August 24, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC
7500 Security Boulevard
Baltimore, Maryland 21244-8013

Submitted electronically via www.regulations.gov

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

Dear Administrator Verma:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services’ (CMS) request for input: Medicare Program; Request for Information Regarding the Physician Self-Referral Law published in the Federal Register on June 25, 2018. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Given the efforts of the health care industry to invest in the development of alternative payment models (APMs) that move health care payment mechanisms away from paying for volume and instead focus on the value and efficiency of the care provided, the College is pleased that the agency is seeking input on how the physician self-referral law (the “Stark Law”) should be modified in order to accommodate these payment reforms.

The American College of Surgeons has made significant investments to promote new payment models, including the development of the ACS-Brandeis Advanced Alternative Payment Model, which is an episode-based payment model built on an updated version of the Episode Grouper for Medicare (EGM) software developed under contract with CMS for measuring resource use. As you are aware, this model was recommended for limited scale testing to the Secretary by the Physician-Focused
Payment Model Technical Advisory Committee (PTAC) and subsequently received a supportive recommendation from the Secretary of Health and Human Services. We believe that in order for models like the ACS-Brandeis Advanced Alternative Payment Model to succeed it is imperative that regulations like those related to the Stark Law are modernized to accomplish successful implementation so that patients, providers, and payers can be supported by payment mechanisms that focus on providing better care to patients. We are pleased to provide input on the topics requested in the pursuit of these goals.

**Input on existing or potential arrangements that involve DHS entities and referring physicians that participate in APMs where the physician self-referral law interferes or does not provide an applicable exception**

It is important to keep in mind that there has already been Congressional recognition that the Stark prohibitions were interfering with the ability to implement new payment models when Congress codified the authority of the HHS Secretary to create exceptions for the self-referral and anti-kickback prohibitions for Accountable Care Organizations (ACOs). As APMs have proliferated beyond ACOs, extending these modifications to new models is imperative, particularly given the focus of ACOs on primary care and the current lack of meaningful participation options for surgeons. This dynamic has intensified with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which promotes new payment models utilizing quality and resource metrics that rely on care coordination by physician practices. The Stark Law unintentionally serves as a roadblock for many physicians who are interested in developing and operating APMs.

As mentioned in the introduction to this comment letter, the American College of Surgeons developed and submitted to the PTAC the ACS-Brandeis Advanced Alternative Payment Model. This proposal is a team-based episodic payment model, and while patients are able to seek care with any provider they choose, the ability for participating physicians to refer patients to other providers in the model with whom they are familiar without the specter of potentially running afoul of Stark Law requirements would be important.

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1 PTAC Report to the Secretary: [https://aspe.hhs.gov/system/files/pdf/255906/ACSReportSecretary.pdf](https://aspe.hhs.gov/system/files/pdf/255906/ACSReportSecretary.pdf)
While we would envision no “kickbacks” or direct profit-sharing between individual participating providers in such a model, the fact that they would have a “financial relationship” (as defined under Stark regulations) where they could be rewarded (or penalized) as an entity for their participation (with flexibility on how the entity distributes the risks and incentives) could reduce opportunities for care coordination. This is unfortunate, because unlike in a straight fee-for-service environment, financial relationships within the context of an episodic, team-based APM such as that proposed by ACS would include additional protections and incentives different than those present at the time the Stark Law was enacted.

In contrast to the circumstances envisioned by Stark, where providers could benefit from referrals that drive up volume unnecessarily, many newly developed models could put participants at risk for financial losses in such cases. Additionally, requirements that payment be tied to quality provide additional safeguards not present at the time of Stark’s passage. The net result of these circumstances is that rather than being a check on bad actors, in the context of value-based care models Stark may actually be having a chilling effect on models designed to bend the cost curve and improve quality of care to patients.

Input on what Stark exceptions need to be created in order to protect arrangements such as Accountable Care Organizations (ACOs), bundled payments, two-sided risk models, and other arrangements

The existing Stark Law exceptions do not provide sufficient protection or guidance for physicians to make fully informed decisions about participating in innovative care delivery models. More clarity is needed as to whether reimbursement models would be protected or whether their payment arrangements, including risk/reward sharing and delivery of services in an integrated care delivery model, violate Stark or other fraud and abuse laws. At a minimum, the current fraud and abuse waivers applicable to the Medicare Shared Savings Program (MSSP), the Centers for Medicare and Medicaid Innovation (CMMI) ACOs, and bundled payment programs should be extended to services furnished under Merit-based Incentive Payment System (MIPS) APMs and Advanced APMs, both those in the implementation phase and those under development, where requirements for innovation, quality of care, efficiency, and care coordination are part of the care delivery model.

We believe that the primary focus of CMS should be on the impediment to APM participation created by the Stark prohibition on payments that are tethered to the...
“volume or value” of referrals and services provided. ACS strongly supports HHS and CMS efforts to curb fraud and abuse in federal health care programs, and we support reasonable program integrity efforts. However, in the current environment where stakeholders have identified potentially unwarranted variation, and we have seen the creation of tools such as appropriate use criteria to ensure that services are relied upon more efficiently, basing payments on that good medical practice could result in changes to “volume or value,” and the Stark Law could inhibit provision of well-designed, patient-centered financial incentives. While we understand that CMS cannot completely eliminate the “volume or value” prohibition, we believe that in the limited context of at least MIPS APMs and Advanced APMs where there are quality measure safeguards (which are also designed to impact the financial dynamics of the model) to protect patients from underutilization of necessary services, that CMS create exceptions so that models are allowed to design financial incentives that encourage the most appropriate use of particular services relative to an historical benchmark.

Input on what Stark exceptions need to be created to address care coordination and care integration initiatives (that are not formal APMs)

As you are aware, CMS has extended until 2021 the exception to the Stark Law to protect certain arrangements involving the donation of interoperable electronic health records (EHRs) software or information technology and training services from protected donors (for example, a hospital) to physicians. We believe that CMS should consider a similar exception for the provision of non-EHR health information technology that can be of assistance to providers in coordinating care, monitoring patient progress, and other technological innovations, many of which will be integral to the success of APMs. While we believe the provision of some of these technologies will be important and in need of protection outside of the context of an APM, we believe that they will be incredibly important to providers participating in APMs, and APM entities and the physicians affiliated with them should be shielded from Stark Law risk if the APM entity believes it is important to provide to the participant physician in order to promote the success of care coordination and/or APM activities. This will be of particular importance for rural practices engaging in care coordination and APM activities that sometimes do not have the resources to make investments in the new technology that is available. We believe that the current Stark exception for EHR donations contains safeguards that could be used as a guide to construct a similar exception for non-EHR care coordination and APM HIT.
Input on to what extent price transparency can mitigate concerns about program abuse and patient care if these arrangements are allowed to exist

The ACS believes that price transparency can help provide patients with meaningful information to help support these programs. While price transparency alone might not provide sufficient programmatic safeguard, it is one of the tools available to provide that security in these types of arrangements. One of the reasons that we believe that price transparency alone cannot provide this protection is because the information currently available to consumers on cost—particularly as it relates to out-of-pocket charges for in- and out-of-network care—is sparse and inconsistent. As such, we believe that, in addition to CMS efforts to directly address the portions of the Stark regulations that are serving as an impediment to APM proliferation, CMS should consider the following issues:

- **Provider Responsibilities:** There is no single source of accurate information on patient out-of-pocket cost or total cost of care, as the contracted price of a given service can vary greatly depending on the insurer and a patient’s individual insurance policy. The prices for the same service can also vary depending on whether the service is provided in an office, an outpatient setting, an ambulatory surgery center, or on an inpatient basis in a hospital. For that reason, a physician—who is focused on providing the best quality of care for a patient—might not know the intricacies of differing contracted rates and site of service costs, particularly in the context of an APM, and is therefore unlikely to know, or possibly even be able to quickly and accurately determine, how much a patient will have to pay out of pocket for a service. We do not believe that physicians should be expected or required to inform patients of their out-of-pocket costs in the current payment environment.

- **Accurate and Relevant Cost Data:** One potential way to fill the current gaps in information available to patients would be to provide narrow, but representative, ranges of expected costs based on the patient’s characteristics and diagnosis. For example, the ACS sees great promise in the kind of granular information that can be provided by the Episode Grouper for Medicare (EGM), which was developed for CMS by a team at Brandeis University to organize claims information into logical episodes of care. As previously mentioned, a version of EGM is a core feature of the *ACS-Brandeis Advanced Alternative*...
Payment Model. It consists of both a software suite and a set of clinical episode definitions that have benefited from multiple rounds of physician review over several years. While originally created to provide Medicare cost information to CMS, the technology is capable of providing remarkable insights to the care team, and, if built for this purpose, could be invaluable for patients trying to determine potential costs for situations that are more complex than for a single service by a single provider. For cost information to be meaningful for consumers, it would need to be put into a proper format—such as an interactive rate book where patients could see estimated ranges based on historical claims of patients with similar comorbid conditions and other factors—to give them a precise estimation of what a patient with their concurrent care issues and medical history might expect. We believe that allowing for the implementation of APMs such as the ACS-Brandeis Advanced Alternative Payment Model will help provide better reimbursement mechanisms to support the provision of quality care and also empower patients by providing more information about price and quality.

We appreciate the opportunity to comment. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Matthew Coffron, Manager of Policy Development, at mcoffron@facs.org.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director