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August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1720-NC - CMS Request for Information Regarding the Physician Self-Referral Law (Stark Law)

DIRECTORS

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Steve Van Hout
Executive Director

Dear Administrator Verma:

I am contacting you on behalf of the American Academy of Sleep Medicine (AASM), which represents over 10,000 sleep medicine practitioners and accredited sleep centers. The AASM improves sleep health and fosters high-quality, patient-centered care through advocacy, education, strategic research and practice standards. The AASM commends you for voicing your openness to reforming the Stark Law - a law that has created a barrier to quality care for Medicare patients with obstructive sleep apnea (OSA) since its inception in 1989.

While well-intended in its mission, the Stark Law is outdated and incompatible with today's goal of providing value-based health care. The law is an example of the red tape that constrains medical professionals, independent clinics, and hospitals from devising innovative care models to promote cost savings. By reforming the Stark Law to allow accredited sleep centers and board-certified sleep medicine physicians to be responsible for therapy, CMS can improve health outcomes for American Medicare patients, one of the most vulnerable patient populations in the country.

In the field of sleep medicine, the administrative and clinical burdens of the Stark Law are best exemplified in the clinical care pathway for treating OSA, a chronic disease that afflicts nearly 30 million Americans, including an estimated 20-30% of the Medicare population. The majority of OSA patients are treated with a positive airway pressure (PAP) machine, which keeps their airway open throughout the night, so they can obtain a healthy, restorative night's sleep with minimal breathing interruptions.

The effective treatment of sleep-disordered breathing may lessen or prevent other serious and potentially lethal comorbid conditions, such as heart disease, stroke, hypertension, type 2 diabetes and depression, which come at a high cost to Medicare. In fact, it is estimated that the effective treatment of OSA decreases a patient's chance of having a stroke by 31%, reduces their risk of a motor vehicle accident by 52%, and lowers their risk of having a heart attack by just under 50%.

The AASM believes that both Medicare patients and CMS would greatly benefit from an exception to the Stark Law for the treatment of sleep-disordered breathing, which would allow Medicare patients to obtain their therapeutic PAP device and receive direct oversight from their sleep physician or an accredited sleep center. Such an arrangement is currently accessible for patients covered by private insurers and should be available to the Medicare population as well, as they are deserving of the same level of quality medical care and oversight. Unfortunately, under the current restrictions of the physician self-referral law, these Medicare patients are receiving inferior and fragmented care for their OSA.

Today, once diagnosed with OSA by a sleep physician, the Stark Law forces patients to travel to a durable medical equipment (DME) supplier to obtain their PAP device. Rather than providing the most appropriate device and accessories to the patient, DME suppliers may be incentivized to choose inferior devices because they have a surplus inventory or have higher margins on them. When dispensing these devices, DME suppliers are supposed to fit patients with their PAP masks, set the device to the appropriate air pressure, and provide coaching for long-term use. However, patients frequently report that this assistance never occurs. Instead of receiving these crucial services from their physician and their supporting staff, patients begin use of their PAP device on their own or under the oversight of an individual with far less professional and educational experience, which can lead to decreased adherence and subpar treatment outcomes. This disconnect is particularly burdensome for rural patients with little access to a nearby DME supplier.

The AASM encourages HHS and CMS to mitigate barriers to PAP adherence in a similar manner to existing exceptions for other time-sensitive treatments. There is currently a Stark Law exception for the prescription drug, erythropoietin, used in outpatient dialysis treatment, as well as an exception for eye glasses and contact lenses following a cataract surgery. In these cases, there is not a wide-ranging exception for the practice of nephrology or for ophthalmology, but rather a targeted exception for a specific practice in which the patient requires a timely solution, one that the Stark Law would adversely complicate in normal circumstances. By receiving direct oversight and proper set-up from their sleep physician, patients with OSA will be more likely to utilize PAP therapy, reducing wasteful Medicare spending.

The AASM also advises CMS that an exception to the Stark Law should be made for all participants in Alternative Payment Models (APMs). Having different specialties develop and implement APMs supports the national shift toward value-based care and helps achieve the 'Triple Aim' of reducing costs while improving population health and the patient experience of care. However, the Stark Law can be an obstacle to implementing successful APMs, including one in sleep medicine. The AASM is

currently developing an APM for OSA that would include patient evaluation and diagnostic testing as well as additional encounters with several different members of the sleep team to review and interpret diagnostic test results, prescribe appropriate therapy, and monitor patient adherence over the first 6 months. Successful implementation of this model would allow OSA patients to receive the best evidence-based care possible from the most highly skilled individuals in the specialty. However, without an exception to the Stark Law for sleep-disordered breathing, it would be impossible for the AASM to implement an APM for OSA that would achieve the ‘Triple Aim.’

On behalf of the AASM, I appreciate 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, quality care to their patients who have OSA. As CMS reviews the current state of the Stark Law, please do not hesitate to use the AASM as a resource in your decision-making process. Please contact the AASM Advocacy Program Manager with any questions regarding this letter by phone at 630-737-9700 or by email at policy@aasm.org.

Sincerely,

Douglas B. Kirsch, MD
AASM President

cc: Steve Van Hout, AASM Executive Director