

October 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

**Subject: (CMS-1734-P)
Medicare Program: CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule**

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 Medicare Program: CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule (CMS-1734-P) published in the Federal Register on August 3, 2020.

The AAOS appreciates the ongoing efforts of the Centers for Medicare and Medicaid Services (CMS) to reduce regulatory burden and facilitate maximum flexibility for physicians and patients during the COVID-19 public health emergency. We request the continued support of the Department of Health

and Human Services (HHS) as physicians navigate the ongoing pandemic and the subsequent needs for personal protective equipment, financial support, and access to testing and therapeutics.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management Visits (E/M)

In the Medicare Physician Fee Schedule (MPFS) Proposed Rule, CMS states that they recognize that there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes. CMS identified specific codes, adjusting the relative value units (RVUs) for these services.

AAOS strongly opposes CMS' failure to incorporate the RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes in all the global codes. We find this unacceptable given that adjustments proposed for other bundled services, such as the maternity services, have this update applied to their global codes. Organized medicine has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values in the global codes, as evidenced by the many comment letters and meetings over the past year. We are, therefore, extremely disappointed that CMS continues to ignore these recommendations, from nearly all medical specialties, in the CY 2021 MPFS proposed rule.

AAOS would like to reiterate that it is inappropriate for CMS not to apply the RUC-recommended changes to global codes starting in CY 2021. Applying the RUC-recommended E/M value increases to stand-alone E/Ms, select global codes (e.g., monthly end-stage renal disease and bundled maternity care), and select bundled services (e.g., monthly psychiatric management), but not to the E/Ms that are included in the global surgical package will result in disrupted relativity between codes across the MPFS. Changing the values for some bundled services that include E/M services, but not for others, disrupts this relativity, which was mandated by Congress in 1992, and refined over the past 27 years.

Per the Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."¹ Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, in violation of the law. In the CY 2021 MPFS proposed rule, CMS points to the method of valuation (i.e. building block vs. magnitude estimation) for a rationale as to why some bundled services should be increased in value to reflect the revised office/outpatient E/M values, while global codes should not. However, this statutory prohibition on paying physicians differently for the same work applies regardless of code valuation method and the incremental increases should apply to all physicians.

¹ 42 U.S. Code §1395w-4(c)(6).

In addition, CMS' proposal to reduce the conversion factor by 10.6% paired with the failure to incorporate the revised office/outpatient E/M values in the global codes will result in drastic cuts to many physician specialties. These cuts come at a time when specialists are struggling with the financial impact of the COVID-19 pandemic such as, suspension of elective surgery, salary reductions, furloughs, and layoffs.

Again, AAOS strongly urges CMS to apply the RUC-recommended changes to the E/M component of the global codes to maintain the relativity of the Fee Schedule.

Add-on code GPC1X

AAOS urges CMS to discontinue the implementation of the add-on code GPC1X as it is no longer necessary given the updated levels for outpatient E/M codes as finalized in 2020. Not implementing this code is likely to provide some relief on the drastic reduction in the conversion factor for 2021.

We are also concerned with the CMS proposed definitions for the HCPCS add-on code GPC1X. Throughout the proposed rule, CMS offers multiple, inconsistent definitions of the code descriptor. In Table 8: CY 2021 Proposed Additions to the Medicare Telehealth Services List on a Category 1 Basis the definition of GPC1X is: "Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit). However, in the CY 2020 Final Rule, which can also be found in the text of the CY 2021 Proposed Rule in Table 24, GPC1X is defined as: "Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)

Also, it is still unclear how CMS has determined the utilization of the code. **However, given the high utilization estimation, not implementing this new code is likely to positively impact the conversion factor.**

CY 2021 Conversion Factor

CMS is proposing to decrease the conversion factor by 11% (\$36.089 for CY 2020 down to a proposed \$32.2605 for CY 2021) citing a statutory mandate for budget neutrality resulting from changes in the work RVUs. This decrease combined with CMS' proposal not to incorporate the RUC-recommended work and time increases for the revised outpatient and office visit E/M code updates to the global surgical codes will result in drastic cuts for orthopaedic surgeons. **AAOS strongly encourages CMS to support Congress in waiving budget neutrality requirements stipulated in Section 1848(c)(2) of the Social Security Act so as to lessen the drastic cuts in the conversion factor.**

This proposed cut comes at a time when surgeons continue to shoulder more financial risk to improve quality for less compensation. Given that many commercial insurers reimburse physicians based on Medicare fee-for-service rates, the impact of these policies would mean that expected payments for orthopaedic surgery by Medicare Advantage and private payer patients would be reduced comparably.

Now is not the time to reduce payment and imperil access to high quality musculoskeletal care. Surgeons are facing an unprecedented public health emergency coupled with economic challenges during the COVID-19 pandemic. Orthopaedic surgeons have been lending their medical services to the response and practices have been intermittently shuttered pursuant to CMS' recommendations to delay elective surgeries. **AAOS strongly urges CMS to maintain the current funding levels. This is critical to preserving access to patient care in the wake of the COVID-19 public health emergency.**

Proposed Valuation of Specific Codes

Hip-Knee Arthroplasty (CPT codes 27130 and 27447)

In the CY 2019 final rule (83 FR 59500 through 595303), CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement [total hip arthroplasty], with or without autograft or allograft) and CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing [total knee arthroplasty]) were added to the list of potentially misvalued codes via a stakeholder nomination.

The stakeholder submitted information stating that there were substantial overestimates in pre-service and post-service time, including follow-up inpatient and outpatient visits that do not take place, included in the valuation of the service. As a result, the codes were resurveyed for the October 2019 RUC meeting. CMS is proposing the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. CMS is also proposing the RUC-recommended direct practice expense (PE) inputs for both codes. Should these changes be finalized in tandem with the changes to the E/M codes, it would further reduce the value of codes 27130 and 27447.

AAOS, in conjunction with the American Association of Hip & Knee Surgeons (AAHKS), maintains that the work RVUs (20.72) and minutes finalized for CY 2014 are still appropriate. The stakeholder's request was insufficient to justify a review and change in the value. The stakeholder cited an Urban Institute report regarding the intra-service time which had shortcomings compared to the robust data from the RUC survey data from 2013. In addition, the sample size used was small in comparison to that of the 2013 RUC survey and important details of the institutions and surgeons were not provided in the Urban Institute report.

Furthermore, AAOS believes that the stakeholder request to review codes 27130 and 27447 is problematic given the request was made by a large for-profit managed care health insurance company. This is clearly a conflict of interest related to the Medicare Physician Fee Schedule.

At the October 2019 RUC meeting, AAOS and AAHKS recommended that the RUC maintain the current work RVUs of 20.72 for codes 27130 and 27447, which is below the 25th percentile of survey work RVUs of 22.50 and 22.14, respectively. These recommendations were based on the results from the survey indicating a median intra-service time of 100 minutes for 27130 (equal to the intra-service time from the 2013 RUC survey) and of 97 minutes for 27447 (three minutes less than then 100 minutes from the 2013 RUC survey) and the pre-service and post-service times from the survey which included two hospital visits, a hospital discharge visit, and three post-discharge office visits in the 90-day global period, with an additional 30 minutes of pre-service time for the time surgeons and/or QHPs spend in pre-operative optimization activities. The total time for 27130, with these recommended times, are equal to the 2013 CMS accepted times of 407 minutes for 27130 and a reduction of three minutes to 404 minutes for 27447. A copy of this presentation is attached below as Appendix A.

Table 1. Comparison of wRVU Survey Results and Recommendations for CPT Codes 27130 & 27447

Current wRVU	Median wRVU RUC Survey Results	25 th Percentile of wRVU RUC Survey Results	AAOS & AAHKS Recommended wRVU	RUC-recommended wRVU
20.72	24.00	22.50 (THA) 22.14 (TKA)	20.72	19.60

The RUC did not accept the initial recommendations and instead recommended a work RVU of 19.60 for both codes. **AAOS strongly disagrees with these recommendations and urges CMS to accept the AAOS and AAHKS recommended times and work RVUs for codes 27130 and 27447.** We believe the 2019 survey supports the 2013 survey data for the intra-time and post-operative office time. Along with the additional data presented on 30 minutes of additional pre-service physician and/or QHP time spent on pre-optimization activities, we believe that the correct total times for 27130 and 27447 are 407 minutes and 404 minutes, respectively.

To support the 30 minutes of additional pre-service physician time on pre-optimization activities, AAOS and AAHKS had requested that a question be added to the RUC survey asking the typical physician time in these activities. The RUC Research Subcommittee did not agree to add the question on physician time but did allow a question about pre-service optimization time spent by clinical staff. That question showed a median clinical service time of 30 minutes spent on pre-service optimization work by clinical staff. This survey data, along with the data submitted by AAOS and AAHKS from

physicians, was recently compiled into a peer-reviewed publication in *The Journal of Arthroplasty*.² There is overwhelming evidence that physicians and/or QHPs are spending 30 minutes or more with the typical patient in pre-service optimization work. **Even though the RUC process did not allow this time to be included, CMS has the authority to increase the RUC recommended time by 30 minutes.** With this additional 30 minutes, the total time for codes 27130 and 27447 are identical or virtually identical to the current time, demonstrating that the overall physician work for the procedure has not changed since 2013 and should be maintained at 20.72 as recommended to the RUC by AAOS and AAHKS.

Further, this survey is evidence of the undisputable fact that preservice time exists. As the transition to value-based care continues to evolve, orthopaedic surgeons will remain committed to quality and efficiency in the performance of these high-volume and high-value procedures. AAOS is concerned that the traditional RUC survey definition of “pre-service” activities fails to capture this pre-operative office-based work that is essential to the clinical success and cost-savings of total knee arthroplasty (TKA) and total hip arthroplasty (THA). In the last 7 years, arthroplasty surgeons have led efforts to reduce the average arthroplasty episode’s cost of care from roughly \$35,000 to around \$20,000. The current surgeon’s fee (20.72 wRVU) accounts for approximately six percent of this reduction in episode cost. The proposed reduction in wRVU (five percent or \$60) is minimal in contrast to the hundreds of millions of dollars that arthroplasty surgeons have saved the Medicare Trust Fund through a commitment to value-based care. Penalizing our surgeons for this successful collaboration would be unthinkable, especially given that the current RUC survey data yielded a median of 24.00 wRVUs.

Examples of what this “pre-service” time is spent on includes patient screening and education, coordination of care with other health care providers including primary care physicians and physical therapists, as well as other activities essential to positive surgical outcomes. Not only is this time essential to improved patient health, it also highlights the value of preservice optimization time to managing overall healthcare costs through efficient and comprehensive care.

Orthopaedic surgeons have been active partners with CMS and the Center for Medicare and Medicaid Innovation (CMMI) on efforts to improve the quality of care for THA and TKA. We would like to continue that progress but reductions in work RVUs, which do not accurately reflect the time spent with patients, undermine the surgeons’ ability to participate in the transition to value based care. Simultaneous reductions in work RVUs during a time when surgeons are facing additional challenges precipitated by the public health emergency threaten access to high quality musculoskeletal care.

AAOS strongly urges CMS to maintain the current values of 20.72 for hip and knee arthroplasty codes 27130 and 27447.

Recommendations for Preservice Work Time

² Grosso, MJ et al, *Surgeons’ Preoperative Work Burden Has Increased Before Total Joint Arthroplasty: A Survey of AAHKS Members*, *The Journal of Arthroplasty* 35 (2020) 2318-2322.

CMS also requested comments from the medical community on how to consider and/or include pre-optimization time (preservice work and/or activities to improve surgical outcomes) and what codes could be used to capture these preoptimization activities that could be billed in conjunction with the services discussed previously.

AAOS and AAHKS propose that the current wRVUs be increased through an addition of 30 minutes of physician time to the standard preservice time of 40 minutes. We further propose to the RUC that a total of 90 minutes of clinical preservice staff time be adopted. This proposal would add 30 minutes to the standard package of 60 minutes for clinical preservice time and is supported by data that the RUC has already permitted to be captured through an additional survey question.

Based on peer-reviewed data, surgeons spend an additional 43.2 minutes, while physician assistants and nurse practitioners spend an additional 97.9 minutes per patient on preoperative care prior to the current RUC-valued 40 minutes of preservice time on the day of surgery.³ The table below includes examples of the most commonly reported preservice work activities surveyed in this study.

Table 2. Most Common Preservice Work by Physicians, QHPs, and Clinical Staff as Surveyed by AAHKS

Screening and risk assessment of comorbidities	Follow-up visits, reassessments
Shared decision-making, goal setting	Discharge planning
Patient education and optimization discussion	Enter data into prospective longitudinal outcome databases or registries
Medical interventions, referrals, consults	Pre-operative planning, templating, packet presentation
Select data with patient and family; schedule surgery in OR scheduling system	Schedule and/or confirm appointments for evaluations by appropriate consultants (PCP, cardiology, neurology, dentist, vascular surgery, endocrinology, etc.)
Obtain prior authorization	Schedule pre-operative assessment with anesthesia
Schedule pre-operative appointment with physical therapy	Schedule pre-operative appointment with case manager and/or social worker

³ Gosso, MJ et al, *Surgeons' Preoperative Work Burden Has Increased Before Total Joint Arthroplasty: A Survey of AAHKS Members*, The Journal of Arthroplasty 35 (2020) 2318-2322.

Schedule pre-operative education class	Coordinate and schedule final clearance assessment
Staff 1-2 hour education class attended by multiple patients	Phone calls, e-mails, other communication with patient, family and other providers to coordinate post-operative visits and optimization
Pre-operative patient and family member form completion	Phone call to patient or family to review preparation instructions (NPO, medications, antibiotic, shower)

To supplement this request for a total of 90 minutes in clinical preservice time, please see Table 3 for a summary of average preservice arthroplasty time, as compiled through an AAHKS review of published, peer-reviewed surveys.

Table 3. Preservice Time (from decision to operate until the day before operation) Prior to Primary TJA (Minutes)

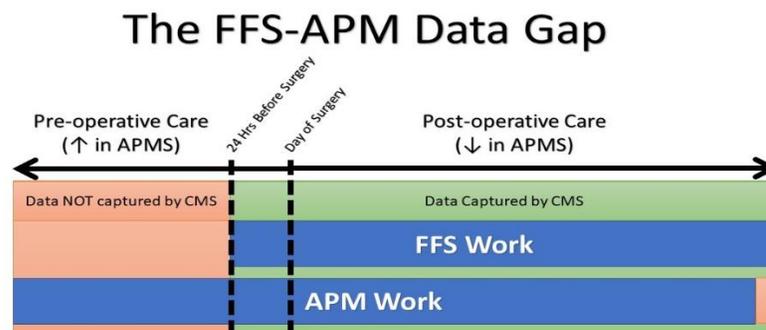
Author	Title	Patients/ respondents	Physician or QHP			Office Staff		
			Mean	Standard dev.	Median	Mean	Standard dev.	Median
Grosso, MJ et al	Surgeons' Preoperative Work Burden Has Increased Before Total Joint Arthroplasty: A Survey of AAHKS Members	Approx. 256	153	179	110	176	176	125
Krueger, CA et al	Substantial Preoperative Work Is Unaccounted for in Total Hip and Knee Arthroplasty	438	134	87.04	n/a	110	72.04	n/a
Halawi, MJ et al	Quantifying Surgeon Work in Total Hip and Knee Arthroplasty: Where Do We Stand Today?	666	22	10	n/a	n/a	n/a	n/a
Husted, H et al	Time-driven activity-based cost of outpatient total hip and knee arthroplasty in different set-ups	1110	50	n/a	n/a	n/a	n/a	n/a
Wasterlain, AS et al	Quantifying the Perioperative Work Associated With Total Hip and Knee Arthroplasty: The Burden Has Increased With Contemporary Care Pathways	1000	42	12	n/a	n/a	n/a	n/a
Totals			76.83	70.46	110	143	124.02	125

AAOS believes that CMS has broad authority to remedy the issues presented by the RUC-recommendations for preservice time.

First, we believe that CMS can reimburse preservice surgical time through the Secretary’s basis for determination of work RVUs. Specifically, the Medicare law states that the work RVUs for a service must be “based on the relative resources incorporating physician time and intensity required in furnishing the service.”⁴ The Social Security Act also states that “activities that occur before and after direct patient contact,” and, with respect to surgical procedures, that “the valuation of the work component for the code would reflect a ‘global’ concept in which pre-operative and post-operative physicians’ services related to the procedure would also be included.”⁵ The Social Security Act also clarifies that the Secretary’s review process may include the validation of work elements that are involved with furnishing services, including time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk, and “validation of the pre-, post-, and intra-service components of work.”⁶

We ask that CMS consider the data presented above in light of the flexibilities provided in the law and add this preservice time to CPT codes 27130 and 27447. AAOS and AAHKS agree that this is the most expedient and straightforward method for capturing this preservice time without disrupting the existing definitions of episodes under the Medicare bundled payment programs. If alternative recommendations for capturing this preservice time were to be chosen, it would effectively unbundle the surgical services and regress toward a fee-for-service model.

The graphic below illustrates the gap in data that currently exists between the fee-for-service and alternative payment models.



CMS Has the Authority and Rationale to Decline the RUC Recommendations

The Social Security Act and CMS rulemaking unambiguously confirm that AMA RUC recommendations are advisory and non-binding on CMS decision. Hence, CMS may accept, modify or reject the RUC’s recommendations. The breadth of published literature provided by AAHKS to

⁴ SSA § 1848(c)(2)(C)(i)

⁵ Id at (c)(1)(A); see also 75 Fed. Reg. 73169, 73215 (Nov. 29, 2020).

⁶ Id at (c)(2)(L).

the RUC and CMS as well as the results from the survey conducted by AAHKS and AAOS confirming the additional preservice optimization time, more than justify CMS declining to adopt the RUC's recommendation of reduced wRVUs for CPT codes 27130 and 27447. CMS reaffirmed in a CY 2012 final rule, a CY 2015 final rule, and again in a CY 2020 final rule, stating that

[w]e establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government.⁷

Hence, given the data we are sharing from our RUC survey results, additional medical literature and the precedent of CMS action regarding new, revised and misvalued codes, we strongly urge CMS to exercise its authority to reject the RUC's recommendation of reduced wRVUs for CPT codes 27130 and 27447.

Issues with Existing CPT Codes to Capture Arthroplasty Pre-Optimization Activities

Currently, existing codes do not sufficiently account for the pre-optimization work that is necessary for arthroplasty procedures. Prolonged service w/o contact codes (HCPCS/CPT 99358 & 99359) do not sufficiently include clinical staff time and accurately reflect arthroplasty pre-service work that is spread out across multiple days. Transitional care management code (HCPCS/CPT 99495 & 99496) activities delineate activities done during the pre-optimization work period, but the code is restrictive to the time immediately before discharge, which is problematic. Lastly, the principal care management code (G2064) appears to be similar to the pre-optimization work that is necessary but is limited to chronic conditions. It is important for CMS to clarify if this is inclusive of osteoarthritis, for which total joint arthroplasty (TJA) is an appropriate treatment, however this would still not cover all appropriate circumstances.

Creating a new G code

AAOS, in alignment with AAHKS, believes that the best path forward is the creation of a new G code to account for arthroplasty pre-optimization work. The code could be inclusive of up to 30 minutes of physician time and up to 90 minutes of clinical staff time per patient for necessary activities. We refer you to tables created by AAHKS outlining these activities in further detail. If pre-optimization work time is not accounted for in existing total joint arthroplasty (TJA) codes, it is imperative that this new code be created and implemented immediately to prevent the one or two cycles it typically takes for a code to be created through the RUC process.

⁷ 84 Fed. Reg. 40482, 40484 (Sept. 27, 2019).

Accepting the RUC Recommendations Has Multiple Adverse Consequences

The impact of accepting the RUC-recommendations is not limited to the 5.4% cut in work RVUs for CPT codes 27130 and 27447. In addition to the overall reduction in physician payment rates for total joint arthroplasty of approximately 3.4%, the reduction will undermine the shift to value-based care across payer environments. As previously discussed, orthopaedic surgeons participate enthusiastically in Medicare's alternative payment models and have created the savings on behalf of the Medicare program. These gains in care and reduction to overall Medicare expenditures should not be punished with reductions in essential and evidence-backed work RVUs.

This proposed reduction is particularly threatening to surgeons and patients alike given the immense strain placed on practices as a result of the COVID-19 public health emergency. Per CMS guidelines regarding elective procedures, many practices were forced to close earlier this year at the detriment of the surgeons and staff they employ. Though we have seen CMS offer maximum flexibility and reduced regulatory burden to ensure payments to physicians during the pandemic, we are disappointed that CMS claims that they do not have the regulatory discretion to ameliorate the issue of accurately accounting for preservice optimization time.

Given that orthopaedic surgeons and others are already facing the proposed 10.61% Physician Fee Schedule reduction as a result of the statutorily imposed conversion factor, and its requirement to maintain budget neutrality, AAOS requests that CMS consider the collective impact of the cuts to orthopaedic surgery and reject the RUC-recommendations. We are further concerned that accepting this RUC-recommendation, which was based on a code review process initiated by a for-profit commercial insurer, would set a dangerous precedent for commercial payers to use limited data to nominate high-volume, high-paying codes as misvalued. This is a slippery slope and could undermine the integrity of the CMS RVU valuation system as a whole. Should CMS continue down the path of reducing the wRVUs for total joint arthroplasty in the Physician Fee Schedule, we request that any reduction be delayed until CMS consults with AAOS and AAHKS regarding which codes orthopaedic surgeons and their staffs may appropriately use to capture pre-optimization time moving forward.

AAOS continues to partner with AAHKS in our response to these misvalued codes. Please also refer to the AAHKS comments on the CY 2021 MPFS Proposed Rule for a more detailed review of the issues surrounding this proposal.

Toe Amputation (CPT codes 28820 and 28825)

These services were identified by the RUC Relativity Assessment Workgroup through a site of service anomaly screen, based on the review of three years of data (2015-2017) for services with utilization over 10,000 in which a service is typically performed in the inpatient hospital setting. Yet only a half discharge day management identified by CPT code 99238 is included.

28820

CMS did not accept the RUC-recommended work RVU of 4.10 for CPT code 28820 (Amputation, toe; metatarsophalangeal joint), stating that it would be more accurate to propose a work RVU of 3.51. CMS supported this value with a crosswalk to CPT code 33958 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, six years and older (includes fluoroscopic guidance, when performed)), which has a work RVU of 3.51, to account for the decrease in the surveyed work time. CMS further stated that they did not believe the RUC-recommended reduction in work RVU from the current value of 5.82 is commensurate with the RUC-recommended 102-minute reduction in total time and that a further reduction in work RVUs is warranted given the significant reduction in the RUC-recommended physician time. **The AAOS disagrees with this analysis and recommends acceptance of the RUC-recommended times and work RVUs.**

AAOS is concerned that CMS may have overlooked the extensive background and compelling evidence that the current work RVU for code 28820 was invalid. The methodology of the previous valuation was flawed. CMS nominated and reduced the RUC-recommended value of code 28820 during a previous five-year review of work. This was based on early Medicare place of service data that erroneously showed code 28820 was performed in the inpatient setting. This error was never acknowledged by CMS. This was further compounded by CMS math which reduced the value for the code, resulting in an intraoperative work intensity (IWPUT) of 0.017 and work per unit time (WPUT) of 0.027.

AAOS and partnering societies also provided evidence of change in patient population which resulted in more complex intraoperative work because of increases in comorbidities that would affect the surgery. It was noted that poorly controlled blood sugar that occurs in diabetes can limit blood flow to the lower legs and toes. This can cause nerve damage that people with the disease may not realize until problems have already developed. Patients with advanced diabetes may develop wounds or sores that do not heal and eventually result in loss of the damaged toe or a portion of the foot or leg. For those who have failed medical management, amputation of the appendage is a last resort.

We believe this background demonstrates that the current value for code 28820 is incorrect, and therefore, the reductions noted by CMS as part of their rationale are not valid because the previous valuation was flawed based on the faulty methodology and change in patient population. AAOS further asks CMS to no longer crosswalk to codes whose values have been altered from the initial RUC-recommendations.

AAOS believes that CMS should consider using key reference code 11044 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less) with a work RVU of 4.10 as a comparator code. This code is typically reported for debridement of a lower extremity ulcer with minimal local anesthesia. While debridement is tedious work, it is not intensive or complex. Code 28820 requires more complex decisions regarding skin and soft tissue incisions and bone resection to be able to fashion flaps for closure after resection. Attention to the vessels and blood flow to adjacent toe(s) add both complexity and intensity to this procedure which warrants a high intensity. Codes 11044 and 28820 require almost identical total time; 11044 total time is

116 minutes while 28820 total time is 113 minutes. The time and work details of code 11044 strongly support a value of 4.10 for 28820.

Based on this additional information, AAOS strongly urges CMS to reconsider the RUC-recommended value of 4.10 for code 28820.

28825

CMS disagrees with the RUC-recommended work RVU of 4.00 for CPT code 28825 (Amputation, toe; interphalangeal joint) and is proposing a work RVU of 3.41 based on the RUC-recommended increment relationship between this code and CPT code 28820 (a difference of -0.10), which we applied to our proposed value for the latter code. CMS does not believe the RUC-recommended reduction in work RVU from the current value of 5.37 is commensurate with the RUC-recommended 97-minute reduction in total time. CMS further stated that a more significant reduction in work RVUs is warranted given the impact of the RUC-recommended reduction in physician time. The AAOS disagrees with this analysis and recommends acceptance of the RUC-recommended times and work RVUs.

AAOS is concerned that CMS may have overlooked extensive background and compelling evidence that the current work RVU for code 28825 was invalid. CMS used a reverse building block methodology to reduce the value for code 28825 which resulted in an IWPUT of 0.010 and WPUT of 0.026. These statistics are significantly less than most of the procedures and services in the Physician Fee Schedule and does not represent relativity.

AAOS and partnering societies also provided evidence of change in patient population which resulted in more complex intraoperative work because of increases in comorbidities that would affect the surgery. It was noted that poorly controlled blood sugar that occurs in diabetes can limit blood flow to the lower legs and toes. This can cause nerve damage that people with the disease may not realize until problems have already developed. Patients with advanced diabetes may develop wounds or sores that do not heal and eventually result in loss of the damaged toe or a portion of the foot or leg. For those who have failed medical management, amputation of the appendage is a last resort.

We believe this background demonstrates that the current value for code 28820 is incorrect, and therefore, the reductions noted by CMS as part of their rationale are not valid because the previous valuation was flawed based on the flawed methodology and change in patient population.

AAOS believes that CMS should again consider using key reference code 11044 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less) with a work RVU of 4.10 as a comparator code. This code is typically reported for debridement of a lower extremity ulcer with minimal local anesthesia. While debridement is tedious work, it is not intensive or complex. Code 28825 requires more complex decisions regarding skin and soft tissue incisions and bone resection to be able to fashion flaps for closure after resection. Attention to the vessels and blood flow to adjacent toe(s) add both complexity and intensity to this procedure which warrants a high intensity. Codes 11044 and 28825 require almost identical total time; 11044 total time is

116 minutes while 28825 total time is 108 minutes. The time and work details of code 11044 support a value of 4.00 for 28825.

Based on this additional information, AAOS strongly urges CMS to reconsider the RUC-recommended value of 4.00 for code 28825.

Direct Practice Expense Inputs

For the direct practice expense (PE) inputs, CMS is proposing to refine the facility pre-service clinical labor times to conform to the 000-day global period standards for both codes in the family for CPT codes 28820 and 28825.

AAOS would like to remind CMS that codes 28820 and 28825 are major procedures with respect to the preoperative clinical staff work. Codes 28820 and 28825 are performed in a facility setting 94-98% of the time, under general anesthesia on a patient with significant comorbidities. The change to a 0-day global period was requested to account for variable postoperative care and in no way changes the major procedure pre-service clinical staff work that is typical for major surgical procedures. We recommended, and the RUC agreed, that the 90-day global major surgery pre-service standard for the facility setting was appropriate. The typical patient requiring a toe amputation in the facility setting will have multiple comorbidities including diabetes and peripheral vascular disease. Clinical staff will have multiple phone calls with the office of the primary care physician and other specialists to obtain medical history, as well as with the patient and/or patient's family to pre-plan for post-discharge at-home assistance and ambulation equipment. Preoperative clearance for anesthesia, scheduling space and necessary equipment in the operating room will be necessary. In addition, the clinical staff will provide education about the procedure, answer patient/family questions, address risks and benefits, and review complications. This is not "extensive use of clinical staff" related to procedures that have always had an assignment of 0-day or 10-day global service, but rather analogous to the clinical staff work for a 90-day global service.

AAOS strongly urges CMS to reconsider the evidence provided to support the pre-service clinical staff requirements and accept the RUC-recommended preoperative clinical staff time of 60 minutes for codes 28820 and 28825.

Non-facility Intra-service Clinical Labor Time (CA011, CA013)

CMS is proposing to refine the non-facility clinical labor time for the "Provide education/obtain consent" (CA011) to conform to an established standard time of two minutes from the RUC-recommended five minutes.

CMS accepted the extensive use of clinical staff in the non-facility setting for both codes, which did not include the seven minutes that applies to the extensive use inputs. AAOS and partnering societies explained this and the RUC agreed that the standard non-facility 0-day global extensive use of clinical staff time for this activity is seven minutes. However, this activity will typically be provided in the office on the day of the service versus in the pre-service period. In the summary recommendation that was provided to the RUC and shared with CMS, we stated that the previous 10 minutes was assigned to

the pre-service period for this activity (CA004). We reiterated that the standard time for non-facility 0-day office extensive use of clinical staff is seven minutes. This was reduced to five minutes as this is typical for education and responding to patient inquiries on the day of the service versus in the pre-service period.

Again, this is a major surgical procedure and should be treated as such. This activity includes the clinical staff re-describing the procedure with a focus mainly on what the patient will undergo/see/hear pre-procedure as well as during the procedure. There will be many tasks being performed that the patient would not normally see in a facility under anesthesia. The patient will be educated to understand how local anesthesia and a block works – that they will still feel pressure during the procedure but should not feel sharp pain as they watch a toe being removed. The education will also include a discussion on what to expect after the procedure, confirming the patient will have the assistance needed post-procedure at home. As with any consent discussion, the details of the procedure will be discussed. This includes the risks, benefits, and complications, and all questions answered by both the clinical staff and physician before the actual signature is obtained. Numerous other codes include non-facility clinical staff time for CA011 that is greater than two minutes. These were approved on a case-by-case basis.

The clinical staff work related to education for this major procedure is not standard and not insignificant. AAOS strongly urges CMS to accept the RUC-recommended five minutes of education for codes 28820 and 28825.

Non-facility Intra-service Clinical Labor Time (CA013)

CMS is proposing to refine the non-facility clinical labor time for the “Prepare room, equipment and supplies” (CA013) activities to conform to an established standard time of 2 minutes from the RUC-recommended five minutes.

AAOS disagrees that two minutes is sufficient for the clinical staff to not only set up the room in standard fashion as for an E/M service, but to also set up the supplies, cautery and suction machines (to confirm they are running correctly) and the medium instrument pack. These supplies and multiple pieces of equipment are not typical for most office procedures. It is important to note that the two minute standard was developed based on setting up a room for an E/M service, not a major procedure. It is also more important to note that CMS proposed accepting the RUC-recommended time of four minutes for CA013 for E/M codes in 2021. Clearly, if an office E/M service room set up takes four minutes, a major procedure with multiple pieces of equipment and many supplies will require more time.

Again, AAOS strongly recommends that CMS accept the RUC-recommended CA013 time of five minutes for both codes 28820 and 28825.

Non-facility Equipment Time

CMS is proposing to refine the equipment time to conform to the proposed changes in the clinical labor time. **AAOS urges CMS to accept the information provided above regarding clinical staff time and apply the RUC-recommended times to the equipment time for codes 28820 and 28825.**

Telehealth and Other Services Involving Communications Technology

We commend CMS on its efforts to improve health care quality and access. This proposed rule touches on several issues which directly impact our membership, and we hope that you will take our comments into consideration when making any final changes in policy. Given the unexpected opportunity for innovation borne out of the misfortune of the COVID-19 pandemic, AAOS urges CMS to consider the value of making the following regulatory flexibilities permanent for telehealth.

AAOS calls for CMS to permanently expand the following telehealth technologies:

- Allow the use of audio-only equipment for office/outpatient E/M codes 99212-99215 and 99202-99205
- Maintain acceptance of Telephone E/M services, CPT codes 99441-99443, including continued reimbursement as similar services rendered in person
- Expand Online Digital E/M Services (E-visits), CPT codes 99421-99423 to both new and established patients
- Expand virtual check-in services (HCPCS codes G2010 and G2012) to both new and established patients
- Telehealth services continue to be reimbursed at the same rate as if services were furnished in-person
- Allow physical therapy and occupational therapy services to be performed virtually with two-way audio/visual capabilities and maintain reimbursement as if rendered in person
- Waive the requirement that out-of-state physicians and non-physician practitioners, such as physical therapists, be licensed in the state where they are providing telehealth services, as long as they are licensed in another state

We request waiving the requirement that out-of-state physicians and practitioners be licensed in the state where they are providing telehealth services to improve access for patients living in border communities of their home state, or in smaller states where cross-state travel is a common practice.

Medicare patients are one of the populations most susceptible to the COVID-19 virus and limiting any and all unnecessary possible exposure through in-person visits is crucial. Additionally, many Medicare beneficiaries do not have access to video capabilities and still require care remotely with audio-only communication. This is an issue of access to care. **Therefore, we strongly urge CMS to maintain the current flexibilities for both new and established patients to receive care via office/outpatient E/M 99201-99215 with the use of audio-only equipment currently in place on a permanent basis.**

In the March 31, 2020 COVID-19 Internal Final Rule with Comment Period (IFC), CMS established separate payment for audio-only telephone E/M services (codes 99441, 99442, 99443). Subsequently the April 30, 2020 CMS Internal Final Rule (IFR) stated that telephone E/M services (codes 99441 - 99443) may be reported for both new and established patients, which was a change from previous

CMS and AMA CPT guidance, as these codes were typically used for established patients only. New and established requirements have been waived for telehealth and telephone visits during the PHE. CMS also increased payments for these telephone visits to be aligned with reimbursement for similar office and outpatient visits. The increase of payments ranged from \$14-\$41 to approximately \$46-\$110. The payments were retroactive to March 1, 2020. However, in the CY 2021 MPFS Proposed Rule, CMS is not proposing to continue to recognize these E/M Telephone codes (99441-99443) for payment under the PFS in the absence of the PHE for the COVID-19 pandemic. Instead, CMS is proposing to develop coding and payment for a service similar to the virtual check-in, but for a longer unit of time and with a higher value, and determine if this provisional policy should remain in effect until one year after the end of the PHE for the COVID-19 pandemic, or if it should be a permanent PFS payment policy. To maintain consistent access to care for all beneficiaries, **AAOS urges CMS to continue to reimburse audio-only E/M Telephone services codes 99441-99443, and strongly requests that CMS continues to allow both new and established patients to have audio-only telephone services with their physician, and furthermore continue the current reimbursement for the physician's time to be equal to that of in-person services.**

Subsequent to the publication of the May 8, 2020 COVID-19 IFC, CMS has determined to include, among other codes, the Online Digital E/M Services (E-Visits) codes 99421-99423, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years, without a link to the duration of the COVID-19 PHE. **We strongly encourage CMS to continue to allow these E-visit codes 99421-99423 to be provided to both new and established patients.**

In the CY 2021 MPFS, CMS is not proposing to add the following physical therapy services permanently to the Medicare telehealth services list and is seeking comment on whether these services should be added to the Medicare telehealth services list in the future: codes 97161-97168, 97110-97116, 97535, 97750-61 (from Table 11). With all aspects of these physical therapy and occupational therapy services being fully and effectively furnished via two-way, audio/video telecommunications technology currently, **we request CMS continue to allow the current PHE flexibilities on a permanent basis and add these services to the Medicare telehealth services list and continue to reimburse these virtual services the same as with identical services rendered in person.**

CMS has proposed to make the following codes either permanent additions to, permanent on an interim basis until after the end of the PHE to the Category 1 Medicare telehealth services list: Established patients (99334-99335), Home Visits, Established Patient (99347-99348), Cognitive Assessment and Care Planning Services (99483), Visit Complexity Inherent to Certain Office/Outpatient E/Ms, and Prolonged Services (99XXX). **AAOS requests these Category I codes be added to the covered Medicare telehealth services list be made permanent.**

With respect to making these telehealth services permanently covered services, we ask that CMS confirm the following items related to the correct reporting of these services, including if the previous reporting guidelines listed in the April 30, 2020 IFR, will remain in effect:

- E/M level selection when furnished via telehealth can be based on MDM or time, with time defined as all of the time associated with the E/M on the day of the encounter; and to remove any requirements regarding documentation of history and/or physical exam in the medical record
- Report the place of service (POS) code that would have been reported as if the E/M service had been furnished in person
- Append the CPT telemedicine modifier, Modifier 95, to E/M services that are reported for telehealth.

We request CMS give a clear determination on the POS codes and appropriate modifiers to be appended to claims going forward with the permanent addition of these E/M codes to the telehealth covered services list.

99072

New Category I CPT code 99072, *Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease*, was created and implemented September 8, 2020 to address the additional practice expenses (PE) related to COVID-19. In the wake of the COVID-19 pandemic, extra safety precautions and office protocols have been adopted to safely provide in-person visits. Physicians have been bearing the brunt of these additional expenses incurred during the Public Health Emergency (PHE), including extra sanitizing supplies, personal protective equipment (PPE), patient masks, installation of plexiglass at check-in, as well as additional staff time to sanitize rooms, assess patients prior to admittance and other safety protocols. To address these additional expenses, the American Medical Association/Specialty Society RVS Update Committee (RUC) worked with 50 national medical specialty societies and other organizations to collect data on the additional costs of maintaining safe protocols during patient in-person visits during the PHE.

Code 99072 may be reported from September 8, 2020 until the end of the PHE. As it stands currently, the PHE expires on October 23, 2020. **AAOS strongly urges CMS to accept the reimbursement rate of \$6.57 for code 99072 as determined from the data received for these additional PE costs, as well as allow reporting of code 99072 retroactively to March 1, 2020, as was allowed with other reporting flexibilities during the PHE.**

Effects of Proposed Changes Related to Scope of Practice

Supervision of Diagnostic tests by Certain Nonphysician Practitioners (NPPs)

CMS' proposal would allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests in addition to physicians. For the services they furnish, NPs, CNS' or PAs would be working either under physician supervision or in collaboration with a physician to provide a wide range of diagnostic tests such as simple strep throat swabs to more sophisticated tests such as X-rays. The public health

emergency has proven that this flexibility is necessary to alleviate some of the demands on physicians as they lend their medical expertise in response to the COVID-19 pandemic. **AAOS strongly urges CMS to maintain these flexibilities.**

Therapy Assistants Furnishing Maintenance Therapy

CMS is proposing to allow a physical therapist (PT) or occupational therapist (OT) – whether they are an enrolled private practice PT or OT, or a therapist working for an institutional provider – who establishes a therapy maintenance program to assign the duties to a PT Assistant or OT Assistant, as clinically appropriate, to perform maintenance therapy services. This flexibility was added under the May 8, 2020 COVID-19 IFC for the duration of the PHE. **AAOS encourages CMS to make permanent the Part B policy for maintenance therapy services to allow PTs/OTs to oversee and assign duties to PT Assistant or OT Assistant for the performance of physical and occupational therapy services as clinically appropriate.**

Appropriate Use Criteria for Advanced Imaging Services

In the CY 2017 proposed rule, CMS addressed the development of a Medicare Appropriate Use Criteria (AUC) program for Advanced Imaging Services such as MRIs, CT scans, ultrasound, and other diagnostic imaging systems. CMS was mandated to develop an AUC program for Advanced Imaging as part of the Protect Access to Medicare Act (PAMA) of 2014.

The AAOS supports the use of AUC as a key tool in promoting cost-effective, quality care for key clinical priority areas such as low back pain. AAOS and other specialty societies that treat low back pain have developed evidence-based guidelines and AUCs and encourage CMS to closely follow these published recommendations in creating their AUC for advanced imaging. The AAOS is happy to share our guidelines and AUC with CMS and to collaborate with CMS and other medical stakeholders in reviewing and finalizing the Advanced Imaging AUC.

We appreciate that the EDUCATIONAL AND OPERATIONS TESTING PERIOD for this AUC Program has been extended through CY 2021 and that there are no payment consequences associated with the AUC program during CY 2020 and CY 2021. However, the current implementation test period for this requirement is proving to be very burdensome for small and solo practices with requirements for additional investments in technology. **We urge CMS to adequately reimburse for the time and practice expenses incurred by physicians and clinical support staff.**

2021 Quality Payment Program (QPP)

Flexibilities Related to the COVID-19 Pandemic: Bundled Payment for Care Improvement (BPCI) Advanced Flexibilities

AAOS asks that CMS apply uniform protections for BPCI-Advanced participants that have been provided to Comprehensive Joint Replacement (CJR) participants. For participants in the CJR program, CMS will waive repayment responsibility if episode costs increase (downside risk) and keep

the ability to share in episode savings (upside risk) if episode costs are reduced. Unfortunately, these same protections do not apply to individuals in the BPCI-Advanced program.

The BPCI-Advanced program requires one of two options:

1. Remove both downside risk and upside risk.
2. Keep both downside risk and upside risk but allow for exclusion of patients with a COVID-19 diagnosis.

The problem with the first option is that many BPCI-Advanced participants rely on the potential savings to continue to invest in the necessary care redesign infrastructure to carry out more comprehensive services. Without the opportunity to generate these savings, they may not be able to support the reinvestments necessary to provide value-based care. Likewise, the second option is problematic because it does not factor in the disruption of the COVID-19 pandemic more broadly on patients who may not have contracted the disease but are approaching care differently.

Additionally, because of the variation in volume of cases compared to historical figures it makes it challenging for individuals to assess performance, and track progress should patients be abruptly removed because of a new COVID-19 diagnosis. For these reasons, we urge CMS to apply the same protections to BPCI-Advanced participants as they have done for CJR participants.

Quality Measure Benchmarks

AAOS is concerned with CMS' proposal to base the 2021 performance period benchmarks on the actual data submitted during the 2021 performance period. Normally for the 2021 performance period, benchmarks would be set for the performance period two years earlier, which is 2019. However, CMS notes that they provided Merit-Based Incentive Payment System (MIPS) eligible clinicians the flexibility to not report data for the 2019 performance period due to the COVID-19 pandemic, which could skew the results. Our concern stems from the fact that the idea of a benchmark is to enable clinicians to understand their targets and plan, prepare and act to achieve realistic goals. This is not possible if the performance period on which they are being assessed is benchmarked after the fact.

This is particularly concerning, given that practices will still be coping with the COVID-19 pandemic or attempting to restart operations to a new level of normalcy in 2021. To truly mitigate significant burden on providers during these turbulent times, we believe that benchmarks for the previous year should be maintained. In other words, for the 2021 performance period, we would encourage CMS to use benchmarks from the 2018 performance period. This provides clinicians with some degree of certainty, helps them to prepare in advance, and reflects flexibilities that will be needed because of the COVID-19 pandemic.

Complex Patient Bonus Payment

AAOS appreciates CMS' recognition of the challenges that clinicians face during the COVID-19 pandemic and the proposal to increase the maximum number of points available for the 2020

performance period for complex patients. This recognition is welcomed and will provide additional support for many practices.

Merit-based Incentive Payment System (MIPS) Performance Threshold

AAOS appreciates CMS' recognition of the challenges that clinicians face during the COVID-19 pandemic and the proposal to reduce the MIPS performance threshold for the 2021 performance period from 60 points to 50 points. This will be very helpful for many clinicians whose daily operations have been disrupted by the COVID-19 pandemic.

Alternative Payment Model Performance Pathways

We understand that CMS is proposing to eliminate the alternative payment model (APM) scoring standard and institute a new APM Performance Pathway beginning January 1, 2021. While we appreciate the intent to streamline the reporting process for individuals who may participate in an APM, but report through MIPS we are concerned that this new process will add significantly more burden and confusion for providers.

A significant concern of the Quality Payment Program (QPP) at-large is that there are many different combinations for how entities can be designated and report their activities (see below):

- MIPS Exempt
- MIPS Opt-In Eligible
- MIPS Eligible – Traditional MIPS Reporting
- MIPS Eligible – MVP Participation (Starting 2022)
- MIPS Eligible – MIPS APM Participant, APM Scoring Standard
- Advanced APM Eligible – Partial Qualifying Participant (QP), No MIPS Reporting Option
- Advanced APM Eligible – Partial QP, APM Scoring Standard (APM Performance Pathway (APP) Option)
- Advanced APM Eligible – QP, No MIPS Reporting, 5% Bonus Payment

A consistent challenge has been that many individuals do not meet the thresholds necessary in order to be a Partial QP, or QP, but may still participate in MIPS APMs and/or Advanced APMs as MIPS Eligible clinicians. This leaves two unmet needs: first, there needs to be a greater number of APMs that can better cover the conditions a clinician treats for their patient population, so that thresholds can be met, and second, there needs to be an easier path for an individual to fully transition to APMs from MIPS reporting. AAOS believes that voluntary MIPS Value Pathway's (MVPs) offer an opportunity to scale the development of more APMs that can cover a larger patient population, when APMs are developed based on measures in an MVP. This would satisfy the two unmet needs mentioned above.

We have serious concerns with the APM Performance Pathway (APP) because it is yet another new reporting mechanism that does not include measures that are meaningful to specialists. We believe that CMS was on the right track with soliciting clinician feedback on development of MVPs, but

that the prescriptive nature of the APP track, and the focus on primary care-specific measures would make this reporting option unavailable to specialists. In fact, it would increase burden should they choose this reporting mechanism because they would have to report measures for any Advanced APMs they are in, in addition to these primary care-specific measures.

The QP threshold, which is currently unattainable to many specialists, has been exacerbated by the postponement of procedures due to COVID-19. The result is that specialists who participate in good faith in Advanced APMs, but do not meet the threshold requirements, have to report through the Advanced APM **and** the APM Scoring Standard or Traditional MIPS. By eliminating the APM Scoring Standard specialists would essentially be forced to report through Traditional MIPS and counted twice on cost-specific performance metrics, with which they may be unfamiliar.

AAOS encourages CMS not to move forward with the APP proposal and instead re-focus their efforts on the promising MVP framework. If done correctly, the MVP framework can effectively align MIPS and APMs, and ultimately enable clinicians to participate in Advanced APMs.

Third Party Intermediaries

Delay of Qualified Clinical Data Registries (QCDRs) measure testing & data collection requirements

In the CY 2020 MPFS Final Rule, CMS finalized the requirement for all QCDR measures to be fully developed and tested at the clinician level prior to self-nomination beginning with the 2021 performance period. Also finalized in the 2020 MPFS, was the requirement for data collection on QCDR measures prior to self-nomination. Due to the COVID-19 pandemic, CMS is proposing a delay in these requirements until January 1, 2022. Additionally, CMS is proposing a two-step structured process for the QCDR measure testing. Measures previously approved for CY 2020 would have to show face validity at the time of self-nomination for CY 2022. Once approved with face validity, a measure must be fully tested (i.e. beta-tested per the CMS Measures Blueprint definition) prior to self-nomination for any subsequent performance period.

While the AAOS appreciates the delay in the QCDR measure development requirements finalized in the CY 2020 MPFS, 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. 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.

As explained in 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 COVID-19 they do not have the resources to put toward QCDR measure auditing.

In addition to the QCDR measure testing requirement, the CY 2020 Final Rule also imposed a requirement for data collection, appropriate to measure type, prior to self-nomination. Again, we are concerned about the lasting effects of the COVID-19 pandemic on the completeness of data for this requirement. Elective, non-urgent surgical procedure volumes have drastically decreased during the pandemic and it is unclear when those volumes will return to normal. Reduced data negatively impacts reliability of any analysis done on the data, which could lead to inaccurate representations of measure validity.

For existing QCDR measures, beta-testing will be required prior to self-nomination for the 2025 payment year, in other words, by September 1, 2022. Though this may seem like the distant future, no one can predict when the pandemic will end nor the extent of its lasting effects on the healthcare system. For this reason and others described above, we urge CMS to delay implementation of QCDR measure testing and data collection requirements prior to self-nomination until at least one year after the COVID-19 PHE ends.

Inclusion of QCDR Measures in MIPS Value Pathways (MVPs)

The AAOS appreciates CMS explicitly stating MVPs may include fully tested qualified clinical data registries (QCDRs) measures. By design, QCDRs have the specialty-specific knowledge and technical expertise to construct and implement meaningful quality improvement reporting mechanisms. In future years of the MVP framework, CMS aims to take reporting burden from providers by increasing CMS provided data and feedback. We believe there is an opportunity for QCDRs to assist and expediate this goal if CMS provides Medicare claims data to QCDRs. With claims data QCDRs could calculate and submit administrative claims quality measures and cost measures on behalf of their Quality Payment Program (QPP) participants. Per previous final rules, QCDRs are required to provide performance feedback to participants at least four times per year. Thus, if QCDRs are reporting administrative claims and cost measures participants will benefit from frequent, timely performance feedback on these measures as well.

We encourage CMS to continue providing QCDR-specific education opportunities and to lean heavily on QCDRs to develop and co-develop MVPs. We also ask CMS to explore utilizing the MVP pathway as a mechanism to comply with Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which directs the CMS to provide QCDRs with access to Medicare data for purposes of linking such data to clinical outcomes data and performing risk-adjusted and scientifically valid and risk adjusted analyses and research to support quality improvement and patient safety.

MIPS Value Pathways

Implementation Delay Until CY 2022

AAOS appreciates the flexibilities allowed by CMS to mitigate the negative impacts of the COVID-19 pandemic throughout this proposed rule, including the proposal to delay implementation of the MIPS Value Pathways (MVPs) until CY 2022. We hope the implementation delay does not slow the momentum of MVP development and encourage CMS to continue reaching out to medical specialty associations directly to collaborate. We maintain that physician input is critical to the success of the MVP program.

Criteria for MVP Development

The CY 2020 MPFS Final Rule left many questions surrounding the MVP framework unanswered and perhaps made organizations hesitant to develop MVPs. In this way, the AAOS appreciates CMS' inclusion of MVP development criteria and process in the CY 2021 MPFS Proposed Rule. One concern we have with the proposed process for candidate MVP collaboration, solicitation, and evaluation is the timing of communication of approval. Per the proposed rule, CMS will not notify stakeholders, or the general public, of the approval of a candidate MVP prior to the publication of the annual proposed rule. Given the severe delays in publication of the MPFS proposed rules over the past years, we are concerned that potential MVP participants will not have adequate time to modify workflows for capturing MVP measures prior to the beginning of the following year. If participants are not given time to successfully implement MVPs, they may choose a different reporting pathway.

The AAOS believes patient-centered improvements to health outcomes are a critical component to measuring quality. We hope to see CMS incentivizing patient-focused care in the QPP, particularly the MVP program. To further capture the patient voice in MVPs, AAOS believes CMS should award bonus points to the final composite score for inclusion of patient reported outcome measures (PROMs) in the Quality category or Improvement Activities related to collection of PROMs.

SUPPORT Act Requirements & The Medicare Program Electronic Prescribing for Controlled Substances: Request for Information

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 requires electronic prescribing of Schedule II - V controlled substances under Medicare Part D beginning January 1, 2021. HHS has the authority to waive participation requirements and enforce penalties for non-compliance. Hence, CMS has issued a Request for Information soliciting feedback on appropriate waivers and penalties.

The AAOS strongly believes that electronic prescribing of medications promotes patient safety and is particularly beneficial to curbing the opioid epidemic. In general, we agree with the push requiring Electronic Prescription for Controlled Substances (EPCS) prescription transmissions for prescribers; however, we also note the burden of purchasing and implementing EPCS software on small practices and/or practices where reliable internet connectivity is not readily available. Similar challenges are encountered in the MIPS, thus the same criteria for the MIPS Promoting Interoperability Performance Category hardship exception could be applied to the EPCS requirements. We recommend CMS adopt

the following exceptions from the MIPS program and allow waivers to EPCS requirements for the following situations:

- Small practice (defined as a TIN of 15 or fewer eligible prescribers).
- Insufficient internet connectivity.
- Extreme and uncontrollable circumstances such as disaster, practice closure, severe financial distress, or vendor/software issues.

CMS is also proposing to delay EPCS requirements until January 1, 2022 due to the impact of the COVID-19 pandemic on the healthcare system. AAOS supports this delay, though we also ask CMS to consider delaying further depending upon when the PHE ends.

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 2021 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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Graham Newson, Director, Office of Government Relations, AAOS

Alabama Orthopaedic Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
Arkansas Orthopaedic Society
Arthroscopy Association of North America
California Orthopaedic Association
Cervical Spine Research Society
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
Iowa Orthopaedic Society
Kansas Orthopaedic Society
Limb Lengthening and Reconstruction Society
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Mississippi Orthopaedic Society
Montana Orthopaedic Society
Nebraska Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North American Spine Society
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
Pediatric Orthopaedic Society of North America
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Scoliosis Research Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Washington State Orthopaedic Association
West Virginia Orthopaedic Society
Wyoming Orthopaedic Society
Virginia Orthopaedic Society

Appendix A

TAB 11	27130	27447
Descriptor	Total hip arthroplasty	Total knee arthroplasty
Current wRVU	20.72	20.72
Recommended wRVU	20.72	20.72

BACKGROUND

A public nomination was submitted to CMS in February 2018 indicating seven CPT codes are potentially misvalued, including total hip arthroplasty and total knee arthroplasty.

This nomination was made by Anthem, Inc., the largest for-profit managed care health insurance company in the Blue Cross and Blue Shield Association. Anthem administers Medicare, Medicaid and commercial health insurance plans.

Prior to publication of the CY 2019 final rule, at the October 2018 RUC meeting, the RAW noted that “this is a process issue and without more information on how these services were identified and a rationale to review these services, the workgroup will wait until the final rule for more information to determine whether to review these services.”

In the final rule, CMS stated there is value in consistent and routine review of high-volume services, because a minor adjustment to a high volume code may have a significant financial impact.

RUC then selected the codes identified by Anthem for review at the April 2019 RUC meeting.

At the April 2019 RUC meeting, the AAOS/AAHKS recommended that the RUC reaffirm the current value of 20.72 and also reaffirm the current time and visits. A new survey was not completed.

The RUC voted against this recommendation and requested that AAOS and AAHKS conduct a standard RUC survey and present a recommendation at the October 2019 RUC meeting.

VALUE BASED PAYMENTS

It is important to understand these codes in the context of value based payment reforms.

Total hip arthroplasty and total knee arthroplasty are often part of an optional Medicare bundled payment program (Bundled Payment for Care Initiative [BPCI]) and more recently CMS has implemented a **mandatory** bundled payment program (Comprehensive Care for Joint Replacement [CJR]).

Similar bundled payment models are employed in many states by both Medicaid and private insurers.

Physicians and hospitals are also more commonly participating in risk based contracts as accountable care organizations with Medicare, Medicaid and private insurers.

In all of these programs, physicians and hospitals have financial incentives to achieve two important goals: reduce costs and improve quality.

For total joint replacement, a key strategy has been the pre-operative identification and optimization of medical co-morbidities, which has been shown to shorten hospital length of stay; reduce complications, including readmissions; and reduce costs.

In a 2019 New England Journal of Medicine (NEJM) study on the outcomes of 280,161 patients in the CJR program, the mean number of chronic medical conditions was seven (7).

Understanding the nature and severity of these conditions as risk factors is critically important.

Considerable work by the surgeon and QHPs is required to facilitate, coordinate, validate and document the assessment and optimization of patients prior to total joint replacement surgery.

In addition, patients are more frequently discharged home rather than to inpatient rehabilitation or skilled nursing facilities. This deliberate reduction in post-acute care service requires considerable work by the surgeon/QHP and clinical staff prior to and after surgery.

All of this work is not explicitly captured in the standard RUC survey, nor is it included in the current RUC pre-time packages, but the work is certainly being performed on a routine basis for the typical patient.

SURVEY PREPARATION AND PROCESS

A request was submitted for a revised survey instrument and discussed at the June 4, 2019 Research Subcommittee conference call.

Several peer reviewed articles and extensive information on the time required for pre- and post-operative work by physicians, QHPs and clinical staff were provided to support this recommendation.

The Research Subcommittee agreed to add questions about clinical staff pre-service time, but declined to add questions about physician/QHP work for both pre-operative planning and optimization and post-operative work.

Subsequent to the June 2019 Research Subcommittee, AAOS and AAHKS finalized the approved survey instrument and conducted a random survey of AAOS and AAHKS members.

A total of 2,650 survey requests were sent out and 206 non-conflicted responses were received.

SURVEY RESULTS AND RECOMMENDATIONS

Work RVU:

The survey median was 24.00 for both THA and TKA.

The 25th percentile values were 22.50 for THA and 22.14 for TKA.

The current wRVU of 20.72 is recommended for both THA and TKA; this is below the survey median and also below the survey 25th percentile.

Pre-service time:

Pre-time package 4 is selected: difficult patient / difficult procedure.

Evaluation time: We recommend adding 30 minutes to the standard package time of 40 minutes (total of 70 minutes) to account for significant additional pre-operative time to optimize a patient prior to total joint replacement surgery.

The additional 30 minutes is based on the personal experience and consensus opinion of surgeons on our expert panel.

Several of the reviewers questioned who is actually doing this work.

Is it the PCP or anesthesia? Is it done in hospital based “pre-op clinics”?

The relationship between hospitals and physicians is evolving.

Our data shows that > 50% of AAHKS surgeons are in private practice and 20% hospital employed; the remaining are in an academic setting or the military.

Many other providers are clearly involved in this process and the protocols with naturally vary throughout the US.

It is our opinion that the surgeon and/or a QHP employed by the practice spend about 30 minutes in aggregate on planning, preparation, risk factor assessment, coordination and optimization.

Positioning: We recommend adding 12 minutes to the standard package time of 3 minutes (total of 15 minutes)

- THA: lateral decubitus or supine on a traction top table
- TKA: supine, tourniquet and limb positioning device

This is consistent with both the survey median and historical RUC precedent for many similar orthopaedic codes.

Scrub, dress and wait: We recommend subtracting 5 minutes from the standard package of 20 minutes (total time of 15 minutes) to be consistent with the survey median.

Intra-Service Time

THA: recommend 100 minutes (survey median); consistent with 2013 survey median (100).

TKA: recommend 97 minutes (survey median); slight decrease from 2013 survey median (100).

This is an important consideration for these codes specifically and the RUC process in general, as one of the concerns expressed by Anthem and other observers is the use of physician time estimates to establish the duration of operative procedures.

There has been considerable discussion and multiple publications regarding the accuracy of survey based time estimates by surgeons compared to empirical data.

For THA/TKA, there are at least 3 publications that suggest the actual time is lower than the RUC/CMS time, including the 2016 Urban Institute report.

On the other hand, there are 3 recent peer reviewed publications from 4 large health systems, involving over 20,000 cases, done by almost 100 surgeons at 21 hospitals that consistently show median times of 100 minutes or greater for both THA and TKA.

These 6 studies are noted in the summary of references we submitted.

Immediate Post-Service Time

Immediate post-time package 9b is selected: general anesthesia or complex regional block / complex procedure.

We have subtracted 13 minutes to be consistent with the survey median (20 minutes).

Hospital Visits

We recommend three (3) hospital visits, which is consistent with the survey median.

This is a decrease of one hospital visit compared to the 2013 data and is reflective of the considerable pre-service time expended on optimizing the patient prior to admission for surgery.

The first hospital visit occurs later on the same day as surgery; 83% of respondents reported that they completed this E/M encounter.

The second hospital visit occurs on post-operative day #1.

The specific tasks for both visits are detailed in the section for the description of the post-service work and support a level 99232 for both encounters.

The patient is typically discharged on post-operative day #2 which is indicated by the discharge day code 99238.

Patients may be seen more than once on these days (e.g. morning and afternoon) to coordinate care and facilitate discharge.

Office Visits

We recommend 99213 x 3 which is consistent with the survey median.

Key Reference Service Comparison

The top KRS was 23472, total shoulder arthroplasty; this was selected by 50% of respondents for THA and 44% for TKA.

	27130 Total Hip	27447 Total Knee	23472 Total Shoulder
wRVU	20.72	20.72	22.13
Total time	407	404	448
Intra-time	100	97	140
IWPUT	0.113	0.116	0.089
Overall intensity and complexity	54% THA > TSA 10% THA >> TSA	50% TKA > TSA 9% TKA >> TSA	

SUMMARY

The transition to value-based alternative payment models has facilitated care delivery redesign for total joint arthroplasty, resulting in a shorter hospital length of stay, diminished utilization of post-acute care facilities, lower rates of complications, including hospital readmissions and reduced costs.

A key change in this evolution is an increasing emphasis on pre-operative optimization of patients prior to surgery and decreased utilization of post-discharge facilities, with a corresponding shift in resource utilization to the pre-service period.

AAOS and AAHKS recommend the current wRVU of 20.72 for both THA and TKA.

This is below the survey 25th percentile and well supported by the results from a representative and robust survey with 206 respondents.

	27130 Total Hip	27447 Total Knee
wRVU	20.72	20.72
Total time	407	404
Intra-time	100	97
IWPUT	0.113	0.116
Hospital visits	3	3
Office visits	3	3

VALUATION IF 30 MINUTES ADDITIONAL PRE-SERVICE TIME IS DENIED

With the 30 minutes of additional pre-service time removed, the total time for THA is 377 minutes and for TKA 374 minutes.

We looked for comparison codes with similar inputs for total time, intra-time and IWPUT and identified 35 codes:

- wRVU: 14.99 to 21.81 19.60
- total time: 309 to 424 377/374
- IWPUT: 0.064 to 0.132 0.113/0.116

We recommend 19.60 for both THA and TKA using a crosswalk to 63075 (anterior cervical discectomy).

This value places the code in the top 1/3rd for wRVU, with 8 codes having greater wRVU.

We also note 35650 Ax-Ax Bypass, with wRVU 20.16, total time 382 and intra-time of 110 as a supporting code.

	63075 Ant Cerv Disc	27130 Total Hip	27447 Total Knee	35650 Ax-Ax Bypass
wRVU	19.60	19.60	19.60	20.16
Total time	380	377	374	382
Intra-time	90	100	97	110
IWPUT	0.132	0.108	0.112	0.107
Pre eval	60	40	40	75
Positioning	20	15	15	
SDW	15	15	15	
Post SD	30	20	20	25
Hospital visits	2	3	3	2
Office visits	3	3	3	2

PRACTICE EXPENSE

We would also like the full RUC to discuss PE, specifically our request for an additional 30 minutes of pre-service clinical staff time.

This was not approved at the PE review.

As noted, the research subcommittee approved a modified survey to assess the pre-operative clinical staff time by health care professionals who **are paid by/employed by the physician practice** and cannot separately bill for their services (e.g. RN, LPN, MA).

Administrative activities were explicitly excluded, even if performed by clinical staff:

1. Obtain referral documents
2. Schedule appointments, remind of appointment
3. Obtain medical records, develop chart
4. Pre-certification and pre-service registration, eligibility verification and authorization
5. Transcription and manage medical records
6. Schedule post-operative visits
7. Billing and collection activities

We asked survey respondents to estimate the total time that clinical staff spend per patient on planning, preparation, optimization, and care coordination activities prior to the procedure, but separate and after the decision for surgery visit:

1. Coordinate pre-operative consultations, including test results
2. Coordinate pre-operative assessment with anesthesia
3. Coordinate with PT/OT, social work, or case manager
4. Provide pre-operative education
5. Coordinate / validate final clearance
6. Phone calls, e-mails or other communication with patient, family or other providers
7. Phone calls, e-mails or other communications with the patient or family to review instructions (e.g. NPO, medications, antibiotic shower)

Note that the current PE process for 90-day global codes includes pre-service clinical staff time for the 30 days prior to surgery.

The survey median was 90 minutes (current standard 90-day global allows 60 minutes).

- Minimum: 0
- 25th percentile: 60
- 75th percentile: 120
- Maximum: 360

Therefore, we recommended 90 minutes of pre-service clinical staff time; 30 minutes > standard.

This was arbitrarily assigned to CA002 as follows:

- Coordinate pre-surgery services (including test results): 20 → 30 min (+10)
- Provide pre-service education/consent: 20 → 40 min (+20)

At the PE review on Thursday, the committee voted to approve compelling evidence based upon at least two factors:

(1) Documentation in the peer-reviewed medical literature or other reliable data that there have been changes in the clinical staff time, supplies and equipment due to one or more of the following:

- technique
- knowledge/technology
- patient population
- site-of-service
- length of hospital stay
- physician time

(2) Evidence that there has been a change in equipment or practice expense cost

However, the committee voted against an increase in 30 minutes and also voted against an increase in 15 minutes.

We would like the opportunity to further clarify the rationale for this request and ask the RUC to reconsider and vote on the PE inputs.

Let me emphasize several key points:

1. Bundled payments are quite prevalent for total joint arthroplasty; almost 50% of Medicare beneficiaries are in a mandatory or voluntary program
2. Other Medicare alternative payment models (e.g. MSSP etc.) are increasingly common
3. Medicaid and commercial payors are implementing similar payment reforms
4. All of these place physicians, hospitals and health systems at financial risk for both cost and quality
5. Orthopaedic surgeons have responded accordingly and the desired results have been obtained: patient care has changed for the better, cost have been lowered and quality outcomes have improved
6. There are really two important changes in the clinical care process:
 - a. Focus on risk factor identification with corresponding protocols for pre-operative optimization/coordination
 - b. Reduction in discharge to acute care facilities
7. These changes have been driven, led, championed, managed and overseen by orthopaedic surgeons
8. The care delivery changes and favorable results are clearly documented in extensive peer review literature

9. A robust survey with detailed and explicit information to assess clinical staff time was approved by the research committee
10. 206 survey respondents resulted completed the survey and responded to this question; the estimated median time for clinical staff paid by and employed by their practice 90 minutes – 30 minutes greater than the standard package

We recommend a total of 90 minutes of clinical staff time; the additional 30 minutes is allocated to PE spreadsheet, row 16, CA code 002 “coordinate pre-surgery services” (total 50 minutes for this row).