March 20, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

Subject: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)

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 and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P) Proposed Rule published in the Federal Register on February 5, 2020.

**Mandatory Drug Management Programs**

The AAOS has concerns regarding limiting prescription medications by way of requiring a generic or alternative. There are some situations in which the more expensive medication is better for a specific patient. In those situations, we would not want it to be unreasonably difficult for the physician and the patient to get the medication that they need. However, with that said, we do support programs to address the cost of prescription medications. In some cases, that effort will involve recommending generic or less expensive equivalent medications when appropriate.

Additionally, the proposed definition of ‘inappropriate prescribing of opioids’ is nebulous. The definition states that patterns of abuse will be established based on facts considered by plan
sponsors. The AAOS requests clarity on who exactly from those Medicare Advantage (MA) plans will be determining what constitutes inappropriate prescribing. We believe that practicing clinicians from the same specialty, in partnership with pharmacists and pain management specialists, are best qualified to assess what is appropriate or inappropriate for a provider from that respective specialty to prescribe.

**Enhancements to the Part C and D Programs**

AAOS supports the proposal to permit additional telehealth benefits (ATBs) provided by non-contracted providers. In accordance with our position statement on telehealth, we believe that all patients should have access to physicians through telehealth when appropriate. More specifically, AAOS endorses the following principles:

1. Telehealth services should receive comprehensive and robust reimbursement rates to ensure patients can receive timely care where they live, when care is needed, in the setting of the patient’s choice.
2. Telehealth services should be reimbursed at the same allowable rates as face-to-face visits. Distant health care services should be decided by patient choice and guided by the patient-doctor relationship.
3. Provision of telehealth services should be based on clinical decision making and left to the discretion of the patient-doctor relationship.
4. Health care providers should be the final arbiter of the need and appropriateness of telehealth services with respect to their patients.

Furthermore, AAOS appreciates the efforts of the MA program to increase patient engagement in care. We believe it is important for patients to voice their concerns regarding quality and access in their insurance plans. However, we caution CMS against creating a situation where certain patient-reported measures outweigh the value of evidence-based measures. Therefore, we ask CMS to reconsider the proposal to increase the weight of the patient experience/complaints and access measures from 2.0 to 4.0 beginning in 2023. Relying heavily on patient experience/complaints to determine the reimbursement for quality may overemphasize the value of patient input relative to other, validated assessments of quality that consider evidence-based measures.

Toward that end, AAOS has recently developed comprehensive definitions of quality and value in orthopaedics. Quality is defined as the successful delivery of appropriate, evidence-based musculoskeletal health care in an effort to achieve sustained patient-centered improvements in health outcomes and quality of life. This is exemplified by a physician-led musculoskeletal team focused on the individual patient’s preferences in the delivery of care that is safe, accessible, equitable, and timely. The AAOS believes that this fosters evidence-based innovation essential for the advancement of professional and scientific knowledge. Value is defined as the relationship of a patient-centered health outcome to the total cost required to reach that outcome,
given that care is: evidence-based, appropriate, timely, sustainable, and occurs throughout a full cycle of musculoskeletal care for a patient’s condition; and that cost of musculoskeletal care is an investment and includes consideration of greater lifestyle and economic impacts. We encourage Medicare Advantage plans to consider these definitions vis-à-vis the goals of assessing quality and value in Part C and Part D plans.

**MA and Part D Prescription Drug Program Quality Rating System**

According to the March 2020 MedPAC Report to the Congress, 14% of Medicare spending on Part D benefits consisted of enrollee premiums. Although the report states that Part D programs have improved access to prescription drug coverage, “in 2017, more than 378,000 enrollees filled a prescription that was so expensive that their cost sharing for a single fill would have been sufficient to put them into the catastrophic phase of the benefit.” Protecting patient access to the medications they need to maintain health and mobility, or manage chronic conditions in order to be strong candidates for needed surgeries is essential to improved quality.

The increasing costs of Part D plans is further highlighted by a 2019 Kaiser Family Foundation analysis, which reports that prescription drug plan premiums vary across the country from as low as $13 per month to as high as $83 per month. This does not include co-pays and co-insurance costs for premium or specialty drugs. With this in mind, AAOS welcomes CMS’s recognition of innovations in biosimilar therapies. There is great potential for biosimilar therapies; however, without metrics it is difficult to accurately determine whether these new treatments are being adopted. More data is desperately needed by providers and patients to better inform and design safe, effective treatment plans. In this way, AAOS urges CMS to share the product-level ‘Biosimilar Utilization Rate’ data with the public. These data should be made easily accessible online and at no cost to the public.

**MA and Cost Plan Network Adequacy**

AAOS is concerned by the significant range in access to physicians depending on geographic location and MA plan. A 2017 Kaiser Family Foundation study found that one-third of MA enrollees were in “narrow network” plans. This means that patients, due to the limited nature of their MA plan, had access to less than 30% of the physicians in their county. When further analyzed based on specialty, on average, plan networks included just 49% of orthopaedic

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surgeons. We ask that CMS consider the impact of limited network adequacy on prior authorization processes and access to care for beneficiaries.

MA plans provide beneficiaries with access to supplemental benefits that improve quality of life and reduce barriers to care. Still, the regulatory burden of some laws impedes this access. The proposal to offer MA plans a 10-percentage point credit to mitigate the impact of certificate of need (CON) laws on network adequacy in certain states is an attestation to the fact that CON laws indeed negatively impact network adequacy and reduce competition. AAOS is steadfastly committed to the repeal of CON laws. Improving competition among all healthcare facilities will lead to improved patient access and quality of care.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ thoughts. 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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President, AAOS

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William O. Shaffer, MD, FAAOS, Medical Director, AAOS

American Association for Hand Surgery
American Association of Hip and Knee Surgeons
American Orthopaedic Foot & Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons

3 Medicare Advantage: How Robust Are Plans’ Physician Networks?, 2017 Kaiser Family Foundation
American Society for Surgery of the Hand
Arizona Orthopaedic Society
Arkansas Orthopaedic Society
California Orthopaedic Association
Cervical Spine Research Society
Colorado Orthopaedic Society
Connecticut Orthopaedic Society
Georgia Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
   Iowa Orthopaedic Society
   Kansas Orthopaedic Society
Limb Lengthening and Reconstruction Society
   Maryland Orthopaedic Association
   Massachusetts Orthopaedic Association
   Minnesota Orthopaedic Society
   Nebraska Orthopedic Society
   New Jersey Orthopedic Society
   North Dakota Orthopaedic Society
   Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
   Orthopaedic Trauma Association
   Pediatric Orthopaedic Society of North America
   Pennsylvania Orthopaedic Society
   Rhode Island Orthopedic Society
   South Dakota State Orthopaedic Society
   Tennessee Orthopaedic Society
   Texas Orthopaedic Association
   Utah State Orthopaedic Society
   Virginia Orthopaedic Society
Washington State Orthopaedic Association
   Wisconsin Orthopaedic Society
   West Virginia Orthopaedic Society