July 25, 2018

Chairman Peter Roskam
House Ways and Means
Health Subcommittee
1100 Longworth House Office Building
Washington, DC 20001

Ranking Member Sander Levin
House Ways and Means
Health Subcommittee
1100 Longworth House Office Building
Washington, DC 2000

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“Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program”

Dear Chairman Roskam and Ranking Member Levin,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on the House Ways and Means Health Subcommittee’s hearing on “Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program” held on July 17, 2018.

AAOS believes that the services we provide, including physician-owned ancillary services, are of the highest quality and that modernization of the Stark law will positively affect the care that our patients receive. As you know, modern Stark law is the result of a cumulative policymaking process stretching back to 1989 when Congress amended the Social Security Act. After 1993, the law expanded considerably to include numerous other designated health services (DHS). This process resulted in a wide-ranging expansion of those original legislative changes in ways that undermined Congress’s efforts to protect patients.

Nearly thirty years later, the American healthcare system has undergone significant change both in how care is delivered and how physicians are paid through federal programs, due in part to the Medicare Access and CHIP Reauthorization Act (MACRA, 2015). AAOS understands the importance of guarding against fraud and abuse in federal healthcare programs. Nevertheless, Stark law prohibitions increasingly present obstacles to care coordination in innovative payment programs like the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).
As the Quality Payment Program (QPP) enacts long-overdue efforts to reform physician payment and care delivery, AAOS urges Congress to reform the difficult and outdated body of Stark law. Given that violations of the physician self-referral law are a matter of strict liability, AAOS believes it is urgent that new exceptions be created so that physicians may more easily comply with both the new payment models and existing safeguards against fraud and abuse. The severity of monetary penalties lack appropriateness and the penalties for technical violations can be upwards of millions of dollars. The strict liability standard of the Stark law often results in technical violations where the parties are functioning in accordance with the “spirit” of the rule (i.e. unsigned agreements and expired leases), and the assessment of treble damages based on a technical violation seems excessive. The time frame for resolution can also impede a medical group’s ongoing business activity. For example, once it has been determined internally that an unintentional violation under the Stark standard may have occurred, the filing for a determination to that effect can take many months, consequently causing a disruption in the practice because the business activity in question is essentially in limbo. AAOS supports the current Medicare Care Coordination Improvement Act (H.R. 4206) which addresses many issues with current Stark law.

Exceptions to the physician self-referral law

Exceptions to the Stark law, as well as modifications to the anti-kickback statute (AKS) and Civil Monetary Penalty law (CMP), can help alleviate impediments to effective orthopaedic practice and allow our surgeons to better manage surgery. Currently, orthopaedic surgery groups participating in certain Centers for Medicare & Medicaid Innovation (CMMI) demonstration projects can obtain waivers from Stark law provisions. These conditional exceptions demonstrate the need for more flexibility when testing new payment models. In order to encourage expansion of these payment models, the greater risk should be balanced with the potential for greater gains. The removal of provider caps in gainsharing arrangements may result in increased provider participation and expansion of APMs.

Under the MACRA definition of an APM in order to avoid a payment reduction, the APM participant must bear more than a nominal risk for monetary loss. The Stark exemption for certain in-office ancillary services may serve as another incentive for providers to participate in APMs. However, these high thresholds can create a barrier to entry for smaller groups. The creation of an APM can be complicated for smaller physician groups as it is difficult to accurately predict the downstream financial risk. By allowing providers to see financial benefits of ancillary services at lower thresholds (and lower risk), these reimbursement arrangements would be seen as more feasible for solo practice and smaller groups. AAOS would consider a threshold of 10% (total patients) as a reasonable entry point to allow providers to begin experimenting with APMs at an acceptable pace.
As CMS itself has acknowledged, “CMS and the [Office of Inspector General] determined it necessary to waive the physician self-referral law’s prohibitions, the antikickback statute, and certain other fraud and abuse laws, in order to carry out or test effectively the Shared Savings Program and certain delivery and payment system reform models that are currently being tested by the Innovation Center.” AAOS urges Congress to create an ongoing exception to allow a physician to treat Medicare patients outside of a given model in the same manner as those within a new model. Without exceptions, under this more case-by-case approach, innovative cost-savings approaches for eligible APM patients may violate Stark, AKS, or CMP if similarly applied to non-APM patients. Currently, orthopaedic surgeons must carefully separate CMMI APM patients from other Medicare patients, denying non-APM patients access to proven, cost-saving approaches.

New value-based payment programs like MIPS and APMs are designed to incentivize value over volume. These programs were carefully crafted to re-orient patient care away from fee-for-service. AAOS believes that Congress should give CMS the authority to waive the physician self-referral law for physicians seeking to develop and operate APMs, the same way Accountable Care Organizations (ACOs) were enabled to do so under the Affordable Care Act (ACA). This would give regulators the administrative authority to promote care coordination, quality improvement, and resource conservation.

Accordingly, Congress should affirmatively exempt participating organizations both within approved APMs and the MIPS program. In order to participate in either program, physicians must already meet pre-determined criteria that are designed and tested to disincentivize the volume-based practices that Stark law was designed to guard against.

Additionally, AAOS believes the existing “volume or value” prohibition is outdated and detrimental to MACRA’s goal of promoting value over volume. Removing this prohibition would allow practices to incentivize providers to abide by the best practices and succeed in the new value-based APMs. This exception would apply to practices that are developing or operating an APM, including Advanced APMs; APMs approved by the Physician-Focused Payment Model Technical Advisory Committee; MIPS APMs; and other APMs specified by the Secretary of Health and Human Services. We discuss the problems with the “volume or value” prohibition further below.

Under 42 CFR 411.357(w), federal law provides for an exception for “Electronic health records items and services.” AAOS believes that this donation exception is a valuable and necessary allowance. We share the concern about information-blocking that prompted regulators to prohibit “[t]he donor … [to] not take any action to limit or restrict the use, compatibility, or
interoperability of the items or services with other electronic prescribing or electronic health
records systems.” We also believe Congress should give regulators more authority to promote
greater electronic health records (EHR) infrastructure that accounts for the fact that hospital
investment in shared infrastructure could create a prohibited financial relationship under the
law.

Given the importance of EHRs to the success of the QPP and to the future of healthcare both in
federal programs and private, AAOS believes the overall EHR donation exception should be
broadened. We believe the exception should be permanently expanded to include donations of
other important technologies that protect patients and improve care, such as cybersecurity and
data analytics tools, as well as training on these technologies. We also believe the requirement
under 42 CFR 411.357(w)(4) (that a provider pay “15 percent of the donor’s cost for the items
and services”) is unnecessarily burdensome and should be either eliminated or significantly
reduced. This requirement can be especially burdensome for small, rural, and solo practices.

Based on advisory opinions from the OIG, many of the physician-owned ambulatory surgery
centers (ASCs) have been hesitant to integrate anesthesia services into their business models.
While some groups have looked into certain models to comply with Stark, third-party payers
may deny claims from an ASC that covers facility and anesthesia services simultaneously,
making a salaried model less financially feasible. There are several benefits in allowing ASCs to
offer their own anesthesia services, such as increased accountability for patient care,
streamlined billing processes, decreased burden of negotiating multiple payer contracts, and
greater potential to participate in bundled payment arrangements. As historically inpatient
services (such as total knee arthroplasty for Medicare along with total hip arthroplasty for
commercial payers) continue to shift into the outpatient setting, ASCs are uniquely positioned
to decrease healthcare costs. Given that delivery of anesthesia is a critical part in performing
these procedures, this is an ideal space for Congress to consider a more precisely defined
exception to Stark laws. Orthopaedic surgeons face similar challenges when they try to
incorporate physical therapy (PT) into their group practices. The same advantages listed above
result from better integration of PT services, including greater accountability and
communication between providers as well as significant cost savings.

Coordination with skilled nursing facilities (SNF) and home health agencies is also disrupted by
the current Stark law prohibitions. Presently, waivers are needed from the Stark, CMP, and AKS
laws in order to effectively coordinate care with these services. CMS and the OIG have issued
waivers toward that end for the current Bundled Payment for Care Improvement (BPCI) Model,
and have seen higher quality, lower cost, and better coordinated care result. By revising the
law, Congress can eliminate the current taxing case-by-case approach.
Physician Owned Hospitals (POHs)

The Stark law also limits the full potential of POHs as innovative health care delivery models. As we have noted elsewhere, its implementation also has not realized the goal of decreasing medical costs. Rather, it has resulted in large hospital systems that dis-incentivize competition. These hospital systems are absorbing surrounding medical practices, becoming de facto monopolies. The presence of POHs serves to incentivize traditional hospitals to improve, innovate, and control costs. Additionally, POHs consistently provide higher quality care for a lower cost.

In Office Ancillary Services

As we have mentioned, the Stark law is a liability statute that leads to heavy penalties for unintentional and technical errors by physicians and their staff. Liability statutes do not encourage physicians to participate in coordinated care models. As AAOS and several of our partners have noted in earlier comments to Congress and CMS, we would like to re-emphasize the importance of protecting the In-Office Ancillary Services Exception (IOASE).

AAOS believes the rules should allow physicians to own free-standing MRI, PT, and durable medical equipment businesses, hospitals, and surgical centers without restrictions. Studies demonstrate that when physicians lead or own these medical operations, patients receive higher quality, less costly services which provide better physician oversight and patient access.

Consolidation and small practices

Consolidation in the provider community in many cases is being driven by restrictions of Stark law, as Deputy Secretary Hargan has acknowledged. Any action Congress takes to reform existing Stark law must ensure that the playing field is level for both large and small practices. AAOS believes healthcare professionals must be allowed to negotiate meaningful contracts that deliver high-quality health services and protect patient safety. Further, this approach would allow healthcare providers to engage in care coordination endeavors, including participation in ACOs and bundled payment models, without fear of antitrust prosecution. Toward this end, AAOS has supported past solutions like those contained in the Quality Health Care Coalition Act. Importantly, the collective negotiation rights contained in the Act would not extend to Medicare and Medicaid, and it would not grant healthcare providers the right to strike. Permitting physicians to have the same negotiating power as other market participants would stifle the current anticompetitive environment, stimulate higher-quality patient care, and do a better job freezing current health insurance market concentration.
AAOS urges Congress to remove these impediments to effective coordination that are spurring increased market consolidation. As we mention elsewhere, these burdens fall differently for small, independent specialty practices than they do for large health systems. Restricting a patient’s ability to access small specialty practices and their affiliated services does not serve patients’ interests, and, in fact, advantages large health systems at the cost of delivering the best care for a patient. Leveraging existing relationships with other providers can help facilitate better care but, absent Congressional action, the current Stark prohibitions can severely handicap small practices.

Eliminating or revising the “volume or value of referrals” prohibition

Under 42 CFR 411.357 “Exceptions to the referral prohibition related to compensation arrangements,” the phrase “volume or value of any referrals” is used seven times without a precise definition. As mentioned above, AAOS supports legislative removal of the “volume or value” prohibition altogether as seen in the current version of H.R. 4206. If Congress does not eliminate the provision altogether, it should encourage CMS to provide meaningful clarification of this phrase given its importance to the Stark law exceptions. A clear-cut definition can demonstrate Congress’s intent to actively integrate the existing Stark law exceptions into the new outcomes-based payment infrastructure regulators continue to test and advance under the QPP. AAOS welcomes MACRA’s shift to rewarding quality care, but the “physician self-referral law presents a particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws.”

We welcome guidance on how this integration might unfold for providers.

As Acting CMS Administrator Andy Slavitt wrote to Congress in 2016, “The prohibition on compensation that takes into account the ‘volume or value’ of referrals by a physician can pose impediments for the implementation of gainsharing arrangements, because compensation paid to a physician for reducing costs or increasing profits through changes to his or her patient care practices could be interpreted to take into account the volume or value of the physician’s referrals of DHS for Medicare beneficiaries.”

Congress could incentivize movement of patients from lower quality, higher cost facilities to lower cost settings that deliver better care through simple changes to the current Stark law. Presently, non-employed physicians cannot be uniformly rewarded or penalized by hospitals for meeting certain benchmarks of care or following certain care pathways. Removing the “volume

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or value of any referrals” prohibition would help remove this unnecessary obstacle to rewarding quality adherence.

**Defining “fair market value”**

The statutory definition given for “fair market value” is arguably nebulous: the “value in arm’s-length transactions, consistent with the general market value.” Although this definition and later clarifications have given providers some insight, the new payment infrastructure (particularly following MACRA) warrants greater clarification about how to measure fair market value under the new rules. Most importantly, measuring these transactions based on fair market value reinforces a healthcare delivery system premised on payment for time and resources rather than one based on payment for quality of the team-based care delivered.

Further, fair market value is susceptible to subjective misunderstanding, particularly in new and innovative arrangements where providers are encouraged to simultaneously work more closely together yet still keep payment arrangements at “arm’s length.” CMS waivers to some Stark law provisions for those participating in certain projects have given a limited number of providers clarity about the risks, but detailed guidance more widely applicable is necessary for greater provider buy-in. As mentioned above, AAOS supports the Medicare Care Coordination Improvement Act, HR 4206, in which items and services are still subject to fair market value except that the Secretary may not take into account “volume or value” of referrals while providers are developing and operating APMs. Nevertheless, Congress should urge CMS to provide greater guidance on how fair market value will be defined and determined within these arrangements. Congress’ intent to encourage greater coordination among providers is being inadvertently handicapped by ambiguity in this space.

**Transparency in the physician self-referral law**

Transparency enables accountability and empowers patients. Numerous sources of data exist which could help reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address. By giving them access to these other data on price transparency and quality of services provided, patients can make more informed decisions about where and how to pursue care in consultation with their provider. Transparency about a provider’s participation in a financial arrangement demonstrated to deliver quality care would help patients make informed choices and diminish the risks the Stark law was designed to correct. By encouraging CMS to provide greater patient access to data on Medicare pricing and quality of services under the new payment arrangements, Congress could substitute transparency and accountability for the current arduous and burdensome regulatory regime.
Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ comments regarding necessary reform to the physician self-referral law. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

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