AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

December 24, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

Subject: (CMS–1720–P)
Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

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 Centers for Medicare and Medicaid Services' (CMS) Medicare Program Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P) Proposed Rule published in the Federal Register on October 17, 2019.

AAOS appreciates the deliberate efforts of CMS and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to advance the quality of healthcare while reducing burden for providers. The proposed exceptions to the Physician Self-Referral (Stark) Regulations 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]

Defining Value-Based Care

By crafting a new universe of value-based care definitions for providers to collaborate within, CMS 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 CMS consider the following questions when finalizing the definitions for the proposed value-based exceptions:

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

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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 "engaged" in a value-based activity?
    a. For example, would engagement 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?

To mitigate the burden associated with this change, 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 exceptions 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, 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 included directly 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 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.

Although we support the updated definition of "designated health services" that would allow for greater physician reimbursement when the service provided by the hospital to an inpatient does not constitute a designated health service payable by Medicare under the Inpatient Prospective Payment System, AAOS requests that CMS considering extending this provision to outpatient hospital settings as well. As more procedures move to the outpatient setting, it would be prudent to ensure consistency across sites-of-service.

Furthermore, there are instances where patients and physicians enter into a presumed bundle (Comprehensive Care for Joint Replacement, for example) under the premise that a procedure will be performed inpatient. However, a hospital may demand that the case be started as an

outpatient procedure thus not triggering the bundle. When this happens, physicians should not be held responsible for a Stark violation. Only the hospital or other third party should be culpable for such infractions. AAOS asks that CMS make this clear in the final rule.

Cybersecurity Technology Exception

AAOS is particularly appreciative that CMS 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, expanding the EHR exception to include the donation of cybersecurity technology and training, and eliminating the 2021 sunset of the exception, 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.

Limited Remuneration Exception

The proposed new exception to allow entities to reimburse physicians up to $3,500 for items or services provided is a welcome change. Such an exception affords physicians the flexibility to practice where their services are needed, when they are needed without fear of violating the regulation or going without reimbursement for their expertise.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We commend CMS 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 Alliance of Orthopaedic Executives
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
Arkansas Orthopaedic Society
California Orthopaedic Association
Connecticut Orthopaedic Society
Florida Orthopaedic Society
Georgia Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
Iowa Orthopaedic Society
Louisiana Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Musculoskeletal Infection Society
Musculoskeletal Tumor Society
Nebraska Orthopedic Society
Nevada Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
Rhode Island Orthopaedic Society
Scoliosis Research Society
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