

August 24, 2018

Seema Verma Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1720-NC, Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

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

Dear Administrator Verma,

On behalf of more than 100,000 specialty physicians from 15 specialty and subspecialty societies, and dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care, the undersigned members of the Alliance of Specialty Medicine (the "Alliance") write in response to your request for information on addressing the undue regulatory impact and burden of the physician self-referral law.

Impact and Burden of the Physician Self-Referral Law on Specialty Engagement in Alternative Payment Model Development and Participation

Specialty physicians are an essential and needed component of the health care system and, particulary, in the Medicare program. Specialists use their deep knowledge and expertise to reach a precise medical diagnosis, present the full array of available interventions, collaborate closely with their patients to determine the most appropriate option based on their preferences and values, and coordinate and manage their specialty and related care until treatment is complete. The value of specialists cannot be overstated nor can it be replaced by any other type of clinician, provider, or health care professional.

With those sentiments in mind, the Alliance is concerned with the lack of alternative payment models (APMs), particularly those that qualify as "advanced" under the Quality Payment Program (QPP), in which specialists can meaningfully engage. In addition, we are concerned that specialists' attempts to develop APMs for certain conditions and procedures face insurmountable challenges, despite the pathway for their establishment under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). While there are a number of contributing factors for this, the Stark law is chief among them.

Some specialists tell us that, as they have attempted collaborative efforts to further engagement in quality improvement programs and efficient resource utilization for key Medicare services, they have met resistance from local hospital and health system administrators and attorneys concerned that such arrangements would prompt potential Stark law violations. For example, some collaborative efforts pursued by specialists sought to improve quality, better coordination of care, and reduce overall spending for a defined set of services across an episode; success under these arrangements would have

resulted in performance bonuses for participating specialists based on savings under the episode. However, these arrangements would have relied on the ability to only make referrals to high-quality, low-cost providers based on publicly-reported quality improvement data, and according to the hospital and health system attorneys, these referrals would have been potential Stark violations.

In another example, specialists have considered opportunities to demonstrate their value within an existing accountable care organization (ACO) through "drop-in bundles." These bundles aimed to reward the ACO and its specialist ACO participating clinicians when quality and resource use improved for a specific population of assigned beneficiaries, given the likelihood of a higher ACO shared savings payment. Because it was unclear whether such arrangements were covered by the existing waivers, the ACO's attorneys ended discussions.

We remind CMS that the Physician-Focused Payment Model Technical Advisory Committee (PTAC) continues to review models that are focused on specialty-driven care. While PTAC has provided favorable recommendations on the majority of models reviewed to date, the Secretary has not proceeded to implementation for a single model, and recent responses by the Secretary to PTAC recommendations suggest the majority of models, if not all, will never be tested. We encourage the new leadership at the Center for Medicare and Medicaid Innovation (Innovation Center) to redirect its resources in a way that will foster new models for a variety of specialists, enabling them to engage as meaningfully in alternative models of care and delivery as their colleagues in primary care, the care for which APMs have been predominately implemented. Furthermore, we urge the agency to proceed with testing and implementation of models recommended by PTAC.

Until that time, the only viable option for most specialists to engage in CMS' QPP is via the Merit-based Incentive Payment System (MIPS). Some specialists have an interest in moving toward alternative models of care and delivery, yet they are unable to overcome multiple hurdles, including the Stark law. We contend that APMs create strong incentives to protect the Medicare program and beneficiaires from unscrupulous provider behavior, as providers in these models must both improve quality and reduce resource use to avoid financial penalties and earn shared savings or bonus payments. CMS recognizes the strength of these incentives to deter abuse and gaming in the Medicare program, which is why participants of several APMs were included in CMS' recent pilot program to reduce medical record review. **Consistent with that appraoch, the Alliance urges CMS to exempt all participants of alternative models of care and delivery who bear financial risk from the Stark regulations.**

We appreciate the opportunity to share our concerns. Should you have any questions, please contact us at <u>info@specialtydocs.org</u>.

Sincerely,

American Association of Neurological Surgeons American College of Mohs Surgery American College of Osteopathic Surgeons American Gastroenterological Association American Society of Cataract and Refractive Surgery American Society of Dermatologic Surgery Association American Society of Echocardiography American Society of Plastic Surgeons American Society of Retina Specialists American Urological Association Coalition of State Rheumatology Organizations Congress of Neurological Surgeons North American Spine Society Society of Cardiovascular Angiography and Interventions