[4] revealed that patients who were self-referred by family practice providers and internal medicine providers received more passive treatment and less hands-on care, the latter of which is more indicative of appropriateness of physical therapy for restoring a patient's functional ability. The GAO also found that once physicians become financially involved with physical therapy services their referral frequency dramatically increases, by as much as 33 percent. This demonstrates capitulation to the perverse incentive of physician ownership of physical therapy practices. GAO expressed concern that in these instances not all physical therapy services may be medically necessary.

4. As mentioned in response to question 15, a *MedPAC* report regarding the growth of ancillary services in physician's offices[5] points out that physical therapy services are not completed the same day, or in a single day for that matter. Furthermore, MedPAC found 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. Ancillary services such as physical therapy are not integral to the physician's initial diagnosis process and do not improve patient convenience because patients must return for physical therapy treatments.

**Conclusion**

PPS appreciates the opportunity to respond to CMS' request for information about factors to consider when deliberating how to modernize the physician self-referral restrictions. We hope our insight and perspective on how these policies impact patients as well as program integrity will be helpful as the Agency considers making changes which will support value-based payment models while improving patient outcomes. Additionally, while CMS might not have been considering how the physician self-referral provisions apply to rehabilitation therapy, we hope that our comments were able to help CMS see how the IOAS impacts Medicare beneficiaries as well as 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,



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[4] MEDICARE PHYSICAL THERAPY: Self-Referring Providers Generally Referred More Beneficiaries but Fewer Services per Beneficiary. *MedPAC.* April 2014. https://www.gao.gov/products/GAO-14-270.

[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.