



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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December 24, 2019

Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5521
330 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via <http://www.regulations.gov>

**Subject: (42 CFR Parts 1001 and 1003)
Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors
Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding
Beneficiary Inducements**

Dear Acting Inspector General Chiedi:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on, we are pleased to provide comments on the Office of Inspector General (OIG), Department of Health and Human Services (HHS) Medicare and State Healthcare Programs; Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (42 CFR Parts 1001 and 1003) Proposed Rule published in the Federal Register on October 17, 2019.

AAOS appreciates the deliberate efforts of the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) to advance the quality of healthcare while reducing burden for providers. The proposed revisions to the Safe Harbors Under the Anti-Kickback Statute (AKS) have the potential to incentivize collaborative care while operating in a less punitive healthcare ecosystem. With 75% of adults in the United States over the age of 65 experiencing a musculoskeletal disorder, the need for value-based, patient-centered solutions is a priority AAOS members share with HHS in addressing.¹

¹ Musculoskeletal Diseases, The Burden of Musculoskeletal Diseases in the United States, 2019
<https://www.boneandjointburden.org/>

Defining Value-Based Care

By crafting a new universe of value-based care definitions for providers to collaborate within, HHS is, in essence, writing the rules for a non-existent atmosphere. While this is ambitious, it leaves many definitions nebulous. In particular, AAOS requests that HHS consider the following questions when finalizing the definitions for the proposed value-based exceptions:

- 1) In the definition of value-based activity, how would the proposed value-based purpose of “refraining from taking an action” be defined and proven?
- 2) In the definition of value-based purpose, what would be the touchstone for determining whether or not one of the four criteria have been met?
- 3) In the definition of value-based enterprise (VBE) participant, how would HHS determine that an individual or entity has effectively “collaborated” in a value-based activity?
 - a. For example, would collaboration be a measure of time that the VBE participant has been active in a value-based activity as part of a VBE? Or, would a particular level of involvement (material or otherwise) be the metric?

In the definition of target patient population, HHS proposes to limit the application of the definition to patients with a chronic condition. As proposed, chronic condition is to be defined as the list of 15 Special Needs Plan-Specific chronic conditions developed by the Special Needs Plan Chronic Condition Panel. However, of these 15, spinal stenosis is the only musculoskeletal condition. This seems disproportionate given the significant percentage of CMS and commercial payor-beneficiaries in the United States who experience arthritis² and osteoporosis³. **Thus, AAOS urges HHS to expand the definition of chronic conditions eligible to be included in the definition of target population to include arthritis and osteoporosis.**

To mitigate the burden associated with this change to value-based care arrangements, AAOS recommends that existing quality measures be used to determine if quality of care has improved within the VBE.

Value-Based Care Exceptions

Broadly speaking, AAOS welcomes the increased latitude for providers to form value-based enterprises. As we have stated previously, 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). The proposal to offer value-based care safe harbors with a direct relationship between level of financial risk and scope of flexibility builds on the premise of alternative payment models already being implemented. However, in light of the current hesitancy for providers and practices to take on substantial meaningful downside risk,

² Arthritis, The Burden of Musculoskeletal Diseases in the United States, 2019

<https://www.boneandjointburden.org/fourth-edition/iii0/arthritis>

³ Current Prevalence by Demographics, The Burden of Musculoskeletal Diseases in the United States, 2019

<https://www.boneandjointburden.org/2014-report/va1/current-prevalence-demographics>

it is unclear whether or not this proposal will lead to considerable participation in these new exceptions.

Clarifying the definition of “volume or value” to state that the volume or value of referrals is only considered to be prohibited within the value-based care exception when it is directly included in the mathematical formula used to calculate the amount of compensation is essential to the success of VBEs. Additionally, by proposing to remove the fair market value definition’s connection to the volume or value of services, CMS is acknowledging that within the context of VBEs some services may be provided at a loss but are nonetheless crucial to the success of the enterprise as a whole and not a threat to the integrity of the arrangement.

Within the Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor the definition of evidence-based is nebulous. Though several examples of selected outcome measures for VBE participants are listed (such as medical journals or an established industry quality standards organization), AAOS believes that there must be a clear definition of “evidence-based” in order for there to be a significant reduction in burden and preservation of the integrity of such arrangements.

Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency Safe Harbor

AAOS applauds HHS for taking a progressive step to support innovation in patient engagement. The proposed safe harbor would allow VBE participants to provide tools and supports to patients in the target population without concern for breaching the limits of remuneration under the AKS. We appreciate HHS’ request for input on specific social determinants of health to improve care coordination. Though transportation to medical appointments, safe housing post-discharge, and nutritional counseling are all essential to improved care, we request that HHS consider the following determinants which are particularly salient to musculoskeletal care:

- **Body Mass Index (BMI)** – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).
- **Smoking Status** – Smoking status may be reported through administrative data, but additional information may be provided from the EHR.
- **Age** – Age is reported in administrative data.
- **Sex** – Sex is reported in administrative data.
- **Back Pain** – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.
- **Pain in non-operative lower extremity joint** – Pain in a non-operative lower extremity joint would be a patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.
- **Health Risk Status** – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions. In order to identify the patient’s comorbid

conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.

- **Depression/Mental Health Status** – The Patient-Reported Outcomes Measurement Information System (PROMIS) Global or VR-12 will collect this variable, as well as the administrative data.
- **Chronic Narcotic or Pre-operative Narcotic Use** – These variables affect patient outcomes and requires additional consideration. The information should be available in the EHR.

Additionally, AAOS encourages HHS to consider how the proposal to have a tool or support be considered unprotected “if the offeror of the remuneration knows or should know that the tool or support is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the patient engagement tool or support is provided” may inadvertently restrict access to these tools. As with many of the definitions and provisions in this proposed rule, we ask that HHS reduce the burden inflicted by ambiguity.

Cybersecurity/Technology and Electronic Health Record Safe Harbors

AAOS is particularly appreciative that HHS took note of our recommendations in addressing the barriers to successful electronic health record (EHR) operation. Updating the definitions of “EHR” and “interoperable” to align with the definitions in the 21st Century Cures Act and expanding the EHR exception to include the donation of cybersecurity technology and training may lead to better streamlined processes for continuity of care. Moreover, the proposal to reduce the 15-percent physician contribution requirement for small or rural physician organizations aligns with AAOS’ intention to improve access to care for historically disadvantaged populations.

Local Transportation Safe Harbor

The proposal to expand the rural communities limit on transportation from 50 to 75 miles is a positive step toward improved access to care for rural populations. In light of the proposals that aim to address social determinants of health, AAOS is pleased to see HHS consider including transportation for non-medical purposes to improve health outcomes in the safe harbor. **We encourage HHS to adopt this policy.**

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ suggestions. We commend HHS on its continued efforts to improve care quality and access. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, FAAOS, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



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American Orthopaedic Foot and Ankle Society
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