December 31, 2019

CMS Administrator Seema Verma
HHS Secretary Alex M. Azar II
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1720-P – Proposed rule: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma and Secretary Azar:

On behalf of the American Academy of Sleep Medicine (AASM), I am submitting comments in response to CMS-1720-P, a proposed rule that would modernize and clarify the physician self-referral regulations in the Medicare program. The AASM is a professional society that represents a membership of 11,000 physicians, scientists, allied health professionals, and accredited sleep centers. The AASM is the leader in setting standards and promoting excellence in sleep medicine health care.

The AASM applauds the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for attempting to address the burdensome impact of the physician self-referral law, commonly known as the "Stark Law." The CMS proposed rule offers a reprieve to some patients and physicians who have been harmed by the fragmented care caused by the Stark Law. Consistent with many other organizations, the AASM urged CMS to reform or greatly alter the law via rule in our August 2018 response to the CMS request for information. The AASM also encouraged the agency to establish exceptions for board-certified sleep medicine physicians who provide care for Medicare patients with obstructive sleep apnea (OSA) and for those physicians participating in alternative payment models. By allowing exceptions for innovative payment models such as value-based arrangements, CMS is taking a step in the right direction to improve patient-centered care for Medicare beneficiaries.

However, because fee-for-service payment models continue to abound, the proposed rule does little to address the fragmented care experienced by most Medicare patients who have OSA, a chronic disease that afflicts about 30 million Americans, including an estimated 20% to 30% of the Medicare

population. The current iteration of the law under the proposed exceptions will still lead to fragmented care for the millions of patients with OSA who require treatment with positive airway pressure (PAP) therapy, a type of durable medical equipment (DME) that keeps the airway open throughout the night so patients can obtain a healthy, restorative night's sleep with minimal breathing interruptions. Only a small minority of patients with OSA whose physicians and/or health care organizations are part of an accountable care organization (ACO) or alternative payment model (APM) will benefit from the proposed rule. Excluded patients will include those who receive care from smaller practices that can't take on the added financial risk or from rural practices that do not qualify for an existing waiver.

Overall, the definitions included in the proposed rule seem clear. However, while we note that it is not necessary to revise the definition of value-based arrangement to require care coordination and management, we advise that it would be helpful to define care coordination and management. The proposed definition, which aligns with the definition under consideration by the Office of the Inspector General (OIG), seems appropriate.

CMS also requested feedback as to whether it would be helpful to require that the purpose of the value-based enterprise is to improve quality or maintain an "already-improved" quality of care for the target patient population. Maintaining an existing improvement in quality of care would help providers and organizations that already have begun the work of implementing quality initiatives to improve patient care. The already improved quality of care for the target patient population may be demonstrated through a review of performance rates for relevant quality measures and/or improved outcomes, as demonstrated in changes in scores from patient-reported outcome measures.

Additionally, it is reasonable to require that performance or quality standard measurements are objective, measurable, and identified in advance of implementation. However, requiring that changes to the performance or quality standards must be set forth in writing will create a huge burden for measure stewards, who are already submitting measure updates to providers, registry vendors, electronic health record (EHR) vendors, and payers (including CMS). If measures are included in the Quality Payment Program, it would be helpful for any updates to be communicated within CMS to remove additional burden from measure stewards. For measures not included in the Quality Payment Program, we suggest a structured annual update process during which measure stewards may submit measure updates (e.g., code changes, measure language, definitions).

In proposing that the target patient population that is the focus of value-based activities be identified using "legitimate and verifiable criteria," CMS is also seeking comment as to whether a non-exhaustive list of selection criteria that would or would not be legitimate and verifiable be specified in regulation text. Alternative payment models generally include inclusion criteria, exclusions, exit criteria/exceptions, and more elaborate risk adjustment models. It is unclear whether these components would impact how target populations would be considered legitimate and verifiable. However, if the "legitimate and verifiable" criterion is finalized, then it would be helpful for CMS to provide either definitions or a non-exhaustive list of criteria, along with specific guidance regarding these components.

While the AASM continues to advocate that board-certified sleep medicine physicians need a Stark Law exception to provide PAP therapy directly to Medicare patients with OSA, we recognize and appreciate the actions of the agency to address and change the status quo. The AASM commends CMS for its efforts to reform outdated policies and promote patient-centered care within the Medicare program. The AASM appreciates the opportunity to comment on the barriers created by the physician self-referral law, which prevents sleep physicians from being able to provide evidence-based, high quality care to their patients who have OSA.

We urge CMS to use the AASM as a resource while you continue to review the current state of the Stark Law. Please contact the AASM Advocacy Program Manager at 630-737-9700 or policy@aasm.org.

I thank you for your consideration of these comments.

Sincerely,

Kelly A. Carden, MD, MBA
President