American Physical Therapy Association

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Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
Attn: CMS-1720-NC
200 Independence Ave, SW
Washington, DC 20201

Submitted electronically

RE: Medicare Program; Request for Information Regarding the Physician Self-Referral Law [CMS-1720-NC]

Dear Administrator Verma:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) Regarding the Physician Self-Referral Law (Stark Law). The mission of APTA is to build a community to advance the physical therapy profession to improve the health of society. Physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability by serving as a dynamic bridge between health and health services delivery for individuals across the age span. While physical therapists are experts in rehabilitation and habilitation, they also have the expertise and the opportunity to help individuals improve overall health and prevent the need for otherwise avoidable health care services. Physical therapists' roles may include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

APTA supports excluding physical therapy services from the in-office ancillary services (IOAS) exception under the physician self-referral law. The expansive use of the IOAS exception by physicians in a manner not originally contemplated by the law undercuts the purpose of the law

and substantially increases costs to the Medicare program and its beneficiaries. This IOAS exception was created to recognize that in some cases patient convenience may justify the risks that are inherent in self-referral. However, permitting physicians to self-refer for physical therapy treatment is no more convenient for a patient than receiving services in another treatment facility in which the physician has no financial ties. APTA believes that this issue should be addressed as part of any fundamental delivery system reform and that it could provide cost savings to help support reform.

We appreciate the opportunity to provide CMS feedback in regards to the physician self-referral law. Please find below our detailed comments responding to the agency's RFI.

General Recommendations

APTA recognizes the need to modify the Stark Law to enable value-based care arrangements that coordinate care, improve quality, and reduce unnecessary costs. However, it is important to ensure that these arrangements do not pose a risk of program or patient abuse. We have concerns that modifications to the self-referral law could potentially result in abusive financial arrangements that may skew incentives. Section 1877(b)(4) of the Social Security Act has always required that a permanent regulatory exception to the physician self-referral law be established only when it is clear that the exception can pose "no risk of program or patient abuse."

One of the biggest loopholes that result in abusive financing arrangements that are created solely for profit without regard to the best interest of the Medicare beneficiary is the IOAS exception of the Stark Law. The IOAS exception is intended to improve coordination of care and promote patient convenience by allowing physicians to self-refer for designated health services integral to primary care that are furnished in their group practices. The intent was to ensure patient can receive efficient and cost effective care, in particular same day services. APTA has concerns, however, that the current use of this exception goes well beyond its original intent, specifically in regards to physical therapy. While including physical therapy in the IOAS exception list was intended to offer convenience to patients, it is incredibly rare for a patient to receive physical therapy services during a regularly scheduled physician visit. Instead, the patient makes an appointment subsequent to the physician visit.

The IOAS exception has been inappropriately applied to physical therapy services, which are not same-day services and *should* be subject to the Stark Law's cornerstone protections. Therefore, we request that CMS work with Congress to remove physical therapy from the list of designated health services under the IOAS exception.

1. **Please tell us about either existing or potential arrangements that involve 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. Please include a description of the alternative payment model(s) and novel financial arrangements if not sponsored by CMS. We recommend that you identify concerns regarding the applicability of existing exceptions to the physician self-referral law and/or the ability of the arrangements to satisfy the requirements of an**

existing exception, as well as the extent to which the physician self-referral law may be impacting commercial alternative payment models and novel financial arrangements.

APTA's member physical therapists participate in a number of alternative payment models (APMs) and other value-based payment arrangements. We support the direction in which CMS is moving to increase flexibility for the creation of financial arrangements essential to value-based payment models. As CMS establishes new APMs, APTA urges the agency to establish a policy that ensures that participating nonphysician providers will receive a proportional share of the Medicare savings. For instance, physical therapists who participate in value-based payment models to manage the health of a specific patient population (e.g., providing ongoing physical therapy to orthopedic patients to reduce further deterioration and/or the need for joint replacement) do not receive a proportionate amount of the shared savings generated by the model, although these services are integral to the models' success in increasing value and reducing costs to patients.

We support CMS's efforts to establish a growing number of models in which physical therapists may participate and share in the savings achieved by the model. To that end, we urge CMS to consider reforms to the physician self-referral law that allow for the equitable distribution of shared savings particularly in episodic or capitated models, which currently are not required to distribute a proportionate amount of shared savings to nonphysician providers, like physical therapists.

Additionally, APTA suggests that CMS evaluate the unintended consequences of the IOAS exception and its impact on care furnished under value-based payment models. For example, under the current law, medical groups participating in APMs have no incentive to refer patients to care that is not self-referred. Instead, there is an incentive for physicians to direct patients to physician-owned facilities, which may not be able to provide the most effective and valuable care to the patient. We encourage CMS to explore alternatives to increase fairness and transparency in the physician referral process, particularly for physicians in medical groups that operate in APMs. For instance, CMS could consider implementing a fair bidding process for providers and facilities with which the referring physician has no ownership interest. These non-affiliated providers and facilities would then have an opportunity to bid for participation in the APM based on criteria which include cost, value of care, and interoperability. The bidding process would ensure that APM physicians refer patients to high quality and cost-effective providers. It also would minimize the risk for program and patient abuse that may result from self-referrals.

As we discussed in greater detail under our *General Recommendations* above, the inclusion of physical therapists and other providers in the IOAS exception restricts patient choice and incentivizes physicians to self-refer patients to providers who may deliver lower value, higher-cost care, in an effort to further their own financial interests. We urge CMS to establish quality thresholds for self-referred services to protect from patient abuse and unnecessary Medicare spending.

2. Please share your thoughts on the utility of the current exception at 42 CFR 411.357(n) for risk-sharing arrangements.

We support the current exception at 42 CFR §411.357(n), particularly as federal health care programs move towards value-based payment, rather than volume. To ensure optimal quality of care, it is imperative to establish risk-sharing arrangements between providers within a value-based care model. We support the continued application of this exception so long as it is clearly tied to arrangements necessary to form and operate APMs and similar care models. APTA looks forward to working with CMS to ensure that physicians use these arrangements to improve quality of care and encourage coordinated care across a variety of health care providers.

3. Please identify and suggest definitions for other terminology relevant to the comments requested in this RFI.

APTA suggests that CMS establish definitions for "value" as well as "outcomes" to aid in the assessment of value-based care models and ensure that stakeholders, providers, and patients have a clear understanding of these terms which are essential in measuring quality of care and the success of models like APMs.

We recommend that CMS define "value" as it is most typically described in health care as the health outcomes achieved per dollar spent.[1]

Finally, we recommend that CMS 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."[2] To achieve this vision of health for its members, a healthy society must establish and sustain conditions, including a healthful natural and built environment, and equitable social and economic policies and institutions, that ensure the "happiness, harmonious relations, and security of all [its] peoples."[3] Positive health outcomes for individuals include being alive; functioning well mentally, physically, and socially; and having a sense of well-being.

4. 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 reevaluates the physician self-referral law, APTA recommends that the agency revisit the IOAS exception at 42 CFR §411.355(b), which allows physicians to self-refer patients to physical therapy when the physical therapist is providing care within the physician group practice. While this exception is intended to improve coordination of care and promote patient convenience by allowing physicians to self-refer for designated health services integral to primary care, the broadly applied exception poses risks for program and patient abuse. Including physical therapy in the IOAS exception list was intended to offer convenience to patients; however, it is incredibly rare for a patient to receive physical therapy services during a regularly scheduled physician visit. The misapplication of this exception to self-refer patients to physical

[1] Porter M. What is Value in Health Care? N Engl J Med 2010; 363:2477-2481
[2] Preamble to the constitution of the World Health Organization. Geneva (CH): World Health Organization; 1946.
[3] 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.

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. We therefore request that CMS work with Congress to revise the IOAS exception and remove physical therapy from the list of designated health services to which physicians may self-refer. CMS should clarify in future rulemaking that physical therapy does not qualify as a designated health service and should tailor the exception to apply to only true same-day services such as diagnostic services and medical equipment.

5. **Please share your thoughts on the role of transparency in the context of the physician self-referral law. For example, if provided by the referring physician to a beneficiary, would transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address?**

APTA recommends that CMS establish policies to increase transparency in physician referrals, particularly when physicians refer to services in which they have a financial interest. Physicians should be required to disclose to the patient, in clear terms, their financial interest in the service for which the patient is being referred. Beyond the physician's disclosure, the patient should be provided with clear options to refuse self-referred services and select an alternative provider. As CMS considers this policy, the agency should also take into account what data may be necessary to help patients make an informed decision on where and from whom they wish to receive ancillary services, including:

- Cost of the service, whether self-referred or not
- Timeliness of the service (when could the service be furnished, whether self-referred or not)
- Patient outcomes and/or patient satisfaction (how did the service impact the patient's condition; on average, how many visits will the patient require (if a therapy service)

Greater transparency in the physician-referral process can reduce the risk for patient abuse so long as patients receive sufficient information to make an informed decision about their care. CMS also should consider educating physicians on adequate methods to share referral information with patients, and require physicians and other health care professionals to hold face-to-face-discussions with patients on their options to receive ancillary services, such as physical therapy.

Finally, we recommend that CMS consider mechanisms by which it can better monitor physical therapy services furnished by a physical therapist in a physician-owned physical therapy practice versus 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. 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.

6. **Please share your thoughts on whether and how CMS could design a model to test whether transparency safeguards other than those currently contained in the physician self-referral law could effectively address the impact of financial self-interest on physician medical decision-making.**

APTA recommends that CMS test transparency safeguards to increase information sharing between physicians and patients. CMS should design a model that would require physicians to disclose any financial relationships that they have with providers to whom they refer patients to. Also under this model, CMS should require physicians to include in their required disclosures price and quality scoring information on the providers to whom they refer patients. This would better allow patients to make informed decisions about their care, and exercise their choice to receive care outside of their physician's practice group.

APTA also suggests that CMS establish a pilot or demonstration to monitor the differences in health outcomes and Medicare spending between patients who receive ancillary care from providers with financial arrangements with the referring physician, and those patients who receive ancillary services from providers with no financial arrangements with the referring physician. CMS could ultimately rely upon this data as it implements reform to the physician self-referral law to protect patients and federal health care programs from abuse, while still allowing flexibility for physicians and other providers who convene and participate in APMs and value-based care models.

7. **Please share your thoughts regarding whether CMS should measure the effectiveness of the physician self-referral law in preventing unnecessary utilization and other forms of program abuse relative to the cost burden on the regulated industry and, if so, how CMS could estimate this.**

APTA recommends the HHS Office of Inspector General (OIG) conduct a more periodic review of utilization rates of health care services to monitor programmatic abuse as it relates to the physician self-referral law. Particularly as CMS moves to increase flexibility under the physician self-referral law to allow for greater participation in APMs, we urge the agency to collect ongoing data on the financial impacts of the rule and its exceptions.

We suggest that CMS, by way of the HHS OIG, monitor the differences in patient outcomes as well as Medicare spending between patients who receive physician self-referred ancillary care and those patients who receive ancillary services from providers with no financial arrangements with the referring physician. CMS should use these findings to inform future reforms to the physician self-referral law to prevent programmatic and patient abuse.

Conclusion

APTA thanks CMS for the opportunity to provide feedback in response to the RFI regarding the physician self-referral law. We look forward to working with the agency to reduce regulatory

burden and craft new payment models that improve the quality of patient care while also ensuring that the models preserve access to quality rehabilitation services. Should you have any questions regarding our comments, please contact Kara Gainer, Director of Regulatory Affairs, at karagainer@apta.org or 703/706-8547.

Thank you for your consideration.

Sincerely,

Sharon L. Dunn, PT, PhD
Board-Certified Clinical Specialist in Orthopaedic Physical Therapy
President

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