



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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September 7, 2018

Seema Verma, MPH
Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

Subject: [CMS-1693-P] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

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; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-P) published in the Federal Register on July 27, 2018.

CY 2019 Updates to the Physician Fee Schedule

Determination of Practice Expense (PE) Relative Value Units (RVUs)

Low Volume Services

CMS finalized a proposal in the CY 2018 PFS final rule to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For a procedure infrequently performed on the Medicare population, low volume status would subject its code to year-to-year fluctuation in

dominant specialty. This creates substantial year-to-year variability in PE RVUs. To address this issue, codes falling into this category are assigned to a dominant specialty based on medical review and input from expert stakeholders. The AAOS will continue to collaborate with the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) on annual maintenance of the list and urges CMS to continue to utilize this list for developing PE and Professional Liability Insurance (PLI) RVUs. This is consistent with AAOS comments to the 2018 MPFS proposed rule highlighting the work being done by the AMA RUC in reviewing low volume codes. We also recommend that CMS follow that same logic for all codes subject to dominant-specialty variation due to low Medicare utilization.

The procedure described by Current Procedural Terminology (CPT) code 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar*) is missing from the proposed list published by CMS. Since CMS has a National Coverage Decision that precludes performing the procedure on patients over sixty-five, the number of Medicare claims has remained well below 100. In fact, Medicare claims have not exceeded 10 for the past several years. A small change in claims data between 2015 and 2016, led to an 18 percent decrease in PE RVUs. To maintain payment stability and exempt it from annual fluctuation, **we request that CMS include CPT code 22857 in the low utilization category and permanently assign it to the orthopaedic surgery specialty.**

Changes to Direct PE Inputs for Specific Services

Market-Based Supply and Equipment Pricing Update

CMS is proposing to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. CMS proposes to phase in the new pricing over a 4-year period. The AAOS has serious concerns with the validity of pricing updates with such dramatic shifts, such as increases for a patient gown (SB026) from \$0.53 to \$3.54. Additionally, SA081 (pack, drapes, ortho, small) includes 4 units of SB019 (drape-towel, sterile 18in x 26in) are currently priced at 1.128 and 0.282, respectively. However, StrategyGen recommended pricing SA081 (four towels) at 1.000 and SA019 (one towel) at 0.920. With such large variation in pricing changes, StrategyGen should supply more granular data for each recommendation, including greater specificity of items and source of pricing. **We urge CMS to delay a pricing update until the information requested above is made available and stakeholders have ample time to produce invoices which may refute the proposed amounts.**

Digital Radiography (DR) PE Inputs

The AAOS would like to raise the issue of the PE inputs for radiology rooms. The 2018 payment year began to apply a 7 percent reduction to the technical component of those services not performed using digital radiography. This action will have a negative impact on orthopaedic physician offices, where computerized radiography (CR) is most commonly used. Currently, PE inputs are based on the less costly CR systems. If CMS presumes that DR is the “standard”, we would argue that **PE inputs should be updated to reflect the cost of digital systems.** This increase should be applied to all x-ray codes, retroactive to January 1, 2018.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

New technology has vastly changed how information is gathered and shared between the patient and provider. The AAOS appreciates the efforts to address these changes through the introduction of communication technology-based telehealth services and supports the addition of the GVC11 and GRAS1 codes. Communication between visits and coordination of care are essential and overlooked activities. Yet, resting outside of evaluation and management, neither are reimbursed. Patient Portals are an entirely new work stream that are not captured by current guidelines, although they often serve as a means of patient-provider communication addressing medical decision-making and alterations in care plans. Often, these are check-ins that provide simple instruction or needed reassurance in lieu of a visit. We support reimbursing all means of patient contact work (i.e., telephone, e-mail, patient portal, fax). The AAOS does feel that the limitation of these services to those that are patient-initiated undervalues recent increases in care coordination efforts. Provider outreach to established patients could obviate the need for unexpected follow up visits.

The AAOS believes care coordination is an implicit necessity for value-based care. We commend CMS for expanding telehealth options to include interprofessional communication with the creation of CPT codes 994X0 and 994X6. **We agree with the RUC that these codes should have work RVUs valued at 0.50 and 0.70, respectively.**

CY 2019 Identification and Review of Potentially Misvalued Services

Public Nominations

CMS received a public nomination for potentially overvalued codes based on the opinion that previous RUC review did not result in appropriate reductions in surveyed times and valuation. This nomination included total hip arthroplasty (27130) and total knee arthroplasty (27447). The submitter requested that the codes be prioritized for review under the potentially misvalued code initiative.

While there is no definitive proposal by CMS to review these codes, the AAOS does not believe any further action on this nomination is warranted. In 2013, the RUC and CMS reviewed and validated the current RVU values. There is no data to indicate a change in the work of performing the procedure or the number of post-op follow up visits since that time. This nomination was not received during the proposed or final rule comment period and is, therefore, not publicly available in the Federal Docket Management System. **The AAOS asks for transparency in these types of nominations by requiring nominations to supply the source and be submitted through the comment period.**

Update on the Global Surgery Data Collection

CMS believes the minimal 99024 reporting during 10-day global periods suggests that post-operative visits are not typically being furnished. CMS requested feedback on alternative explanations for the low percentage of reporting of this code.

The AAOS appreciates the intention to use the data already gathered to further evaluate an

explanation for low reporting, but we do not have the raw data for the procedures, beneficiaries, and specialties that CMS used for analysis. In the presentation of statistics, CMS notes that "multiple procedures performed on a single day and procedures with overlapping global periods were excluded because matching may be unclear in these circumstances." Although CMS indicates it excluded records where more than one code was reported on the same date, we wonder if codes reported with modifiers were considered. For example, a 10-day global code, reported almost exclusively by orthopaedic surgeons, was also reported with modifier 58 (Unplanned Return to the Operating/Procedure Room by the Same Physician or Other QHP Following Initial Procedure for a Related Procedure During the Postoperative Period) 50 percent of the time. Modifier 58 does not reset the global period of the primary procedure and is paid at a reduced rate. This is also true for several other 10-day global codes reported by orthopaedic surgeons. It is possible that a post-op visit was performed, but not reported in conjunction with procedures reported with modifier 58. Instead, the visit would have been related to another 90-day global primary procedure that may or may not have been on the list of codes under review by CMS.

Alternatively, the measured low frequency of post-operative visits in the 10-day global period could be explained by system and process errors. CMS conducted research and collected data to assess whether global codes are correctly valued. If there were accurate and valid data to indicate that a visit is "not typical", the code should be revalued using a standard RUC process. However, the data did not show that global codes are misvalued and we believe CMS has met its statutory requirements.

Regarding "transfer of care" modifiers (-54, -55), it is our opinion that the formal transfer of care policy is clear and should be used when postoperative office visits are transferred to another provider. For orthopaedic surgeons, this might occur if a patient is treated for a fracture, while on vacation or in an emergency department, but follow-up is assumed by another provider. We believe orthopaedic surgeons understand how to report the correct modifiers and that a change in policy is unnecessary.

Valuation of Specific Codes

Injection Tendon Origin/ Insertion (20551)

The RUC recommended direct PE inputs of 3 minutes for "Education and consent" and 2 minutes for "Review home care instructions" for this procedure. These clinical staff activities are not included in an E/M service. This injection is more involved and invasive than a vaccination (90470, 90471), which was allowed 3 minutes for "F/u on physician's discussion w/patient/parent & obtain actual consent signature" and an additional 3 minutes for home care instructions and recording vaccine information in the medical record (expiration, lot number), in addition to the inputs for an E/M service that would be reported on the same day. We urge CMS to accept the RUC recommended times for these clinical staff activities.

Application of Long Arm Splint (29105)

CMS did not accept the RUC- recommended direct PE inputs for equipment used in the application of a long arm splint. CMS does not indicate what service period time was removed from the calculation. This makes it difficult to determine if this is accurate or not. Since CMS is

present and corrects times at the RUC meeting, we do not know what further corrections were made. **We request more information about this change and that CMS publish the specific calculations used to determine time for different pieces of equipment.**

X-Ray Codes (72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, 72120, 72200, 72202, 72220, 73070, 73080, 73090, 73650, and 73660)

The RUC reviewed twenty x-ray codes employing a “crosswalk methodology,” in which they derived physician work and time components for CPT codes by comparing them to similar CPT codes. CMS chose not to accept the RUC recommendation because the crosswalk was applied to several codes that have not been surveyed since 1995. Since all twenty of the CPT codes in this group have very similar intraservice time (3-5 minutes) and total time (5-8 minutes), instead CMS calculated the utilization weighted average RUC-recommended work RVU for the codes as an alternative to the crosswalk. We disagree with this methodology, as it is not resource-based. More physician time is required to review five to six views, when compared with one to two views. A greater number of views also utilizes more clinical staff time, supplies, and equipment time. Lastly, beneficiaries’ out of pocket expenses will not be reflective of the particular service they received. **We urge CMS to accept the RUC recommendations which differentiate work and practice expenses between these services.**

CMS also did not accept the RUC-recommended time for the basic radiology room for x-ray codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120. However, CMS does not indicate what service period was removed from the calculation for equipment time. This makes it difficult to determine if this is accurate or not. Since CMS attends and corrects times at the RUC meeting, we do not know what further corrections were made. **We request more information about this change and that CMS publish specific calculations that it uses to determine time for different pieces of equipment.**

Regarding code 73660, X-Ray Exam Toe, the specialties and the RUC PE Subcommittee agreed that the typical patient for this service would not require a patient gown. This is different than other codes in the family where the patient may need to be rotated lateral and prone for different views. The RUC PE Subcommittee pays special attention to resource-based differences between codes. The AAOS was included in the review of PE inputs for 73660 and agrees that a patient gown for this code is not typical.

Evaluation and Management (E/M) Visits

The AAOS applauds CMS’ attempt at reducing the administrative burden on physicians by proposing to reduce documentation requirements for office visit E/M codes, as described in the 2019 MPFS proposed rule. We acknowledge the importance of this opportunity to make a generational and fundamental change to guidelines that provide clarity, consistency, and simplicity. We agree that, if constructed correctly, updating guidelines will be beneficial to patients, physicians, and overall quality. Moreover, the guidelines, which were last updated in 1997, do not reflect the significant changes in the workstream of today’s physicians. As we continue to focus on value-based care, increase our reliance on technology, and explore the utilization of team-based care, we must re-evaluate our methods of documentation. The AAOS is

pleased to provide comment on multiple components of E/M updates under consideration in this proposed rule.

CMS states that a thorough analysis was undertaken to inform the proposed changes to the guidelines. An independent AMA evaluation of the effect on specialties of a single payment rate was inconsistent with CMS' results. We question the reliability of the analysis and are concerned that savings in labor costs have been miscalculated. We believe that most of the time and labor saved on documentation will be after hours and on weekends, which does not equate to savings in "work time".

Documentation Changes for Office or Other Outpatient E/M Visits

AAOS appreciates the efforts of CMS to comprehensively apply the tenets of the Patients Over Paperwork initiative. The AAOS supports a history and physical exam with documentation guidelines that exclude unnecessary data points and redundant information. Interim history and physical documentation for established patients should be focused and relevant. We believe that the history and physical and Medical Decision Making (MDM) are both necessary components of E/M. However, the point system for history and physical documentation remains time consuming despite the use of electronic health records (EHR). Components of patient history are stored and remain available in the electronic health record; re-entering data serves no purpose. We also encourage CMS to support team-based care by finalizing the proposal to allow non-physician staff to enter clinical information into the health record. Physician attestation should be sufficient to support the documentation requirement.

The AAOS maintains that the MDM component of E/M is exceedingly complicated. E/M should be based on intensity, complexity, and time. MDM should account for the complexity of the diagnoses discussed, regardless of whether treatment is required, complexity of the treatments discussed, and level of risk associated with the medical conditions and treatment options. Time alone does not sufficiently account for the intensity, complexity, or medical necessity of the visit, as intense or complex conversations don't necessarily take much time. Under current guidelines, a new patient with a straightforward problem, such as tendonitis, will have a higher level of service than an established patient discussing alternative options after failed treatment due to the limited history and physical that may be documented. New guidelines should address this inconsistency.

The AAOS questions whether the perceived burden reduction is entirely attainable. The minimum standard of Level 2 documentation requirements is a welcome change. However, one of our concerns involves the creation of disparate Medicare, commercial payer, and legal documentation requirements. Implementation of any new guidelines would require significant and time-consuming changes. The incorporation of the new add-on codes would require staff training and novel activities to defend against audits. Additionally, many EHR and institutional billing systems are currently programmed to code visits based on documentation elements.

We believe it is essential that the agency adhere to the multi-year timeline described in the proposed rule with the goal of creating the most current and appropriate set of E/M guidelines. CMS should work closely with medical specialty societies to ensure that the guidelines reflect levels of E/M services. It is critical that all providers be involved throughout the process. Of note, the AMA has convened a CPT/RUC E/M Workgroup to tackle this complicated issue. The

AAOS will certainly follow their progress. We expect that it will appropriately represent the interests of both proceduralists and non-proceduralists. Importantly, the January 2019 timetable is too aggressive and unrealistic and should be slowed to allow time for an optimal update. Thus, the AAOS urges CMS to delay any changes to the E/M.

Minimizing Documentation Requirements by Simplifying Payment Amounts

CMS has stated that it wishes to decrease the documentation burden of physicians. The modification of documentation to correctly reflect work is a worthwhile goal, but compensation must reflect the work being done. A proposal that inextricably links decreased burden with a reduction in provider reimbursement is unacceptable. The AAOS believes any guideline update must ensure appropriate valuation of work and decreased reporting burden.

The AAOS does not believe that the proposal to provide a single payment for Level 2-5 E/M visits is acceptable. This proposal is not resource-based for the provider or the patient. A single payment based on a snap shot calculation of all providers and all Medicare patients disregards the complexity of a patient or intensity of a service and does not conform to the resource-based relative value scale (RBRVS) methodology used since 1992. The “average” visit level cannot be presumed on a granular level. Certain orthopaedic subspecialties (i.e., trauma, oncology, spine) and tertiary care subspecialists who see more complex patients or those with multiple conditions and tend to bill a higher percentage of Level 4 and 5 visits will be negatively affected. We believe this issue is ubiquitous for all medical specialties and would result in unfair compensation. We anticipate that visits will become more focused and patients will be required to attend additional appointments for multiple issues. This will lead to the provision of more E/M services, a greater number of copayments, and decreased access for more complex patients. Ultimately, charging healthy patients a higher copay for the provision of a low-level service creates a de facto subsidy for those consuming a greater number of health care resources.

It may be necessary to uncouple documentation and payment for acceptable updates to the guidelines. Whatever the outcome, commercial payers must accept any changes made to E/M. Additionally, the AAOS is very concerned about how these changes will affect our surgeons who currently receive RVU-based compensation.

Education Initiatives on E/M Updates

Two sets of guidelines currently exist and regional claims processors, often interpret the guidelines subjectively. Lack of uniformity and inconsistency in Medicare Administrative Contractors (MAC) requirements have created confusion and increased administrative burden. Regardless of whether changes are made to the guidelines now or in the future, there must be clarity and consistency to prevent subjective interpretation by MACs. We appreciate that CMS states that it will work with OIG and begin educating MACs, which may not have an orthopaedic surgeon to prevent misinterpretation. However, we have grave concern that education efforts cannot fully prevent fallout.

Since 2010, the National Correct Coding Initiative (NCCI) software has incorrectly defined the shoulder as a single joint. The AAOS, Association of Shoulder and Elbow Surgeons (ASES), American Orthopaedic Society for Sports Medicine (AOSSM), and Arthroscopy Association of North America (AANA) have worked tirelessly to correct the error in educational materials, as it directly influences coverage denials by commercial payers. Despite multiple discussions and

agreements on the need for the correction, CMS has not altered the CCI edits and coverage denials continue.

Additionally, the recent removal of TKA from the inpatient only list has demonstrated the difficulty in controlling the activities of the Quality Improvement Organizations (QIO). We are more than halfway through the year and have not made progress on efforts to stem forced outpatient TKA by hospitals ill-equipped to manage those patients. In a recent poll of the American Association of Hip and Knee Surgeons (AAHKS) membership, over 60 percent orthopaedic surgeons continue to experience forced outpatient TKAs for Medicare recipients, regardless of comorbidities or other factors. Recent reports in the lay press have highlighted severe complications in sleep apnea patients. We urge CMS to correct this behavior to prevent further patient injury.

For these reasons, we cannot support the proposed E/M updates, which would rely so heavily on educational efforts for proper implementation.

Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

The AAOS supports the elimination of the prohibition on same-day billing by practitioners of the same group and specialty. It is common for a patient to be seen for shoulder pain, which turns out to be caused by a neck issue. This requires referral from the shoulder specialist to a different orthopaedic surgeon in the practice specializing in spine. The current instruction precludes an additional visit on that day, creating a burden for patients, particularly in rural areas or when seeing specialists. Ultimately, the patient only perceives the inconvenience and treatment delay.

Accounting for E/M Resource Overlap between Stand-Alone Visits and Global Periods

CMS claims that there are significant overlapping resource costs when a standalone E/M visit occurs on the same day as a 0-day global procedure. Using the surgical multiple procedure payment reduction (MPPR) as a template, CMS is proposing to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. There is no corollary between multiple global surgical procedures performed on the same day and multiple office E/M services. For example, an orthopaedic surgeon provides a shoulder injection on the same day as an E/M visit for low back pain. In this instance, the work and PE are not overlapping and should not be discounted. The AAOS reminds CMS that the RUC has already subtracted the resource cost overlap from the RVU when modifier -25 is typically applied. CMS is proposing a double reduction, which we oppose. We do agree that there may be some overlapping resources and that some payment reduction may be appropriate. However, **we believe that a 50 percent reduction is inappropriate and excessive.** If this proposal is finalized the overlap in codes that have been previously addressed by the RUC and CMS will need to be adjusted again to add back the duplicative resources.

Proposed Add-on G-Codes for Different Types of E/M Visits

CMS has proposed three new add-on codes to account for additional costs beyond the typical resources accounted for in the single payment rate for the levels 2 through 5 visits. These codes

are an arbitrary movement of funds to offset disproportionately negative payment adjustments under the proposed payment collapse.

The AAOS has several concerns regarding the development of these codes. Most notably, the creation of multiple "add-on" codes negates any decrease in documentation burden. The methodology CMS used to value these codes is neither transparent nor resource-based. It does appear to be an attempt to artificially transfer funds to a specific group of providers by reassigning the RVUs resulting from the proposed changes. Although CMS clarified that the add-on codes are open to all specialties, by restricting use of this code to services that address "conditions" common to specific specialties, there is a de facto increase in payment for certain specialists. There is little understanding of how this would look in practice. As explained by CMS, an orthopaedic surgeon treating a patient with knee arthritis caused by rheumatoid arthritis could report this code. However, a rheumatoid diagnosis alone is not sufficient for reporting the code. Causality and relatability of conditions is beyond what can be expected of MACs. Therefore, the codes cannot reasonably be reported or audited in their current form. We continue to recommend that CMS work through the CPT and RUC process to define and value work.

GPC1X (*Visit complexity inherent to primary care services*): We are not aware of any literature to support the premise that an E/M associated with a primary medical care service is always more complex than those associated with specialties. Primary care providers treat a wide variety of patients. In fact, the majority of these patients are without comorbidities and are not Medicare-aged.

GCG0X (*Visit complexity inherent to endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care*): CMS states that this code is intended to address the additional resource costs for specialists for whom E/M codes, rather than procedural codes, make up a large percentage of overall charges and who bill a high number of Level 4 and 5 visits. However, there is no evidence that the selected specialties have "inherent complexity that require extra work." In addition, the proposal does not address the Agency's concern about "code-creep". This accepts that any provider who typically reported a Level 4 or 5 visit did so appropriately. CMS notes that there was no cutoff percentage for determining the specialties which provide more Level 4 and 5 codes, making inclusion on this list a bit arbitrary. Creating different payment for a subset of specialties is prohibited by statute and we oppose any action that singles out a particular specialty.

GPRO1 (*Prolonged evaluation and management*): The AAOS is concerned at the significant reduction of the required time to report additional face to face time. Time-based codes only require 50 percent plus one minute of the stated time. Therefore, this new code may be reported when 16 minutes of additional face-to-face time occurs. The similar codes (99354 and 99355) were created in 1993 and include a full 60 minutes in the inputs, based on the typical physician face to face time for a 20-year old asthmatic being monitored in the office over a 2- to 3-hour period. No specific physician work other than periodic checking is indicated. The typical patient requiring this additional face-to-face monitoring of hypertension, diabetes and heart disease is not yet known. Nor do we know what procedure is being performed and monitored. Perhaps, it

would be more appropriate to review the current codes and create a new Category I code for time and typical patient.

Podiatric Evaluation and Management Services (HCPCS codes GPD0X and GPD1X)

CMS believes that the majority of podiatric visits are billed at lower E/M levels and will not be accurately represented by the proposed consolidated E/M payment structure. For this reason, CMS is proposing to create two HCPCS G-codes to describe podiatric E/M services. CMS references separate E/M codes for ophthalmology as a precedent, but does not acknowledge that the basis for this differential coding, even before the fee schedule was implemented, was the acceptance of allowing significant practice expense equipment as standard for every ophthalmology E/M service. In fact, the ophthalmology base code for an established patient (92012) includes three "lanes" that total over \$60,000 for every one of the 6.7 million Medicare visits in 2017. Given this information, **the AAOS does not agree that separate E/M codes are justified.** We believe the E/M structure is properly designed to describe services provided by all providers and adequately describes the services provided by podiatry.

Proposed Adjustment to the PE/HR Calculation

The AAOS strongly disagrees with the proposal to create a new Evaluation and Management "specialty", for purposes of calculating a PE/HR for the ten office E/M codes. The specialty PE/HR is based on the AMA Physician Practice Expense Information Survey (PPIS) and information within the survey is not based on a percentage of E/M provided by each specialty. The calculation that CMS performed to create a single \$136 PE/HR value for the 10 office visits is based on statistically unsound methodology, opaque analytics, and is not resource-based. The change would also result in significant upset to the indirect practice cost index (IPCI) for specialties, as it applies to the PE RVU methodology equation. **The AAOS does not support this proposal and urges CMS to abandon this change.**

CY 2019 Updates to the Quality Payment Program

Meaningful Measures Initiative

The AAOS appreciates CMS' effort to reduce the regulatory burden through various new initiatives and projects, including the Meaningful Measures Initiative Framework. Among the Framework's objectives, CMS has identified: (1) addressing high-impact measure areas that safeguard public health; (2) ensuring measures are meaningful to patients; and (3) minimizing the level of burden for health care providers. The AAOS agrees that each of these objectives is important to the success of the Framework and the Quality Payment Program (QPP). However, we do have several recommendations related to the Framework. Regarding the first objective listed above, the AAOS wants to stress that not all high impact measures to safeguard public health are applicable to all practices. As it further develops the Initiative Framework, **we encourage CMS to consider high impact public health measures specific to a given specialty.** The Meaningful Measures Framework needs to be physician-led. As the second

objective above emphasizes, these measures must be meaningful to patients, and physicians are best situated to understand what is most meaningful for their patients. We discourage promoting activities that are too far outside a given specialty's scope of practice in a one-size fits all approach. We also point out that greater use of registries comes with significant benefits. Specifically, Qualified Clinical Data Registries (QCDRs) are an important tool to develop better outcome measures to improve quality, safety, and value.

New Types of Eligible Clinicians, Low Volume Threshold, and New Opt-In Scenarios

The AAOS understands the need to admit new types of eligible clinicians into the program as it develops. We also appreciate the flexibilities offered to small practices and support the inclusion of "covered professional services" in the revised low-volume threshold.

Our comments on the QPP Final Rule last year encouraged CMS to expand its opt-in policies to permit more voluntary participation, and we appreciate CMS' proposal in this regard. As we pointed out then, many providers expended resources in preparation for MIPS inclusion under the 2017 low-volume threshold and should be allowed to participate voluntarily. **We continue to support voluntary, rather than mandatory, participation in all models, and encourage CMS to allow providers who do not meet any of the three low-volume criteria to opt into the program, as well.**

Virtual Group Election Process

It is difficult to comment on the pending virtual group election process until it is better defined. However, we agree that a web-based system would be less burdensome and offer unlimited potential to help make the virtual group reporting option more appealing and easier to use. As CMS points out, much of the MIPS user experience is already conducted via the QPP portal and consolidating the various activities into one location helps reduce provider burden. A web-based system linked to the existing QPP online portal could give interested participants a much easier means of connecting with other possible virtual group members than the current election process (via e-mail) and we encourage CMS to explore building the online portal in such a way as to facilitate these types of connections and group-building. In previous comments, we have expressed our concern about the difficulty of finding other potential group members.

Orthopaedic surgeons are interested in the virtual group reporting option but we encourage CMS to further streamline the process for forming one. This reform of the election process represents a great opportunity to do exactly that.

MIPS Performance Period

We continue to believe any changes in the performance periods should be implemented gradually and appreciate CMS' decision to keep the minimum performance periods for each performance category the same.

Quality

Submission Mechanisms

The AAOS understands (and has shared at times) the confusion that might arise from the submission mechanism terminology. We recognize that updating the terminology may more accurately reflect how clinicians and vendors interact with MIPS, but we urge CMS to maintain a single, settled, uniform vocabulary for the MIPS program as it develops to avoid further confusion. **We welcome the decision to permit individual eligible clinicians to submit a single measure via multiple collection types.**

Definition of a High Priority Measure

In the proposal to redefine a high priority measure, to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority, CMS asks what aspects of opioids should be measured (e.g. solely opioid overuse)?

Any opioid quality measures, especially those designated high-priority measures, need to recognize that numerous factors play a role the current opioid crisis, including habits outside of providers' control such as combining opioids with other medicines, using opioids for something other than pain, and failure to adhere to medicines as prescribed. There are many options available to help address this crisis, and the AAOS understands the important role surgeons must play. Accordingly, the AAOS has developed a Pain Relief Toolkit for our surgeons that includes doctor-patient scripts for successfully navigating common pain relief situations. The toolkit is designed to promote patient safety and comfort during the peri-surgical period, implement strategies that rely on alternative pain management tools and behaviors, and promote safe use and disposal of opioids.

Topped Out Measures

The AAOS understands the need to “top out” measures as the evidence reflects a need for their removal. Certainly, over time, the success of the QPP will justify the removal of certain measures sufficiently adopted to no longer require incentives. However, given the minimum time window necessary to develop and prepare a substitute in instances where a measure has been flagged for removal, **the AAOS urges CMS to revisit its proposal regarding removal of “extremely topped out” measures.** This proposal is particularly alarming for those specialties and sub-specialties with limited numbers of applicable measures. As we have stated in the past, CMS should announce the status of the measure with sufficient time lag before it is removed from service to allow clinical processes time to adjust and redirect their resources. A topped out measure may serve as a dynamic control for new or provisionally adopted measures.

We appreciate CMS' acknowledgement that it would consider retaining the measure if there are compelling reasons as to why it should not be removed. The current measure development and approval process has experienced some growing pains. While this has resulted in confusion and disorganization as some participants have received inconsistent feedback, the process has improved over time. Sun-setting measures without adequate infrastructure in place to respond would subject measure developers to an even starker cliff than already exists. If other high-quality alternatives cannot take the place of retiring measures, it could leave some specialists with few reasonable reporting options. Undoubtedly, CMS recognizes physicians' desire to not report on inapplicable measures solely for the lack of available, relevant measures.

Categorizing Measures By Value

Regarding the proposal to classify measures by a value (gold, silver, and bronze), the AAOS understands and appreciates CMS' intention. As we have acknowledged in the past, not all measures are created equal. The resources that go into developing "gold" measures deserve recognition. However, we cannot support the proposal as described in the proposed rule. As outlined, it creates an even more byzantine process for providers that increases burden in an environment where CMS is otherwise trying to reduce burden. The AAOS shares CMS' priority to combat opioid misuse, which is listed as a "gold" measure example in the proposed rule. However, non-opioid prescribers participating in the MIPS program would not be able to utilize this "gold" measure example, potentially putting them at a disadvantage. The current proposal creates yet another obstacle for those specialties and sub-specialties that may have too few "gold" or "silver" measures to achieve full points for a category. CMS should consider a classification that speaks to the quality of the measure. An evidence-based quality measure should be valued greater than a consensus-based measure, and a patient reported evidence-based measure should be of greater value than a consensus-based PRO or a non-validated PRO. **We encourage CMS to shelve this proposal for a future date when the MIPS program is more fully developed and tested.**

Small Practice Bonus

Last year, the AAOS welcomed the added flexibilities for solo and small practices that CMS finalized, including the bonus points for small practices participating in the MIPS program. Although we understand the need to transition all practitioners into ordinary participation in the MIPS program, we believe both reducing and moving the small practice bonus points is too severe. By reducing the bonus points' overall value (5 to 3), reducing the total value of the Quality category to 45%, and shifting the (existing) total bonus point allocation to a single category, the proposal effectively results in three levels of reduction to the current small practice bonus.

Small practices are among those most in need of more time and flexibility to adapt to the QPP given their limited resources. Rewarding physicians diligently trying to transition their practices to MIPS is an important tool to encourage maximum participation. We understand that CMS based its decision on the Quality category performance gap it observed for small practices in comparison to larger practices (based on historical PQRS data). As you know, both the structure

of and provider participation in PQRS was very different from the QPP. It would be unwise to penalize participants in this new program based on their performance in a legacy program CMS is actively transitioning away from.

As CMS points out in the proposed rule, for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR. However, hypothetically substituting overall bonus points with the expectation that a small practice should apply for a significant hardship exception is unduly burdensome on small practices after only one year.

CMS acknowledges that it considered whether to apply the small practice bonus via bonus points in all four performance categories. The AAOS would welcome bonus points applied evenly across Quality, Improvement Activities, and Promoting Interoperability. If CMS believes it is necessary to move the bonus points to the Quality performance category, **the AAOS would encourage CMS to keep it at five points before further reducing it in future program years.**

Measures Impacted by Clinical Guidance Changes

Although the AAOS appreciates that CMS will not penalize providers for circumstances beyond their control, we encourage CMS to provide more clarity about this policy. We agree that clinical guidelines and protocols developed by clinical experts and specialty medical societies underpin evidence-based quality measures, and we discourage the proposal to suppress a measure without rulemaking. Decisions regarding evidence-based measures based on clinical guidelines developed by medical specialty societies should involve significant engagement with the affected societies and their members. The AAOS recognizes the urgent need to ensure that patients are not negatively impacted by evidence-based measures based on reassessed clinical guidelines. However, before CMS moves forward with this policy, **we would appreciate clarity on several terms used in the proposal, including: what would constitute “significantly impacted”; and what “other changes” beyond clinical guideline changes would CMS consider sufficient to suppress a measure without rulemaking?**

Cost

As part of the Musculoskeletal Clinical Subcommittee, the AAOS helped develop the Knee Arthroplasty measure included among the eight episode-based Cost measures in the Proposed Rule. We appreciated the measured pace of this process and hope CMS continues this level of engagement with stakeholders in other areas of the QPP.

In the meantime, the AAOS appreciates that the Cost category weight is not being increased to 30 points. Nevertheless, we believe that raising its weight before CMS and providers can more fully digest and analyze the outcome of the program’s first year is imprudent. Further, the quality program has not fully matured. Until it has, the Cost category will have too great an influence on scoring and gaming behaviors are predicted.

Promoting Interoperability (formerly ACI)

The AAOS recognizes that CMS is committed to its decision to require 2015 CEHRT. As we have asked in the past, we would encourage CMS to allow for a longer window under the hardship application (e.g. two years). As surgical specialists, we have unique health information technology (HIT) needs and welcome proposals to accelerate HIT adoption by orthopaedic surgeons that combine adequate time for adoption, sufficient buy-in by all stakeholders, and incentives for early adopters. Given the expense and time that goes into integrating these products into a practice, many providers—especially small, solo, and rural surgeons—will rarely have the resources to quickly transition between products and re-train staff. **We urge CMS to recognize the difficulties surgeons and other MIPS participants face as mandated users for these products, which gives us limited bargaining power and gives developers no incentive to respond to customer input.**

Regarding the overall Promoting Interoperability scoring methodology changes, the AAOS appreciated CMS' flexibility under ACI that allowed physicians to focus on measures that were the most relevant to them and their practices. We continue to believe that this idea should drive the development of the Promoting Interoperability performance category. We appreciate that, despite the overhaul of the methodology, three of the four 2017 ACI transition measures were carried over to the Promoting Interoperability scoring framework.

The AAOS does not believe it is prudent, however, to substitute the methods for achieving bonus percentage points under ACI with the two limited bonus point options under the proposal. As CMS is aware, the new e-prescribing measures (e.g. Verify Opioid Treatment Agreement) may not be applicable to all provider types, medical record platforms, or state regulation. This is undoubtedly one reason why CMS designated these as bonus point-only measures. We would encourage CMS, as a transitional policy, to retain the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, as a component of the scoring methodology until another bonus point-only measures more widely applicable are available. CMS should cautiously approach these changes while it is simultaneously overhauling the entire scoring framework for the Promoting Interoperability category.

Further, the reduction in the Provider to Patient Exchange objective percentage between 2019 and 2020 is a move in the right direction, but we still believe 35 points on this objective is over-weighted. If a provider claims two exclusions under the Public Health and Clinical Data Exchange objective, these 10 points are reassigned to the Provider to Patient Exchange objective, further raising it to 50 points in 2019 and 45 in 2020. Obviously, not all the measures under the Public Health and Clinical Data Exchange objective may be applicable to all MIPS eligible clinicians. **The AAOS encourages CMS to make clear whether providers can choose two of the same measures under the objective, for example, by reporting to two Clinical Data Registries.** We continue to believe that CMS should encourage QCDR participation to relieve MIPS burdens where possible. It is more important that registry participation be encouraged for surgical specialties than pursuing Public Health measures out of the purview of surgical specialists.

We believe this scoring methodology overhaul is unduly complicated and confusing just as surgeons were beginning to acclimate to the current rules. Substituting the base, performance, and bonus scores for an “all-or-nothing plus performance” system is premature this early in the MIPS program.

Improvement Activities

The AAOS disagrees with CMS’ decision to end its bonus for performing an improvement activity using CEHRT. Although CMS makes it clear in the Proposed Rule that it is shifting the focus of this performance category to put a greater emphasis on interoperability and patient access to health information—and does not believe this bonus would directly support those goals—use of CEHRT remains valuable and vital to practice improvement. Eliminating this bonus, as so many practices work to integrate 2015 CEHRT (per CMS’ definitive requirements), while also modifying the Promoting Interoperability scoring methodology creates too much unpredictability for MIPS participants. We would strongly encourage CMS against this proposal as surgeons are only just beginning to understand the priorities and rules for compliance. CMS should give providers more time to acclimate to the original rules before adjusting so many interlocking parts of the program, which only creates undue regulatory complexity.

Complex Patients Bonus

The AAOS supports CMS’ decision to maintain consistent policies for the complex patient bonus in the 2021 MIPS payment year until sufficient evidence and new data sources are available that support an updated approach to account for patient risk factors.

Part B Services Subject to MIPS Payment Adjustments

As our previous comments have suggested, the AAOS welcomes the change that the MIPS payment adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician but will apply to furnished covered professional services.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

The AAOS applauds CMS’ efforts, through its waiver authority, to increase the overall accessibility of the QPP. CMS previously stated its intention for clinicians to move out of MIPS and increase participation in APMs. The AAOS greatly appreciates any regulatory relief that addresses the inability of orthopaedic surgeons to participate in risk-bearing value-based models. Despite the desire to engage in these payment arrangements and escape the reporting burden of MIPS, our members have experienced two major obstacles: (1) a lack of Advanced APM opportunities for specialists and (2) an inability to satisfy the QP threshold. MAQI addresses both the lack of specialist Advanced APMs and the obstacle of meeting the QP threshold. The expansion of the Advanced APM definition to include eligible MA plans provides an incentive for clinicians to “opt in” to the QPP. Moreover, by rewarding the provision of care for the 19

million MA enrollees, this demonstration will hasten the transition to value-based care. The AAOS has provided more detailed comments on the RFI related to this demonstration.

Facility-based measurement

The AAOS welcomes the regulatory relief that facility-based scoring will provide for these physicians. We encourage CMS to find other seamless avenues for MIPS compliance like the proposed automatic application of facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined Quality and Cost scores.

Performance threshold

In the proposed rule, CMS uses data from the CY 2017 QPP final rule regulatory impact analysis to estimate that the mean and median for the 2024 program year will be (at the low end) 63.50 and 77.83. For the purposes of estimating the 2024 performance threshold, CMS chose the mean to work back five years and set the performance threshold for 2021 Program Year at 30 points (up from 15). CMS describes its proposal as “a modest increase” that “would provide a gradual and incremental transition” to the potential 2024 MIPS threshold, estimated to be between 63.50 and 68.98 points. Although the AAOS understands that MACRA restricts CMS’ flexibilities as it gears up to the 2024 program year, doubling the performance threshold between payment years 2020 and 2021 would be unduly taxing. CMS undoubtedly recognized the steep gradient it is proposing when it solicited further comment on “whether the performance threshold should be set at a higher or lower number, for example, 25 points.” **The AAOS believes a more modest increase (e.g. 20 points) would still allow for a meaningful increase compared to the current threshold as providers adjust to the other simultaneous changes contained in the Year 3 proposed rule.** Using only the data from the CY 2017 QPP final rule regulatory impact analysis to estimate the mean and median for the 2024 program year seems premature.

In the proposed rule, CMS also asked if it should establish a path going forward for 2022 and 2023 so that the incremental increases between now and 2024 are known in advance or determine it each rulemaking cycle until 2024? **The AAOS would caution CMS to wait until it has accrued and analyzed more impact data from successive years of MIPS participation before finalizing such a steep increase in the performance threshold.** CMS should more slowly increase this threshold until MIPS participants have a greater sense of how they performed vis-à-vis the program overall. As CMS acknowledges in the rule, “estimates for the 2024 MIPS payment year performance threshold may change as we analyze actual MIPS data and, therefore, it may be appropriate to propose the performance threshold annually as we better understand the mean and median final scores.” **CMS should consider tying the threshold level to participation in registries.** By this, if a provider is reporting to a registry a percentage of patients, that percentage would be added to the APM percentage to calculate the threshold percentage. After all, the goal is to collect the data within and outside of APMs and every activity should be valued.

By design the additional performance threshold for extraordinary performance is already very difficult to meet. The AAOS understands CMS' desire to incentivize and reward extraordinary performance and appreciated CMS' willingness to maintain the additional threshold at 70 points last year. If the proposal to increase the additional threshold beginning with Year 3 is finalized, **we would encourage CMS to increase it by a more modest five points, rather than the proposed 10.**

Third Party Intermediaries

QCDRs Seeking Permission from Another QCDR to Use an Existing, Approved QCDR Measure

Under the proposed rule, CMS requires a QCDR measure owner "to agree to enter into a license agreement with CMS, permitting any approved QCDR to submit data on the QCDR measure." The AAOS has serious concerns with this language and strongly opposes this proposal. This proposal essentially nullifies a QCDR's right to their intellectual property interests when a performance measure is developed, by expulsion and potential replacement of the QCDR measure in question. Also, if the measure is released into the public domain, development costs could not then be retrieved from electronic medical record vendors, other associations or registries. Many QCDRs expend significant capital, resources, staff, and time (1-2 years), and go through a rigorous costly approval process to get performance measures prepared for approval by CMS. This proposed "licensing arrangement" undervalues that hard work and effort, but also will stifle innovation.

The proposed rule, as written, would create perverse market incentives for other QCDRs to rely on QCDR measure owners instead of developing their own. The goal should be developing evidence-based measures with clear-cut EBM methodology and content expert participation. Other QCDRs will be able to offer the same products, at a lower cost, and through lower prices, than more innovative QCDRs who are developing measures. The very nature of registries is to be an incubator of thoughtful evidence-based measures that have been used and validated within the registry. Another concern is that QCDRs who are using another QCDRs performance measure, may not have the requisite expertise and be ill-equipped to accurately measure, instruct, provide feedback, and issue reports to its users, further downgrading the quality of the measure. They are more likely than not consensus-based measures that have not gone through an evidence-based process. While the AAOS understands and appreciates CMS interest in harmonizing the proliferation of similar performance measures, and subsequent confusion by those using such measures, we do not believe this current proposal is the right approach to solve this problem. At the very least such a license should be non-exclusive, and the measure's value should be in some way returned to the developers. CMS should consider adjustments to those physicians' reimbursement or a bonus structure leading to reimbursement. For these reasons, **the AAOS opposes this proposal and encourages CMS to revisit this issue.**

Updated Definition of a QCDR

The AAOS supports the proposal by CMS to redefine the definition of a QCDR as an entity that has “clinical expertise in medicine and quality measure development.” Physicians and medical specialty societies are uniquely positioned with the clinical expertise to identify effective, relevant and timely quality measures, and are also able to balance patient safety. The AAOS appreciates that CMS recognizes the meaningful contributions of such societies to quality measure development. Further, commitment to the NQF pathway to develop evidence-based performance measures and patient reported outcomes must not be disincentivized.

Revised Self-Nomination Period for QCDRs

We appreciate that CMS is interested in finding additional time to discuss and review evidence-based performance measures submitted by QCDRs before the following year performance period. However, the AAOS reiterates a recommendation we suggested in our comments to last year’s QPP Final Rule (not specified in this proposed rule): to **separate out the performance measurement development process from the self-nomination process, so that they are two distinct processes and timelines.** This would allow CMS to provide an earlier timeline for the performance measurement development process without moving up the timeline for the self-nomination process. Under this recommendation, QCDRs and CMS will have extra time to consult on performance measures, and the additional burdens that would result from an earlier self-nomination timeline can be mitigated. Additionally, CMS should support the NQF initiative of provisionally approved measures to be used in the registry and validated by real-time data collection and analysis rather than claims data. This would speed performance measure development and validation.

QCDR Measure Benchmarks Based off Historical Measure Data

The AAOS thinks that an approach to develop QCDR measure benchmarks based off historical measure data has the potential to be beneficial, useful and valuable. We appreciate that the proposal would identify the QCDR as the source of data to inform benchmarks. Like CMS concerns about QCDRs being able to filter “historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical data to CMS for QCDR measure benchmarking consideration,” the AAOS believes some specialty societies may not have enough time to complete tasks by the deadline to self-nominate. The AAOS does not want to stifle innovation, but it would be appropriate for QCDRs to be leaders of the historical information and benchmarking. Indeed, registries should become the validation platform for provisional evidence-based performance measures. Evidence-based measure development and acceptance should be fast tracked through such a streamlined mechanism.

Future Approaches to Scoring the Quality Performance Category

Registries play a prominent role in improving the quality and cost-efficiency of care and should continue to be a meaningful part of the quality performance category. Continued focus within the quality performance category should be centered on the long-term migration to patient-reported outcomes (PROs) with reasonable expectations and sensible timelines. Registries are uniquely positioned to capture this information, not just at one single point in time, but across time, and

risk-adjust it to identify nationwide trends and inform future approaches to health. Additionally, there is useful information that is not routinely collected by EHRs, and administrative or claims data. The development of evidence-based PROs, validated by registries, can help address this issue.

Advanced Alternative Payment Model CEHRT threshold

As we have consistently argued, there should be more pathways for specialists to participate in the QPP through the Advanced APM track. Burdensome CEHRT requirements necessitate practices at the margin with limited resources to hire additional HIT staff or pay for third-party reporting. **We do not support raising the Advanced APM CEHRT threshold by 25% as proposed.** CMS has expressed its desire to encourage greater APM participation. While CEHRT is unquestionably a valuable tool for providers, mandating such a burdensome CEHRT-use threshold for those willing to take on greater risk and test pioneering payment models could only further dis-incentivize providers. CMS should consider leaving the threshold at its current 50% rate and providing other bonuses for those who exceed this threshold to more organically and gradually stimulate adoption. Our comments relate similarly to the Other Payer Advanced APMs proposed threshold increase.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current care delivery. 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, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



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Joseph A. Bosco, III, Second Vice-President, AAOS
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This letter has received sign-on from the following orthopaedic specialty societies:

American Association for Hand Surgery (AAHS)

American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
American Spinal Injury Association (ASIA)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Musculoskeletal Infection Society (MSIS)
California Orthopaedic Association
Connecticut Orthopaedic Society
Florida Orthopaedic Society
Kansas Orthopaedic Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
New Jersey Orthopaedic Association
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
South Carolina Orthopaedic Association
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Virginia Orthopaedic Society
OrthoForum