AAOS
American Association of Orthopaedic Surgeons

September 10, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8010, Baltimore, MD 21244-1850.

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

Subject: CMS-1751-P Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirement

Dear Administrator Brooks-LaSure:

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 Medicare Program: CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirement (CMS-1751-P) published in the Federal Register on July 23, 2021.

The AAOS appreciates the ongoing efforts of the Centers for Medicare and Medicaid Services (CMS) to reduce burden and address the health equity gap during the COVID-19 public health emergency. We request continued support from the Department of Health and Human Services (HHS) as physicians navigate the ongoing pandemic accompanied by the continuous needs for personal protective equipment, financial support, vaccines and access to testing and therapeutics.

Appropriate Use Criteria Policy

AAOS is pleased to see that CMS is once again delaying the Appropriate Use Criteria (AUC) for advanced diagnostic imaging until at least January 1, 2023, or the first January following the end of the public health emergency. Although AAOS is supportive of programs that improve quality and reduce unnecessary testing, we are concerned that the implementation of the AUC program will detract from the developments of the Quality Payment Program (QPP) made in the years since the AUC program was signed into law. Meanwhile the continued delays create unnecessary costs at a time when reimbursement continues to face cuts and expenses rise as a result of the pandemic. In light of

the above factors, we request that CMS indefinitely delay the implementation of the AUC for advanced diagnostic imaging.

Conversion Factor

CMS is proposing to reduce the conversion factor from $34.89 to $33.58 (a decrease of 3.75%). This change is largely a result of the planned expiration of the 3.75% increase that was implemented through congressional action at the end of 2020 in the Consolidated Appropriations Act. While the calculations by the American Medical Association (AMA) estimate a combined impact of the work, practice expense, and malpractice RVUs and the expiration of the 3.75% increase from Congress will be a 2.7% total decrease to the 2022 allowed charges for orthopaedic surgery, CMS estimates a 1% increase to orthopaedic surgery if the conversion factor increase is extended. This comes at a time when surgeons are still facing an unprecedented public health emergency. **AAOS strongly urges CMS to maintain the current funding levels. This is critical to preserving access to patient care during the COVID-19 public health emergency.**

Split/Shared Billing

The current CMS regulations for split/shared visits furnished under facility settings, provide payment only to the physician or non-physician provider (NPP) who personally performs all elements of the service, and no payment is made for services furnished "incident to" the billing professional's services. In certain institutional (facility) settings, CMS' longstanding split/shared billing policy allows a physician to bill for an evaluation and management (E/M) visit when both the billing physician and an NPP in their group each perform portions of the visit, but only if the physician performs a substantive portion of the visit. In accordance with sections 1833(a)(1)(N) and (O) of the Act, when the physician bills for this type of split/shared visit, the Medicare Part B payment is equal to 80% of the payment basis under the PFS which is the lesser of the actual charge or the fee schedule amount for the service. However, if the physician does not perform a substantive portion of a split/shared visit and the NPP bills for it, the Medicare Part B payment is equal to 80% of the lesser of the actual charge or 85% of the fee schedule rate.

The 2021 Current Procedural Terminology (CPT) guidelines for E/M services introduced a new definition of a split/shared visit. This CPT definition was part of the new guidelines indicating how to select the E/M visit level based on time, which can be done for all office/outpatient E/M visits beginning January 1, 2021. The 2021 CPT E/M Guidelines state, *"A split or shared visit is defined as a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physicians and other qualified health care professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for split or shared visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted)."* The CPT definition does not state which individual is reporting the service, only that the time is summed to define the total time to report.

CMS is proposing to define split/shared visits in the facility setting as the physician may bill for a split/shared visit *only* if they perform a *substantive portion of the visit (*defined as more than half of the time), and the practitioners must be in the *same group* and furnishing the visit in *specified settings* in order to bill for a split/shared visit. CMS is requesting comments to revise the policies to account for recent revisions to E/M visit coding and payment.

AAOS strongly urges CMS not to revise the guidelines to split/shared E/M services as it will it create confusion among providers. Having two different definitions and policies from CPT and CMS will cause confusion for practitioners on how to document and report split/shared services. **It is important that physicians can focus on one consistent set of guidelines in reporting their services. Therefore, we strongly encourage CMS to work with the AMA's CPT Panel in order to clarify the reporting of split/shared visits in CPT Guidelines and CMS policy.**

The proposed CMS definition for the term "substantive portion" will be *based on time.* **AAOS strongly urges CMS to consider revising the definition for "substantive portion" to be based on medical decision making (MDM) and not time.** AAOS would like to also note that time parameters may be different in the office versus the facility setting. The proposed policy for split/shared E/M visits should not be based off keystrokes, but by who is providing the dominant MDM portion of the service. It is not uncommon for a mid-level NPP to have a prolonged visit with a patient, without performing any MDM. It would not be appropriate to allow that NPP to bill based on the time component, when the physician takes on the onus of performing the MDM. **Therefore, AAOS strongly believes the determining factor of who bills for the split/shared service should not be time based and should be focused on the practitioner that contributed the most towards the MDM, as they are ascertaining the majority of the risk.**

CMS is further requesting comment on the proposal requiring the reporting of a modifier on the claim to indicate split/shared billing. **AAOS urges CMS not to require a modifier to be reported for split/shared services, as this will be an additional administrative burden.**

Valuation of Specific Codes

For CPT Code 28002 *(Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space)* the RUC recommended a work RVU of 3.50 which CMS disagrees with, proposing a work RVU of 2.79. CMS reached this proposed RVU by selecting a crosswalk closer to the survey's 25th percentile. **AAOS has concerns regarding the crosswalk and the methodology used by CMS.**

CMS used CPT code 43193 *(Esophagoscopy, rigid, transoral; with biopsy, single or multiple)*, as a crosswalk based on similar intra-service time and total time. AAOS believes that this

comparison fails to consider the intensity of work required to perform procedure code 28002. While, both codes have a 000-day global with the same intra-service time, CMS use of code 43194 as a crosswalk is not an appropriate comparison. Based on the RUC's review of all 000-day global codes with 30 minutes of intra-service time and similar total times. CMS's suggested crosswalk was the second lowest value within the range. The RUC compared CPT code 28002 to CPT code 31287 (*Nasal/sinus endoscopy, surgical, with sphenoidotomy)* which has a work RVU of 3.50 with 30 minutes of intra-service time, and 86 minutes of total time. This has the same intra-service time and is consistent with the clinical intensity and complexity required for code 28002 as determined by the specialty societies that dominantly perform the service.

CMS also mentions that the change in the code's global period warrants the comparison with CPT code 43193 based on similar intra-service time and total time. While the comparison code has similar intra-service time, CMS neglected to properly justify why the 25th percentile would be used over the median. The RUC strongly disagreed with this crosswalk as it is not a clinically rational comparison based on relativity within this code family. Additionally, CMS failed to recognize the gradient increase in intensity level from 28001 to 28003.

The RUC did not use the survey's 25th percentile owing to physician input that the intensity of work required to perform the service was greater than 2.80 but lower than the median at 3.73. If compared to the family codes 28001 and 28003, the intra-service time, total time and intensity further justify a work RVU of 3.50, as the time increments are evenly spaced as intensity increases. When the description of intra-service work is reviewed, a clear depiction of intensity increase is seen from 28001 to 28002. CPT code 28002 requires significantly more precision, mental effort, and judgement to avoid damage to the plantar nerve, flexor tendons, or short tendons as well as the vascular structures of the foot. This same level of precision is not required for 28001. **AAOS would like to stress the importance of taking intensity level into account as the as the survey 25th percentile is not a justified reference point for valuing this service within the code family.**

Lastly, the intra-service work from 28002 to 28003 increases substantially as multiple incisions are made and this greater complexity justifies a slightly higher RVU increase compared to that of 28001 to 28002. Thus, lowering the work RVU to the CMS suggestion distorts relativity across the code family and creates payment disparities in a payment system that is based on relative valuation. **Therefore, AAOS strongly urges CMS to accept a work RVU of 3.50 for CPT code 28002.**

<u>Global Codes Update</u>

AAOS would also like to remind CMS that it is inappropriate for CMS not to apply the RUC-recommended changes to the global codes. **AAOS strongly urges CMS to reconsider this policy and apply the E/M value increases from CY 2021 to the global codes.** AAOS continues to find CMS' failure to incorporate the incremental increase for work and time for the revised office/outpatient visit E/M codes in all global codes unacceptable. Including the value increases to

all global codes is essential to maintain fee schedule relativity.

Clinical Labor Pricing

For CY 2022, CMS is proposing to make changes to all three components of Practice Expense (PE) RVUs (clinical labor, supplies, and equipment. This is the final year of a four-year transition of an update to the supplies and equipment prices used for code-level direct PE calculations. **AAOS is concerned with these pricing updates, specifically use of the average (mean) hourly wage, fringe benefit multiplier, and implementation of these changes.**

CMS proposes to use the mean hourly wage instead of the median. AAOS disagrees with use of the mean hourly wage as the clinical staff time for codes has always been based either on the typical time or median time when RUC survey data is used. Furthermore, we recommend that CMS use the Bureau of Labor Statistics (BLS) median wage rate to update the clinical labor pricing.

CMS is also proposing to use the same benefit multiplier (1.366) that was utilized in CY 2002 to account for employers' cost of providing fringe benefits (e.g., sick leave). AAOS disagrees with this proposal as this multiplier is not accurate according to current BLS data. AAOS urges CMS to use the BLS median wage rate and apply the current fringe benefit multiplier of 1.296 in the calculation to update the clinical labor rates as we feel this is a more accurate reflection of industry benefits.

Lastly, AAOS strongly recommends CMS wait to update the clinical labor rate until CY 2023 which is the final transition year of the update to supply and equipment items. This will allow more time for stakeholders to respond to CMS' request for additional information regarding wage price data.

Critical Care Visits and Global Surgery

CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. **CMS should not finalize this policy as proposed. The AAOS strongly opposes a proposal that would prevent surgeons from being able to appropriately use modifier -24 (*Unrelated E/M Service During Post-Operative Period*) or modifier -25 (*Significant Separately Identifiable E/M Service on the Same Day of a Procedure or Other Service*).** Not only do CMS' rationales not support this policy, but this policy will prevent surgeons who provide both operative and critical care services from being fairly reimbursed for their time spent legitimately caring for some of their sickest patients in and out of the operating room.

Specifically, this policy undervalues the ICU care required for some post-surgical patients and undervalues the expertise of those intensivist surgeons caring for the most complex patients. Most surgical patients do not require ICU care, and ICU care is not included in the value of most 10- and 90-day global codes. But some patients are either already critically ill when requiring surgery or become critically ill unpredictably after surgery. In these cases, surgeons and surgical intensivists are best

equipped to manage the critical care services for these patients postoperatively. The surgeons are most familiar with their patient's case and their postoperative course. They are also most familiar with complex operations and the impact of comorbidities. And surgeons have the best skillset to identify and manage postoperative issues as well as recognize the expectations/pitfalls of surgery. The critical care that surgeons provide accounts for the constant attention, availability, interaction, and coordination with multiple other specialties that may be required for these patients.

CMS should instead maintain the current provision in the Medicare Claims Processing Manual that specifically allows modifiers -24 and -25 to be used to indicate that the critical care service can be billed when unrelated to the procedure. This section states:

Critical care services provided during a global surgical period for a seriously injured or burned patient are not considered related to a surgical procedure and may be paid separately under the following circumstances.

Preoperative and postoperative critical care may be paid in addition to a global fee if:

- *The patient is critically ill and requires the constant attendance of the physician; and*
- *The critical care is above and beyond, and, in most instances, unrelated to the specific anatomic injury or general surgical procedure performed.*

Such patients are potentially unstable or have conditions that could pose a significant threat to life or risk of prolonged impairment.

Modifier -24 (post-operative) or -25 (same day pre-operative) is used to indicate that the critical care service is unrelated to the procedure.[1]

Telehealth

For CY 2021, CMS created a third category of criteria (Category 3) for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE for the COVID-19 pandemic. This new category describes services that were added to the telehealth services list during the public health emergency (PHE) for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria.

We commend CMS' proposal to retain services listed in Category 3 (temporary code during PHE) until the end of CY 2023. This will allow sufficient time to gather data on utilization of these services and additional input from stakeholders prior to adding them permanently through rulemaking under

[1] Centers for Medicare & Medicaid Services. (2018). *Medicare Claims Processing Manual, Chapter 12, Section 40.1*. U.S. Department of Health and Human Services. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf

Category 1 (services like professional consultations and office visits) or Category 2 (services not similar to those approved for telehealth). Examples of Category 3 CPT codes include: Hospital inpatient care, per day, for the evaluation and management of a patient (99221, 99222, 99223); Office/Outpatient services, telephone evaluation and management (99441, 99442, 99443); and Observation care services for initial observation or inpatient hospital care (99218, 99219, 99220, 99234, 99235, 99236).

CMS is proposing to permanently adopt coding and payment for HCPCS Level II code G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous seven days leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*). CMS proposes to continue a direct crosswalk of relative value units to CPT code 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion).* **While we commend CMS for permanently allowing reimbursement for audio-only telehealth services, AAOS recommends that CMS work with the CPT Editorial Panel to editorially revise telephone CPT codes 99441-99443 so that these CPT codes may be consistently reported by all payors.**

CMS is soliciting comment on whether the current timeframe for continuing telehealth flexibilities, which is the end of the year in which the PHE for COVID-19 ends or December 31, 2021, remains appropriate. Due to the ongoing nature of the PHE for COVID-19, we believe the timeframe for continuing telehealth flexibilities should be extended through a later date. We believe that this will facilitate the gathering of additional information that practitioners may need to assess the implications of a permanent change in this policy. Further, we will continue to protect the most susceptible patients from the COVID-19 virus by limiting any and all unnecessary possible exposure with in-person visits. **As in our comments on the CY 2021 MPFS, we again urge CMS to continue the current PHE flexibilities for telehealth on a permanent basis.**

CMS seeks comment on whether a service level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology. **AAOS supports the development of a CPT modifier to indicate when a service is provided via an audio-only technology (primarily via telephone)** for the following reasons: data collection, knowledge translation / policy implementation, health care equity, widespread need, and service specificity. The modifier should be used for E/M services that are structured like a classic history, exam, and plan, as with two-way audio-visual codes, when patients are unable to use the video function and are only able to use the audio portion for the history, exam and plan performed. The modifier should not be for general telephone E/M visits that are only telephone encounters.

Request For Information to address Closing the Health Equity Gap in CMS Clinician Quality Programs

AAOS appreciates the opportunity to comment on the Agency's request for information on closing the health equity gap in CMS Clinician Quality Programs. As we have stated in prior comments, AAOS is supportive of gathering meaningful patient data to support both the individual and population-level mitigation of health disparities. We request that CMS consider the following determinants which are of relevance 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).[1]
- Smoking Status – Smoking status may be reported through administrative data, but additional information may be provided from the EHR[2]
- Age – Age is reported in administrative data.[3]
- Sex – Sex is reported in administrative data.[4]
- 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.[5]
- 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.[6]
- 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.[7] 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.[8]

[1] ASPE (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available: https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs

[2] Ibid

[3] Ibid

[4] Ibid

[5] Karran, E. L., Grant, A. R., & Moseley, G. L. (2020). Low back pain and the social determinants of health: a systematic review and narrative synthesis. *Pain*, *161*(11), 2476–2493. https://doi.org/10.1097/j.pain.0000000000001944

[6] Perruccio, A. V., Power, J. D., Evans, H. M., Mahomed, S. R., Gandhi, R., Mahomed, N. N., & Davis, A. M. (2012). Multiple joint involvement in total knee replacement for osteoarthritis: Effects on patient-reported outcomes. *Arthritis care & research*, *64*(6), 838–846. https://doi.org/10.1002/acr.21629

[7] Austin, S. R., Wong, Y. N., Uzzo, R. G., Beck, J. R., & Egleston, B. L. (2015). Why Summary Comorbidity Measures Such As the Charlson Comorbidity Index and Elixhauser Score Work. *Medical care*, *53*(9), e65–e72.

[8] National Alliance to Impact the Social Determinants of Health. (2019). (issue brief). *Identifying Social Risk and Needs in Health Care*. Retrieved from https://www.nasdoh.org/wp-content/uploads/2019/01/NASDOH-Social-Risks-Issue-Brief.pdf

- 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.[9]
- Chronic Narcotic or Pre-operative Narcotic Use – These variables affect patient outcomes and requires additional consideration. The information should be available in the EHR.[10]

In addition to the above clinical factors which impact outcomes on the individual level, we ask that CMS also consider access to transportation, social support, and health literacy.[11] These factors all contribute to a patient's successful treatment and lead to improved outcomes for both chronic and acute musculoskeletal care. Particularly in light of the disparities made evident during the pandemic, it is essential that patients and physicians have the tools to support a robust model of shared decision-making.

Moreover, AAOS has developed comprehensive definitions of quality and value in orthopaedics. Whereas quality is defined as the successful delivery of appropriate, evidence-based musculoskeletal healthcare in an effort to achieve sustained patient-centered improvements in health outcomes and quality of life 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; and that fosters evidence-based innovation essential for the advancement of professional and scientific knowledge.

The AAOS has defined 'value' of health care 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 CMS to consider these definitions vis-à-vis the goals of assessing quality and value in an equitable health care environment.

Request for Information (RFI) on Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

CMS is considering expanding and establishing policies for data aggregation, measure calculation, measure reporting, process integrity, and market innovation to third-party aggregators, including, but not

[9] Oak, S. R., Strnad, G. J., Bena, J., Farrow, L. D., Parker, R. D., Jones, M. H., & Spindler, K. P. (2016). Responsiveness Comparison of the EQ-5D, PROMIS Global Health, and VR-12 Questionnaires in Knee Arthroscopy. *Orthopaedic Journal of Sports Medicine*, *4*(12), 232596711667471. https://doi.org/10.1177/2325967116674714

[10] Kidner, C. L., Mayer, T. G., & Gatchel, R. J. (2009). Higher opioid doses predict poorer functional outcome in patients with chronic disabling occupational musculoskeletal disorders. *The Journal of bone and joint surgery. American volume*, *91*(4), 919–927. https://doi.org/10.2106/JBJS.H.00286

[11] Artiga, S., & Hinton, E. (2018). (issue brief). *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity* Kaiser Family Foundation. Retrieved from https://files.kff.org/attachment/issue-brief-beyond-health-care

limited to, Health Information Exchanges, Qualified Registries, and Qualified Clinical Data Registries (QCDR). The AAOS Registries have achieved QCDR designation, and we can attest to the significant resources required to operate and maintain a QCDR. As a part of the QPP QCDR self-nomination process, CMS already requires thorough measure testing and validation to ensure measure calculation and reporting integrity. **Rather than creating separate, and potentially disjointed criteria and processes, CMS should borrow the established policies from the QPP and align wherever possible. Additionally, the AAOS recommends CMS apply full credit to any registry achieving QPP QCDR designation for similar Medicare Physician Quality Program requirements.**

Furthermore, in any proposal on standards for measure calculation, CMS should carefully consider the types of data readily available for submission from electronic records versus data types that would require manual abstraction from medical records. It is important to realize the trickle-down impact to healthcare providers as the end users of the systems collecting data for measure calculation. CMS is also considering the future potential development of a common portfolio of digital quality measures (dQMs) across its regulated programs, agencies, and private payers. In general, AAOS is supportive of policies that seek to simplify quality reporting for our members with caveats. It is important that efforts to standardize measures do not interfere with the flexibility for measure developers to innovate in the QCDR measure space. **Transparency is the crux of widespread adoption of a common measure portfolio; thus, we believe specifications for the CMS-developed dQMS are made available publicly, in a timely manner, and at no cost.**

Though we understand CMS will not be responding to specific comments submitted in response to this RFI in the FY 2022 MPFS final rule, we appreciate the opportunity to provide comments and look forward to future communication from CMS on the proposals in this RFI.

Updates to the Quality Payment Program

Subgroup Reporting

CMS proposes to establish a subgroup reporting option for Merit-based Incentive Payment System (MIPS) and MIPS Value Pathways (MVP) participation starting with the 2023 Performance Year. For the 2023 and 2024 performance years, CMS proposes that subgroup reporting would be voluntary and that at first subgroup reporting would be limited to clinicians reporting through MVPs or the APM Performance Pathway (APP). To form a subgroup, interested participants must identify the clinicians in the subgroup by TIN/NPI and provide a plain language name for the subgroup for purposes of public reporting. If participating in an MVP, the subgroup would need to identify which MVP it plans to report at the time of MVP registration. Subgroups would be scored at the subgroup level on Quality, Cost, and Improvement Activities and would receive the group's Promoting Interoperability score under the proposal.

In general, AAOS sees the subgroup reporting option as a valuable addition to the MIPS program. It is our understanding that it would allow orthopaedic surgeons working within a multispecialty group to report measures and/or MVPs more meaningful to their specialty; however, we seek clarification from CMS on who and how MVPs will be defined. As proposed, subgroups would consist of "a subset of a

group which contains at least one MIPS-eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI." We share concerns with CMS regarding use of Medicare Provider Enrollment, Chain, and Ownership System (PECOS) specialty data to determine subgroup composition and believe a subgroup should have the flexibility to self-identify the specialties it represents.

Perhaps the most concerning of the subgroup reporting proposals is the discussion on placing limits how clinicians can organize and be assessed by subgroups. CMS is considering restricting subgroup reporting to a single specialty. **We believe this restriction is antithetical to the goal of promoting team-based care and would discourage collaboration among specialties when developing MVPs.**

We ask CMS to proceed cautiously with subgroup reporting requirements and provide flexibility to groups in subgroup composition. Prior to implementing subgroup reporting, we encourage CMS to actively engage clinicians, healthcare administrators, and specialty societies in Town Hall-style meetings to better understand the impact to physicians, their practices, and patients.

MIPS Cost Measure Development

To increase the inventory of cost measures, CMS is proposing a new process for cost measure development and requests feedback on the proposed measure prioritization criteria as well as priority areas for future episode-based measure development. AAOS is glad to see an increased focus on growing the cost measure inventory and appreciate the proposal to create a development process that is open to the public; however, we believe taking the process from concept to reality may be more challenging than anticipated. We are concerned that the proposal does not address the obstacles faced by measure creators and the impact to the MVP program.

At present, the limited inventory of cost measures stifles the ability of specialty societies to create MVPs that meet the needs of their membership. For example, while there are knee and hip arthroplasty cost measures, orthopaedic surgeons who specialize in other anatomical areas are left to report the Medicare Spending Per Beneficiary Clinician measure, which only measures inpatient costs. Specialty societies have the clinical expertise to help CMS expand the cost measure inventory; however, the current pathways to obtaining Medicare claims data are unduly resource prohibitive because they are designed for research studies that capture data for discrete time period instead of continuous quality improvement initiatives.

Specifically, the AAOS recommends that CMS provide Medicare claims data, cost performance data, and funding to help specialty societies identify and develop clinically appropriate cost measures. We understand QPP data may be limited in years affected by the COVID-19 pandemic due to the Extreme and Uncontrollable Circumstances Hardship Exception policy in place. However, we urge CMS to provide as much detail as possible in a timely manner.

Lastly, CMS should also provide flexibility for cost measures developed by specialty societies as part of a candidate MVP. For example, a specialty society may wish to leverage their QCDR to

research and develop a cost measure that is aligned with an applicable quality measure. This type of development could result in a greater number of clinically relevant cost measures for specialists and advance CMS' goal of moving toward value by linking cost and quality in MVPs. Furthermore, providing a mechanism for QCDR's affiliated with specialty societies would help meet the requirements of Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which directs the CMS to provide qualified clinical data registries (QCDRs) with access to Medicare data for purposes of supporting quality improvement and patient safety.

MIPS Value Pathway (MVP) Development and Implementation

Since introduction of the MIPS Value Pathway (MVP) concept, AAOS has taken advantage of any opportunity to share the orthopaedic perspective and we appreciate CMS's commitment to communicating with stakeholders. As noted in our previous comments on the CY 2021 MPFS Proposed Rule, we continue to feel that MVPs have the potential to alleviate some of the challenges of the traditional MIPS program; however, more clarity and transparency are needed in key areas of the MVP development process, including collaboration with stakeholders and the return of feedback. Based on our experience developing and submitting candidates for the first wave of MVPs, we are offering several recommendations to improve and smoothen the MVP development process below:

Collaboration with Stakeholders

While we understand the need to discourage unnecessary spending in the Medicare program, cost and volume of procedures should not be the singular driver of future MVPs. Instead, we believe future MVP topics are ideally sourced from clinicians and the specialty societies that represent them. If CMS identifies areas for future MVP development, it is in the best interest of the program for those intentions to be made clear and accessible to the public so that relevant stakeholders may be included early and often in the development process. In this way, we are offering two recommendations to ensure all clinically appropriate stakeholders receive notice of MVP development.

First, we recommend CMS maintain a list of MVPs under consideration on the QPP website along with the MVP development point of contact. Second, CMS should also publish a list of topics it considers high priority for MVP development so that potential developers can align their efforts with the agency. Knowing CMS's intentions for future MVP development could also facilitate collaboration among specialty societies. From our initial experience co-developing MVPs, we have been encouraged by the enthusiasm of our members to contribute their clinical and policy expertise. We understand the burden that identifying all interested parties presents to CMS. It is difficult at times for specialty societies, even those who work with each other frequently, to identify the right contact person for MVP development. For future rounds of MVP development, we encourage CMS to formalize an internal process to ensure transparency and coordination among the relevant specialty societies in the early development of an MVP.

Completing Feedback Loops

AAOS encountered significantly different levels of feedback for the two orthopaedic-related MVPs with which we were involved. The feedback process for lower extremity joint replacement was exactly as

described in the 2021 MPFS Final Rule – timely, clear, and iterative. For the rotator cuff repair candidate MVP, we received feedback only after reaching out to the MIPS Practice Improvement and Measures Management Support (PIMMS) team. The feedback received was brief and that it did not commiserate with the time and effort our organization put into developing the MVP.

When CMS decides to not consider a candidate MVP submission for implementation, why that MVP was not considered should be communicated in a clear and well-timed process. From experience, AAOS can attest that MVP creation is a resource intensive process; therefore, timely feedback is necessary to making business decisions around whether an organization can begin or continue an MVP development project. We understand the feedback process on CMS's end is also resource intensive, yet we believe the investment in providing valuable feedback on all candidate submissions will pay dividends in future MVP development. In this way, we encourage CMS to change its current MVP feedback protocol to include all MVP candidate submissions, including those it does not initially deem feasible.

The Future of MVPs

CMS proposes delaying implementation of MVPs once more "to provide clinicians and third-party intermediaries with sufficient time to prepare for a shift to this new participation framework" and is now proposing MVP implementation beginning January 1, 2023. AAOS appreciates acknowledgement of the time needed to develop meaningful, clinician-lead MVPs, but would be remiss if we did not highlight the impact to our members who are ready now and need an alternative to reporting traditional MIPS. In our comments on the 2021 MPFS Proposed Rule, AAOS expressed concerns with the concurrent elimination of the APM Scoring Standard and introduction of the overly prescriptive APM Performance Pathway (APP). We urged the agency to keep the APM Scoring Standard available for those who do not meet the Qualifying Participant (QP) or Partial QP thresholds for Advanced APMs and/or do not have clinically meaningful measures in the APP measure set. Without the APM Scoring Standard, we anticipated many orthopaedic surgeons having no other option than to report traditional MIPS. Our concerns have been realized as some of our orthopaedic group practices have shared they have had to develop plans and institute new workflows to report traditional MIPS for the first time in 2021.

While we appreciate delaying MVP implementation until the 2023 Performance Year to allow more time for developers and CMS to grow the MVP inventory, AAOS recommends that CMS not delay implementation beyond 2023. Should CMS feel the MVP program will not be ready by the 2023 Performance, we request that the APM Scoring Standard be reinstated.

Looking ahead to the eventual implementation of MVPs in 2023, we are concerned that the incentive to report MVPs is not strong enough to persuade those currently reporting successfully through traditional MIPS. While CMS proposes fewer measures in the quality and improvement activity (IA) performance categories to offer some burden reduction, potential MVP participants may still be hesitant to change established processes for a novel pathway. MVP participation may be less attractive for specialists who have never had performance tied to population health measures. For these reasons, AAOS recommends providing stronger incentives to MVP participation by pairing multi-

category credit (e.g. promoting interoperability credit for reporting electronic clinical quality measures) with an introductory year hold harmless scoring policy on the foundational population health measures.

Another way to encourage adoption of MVP reporting would be to offer automatic category credit for those reporting via a QCDR. QCDR's must demonstrate the ability to improve health quality and as such its participants demonstrate commitment to that goal. In fact, there is already a medium weight improvement activity (IA_PSPA_7), available to QCDR participants. Allowing automatic IA credit for QCDR participants would remove the extra step of attesting to the IA and make MVP participation more attractive.

Within the proposed rule CMS also lays out the timeline for MVP implementation, which references the Agency's intent to eventually sunset the traditional MIPS program and make MVP reporting mandatory beginning with the 2028 Performance Year. Adoption of MVPs is highly dependent upon the availability of a robust and clinically relevant inventory and it remains unclear when the program will be developed to a point where all eligible clinicians can succeed. **AAOS urges CMS to reconsider prematurely defining a date for sunsetting traditional MIPS, and we encourage the agency to keep MVP reporting voluntary until all eligible clinicians are captured by an appropriate MVP.**

Proposed Introductory MVPs for 2023 Performance Period

Included in the proposed rule is an introductory set of seven MVPs to be reportable starting with the 2023 Performance Year, one of which is aimed at lower extremity joint repair (LEJR). We appreciate an option for some orthopaedic surgeons to report via an MVP in the inaugural year and have taken the time to review the proposed Improving Care for Lower Extremity Joint Repair MVP. Overall, we agree with the measures included in the MVP and are happy to see feedback from meetings with the agency was incorporated into the proposal.

Candidate MVPs Not Considered for 2023 Performance Period

As noted above, AAOS submitted a candidate MVP, Improving Rotator Cuff Repair Outcomes, because we identified a gap in value-based payment programs for rotator cuff repair. To date most value-based payment models have focused on hip and knee arthroplasty, which are a logical target due to their high volume and associated costs. However, with rotator cuff repair procedures coming off the inpatient only list in 2021, we anticipated more Medicare Part B claims for these procedures and a need for more quality data collection. By creating an MVP focused on rotator cuff we hoped to increase the collection of data, including patient-reported outcome data, thus creating an opportunity for analysis and outcome improvement plans.

In the feedback we received via email from the PIMMS team, we were advised that CMS determined the rotator cuff MVP is not feasible at this time due to the topic being too narrow. It was explained that CMS's goal is to create MVPs that have a broader topic for more clinicians to be able to report the MVP. Hearing this goal raised concerns for us as it is not included in the previously codified MVP development criteria or MVP guiding principles. Additionally, a goal to create broad topic MVPs will potentially expand the number of measures included in a single MVP, for which CMS has proposed

limiting in this proposed rule.

If the goal is truly to move toward broad topics for MVPs, CMS should make their intent transparent to MVP developers and revise the MVP guiding principles and development criteria through rulemaking. Stakeholders should have the opportunity to share feedback on CMS's intent to move toward such a significant goal.

With any new regulations there are growing pain and lessons learned. We appreciate the opportunity to share our recommendations for improving the MVP development process and look forward to working with CMS in future years of the program.

Third-Party Intermediaries

In tandem with the significant proposals on subgroup reporting and MVP implementation, CMS plans to place more requirements on QCDRs, qualified registries, and other third-party intermediaries in the coming years. Briefly, CMS is proposing policies that would require third-party intermediaries to support reporting and submission by APM Entities and subgroups. Beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries would be required to support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. CMS also expresses concerns about vendors self-nominating to achieve the QCDR title, but not actively participating in the MIPS program, thus they propose new requirements that effectively force QCDRs and qualified registries to submit data or participation plans to keep their designations.

The continued regulatory burden placed on third-party intermediaries without recognition for the time and resources needed to a comply with these significant changes year over year is discouraging. We ask that CMS consider delaying some or all of these new requirements, particularly the requirement to submit MIPS data or participation plans.

In prior years, CMS finalized policies that will eventually require all QCDR measures to be fully tested (i.e. beta-tested per the CMS Measures Blueprint definition) at the clinician level prior to self-nomination to be considered for inclusion in traditional MIPS and MVPs. Also finalized in the 2020 MPFS, was the requirement for data collection on QCDR measures prior to self-nomination.

While the AAOS appreciates the previous delays in the QCDR measure development requirements, we strongly urge CMS to reconsider delaying implementation of QCDR measure testing to the clinician-level and pre-submission data collection until at least one year after the PHE ends. These requirements were overly burdensome to QCDRs prior to the COVID-19 pandemic and are even more so now that QCDRs must navigate the challenges of reduced data due to suspension of elective procedures and the threat of another wave of hospitalizations due to the Delta variant. While we agree that data integrity is of utmost importance and appreciate CMS's consideration of a gradual process to ease the requirements, the uncertainty of the pandemic makes it challenging for QCDRs to implement these requirements. We would like to reiterate concerns from our comment letter on the CY 2020 MPFS Proposed Rule. Measure testing at the clinician level is resource intensive and time consuming for not only the measure

developer, but also the provider. QCDRs must rely upon participant clinicians or groups willing to test the measure voluntarily, which can be a lengthy process. Most often a staff member at the clinician's office must then be identified and trained on how to audit the measure correctly. Most medical practices do not have employees dedicated to auditing medical records and at a time when clinics are focused on stemming the spread of SARS-CoV-2 they do not have the resources to put toward QCDR measure auditing.

AAOS encourages CMS to adopt a more strategic and flexible approach to MIPS and QCDR measure selection and testing, including allowing alternative testing approaches and additional time to collect data for testing, in order to ensure that measures are appropriate, reliable, and valid. Unless action is taken, measure testing and data collection requirements will be effective January 1, 2022. We ask that CMS consider delaying these burdensome requirements indefinitely or at least until the COVID-19 public health crisis resolves.

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on the significant proposals made in the CY 2022 MPFS proposed rule. The AAOS looks forward to working closely with CMS on further improving the payment system, and to enhancing the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,

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Alabama Orthopaedic Society
American Association for Hand Surgery
American Association of Hip and Knee Surgeons
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
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New Jersey Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Orthopaedic Rehabilitation Association
Orthopaedic Trauma Association
Pediatric Orthopaedic Society of North America
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