February 3, 2016

The Honorable Orrin Hatch  
Chairman  
Senate Committee on Finance  
219 Dirksen Senate Office Bldg.  
Washington, DC 20510

The Honorable Kevin Brady  
Chairman  
House Committee on Ways & Means  
1102 Longworth House Office Bldg.  
Washington, DC 20515

Dear Chairman Hatch and Chairman Brady:

On behalf of our more than 13,000 gastroenterologists that deliver care to millions of patients in a variety of clinical settings each year, the American College of Gastroenterology (ACG) appreciates the opportunity to provide comments on the Physician Self-Referral, or “Stark Law,” prohibitions and regulations under the Social Security Act. ACG commends the Committees for their work in examining options for modifications to the outdated Stark Law restrictions that no longer make sense in an increasingly integrated and coordinated health care system. Our member physicians and clinicians navigate the siloed-payment environment impacted by Stark Law limitations and can provide valuable insight on physician self-referral issues.

AN ANTIQUATED LAW

The Stark Law has run its course and is actually hindering the drive toward better coordinated and cost-effective care. The bipartisan passage of Medicare Access and CHIP Reauthorization Act (MACRA) in 2015 is evidence that both Republican and Democratic Members of Congress share the goal of better and more coordinated health care delivery through innovative alternative payment models (APMs), or through a modified fee-for-service (FFS) system that measures quality and resource-use at the individual physician and practice level. Regardless of whether the physician chooses to participate in an APM or remains in this newly modified FFS structure, there is an ongoing shift in the way Medicare reimburses physicians for healthcare services. Unfortunately, the Stark Law stands in the way of this transformation by imposing undue compliance burdens and prohibiting necessary arrangements.

Like other specialties, ACG members face undue burden in complying with fraud and abuse laws including the Stark Law and the Anti-Kickback Statute (AKS). Feedback from our members in states such as Arkansas, New York, Ohio, and Rhode Island cite the Stark Law and the AKS as requiring onerous steps and procedures, as well as significant legal fees that practices must undergo in order to provide these services in a cost-effective and coordinated manner.

Our members are willing to accept the financial and practice risks in investing in these services; however, they are fearful to adopt new and innovative methods of health care delivery as they may trigger some gray area of this antiquated law. For example, ACG members in Pennsylvania cite the Stark Law $32 de minimis limitation for incidental medical staff benefits as prohibiting ways to develop new professional
relationships with referring physicians, which would allow more participation among private practicing physicians in alternative payment models.

The consequences of Stark Law compliance can have serious adverse effects. For example, despite investing in a health care attorney and Stark Law expert, a practice in Rhode Island subsequently learned that it may have violated the Stark Law despite the practice’s due diligence in retaining these resources to ensure compliance with the Stark Law and AKS.

ACG urges Congress to help foster an environment where small physician practices can remain independent. “Integration” and better coordination among providers does not require everything to be “in house.” This only creates a monopoly or oligopoly in health care markets. Competitive markets and small businesses (i.e. physician practices) are crucial to lower costs and patient choice.

In gastroenterology, both the Stark Law and the AKS especially pose challenges in the provision of anesthesia and pathology during an endoscopic procedure. These services are natural and necessary components to an underlying endoscopic procedure. Thus, gastroenterologists are not directing patients to undergo these services: The patients are there for the underlying endoscopy procedure itself.

Using anesthesia or moderate sedation is the standard of care prior to performing an endoscopic procedure. The Centers for Medicare & Medicaid Services (CMS) ruled in 2015 that anesthesia is an integral aspect to a colorectal cancer screening examination and included anesthesia services in the definition of a “screening.” Therefore, CMS waives certain Medicare beneficiary cost sharing for anesthesia services during screening colonoscopy.1 However, under the Stark Law and the AKS, these services are still considered separate. Our members that invest in anesthesia services in states such as Ohio and Texas, for example, must spend a significant amount of limited financial resources to help ensure that they comply with the Stark Law and the AKS. Indeed, the fact that the Stark Law is outdated is demonstrated by the ongoing need to continue adding “exceptions” to the rule each time CMS implements a new coordinated-care payment model authorized by Congress.

Pathology is another necessary component in endoscopy, as any diagnosis is contingent upon examining biopsies taken during the endoscopic procedure. Moreover, because of recent payment policy changes, pathology is an even more critical component of endoscopic procedures provided to Medicare beneficiaries. For example, beginning in 2014, CMS measures a gastroenterologist’s “adenoma detection rate,” (ADR), or the rate at which precancerous polyps are detected. ACG agrees that this is one of the most useful and widely accepted quality metrics in benchmarking the quality of a screening colonoscopy. The ability to find and remove precancerous polyps prevents colon cancer from occurring in the first place. The only way a polyp may be determined to be “precancerous,” however, is via pathology, which requires a biopsy.

The ability to provide pathology in connection with an endoscopic procedure also has reimbursement implications for ACG members. The ADR is a measure that is part of the Physician Quality Reporting System (PQRS), where Medicare physicians must participate in PQRS or face lower Medicare reimbursement. Also, PQRS participation is tied to a physician practice’s resource-use under the Medicare Value-Based Payment Modifier. As you know, the value modifier is designed to benchmark a practice’s costs and potential over-utilization. Furthermore, quality and resource use measures will continue to play a prominent role beginning in 2019 under MACRA, allowing CMS to review and monitor business practices of our members. Unfortunately, compliance with the Stark Law and the AKS

---

in order to provide pathology services requires significant time and resources, which instead could be devoted to efforts to improve care quality and efficiency.

Fortunately Congress has passed provisions in the Patient Protection and Affordable Care Act (ACA) and MACRA to provide additional safeguards against fraudulent self-referral and over-utilization. Thus, it is time for program integrity laws like the Stark Law and the AKS to be repealed or modified in order to better foster the goals of improving quality of care to Medicare and Medicaid patients. We must also eliminate the assumption that physician-investment leads to illicit profiteering. Independent physician practices are still made up of physicians who have personal ties to their patients and communities, and have the fiduciary responsibility to uphold their oaths as health care providers.

**ASC ISSUES: HOSPITAL-PHYSICIAN JOINT VENTURES**

Gastroenterologists are faced with increasing uncertainty regarding the feasibility of engaging in joint ventures with hospitals to operate ambulatory surgical centers (ASCs), particularly when the gastroenterologist is employed by the hospital. These arrangements are examples of the integration taking place in a post-ACA environment. Although the Stark Law itself provides for relatively few restrictions on physician-hospital joint venture ASCs, the AKS contains extremely narrow safe harbor exemptions that make it virtually impermissible for hospital-employed physicians to establish an investment ownership in a joint venture ASC. Since a hospital would have control over the schedules of its physician employees and could direct physician employees to perform surgeries at the joint venture ASC in which the physician has an ownership interest, the arrangement would almost certainly violate the AKS.

When examining policy reforms to the Stark Law, ACG encourages the Committees also to focus on this intersection between the Stark Law and the AKS and better align exceptions and safe harbors between the two policies. Better alignment would avoid conflicting signals to integrated provider groups that are attempting to move surgery patients into the more efficient ASC setting. This alignment of exceptions and safe harbors will be become increasingly important as hospitals and physicians are pushed towards increased integration via the CMS emphasis on delivery system reform models, as well as the incentives for APM participation that are inherent in MACRA and the landmark changes that the law makes to Medicare physician payments.

**FAIR MARKET VALUE COMPENSATION**

Under the existing Stark Law exception for “fair market value compensation,” a contractual compensation arrangement between a hospital and a physician employee is exempted from the prohibition on self-referral so long as, among other things, the compensation is not based on the volume or value of referrals by the employee physician and is “set in advance, consistent with fair market value.” In practice, many hospital employers use this “fair market value” requirement to establish predetermined “market rates” for physician salaries that they argue cannot be exceeded for fear of Stark Law non-compliance.

In fact, ACG members in states like Arkansas, Massachusetts, Oregon, and Pennsylvania report that hospitals are driving the way care is delivered and how a physician is paid by using the Stark Law to their advantage. This is important to note because part of the goal of coordinated and cost-effective care is to reduce hospital admissions. Yet many hospitals have become central to ACOs and other alternative payment policies such as bundled payments, which make a viable and independent practice more difficult to sustain in the current environment.

---

2 42 C.F.R. 411.357(j)(3)
This dynamic places gastroenterologists and other specialists at a distinct disadvantage in hospital employment contract negotiations and ultimately creates barriers to access of physician services in certain geographic areas. ACG urges the Committees to examine whether this “fair market value” requirement interferes with the free market for physician employment, and whether such forces result in the exacerbation of physician shortages in certain geographic areas.

NEW EXCEPTIONS & WAIVERS FOR NEW MODELS

In 2011, CMS and the Department of Health & Human Services-Office of the Inspector General (HHS-OIG) provided important Stark Law, AKS, and Civil Money Penalty (CMP) exceptions and waivers for health care providers that participated in the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs). In addition, the CMS Center for Medicare and Medicaid Innovation (CMMI) was provided with statutory authority to waive the Stark Law, AKS, and other provisions as necessary to test and advance new payment models in Medicare. In some instances, CMMI has taken advantage of this waiver authority when testing new models, such as the Bundled Payments for Care Improvement (BPCI) initiative.

ACG strongly encourages the Committees to consider broadening the scope of such new payment exceptions and safe harbors from the Stark Law and AKS by requiring that CMS provide these exceptions for modified-FFS and for APM-participating physicians implemented under MACRA. These physician and practices would not pose self-referral or kickback risks because these practitioners will be financially at-risk for the cost of care for attributable beneficiaries.

CONCLUSION

The Stark Law and AKS continue to inhibit physician innovation precisely at the time when both the Administration and Congress are looking for more innovative strategies to achieve high quality and cost-effective healthcare services. In order to ensure that this innovation becomes a reality, significant changes must be made to these laws.

We thank you again for this opportunity to provide comments and suggestions as the Committees consider changes to the Stark Law. Please do not hesitate to contact Brad Conway at bconway@acg.gi.org or 301.263.9000 if you have any questions.