October 24, 2018

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0803-N, “Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding Anti-Kickback Statute and Beneficiary Inducements CMP”

Dear Ms. Edwards,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the Office of Inspector General’s (OIG) invitation to submit comments on how to address any regulatory provisions that may act as barriers to coordinated or value-based care. AAOS shares the Administration’s desire to foster mutually beneficial relationships and arrangements, while protecting beneficiaries of federal health care programs from abuse and fraud. New safe harbors can help empower physician collaboration and cooperation at a critical moment in the development of new value-based payment endeavors.

Promoting Care Coordination and Value-Based Care

The OIG should create anti-kickback safe harbors for physicians engaged in care coordination efforts. Care coordination is an essential element of a value-based healthcare system and an integral component of the structure set out by the Medicare Access and CHIP Reauthorization Act (MACRA). Yet the anti-kickback law and its limited safe harbors can act as impediments to effective physician coordination, especially with regards to alternative payment models (APM).

Just as MACRA reevaluated how patient care is delivered, these outdated impediments must be similarly reevaluated to ensure that this new approach to delivering care is given room to successfully develop. To this point, the OIG in December 2016 acknowledged that this transformation requires “new and changing business relationships among health care providers,” but purposefully left many emerging arrangements unaddressed. The movement from volume to value-based care requires greater reliance on physicians’ judgment in prescribing and coordinating the delivery of care for their patients. Specifically, if greater

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc
coordination of care is expected to succeed, additional safe harbors are necessary to foster thoughtful, innovative partnerships among providers and other participants.

In addition to helping with care coordination, addressing anti-kickback issues can address consolidation issues. The House Energy and Commerce Committee’s Oversight and Investigations Subcommittee held a hearing on February 14, 2018, to discuss the trend of health care provider consolidation. The anti-kickback law itself can facilitate greater consolidation within the health care market as hospitals acquire more group practices to avoid violating the law. This trend toward consolidation considerably limits competition and choice. Developing more pathways by which physicians can participate in innovative coordinated care models and still help guard against fraud and abuse is ideal for both patients and providers.

Additionally, the OIG has rejected proposals for safe harbors that could address some of our concerns. The AAOS feels it is important to stress the need for two proposals from the OIG’s Semiannual Report. In the past, the OIG has rejected a proposal to develop a “new safe harbor that would protect value-based payment arrangements that bundle products and related services and allow for price adjustments if a measurable clinical and/or cost outcome is not achieved,” as well as a new safe harbor that would generally protect these types of arrangements. As expressed above, the AAOS strongly supports providing a safe harbor within the anti-kickback law for physicians seeking to develop and operate APMs and other care coordination efforts. The Centers for Medicare and Medicaid Services (CMS) has emphasized its commitment to making the transition to value-based payment as successful as possible. Removing administrative barriers to participation in these bundled payment arrangements and providing adequate participation flexibility to physicians will ensure that these new arrangements are worthwhile.

The OIG has also previously rejected a proposal to “protect arrangements that support patient adherence to a treatment regimen that has been recommended by the patient’s health care provider.” The AAOS understands the United States has an epidemic of opioid drug use, misuse, and abuse. Opioid adherence is particularly critical given the fact that orthopaedic conditions naturally require narcotic pain management for weeks or months—particularly those involving trauma or aggressive post-surgical physical therapy. The AAOS believes that programs which promote adherence to a prescribed treatment are an important element of any strategy to combat nationwide opioid abuse and misuse. Importantly, such programs respect physicians’ judgment regarding the proper treatment for their patients’ postsurgical pain and enable shared decision-making. Moreover, adherence to a provider’s prescribed treatment is even more important in a system where provider payment is based upon the value they bring to the patient-physician relationship rather than the volume of care they provide.

Lastly, consolidation in the provider community in many cases is being driven by the restrictions of the fraud and abuse laws, as Deputy Secretary Hargan has acknowledged. Any action the OIG takes to reform existing fraud and abuse laws must ensure that the playing field is level for both
large and small practices. The burdens we outline in this letter often impact small, independent specialty practices differently than they do 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. The anti-trust exemption that hospitals enjoy creates an unfair competitive environment. For example, many hospitals and hospital systems (even carriers) are acquiring physician practices in order to enhance their ability to participate in ACOS and APMs. This employee relationship, in essence, skirts the anti-kickback statutes that physicians in independent practice need to follow. If this behavior becomes widespread, it could have a chilling effect on competition and higher costs to consumers, due to the anti-trust protections.

Electronic Health Records (EHR) and Cybersecurity Safe Harbors

In response to the Physician Self-Referral Request for Information (CMS-172-NC) earlier this year, the AAOS reiterated our belief that the EHR donation exception is a valuable and necessary allowance. Relatedly, the EHR safe harbor should be extended and made permanent beyond its current 2021 expiration date. As CMS has recognized, EHR adoption and use is a critical component of care delivery both inside and outside of the Medicare program. The law should find ways to promote greater EHR infrastructure which accounts for the fact that hospital investment in shared infrastructure could create a prohibited financial relationship under current regulations. Given the importance of EHRs to the success of the Quality Payment Program and to the future of healthcare both in federal and private programs, the overall EHR donation safe harbor should be broadened. We believe the safe harbor should be permanently expanded to include donations of other important technologies that protect patients and improve care, such as data analytics tools, as well as training on these technologies.

Along with the changes recommended above, the AAOS strongly urges the OIG to consider creating a safe harbor for the donation of cybersecurity technology, training, and other related services. The absence of such an exception can chill cooperation among stakeholders if some are unwilling to take on the risk of collaborating with those who have a less secure data infrastructure. As the electronic exchange of patient data continues to increase, and cyber risks proliferate throughout all sectors, providers are eager both to participate in the new digital health incentive programs and to ensure their patients that their data are safe. As we have said in the past, the AAOS believes that the 15 percent contribution value to be incurred by the recipient of donated technology should either be eliminated or reduced due to the burden it can put on small and solo practices. It is more important now than ever that these practices adopt new essential technologies as part of the pivot to value-based care.

ASC Safe Harbor

In addition to the safe harbor modifications we have recommended above, the AAOS encourages the OIG to reexamine the Ambulatory Surgery Center (ASC) safe harbors’ one-third
requirements. As you know, under the one-third practice income test, at least one-third of each surgeon investor’s medical practice income—from all sources for the previous fiscal year or previous 12-month period—must be derived from the surgeon’s performance of procedures. Under the one-third practice test, at least one-third of the procedures performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

We understand that the OIG sought to ensure that “an ASC investment represents the extension of a physician’s office space and not a means to profit from referrals” (64 Fed. Reg. 63535). Yet the AAOS does not believe such examples of passive investment represent a notable risk of prohibited payments or remuneration for referrals. An investing physician may still use the ASC as an extension of his or her practice, even when the one-third requirements are not met. In fact, the one-third requirements may actually incentivize over-referral rather than proper referral if a particular member of a group feels pressured to meet that floor solely to comply with the safe harbor. The AAOS believes that these safe harbor requirements should be modified to more fairly safeguard patients and allow suitable physician investment.

We believe that the single specialty safe harbor requirement should protect a physician who refers surgical cases to an ASC in which they have an investment, as long as one-third of the individual physician’s practice income for the previous year is derived from his performance of surgical procedures at an ASC or hospital surgical setting; and that the multi-specialty safe harbor protections should apply, as long as one-third of the physician’s surgical procedures are performed in the ASC in which he or she is investing.

Technical Clarifications

Under the current safe harbor regulations, “fair market value” remains an important metric. 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.” Detailed guidance that is more widely applicable is necessary for greater provider buy-in. Any guidance should include specific examples relevant to participation in programs like MIPS or APMs, such as the types of data, surveys, and other information surgeons can reliably use to estimate fair market value while also encouraging care coordination.

Under the current “one purpose” test as articulated in case law, providers can be liable if only one of their purposes was intended to induce referrals. The AAOS understands the reasoning behind this conclusion and recognizes the need to protect against fraud couched within other explanations for a provider’s behavior. However, incorporating into this determination some measurement of actual harm to patients or program integrity would more adequately protect patients without discouraging referral arrangements meant to facilitate better care coordination.
Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ suggestions to encourage mutually beneficial partnerships while guarding against fraud and abuse. 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,

David Halsey, MD
President, American Association of Orthopaedic Surgeons

cc: Kristy L. Weber, MD, AAOS First Vice-President
    Joseph A. Bosco, III, MD, AAOS Second Vice-President
    Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer
    William O. Shaffer, MD, AAOS Medical Director
    Graham Newson, AAOS Director of the Office of Government Relations