

September 5, 2017

Seema Verma, MPH Administrator, Centers for Medicare & Medicaid Services Department of Health and Human Services, Attention: CMS-1676-P P.O. Box 8016 Baltimore, MD 21244-8013

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

Subject: [CMS-1676-P] RIN 0938-AT02

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma:

On behalf of the more than 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS) and that of the orthopaedic specialty societies who agreed to sign-on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Program; CY 2018 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for C 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P) published in the Federal Register on July 20, 2017.

The AAOS commends the Administration's efforts to provide regulatory relief by seeking greater flexibility and efficiencies. The AAOS has long commented to CMS that the continual expansion of reporting and tracking requirements for physicians and their office staff have escalated practice expenses. The AAOS recommends that the agency rigorously review the multiple reporting requirements under the Physician Fee Schedule and consider methods that would simplify, reduce, and streamline these requirements. This will free physicians to spend more time in patient care, improving the care delivery experience for patients and providers alike. The AAOS welcomes the opportunity to directly engage with CMS on these issues and looks forward to future meetings and discussions with CMS on reducing administration inefficiency and streamlining the process for physician and physician offices.

Low Volume Service Codes

In the proposed rule, CMS proposed to override claims data for low volume services with an expected specialty for both the practice expense and professional liability insurance valuation process. This proposal is consistent with a long-standing AMA RUC recommendation to use the expected specialty for services performed less than 100 times per year. Even a few claims made in error by one physician could result in substantial year-to-year payment swings to these codes. This has been particularly problematic when the low volume services in Medicare are done in significantly higher volumes in the non-Medicare populations.

Subsequent to the publication of the proposed rule, the AMA RUC requested a review of all codes in the Medicare Physician Fee Schedule with fewer than 100 claims and asked participating societies to submit recommendations for their commonly used codes. The AAOS reviewed the list and provided input to the AMA RUC and recommends that CMS utilize this list for rate-setting for the CY 2018 Medicare Physician Payment Schedule. We understand that the list will require maintenance on an annual basis and the AAOS will collaborate with the RUC on future maintenance of the low volume list. The AAOS also recommends using the RUC recommendations for specialty assignments for codes in the fee schedule with no volume.

Preservice Clinical Labor for 0-Day and 10-Day Global Services

CMS indicates that for the 1142 0-day global codes, 741 of the codes had preservice clinical labor of some kind (65 percent). CMS also noticed a general correlation between preservice clinical labor time and when the code was reviewed. CMS is seeking comment specifically on whether the standard preservice clinical labor time of zero minutes should be consistently applied for all 0-day and 10-day global codes in future rulemaking.

The RUC Practice Expense (PE) Subcommittee assumes that 0- and 10-day global codes have no preservice clinical staff time unless the specialty can provide evidence to the PE Subcommittee that any preservice time is appropriate. The RUC agreed that - with evidence - some subset of codes in the facility setting may require minimal use of clinical staff and the RUC has allocated 15 minutes when appropriate. The RUC also agreed that with evidence some subset of codes may require extensive use of clinical staff and has allocated 18 minutes for the non-facility and 30 minutes for the facility when appropriate. On a case-by-case basis, the RUC PE Subcommittee reviews the evidence that is submitted to determine if the evidence justifies preservice time. For example, many recently reviewed interventional codes are actually major procedures, but have been assigned a 0-day global status. Clinical staff pre-service work is consistent with 90-day global codes. However, because these codes are 0-day, the preservice clinical staff work has been discounted. Another example is with the endoscopy services, where clinical staff will, among other activities, coordinate clearance for anesthesia and confirm diet and bowel prep. This necessary preservice clinical staff work cannot be performed on the day of the procedure after the patient has arrived. This is different from "minor" procedures (for example, laceration repair) where minimal or no preservice clinical staff work is required.

We believe that CMS is only seeing a "trend" because of the significant number of 0-day endoscopy and interventional codes that have recently been reviewed. If CMS considers "minor" procedures in the mix (for example, lesion excision), they will see that the RUC PE Subcommittee assigns zero minutes appropriately.

The AAOS respectfully disagrees with the proposal that all 0-day and 10-day global codes should have zero preservice clinical staff time and urges CMS to allow the RUC PE Subcommittee to continue to review compelling evidence on a code-by-code basis to determine the need for preservice clinical staff time.

Equipment Recommendations for Scope Systems

In the Proposed Rule for CY 2017, CMS outlined a pricing structure that separated out the components for scopes, scope video systems, and scope accessories. Because of the complexity of the issues CMS raised, and the need to incorporate input from all specialty societies, it was recommended by stakeholders at the time that CMS should work with the RUC to review the Agency's issues. CMS agreed to delay implementation until the 2018 Medicare Physician Fee Schedule and in this proposed rule reiterated its previous recommended approach for pricing scope systems.

The AAOS generally supports the proposed structure as outlined by CMS, but is concerned that the proposed approach does not sufficiently account for the different categories of scopes used in current practice and that it also does not sufficiently capture variation by specialty in terms of typical scopes and typical costs. As an additional step, the AAOS encourages CMS to continue to describe scope accessories as justified per each individual procedure so as to reconfigure the packages by specialty. The AAOS would support an additional year delay in implementation to accomplish this step rather than make changes for CY 2018 and, again, shortly thereafter.

CMS Identified Potentially Misvalued Services

In the proposed rule, CMS identified CPT code 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device, as potentially misvalued based on stakeholder comments. It is the AAOS' understanding that the RUC has added these services to the potentially misvalued services list and will review under that process. As the AAOS was one of the societies involved in the 2014 survey and valuation of 27279, we are supportive of deferral of the valuation of the code to the RUC and the RUC's standard processes for reviewing potentially misvalued and new technology codes like 27279. We note that 27279 is scheduled for RUC review in October 2018 by the RUC's new technology screen process. AAOS and other reviewing societies recommended new technology status and review at the time of the 2014 RUC survey and valuation process and will continue to work

within that process and timeline and recommend CMS consider any change in RVUs only upon completion of the RUC new technology review process.

Physician Work and Practice Expense Recommendations

The AAOS wishes to comment on physician work and practice expense RVU recommendations in the proposed rule for services commonly performed by orthopaedic surgeons.

Bone Marrow Aspiration

CMS reviewed CPT code 2093X, *Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision*, and assigned a work RVU of 1.16 for 2018. The AAOS supports the proposed work RVU of 1.16, which is what was recommended by the RUC and by the surveying societies. We believe this work RVU accurately captures the physician work involved in the service and recommends CMS finalize this value and not the alternative work RVU of 1.00 which CMS mentioned as a potential wRVU for 2093X because they were concerned that 2093X is a ZZZ (add-on) code. However, 2093X has parentheticals in CPT that would limit use of the service to only a small set of spinal surgical procedures which are medically appropriate.

Application of Long Leg Cast

CMS review CPT code 29445, *Application of rigid total contact leg cast*, and recommended a wRVU of 1.78. The AAOS supports this work RVU, which is also the current wRVU for 29445 and was the recommended value at the RUC, thereby reinforcing the appropriateness of this value for 29445.

For the Practice Expense RVUs for 29445, CMS recommended a reduction in clinical labor time for cast removal from the 22 minutes recommended by the AAOS and the RUC to 11 minutes. CMS indicates this is appropriate because the cast removal is only done at the beginning of the service prior to initial casting and that the clinical time for subsequent cast removal is not appropriate. We believe this statement and analysis is a misunderstanding by the agency of the standard approach to casting codes like 29445. The cast removal time in a casting code like 29445 is for a single cast removal technically done post-service, which seems counter intuitive. However, the way the work is structured assumes the cast removal will be done subsequently and is not included in the initial casting, but is also not separately billable. If the practice expense inputs are revised to 11 minutes, physicians providing the service would be losing compensation for standard work done as part of the procedure. We recommend adopting the RUC recommended clinical staff time for cast removal of 22 minutes in lieu of the 11 minutes proposed in the rule.

Suprascapular Nerve Injection

CMS reviewed CPT code 64418, *Injection, anesthetic agent; suprascapular nerve* and proposed a wRVU of 1.10. This is the work RVU recommended at the RUC and accepted by the RUC and we support the proposed value.

Nerve Repair with Nerve Allograft

CMS reviewed 4 CPT codes, two new and two existing, 64910, Nerve repair; with synthetic conduit or vein allograft (e.g., nerve tube), each nerve, 64911, with autogenous vein graft (includes harvest of vein graft), each nerve, 64X91, with nerve allograft, each nerve, first strand (cable), 64X92, with nerve allograft, each additional strand (List separately in addition to code for primary procedure).

Two new CPT codes were created to report repair of a nerve using a nerve allograft. Codes 64910 and 64911 were added as family codes for review, even though there was no change in the descriptors for these codes. For code 64910, CMS noted a decrease in preservice time (7 minutes) for code 64910 and considered an alternate work RVU of 10.15, crosswalking to CPT code 15120, Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children (except 15050), which has similar service times. CMS asked for comments on whether an alternative work RVU of 10.15 for CPT code 64910 would better reflect relativity among PFS services with similar service times.

The AAOS does not believe the decrease of 7, which is not in the pre-service time, but in the total time (from 264 minutes to 257 minutes) requires a further adjustment in RVUs. This represents a 2.6% decrease in total time. The RUC and specialty societies recommended a decrease in work RVUs from 11.39 to 10.52 (survey 25th percentile), which represents a decrease of 7.6%. The RUC recommended decreased work RVU results in essentially the same intraoperative intensity (current = 0.067; recommended = 0.066) for an extremely low volume code with work that has not changed. In addition, this is the same relative intraoperative intensity for 15120 (0.068), so we do not understand CMS logic to reduce the value further to an alternative code (15120) that has one less office visit than 64910. The AAOS believes the correct relative value for code 64910 is 10.52 work RVUs and recommends CMS finalize 10.52 as the work RVU for 64910.

For CPT code 64911, CMS considers an alternative work RVU of 13.50, crosswalking to CPT code 31591, *Laryngoplasty, medicalization, unilateral*, which has similar service times and seeks comments on whether a work RVU of 13.50 for CPT code 64911 would better reflect relativity among other PFS services with similar service times.

AAOS notes that code 31591 has a work RVU of 13.56, not 13.50. We also note that there was only a decrease of 2 minutes for 64911 from the previous review, a recommendation that CMS accepted. Third, even though there was only a two-minute difference, the RUC and specialty societies recommended a decrease in work RVUs from the current value of 14.39 to 14.00 (survey median). The RUC recommended work RVU results in essentially the same

intraoperative intensity (current = 0.075; recommended = 0.077) for an extremely low volume code with work that has not changed. In addition, the alternative code (31591) has one less office visit than 64911.

The AAOS believes the correct relative value for code 64911 is 14.00 work RVUs and recommends that CMS finalize this value.

For CPT codes 64X91 and 64X92, CMS questions the coding structure for these new services, which increases granularity by including an add-on code for each strand of nerve repair. CMS acknowledges that while additional granularity may be important and useful for purposes of data collection, the advantages to Medicare for such granularity for purposes of payment are unclear, especially since CMS is unaware of a payment-related reason for such coding complexity. CMS considers proposing a bundled status to the new add-on codes and incorporating the relative resources in furnishing the add-on code (CPT code 64X92) into the base code (CPT code 64X91) based on the utilization assumptions that accompanied the RUC recommendations.

The AAOS believes that CPT coding should define distinct physician work, for appropriate reimbursement (both physician work and practice expense) and for data collection relative to outcome and risk. Bundling the add-on service as CMS suggests would undermine the premise of coding and relative reimbursement. Bundling the service as CMS suggests would also place a financial burden on the patients who do not require multiple strands because they would be paying 120% of what they should be paying.

We disagree with the CMS recommendation to bundle atypical work and payment into a single code. The RUC recommended work RVU of 12.00 for CPT code 64X91 and a work RVU of 3.00 for CPT code 64X92 and we believe these values and codes correctly reflect the distinct work for each procedure when performed. Additionally, we believe the variation in practice expense and PLI RVUs accounts for the differences in relative resources.

Wrist, Hand, and X-Ray Codes

CMS reviewed CPT codes 73100, Radiologic examination, wrist; 2 views, 73110, Radiologic examination, wrist; complete, minimum of 3 views, 73120, Radiologic examination, hand; 2 views, 73130, Radiologic examination, hand; minimum of 3 views, and 73140, Radiologic examination, finger(s), minimum of 2 views, which were recommended for maintaining current wRVUs by the RUC. The AAOS supports the recommendation to maintain the wRVUs for all these codes.

Ultrasound Extremity Exam codes

CMS reviewed 76881, *Ultrasound extremity general* and 76882, *Ultrasound extremity limited* and agreed with the RUC recommendations to maintain current wRVU and change equipment setting for a general ultrasound room from 76881 to 76882 which shifts the PE RVUs from

76881 to 76882, lowering 76881 and raising 76882 RVUs. CMS is seeking comments on whether it is more reasonable to assign portable ultrasound machine to both codes. There was significant discussion regarding this issue at the RUC and the RUC's written recommendations discuss this issue in detail. The anatomic specific code (76882) describes a service most commonly performed by radiologists. The RUC and the reviewing societies noted at the time that 56% of the claims are submitted by radiologists. The CMS statement that "the dominant specialty for both of these services is podiatry" is inaccurate when taking into account services that are split by professional and technical components. This makes it necessary to review both the global claims data and the 26 modifier claims data in aggregate to determine the dominant specialty. Radiologists would typically use an ultrasound room and, therefore, the ultrasound room should be allocated to 76882. Podiatry typically performs the complete ultrasound study (76881) and typically utilizes a portable ultrasound room. We agree with CMS that these changes should be implemented immediately for 2018.

In addition to the change in PE, the AAOS, the American Podiatric Medicine Association, and the American College of Radiology are concerned that the definition of "complete" and "limited" was not clear in CPT and, accordingly, recommended that updated guidelines be added to CPT to clarify the intended reporting of each code. Additionally, changes were made to the descriptors, which will implement the following changes for CPT 2018. Based on these changes, the AAOS recommends accepting the RUC recommended Practice Expense inputs for 76881 and 76882.

Evaluation and Management (E/M) Guidelines

In the proposed rule, CMS asked for a multi-year effort to revise the CMS Evaluation and Management Guidelines, which have not been updated since 1997. The agency indicates a desire to use this effort to reduce administrative burden on physicians and streamline E/M guidelines. CMS suggests a focus on eliminating guidelines related to history and physical examination, with greater importance placed on medical decision making and time spent performing the service.

The AAOS agrees that streamlined guidelines and requirements for E/M codes would be beneficial to physicians and practices. We also believe that, if constructed correctly, streamlined E/M guidelines could improve patient experiences and overall quality. 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 the guidelines reflect and accommodate the significant variation in E/M requirements across medical specialties. It is critical that all providers be involved throughout the process. The AAOS looks forward to working with CMS and other stakeholders on this important effort.

Appropriate Use Criteria (AUC)

The Protecting Access to Medicare Act (PAMA) required CMS to create a program that, effective January 1, 2017, would have denied payment for advanced imaging services, unless the physician ordering the service had consulted appropriate use criteria. In previous rulemaking, CMS delayed implementation of the advanced imaging AUCs until 2018. In the 2018 proposed rule, the agency is proposing to further delay the requirement until January 1, 2019. This first year of reporting would be regarded as an opportunity for testing and education and would not affect payment to the physician providing the imaging. CMS is proposing that physicians who wished to begin testing earlier could participate in a voluntary reporting period expected to begin on July 2018.

The AAOS believes this delay is appropriate and timely and supports the recommended actions. We also encourage CMS to provide data from testing as quickly as possible to allow the agency and stakeholders to review the testing and access potential future revisions based on actual data. We also strongly support the increased education in this space as outlined in the proposed rule.

Physician Quality Reporting System (PQRS)

Under the PQRS 2016 reporting period, physicians were required to report nine measures across three National Quality Strategy Domains, with one cross-cutting measure included. In this rule, CMS proposes to revise CY 2016 PQRS quality reporting requirements to only require physicians to report six measures with no domain or cross-cutting measure requirements. This proposal aligns the PQRS quality reporting requirements with the new quality reporting requirements for physicians under the Quality Payment Program (QPP).

In addition, CMS previously finalized in CY 2016 that groups of 100 or more eligible clinicians who participated in 2016 PQRS under the group reporting option (GPRO) were required to administer the CAHPS for PQRS survey. To align with the QPP requirements, CMS is proposing to make the CAHPS for PQRS survey optional under GPRO for practices of 100 or more eligible clinicians in 2018.

The AAOS strongly supports this proposal and the effort to align the current quality programs with the standards for QPP, which will take effect for CY 2019. We appreciate the agency incorporating the input of AAOS and other stakeholders, which has frequently been provided to the agency, but had not previously been acted upon.

Value-based Modifier

In addition to the PQRS changes, CMS also proposed revisions to the value-based modifier (VM), which is designed to incentivize physicians to provide high quality care with lower costs. The agency proposes to hold all groups and solo practitioners who met 2016 PQRS reporting requirements harmless from any negative VM payment adjustments in 2018 and halve penalties for those who did not meet PQRS requirements to -2 percent for groups with 10 or more eligible professionals, and to -1 percent for smaller groups and solo practitioners.

The AAOS strongly supports the changes to the value-based modifier outline in the proposed rule. We appreciate the agency acting to better align the legacy quality programs with QPP and easing penalties under the VM, which has not been sufficiently developed. Reliance on the VM standards for a significant incentive might have unfairly and inaccurately punished physicians.

Collecting Data on Resources Used in Furnishing Global Services

Section 523 of MACRA requires CMS to use rulemaking to obtain information needed to value surgical services from a representative sample of physicians, and it requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery. Beginning in 2019, the information collected, along with any other available data, must be used to improve the accuracy of the valuation of surgical services. In the CY2017 MPFS, CMS finalized a policy (that began on July 1, 2017) whereby practitioners who are in groups of 10 or more practitioners and who are located in any of the nine specified states would be required to report CPT code 99024 for every post-operative visit that they provide related to any CPT code on a list of 293 10- and 90-day global codes specified by CMS. While not addressed in this proposed rule, this mandatory reporting requirement is of importance to orthopaedic surgeons and the care they provide to Medicare beneficiaries. Therefore, we request more information regarding the global codes list for 2018 in addition to information on the survey conducted by the RAND Corporation. We strongly urge that CMS not use data collected via the claims-based data collection methodology to revalue global codes starting in 2019. There was not sufficient time or CMS effort for provider education on this policy and there was no detailed plan for data validation. We strongly believe that it is not appropriate to use these data to revalue global codes, especially if CMS assign values to some CPT codes using a methodology that is completely independent from the RUC process.

In addition, in early 2017 CMS posted the list of 293 10- and 90-day global codes to be reported starting July 1, 2017 based on the articulated frequency criteria. However, there were no updates in this proposed rule for 2018. We are now uncertain whether these are the same codes that practitioners should use for reporting in 2018. If CMS continues to require the reporting of 99024 in certain scenarios, we ask that CMS clarify whether practitioners should use the 2017 list of high volume/high value 10- and 90-day global codes or whether CMS plans to release a new list for 2018 reporting. Also, we strongly urge CMS to revise the definition of a "practice" to conform to one common definition of a group that is used for any and every CMS reporting. That definition should to be a group of practitioners sharing a TIN. Usage of different definitions for a group practice is confusing for reporting purposes.

In conclusion, the AAOS and our co-signing orthopaedic specialty societies appreciate your efforts to update and improve the Medicare Physician Fee Schedule, particularly the emphasis on reducing the administrative burden and inefficiency faced by physicians in the United States. We are thankful for the opportunity to comment on this proposed rule and if you have any additional

questions on our comments, please do not hesitate to contact AAOS Medical Director, William O. Shaffer, MD at shaffer@aaos.org.

Sincerely,

William J. Maloney, MD

President, AAOS

CC: David A. Halsey, MD, First Vice-President, AAOS Kristy L. Weber, MD, Second Vice-President, AAOS Thomas Arend, Esq., AAOS Chief Executive Officer William O. Shaffer, MD, AAOS Medical Director

This letter has received sign-on from the following orthopaedic specialty societies:

American Alliance of Orthopaedic Executives (AAOE) American Association for Hand Surgery (AAHS) American Association of Hip and Knee Surgeons (AAHKS) American Orthopaedic Foot and Ankle Society (AOSSM) American Orthopaedic Society for Sports Medicine (AOSSM) Cervical Spine Research Society (CSRS) Limb Lengthening and Reconstruction Society (LLRS) Musculoskeletal Infection Society (MSIS) Musculoskeletal Tumor Society (MSTS) Orthopaedic Rehabilitation Association (ORA) Orthopaedic Trauma Association (OTA) Pediatric Orthopaedic Society of North America (POSNA) Ruth Jackson Orthopaedic Society (RJOS) Scoliosis Research Society (SRS) The Knee Society (KNEE) The OrthoForum