

September 2, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8010
Baltimore, MD 21244-1850.

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

Subject: CMS-1770-P Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts.

Dear Administrator Brooks-LaSure:

On behalf of over 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty and state societies that agreed to sign on, we are pleased to provide comments on the Medicare Program: CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirement (CMS-1770-P) published in the Federal Register on July 7, 2022.

The AAOS appreciates the ongoing efforts of the Centers for Medicare & Medicaid Services (CMS) to reduce burden and address the health equity gap during the COVID-19 public health emergency. We request continued support from the U.S. Department of Health and Human Services (HHS) as physicians navigate patient care, financial and practice management challenges exacerbated by the pandemic.

CY 2023 PFS Ratesetting and Conversion Factor

For CY 2023, CMS is proposing a conversion factor of \$33.08, a decrease of \$1.53 (almost 4.5%) to the CY 2022 PFS conversion factor of \$34.61. Such reduction to the Medicare Physician Fee Schedule conversion factor for the past several years is clearly unsustainable. Taking inflation in practice costs into account, the American Medical Association (AMA) estimates that Medicare physician payment decreased by 20% from 2001 to 2021. It is important to note that while Medicare spending on physician services per enrollee decreased by 1% between 2010 and 2020, spending per enrollee for other parts of Medicare jumped by between 3.6% and 42.1%. With inflation soaring to 40-year highs this year, on-going and scheduled statutory payment cuts, and

many physician practices still dealing with pandemic-related financial and staffing issues, the current proposal from CMS undermines the long-term sustainability of physician practices while threatening patient access to physicians participating in Medicare.

The AAOS joined the AMA and several other organizations to call for a rational reform plan¹ for Medicare's physician reimbursement system which includes principles for fixing prior authorization, supporting telehealth, reducing physician burnout and stopping scope of practice creep. This progress is impossible without reforming the current physician payment system in Medicare. One of the biggest problems under the current payment system is the fact that other Medicare providers benefit from built-in updates, such as a medical economic index or an inflationary growth factor, that help offset increases in the cost of providing services – but no such offset exists for physicians.

Orthopaedic surgeons have been leaders in providing high-value musculoskeletal care to patients², while generating cost savings for Medicare. We urge CMS to work with us to create value-based payment models that include incentives tailored to the distinct needs of our patients and practice settings, along with a financially viable fee-for-service model. **Reforming the current physician reimbursement system together is the only way that we can ensure high quality care and equitable access to care for Medicare beneficiaries.**

Payment for Medicare Telehealth Services

Audio-only telephone E/M Services (CPT codes 99441, 99442, and 99443), which are reimbursed equal to the number of in-person visits during the PHE, will end after the PHE expires. CMS maintains that after the PHE expires, all telehealth services, other than mental health care, must have two-way, audio/video communications for telehealth services. As in previous comment letters, **AAOS urges CMS to maintain coverage for audio-only coverage beyond the expiration of the PHE.**

Valuation of Specific Codes

Arthrodesis Decompression (22630, 22633, 22634, 63052, 63053)

CMS did not accept the RUC recommended work RVU for CPT code 22630 (*arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar*), instead proposing a work RVU of 20.42, stating that it would be inappropriate to maintain the current value given the significant decrease in intra-service time, absent an obvious or explicitly stated rationale for why the relative intensity increased. The proposed recommendation was based on a reverse building block methodology accounting for the surveyed reductions in physician time. AAOS believes using the reverse building block methodology disregards the input from neurosurgeons, orthopaedic spine surgeons and the AMA RUC process itself. The reductions in intraoperative time from the current value to the survey values were due to improvements in intraoperative work-flow as well as techniques related to low-risk aspects of the procedure that do not involve work around the neural elements and the spinal cord. AAOS believes that CMS should not use the reverse building block methodology as the primary methodology for valuing services as

¹ [Recovery Plan for America's Physicians](#)

² CMS Comprehensive Care for Joint Replacement Model: Performance Year 4 Evaluation Report <https://innovation.cms.gov/data-and-reports/2021/cjr-py4-annual-report> and BPCI Advanced <https://innovation.cms.gov/data-and-reports/2022/bpci-adv-ar3-findings-aag>

magnitude estimation has been used to establish work RVU's for services since 1992. **AAOS strongly urges CMS to accept the RUC-recommended work RVU of 22.09 for CPT code 22630.**

Similarly, CMS disagreed with the approved RUC recommended work RVU of 26.80 for CPT code CPT code 22633 (*arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar*). CMS proposed a work RVU of 24.83 using the reverse building block methodology. The RUC valuation is based on magnitude estimation, not the reverse building block methodology. Again, AAOS believes that CMS should not use the reverse building block methodology as the primary methodology for valuing services and **strongly urges CMS to accept the RUC-recommended work RVU of 26.80 for CPT code 22633.**

CMS disagreed with the RUC recommended work RVU of 7.96 for CPT code 22634 (*arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment (List separately in addition to code for primary procedure)*), and instead recommended a work RVU of 7.30. This recommendation was based on a comparison to the base code (22633) for code 22634. The new approach in which CMS used to determine the proposed RVU is flawed. CMS reached its proposed recommendation by dividing the proposed parent code's work RVY by its current work RVU and multiplying it by the current work RVU for the add-on code (22634). AAOS believes this new methodology disregards the input from neurosurgeons, orthopaedic spine surgeons and the AMA RUC process itself. AAOS believes that the RUC's methodology which utilizes survey data, comparison to key reference codes based on similar intra-service and total time is a more appropriate approach. **AAOS strongly urges CMS to accept the RUC-recommended work RVU of 7.96 for CPT code 22634.**

CMS disagreed with the RUC's work RVU recommendation of 5.70 for CPT code 63052 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)*). The RUC-recommended work RVU was based on the most recent survey which accounted for an increase in intra-service time. CMS is proposing to maintain a work RVU of 4.25 while using the crosswalk of CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*) stating that the intra-service times will now match. AAOS believes that code 22853 is not an appropriate crosswalk code as it does not capture decompressing the neural elements and removing compression around the spinal cord. Again, AAOS believes CMS is using a flawed method to determine work RVUs. **AAOS strongly urges CMS to accept the RUC-recommended work RVU of 5.70 for CPT code 63052.**

CMS disagreed with the RUC-recommended work RVU of 5.00 for CPT code 63053 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each additional segment (List separately in addition to code for primary procedure)*). The RUC compared code 63053 to several codes with the same intra-service time as well reference service code 22614 (*Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)*). This in combination with the survey input of neurosurgeons and

orthopaedic spine surgeons who perform the procedure justified the RUC-recommended work RVU which supported the survey 25th percentile. CMS proposes a work RVU of 3.78 for code 63053 based on a revised intra-service time ratio between codes 63052 and 63053. AAOS disagrees with calculating intra-service time ratios to account for time changes and encourages CMS to use the magnitude estimation methodology consistent with the RUC process. **AAOS strongly urges CMS to accept the RUC-recommended work RVU of 5.00 for CPT code 63053.**

Lumbar Laminotomy with Decompression (63020)

CMS disagreed with the RUC-recommended work RVU recommendation of 15.95 for CPT code 63020 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical*) which was based on the survey 25th percentile work RVU using magnitude estimation from the survey data collected by physicians performing the service. CMS' recommendation was based on a time ratio calculation, crosswalking to CPT code 27057 (*Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (e.g., gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral*). AAOS believe that the crosswalk is inappropriate as it performed in a different patient population in addition to it being a rarely performed procedure. AAOS believes CMS should use valid survey data to determine work RVUs versus a time calculation based on a crosswalk code with no clinical relevance. **AAOS strongly urges CMS to accept the RUC-recommended work RVU of 15.95 for CPT code 63020.**

Payment for Skin Substitutes

CMS proposes to treat skin substitutes (including skin substitutes) as incident-to supplies as described under section 1861(s)(2)(A) of the Act when furnished in a non-facility setting. CMS is also proposing to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024. **AAOS strongly opposes this proposal and urges CMS not to include skin substitute products as incident-to CPT codes.**

Evaluation and Management (E/M) Visits

Revised Office/Outpatient (O/O) E/M codes, effective January 1, 2021, were mostly accepted by CMS, with the exception of the revisions for prolonged O/O services, over concern that overpayment may result and would impact the ability to determine the total time spent with the patient. Therefore, CMS created HCPCS add-on code G2211 and G2212 (O/O E/M visit complexity). The Consolidated Appropriations Act, 2021, imposed a moratorium on Medicare payment for these services by prohibiting CMS from making payment under the physician fee schedule for HCPCS code G2211 before January 1, 2024. For 2023, CMS has proposed three new HCPCS codes for prolonged E/M care beyond the total time for the primary service (i.e., GXXX1, hospital inpatient or observation; GXXX2, nursing facility; and GXXX3 home or residence). These codes will replace prolonged services CPT codes 99356 and 99357 that will be deleted for 2023. CPT 2023 instructs users to instead report new CPT code 993X0 for prolonged E/M services on the date of an inpatient or observation or nursing facility service. Guidance from the 2023 CPT Codebook further states, "*Code 993X0 is used to report prolonged total time (that is, combined time with and without direct patient contact) provided by the physician or other qualified health care professional on the date of an inpatient service. Prolonged total time is time that is 15 minutes beyond the time required to report the highest-level primary service.*" CMS does not propose to adopt CPT code 993X0, believing that the instructions for the code will lead to administrative complexity, potentially duplicative payments, and limit the ability to determine how much time was spent with the patient.

CMS is instead proposing that HCPCS prolonged service code GXXX1 can only be applied to the highest-level hospital inpatient or observation care visit codes (CPT codes 99223, 99233, and 99236), and can be used when selecting the E/M visit level based only on time. **AAOS strongly urges CMS to adopt and reimburse new CPT code 993X0 for prolonged services and disagrees with the usage of new HCPCS G codes. Requiring physicians to report different code sets for Medicare patients prolonged services and non-Medicare patients creates another layer of administrative burden.**

With the 2023 revised CPT guidelines for Other E/M visits, in which time or medical decision making (MDM) is used to select the E/M level, CMS will not adopt the general CPT rule where a billable unit of time is considered to have been attained when the *midpoint is passed* and instead requires the full time within the CPT code descriptors to be met in order to select an O/O E/M visit level using time, rather than half of the descriptor time. According to the 2023 CPT Codebook, CPT code 993X0, which represents a 15-minute interval, would apply to for example CPT code 99223 when a practitioner reaches 90 minutes; the time represents only 15 minutes more than the codes' descriptor times. CMS disagrees with this instruction and believes that a prolonged code is only applicable after both the total time described in the base E/M code descriptor is complete and the full 15-minutes described by the prolonged code are complete as well. CMS noted the CPT instructions for CPT code 993X0 do not align with CMS payment policy. **AAOS urges CMS to accept the long-standing CPT definition for billable units of time, which is the standard in the industry. Again, having different reporting requirements for Medicare patients related to treatment time will cause undue administrative burdens on physicians.**

CMS maintains it does not recognize the term “subspecialty” and proposes amending CPT definitions of initial and subsequent services to remove the term “subspecialty”. **AAOS would encourage CMS to recognize the term subspecialty when reporting E/M services.**

Split/Shared E/M Visits

In the CY 2022 MPFS final rule CMS finalized a policy for E/M visits furnished in a facility setting (hospital), to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP provide the service together (not necessarily concurrently) and the billing physician personally performs a “*substantive*” portion of the visit, and in the non-facility (office) setting, the rules for “incident to” billing apply but are not available for services furnished in a facility setting. Previous CMS policy has been that, for split (or shared) visits in the facility (hospital) setting, the physician can bill for the services if they perform a *substantive portion* of the encounter and payment is made for services furnished and billed by a physician at 100% of the PFS rate, and NPPs are paid for the services they furnish and bill for at a reduced PFS rate (85% of the PFS).

CMS is proposing to delay implementation of the definition of the “substantive portion” as more than half of the total time until January 1, 2024. In the CY 2022 MPFS final rule, CMS defined substantive portion for billing of split (or shared) visits in certain settings and for certain patient types (new and established), as one of the following: history, or exam, or medical decision making (MDM), or more than half of total time. The CY 2022 PFS final rule further defined “substantive portion” as being “more than half of total time”. Ongoing concern from interested parties remain as practice patterns where the physician does not spend half or more of the time with the patient, as well as possible adjustments needed to the practice’s internal processes or information systems to track visits based on time, rather than MDM. Our position remains the same as in our CY 2022 comment letter, **AAOS strongly urges CMS to consider revising the definition for “substantive portion” to be based on MDM and not time.**

The 2021 Current Procedural Terminology (CPT) E/M Guidelines state, “A split or shared visit is defined as a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physicians and other qualified health care professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for split or shared visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).”

The CPT definition does not state which individual is reporting the service, only that the time is summed to define the total time to report. AAOS strongly urges CMS not to revise the guidelines to split/shared evaluation and management (E/M) services as it will create confusion amongst providers. Having two differing definitions and policies from CPT and CMS will cause confusion for practitioners on how to document and report split/shared services. It is important that physicians can focus on one consistent set of guidelines in reporting their services. **Therefore, we continue to strongly encourage CMS to work with CPT for cohesive guidance on the reporting of split/shared visits in CPT Guidelines and CMS policy.**

AAOS would like to also note that time parameters may be different in the office versus the facility setting. It is not uncommon for a mid-level NPP to spend an excessive amount of time with a patient, without performing any MDM. It would not be appropriate to allow that NPP to bill based on the time component, when the physician takes on the onus of performing the MDM. **Therefore, AAOS strongly believes the determining factor of who bills for the split/shared service should not be time based and should be focused on the practitioner providing the dominant service that contributed the most towards the MDM, as they are ascertaining the majority of the risk.**

Solicitation on Global Surgical Services

AAOS, along with our surgical colleagues, have responded to CMS questions about improving the global surgical package valuation through comments, letters, and meetings since 2012. We are disappointed that CMS has still not been able to arrive at a conclusion on this policy decision. We strongly encourage CMS to disregard the RAND recommendations for revaluation of the global codes given that the RAND methodology is not only flawed but is based on numerous assumptions that are not transparent to the public. We encourage CMS to release the underlying data and assumptions used by RAND.

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. AAOS would like to reiterate that it is inappropriate for CMS not to apply the RUC-recommended changes to global surgical codes. 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 packages 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 code relativity, which was mandated by Congress in 1992, and refined over the past three decades. 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.”³ Failing to

³ 42 U.S. Code §1395w-4(c)(6).

adjust the global codes tantamount to paying some doctors less for providing the same E/M services, which is 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. **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.**

In this CY 2023 rule, it seems that the impetus for asking comments on the global surgical packages is provided by concerns that the packages are overvalued especially post-surgery. The AAOS believes that the theory that the total wRVU in the global package is overvalued has not been proven “beyond a reasonable doubt”. The evidence has been obtained with bias and includes a relatively small sample size compared to the total claims submitted. Also, we would like to note that many codes with global packages are accepted by the RUC and CMS at the 25th percentile or less, suggesting they might be undervalued in aggregate. Requiring physicians to submit claims for each individual post-operative visit adds administrative burden and cost. If the number of visits is accurate, revenue would increase (higher wRVU for office and hospital visits submitted individually), which might offset the cost to collect and work. If visits in the packages are reduced, the net impact may be unfavorable for surgeons. There is also additional physician work to enter accurate charges for each visit; there may also be additional work for documentation. Additionally, office visits commonly involve copayments from patients so unpacking the post-operative visits may also increase the cost to patients. Collecting co-pays adds to the administrative burden and cost. The method to value the codes as 0-day global has not been defined; simply subtracting the wRVU for hospital and office visits may not be an accurate estimation of all the costs.

Hence, the AAOS recommends that CMS

- a. Continues to collect data from a subgroup of physicians by having them submit tracking codes for post-operative visits. We encourage CMS to reach out to EHR vendors and Medicare Administrative Contractors (MACs) to obtain actual data on the number of postoperative visits actually provided.**
- b. Re-survey high-value procedures (price x volume) with a focus on post-operative visits.**
- c. We suggest that CMS consider eliminating the 10-day global period and review codes with that global period to determine if a 0-day or 90-day global period is most appropriate, but this must only be done by engaging stakeholders and reviewing the codes for relative valuation, not by using a formulaic building block valuation approach.**
- d. We encourage CMS to continue to work with specialty societies as it moves forward, so we can weigh in on the Agency’s policy considerations related to revaluation of global surgical packages.**

Rebasing and Revising the Medicare Economic Index (MEI)

CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau’s Service Annual Survey (SAS). However, the rule clarifies that CMS will not implement these new weights in 2023 before reviewing additional comments due to significant redistribution among physician specialties. This proposal is particularly inappropriate as physicians face uncertainty about the Medicare conversion factor,

experience practice financial hardships and continue to suffer from burnout. The AMA has pointed out that in addition to significant specialty redistribution, geographic redistribution would also occur, as CMS proposes to modify weights of the expense categories (employee compensation, office rent, purchased services and equipment/supplies/other) within the practice expense Geographic Practice Cost Index (GPCI). The changes in the MEI that CMS is proposing are almost entirely related to the category weights. A change in the price proxy is recommended for just one of the cost categories which accounts for only 2% of the index. CMS is not proposing a change to the productivity adjustment. The Census Bureau's 2017 SAS for the "Offices of Physicians" industry was not designed with the purpose of updating the MEI. As a result, there are key areas (physician work, nonphysician compensation and medical supplies) where CMS must use data from other sources to update the weights appropriately.

CMS has relied on AMA physician cost data for 50 years in updating the MEI and 30 years in updating the resource-based relative value scale (RBRVS). The current MEI weights are based on data obtained from the AMA's Physician Practice Information (PPI) Survey. This survey was last conducted in 2007/2008 and collected 2006 data. Hence, we fully agree with CMS that the MEI weights must be updated. However, the AMA is currently engaged in a process to collect this data again. It is expected that the new data collection efforts will be completed by 2023 and will be based on 2022 cost data. **We, therefore, ask CMS to collaborate with AMA and national specialty societies like us and postpone updating the MEI data updates until the AMA survey is complete.**

Appropriate Use Criteria Policy

AAOS is pleased to see that CMS is indefinitely delaying the Appropriate Use Criteria (AUC) for advanced diagnostic imaging payment penalty. Although AAOS is supportive of programs that improve quality and reduce unnecessary testing, we are concerned that the implementation of the AUC program will detract from the developments of the Quality Payment Program (QPP) made in the years since the AUC program was signed into law. Meanwhile, the continued delays create unnecessary costs at a time when reimbursement continues to face cuts and expenses rise as a result of inflation and the pandemic. As AAOS commented in the past, given the many issues with implementation, we urge CMS to consider ending this program altogether.

Updates to the Quality Payment Program

CMS is seeking comments on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR Application Programming Interfaces (API) as well as to combine data needed for measure score calculation for measures that require aggregating data across multiple providers. CMS is also requesting information on activities related to leveraging and advancing standards for digital data and approaches to transition to the FHIR eCQM reporting as first steps in the transition to digital quality measurement.

As AAOS has stated in the past, a successful, interoperable system should not focus simply on the electronic sending, receiving, finding, integrating, and use of data from outside sources. True interoperability must allow the exchange and use of information to be secure, useful, and valuable to the patient and the provider. APIs are increasingly used across industries to accelerate progress and improve the sharing of electronic information. They enable different apps, platforms, and entities to connect and share data. AAOS supports this proposed rule's interest in accelerating the use of open APIs to improve the exchange of health information to improve patient satisfaction and care. As discussed above, such moves will enable faster implementation of PRO-PMs and other quality improvements.

In particular, the voluntary adoption of the Health Level 7 (HL7) FHIR API standards has been significant across the health care industry. Per previous estimates from the Department of Health and Human Services' (HHS) Office of National Coordinator of Health IT, roughly 51 percent of health IT developers have adopted a version of FHIR. Such standards are essential for enabling interoperability, and the significant adoption of a common standard may suggest a palatable step forward. For this reason, AAOS supports the proposal to use the FHIR standards as a baseline for the newly defined API standards criteria, as well as a new proposed patient and population services API criteria. Additionally, AAOS supports replacing the Common Clinical Data Set (CCDS) for information exchange for the more robust United States Core Data for Interoperability (USCDI). However, AAOS is concerned that API Data Providers may be unfairly burdened by several fees that an API Technology Supplier can charge, but there is no similar mechanism for API Data Providers to recoup such costs. API implementation costs will be shifted onto health care systems and physician practices, which could have a significant deleterious effect on smaller practices. There should be some consideration given to this and a mechanism must be created for API Data Providers to recoup these costs.

Clinical data registries are an integral component of the health care quality system. As health care costs increase and the imperative to shift towards value-based care accelerates, it becomes more critical to support these entities that effectively collect, analyze, and share important clinical information to inform treatments and improve outcomes. We recommend that data exchange parameters be harmonized between EHR vendors and registries. The HL7 FHIR standards and the USCDI data set improve the ability of registries to receive electronic health information with less effort and greater speed, since most EHR vendors that registries work with have some form of certified health IT. However, CMS should also consider the costs a registry may face to implement API functionality, the time needed to make such a transition, and the use cases that would benefit from such an arrangement. Smaller registries may find adding additional functionality to be financially cumbersome and may not have the resources to implement changes quickly if given a short timeline. Albeit such an arrangement would allow providers the ability to receive relevant clinical insights that registries produce to improve patient outcomes.

Previously Finalized Quality Measures Proposed for Removal in the CY 2023 Performance Period/2025 MIPS Payment Year

AAOS is concerned that CMS is proposing to remove four quality measures which are reported through our qualified clinical data registry (QCDR). While we understand that CMS is proposing to remove measure numbers 375 (Functional Status Assessment for Total Knee Replacement), 460 (Back Pain After Lumbar Fusion), 469 (Functional Status After Lumbar Fusion), and 473 (Leg Pain After Lumbar Fusion) in order to decrease the number of duplicative measures, we are dismayed by the churn of measures the MIPS program. Significant time has been expended to test these measures and include them among the data that the AAOS QCDR captures for our members. In fact, the AAOS QCDR team is actively working on our patient-reported outcomes measures (PROMs) tool and has engaged sites that want to capture and report this assessment data. While we support creating a nimble and evolving quality reporting program, it is equally important to consider the resources required to test and implement measures with the QCDR system. When abrupt changes are made, it has a ripple effect which negatively impacts the ability to robustly participate in quality reporting. With this in mind, we request that CMS consider longer intervals between the proposed removal of measures and the finalization of such changes.

Moreover, we would like to point out that measure 375 (Functional Status Assessment for Total Knee Replacement) also impacts the Comprehensive Care for Joint Replacement (CJR) model and the proposed future requirement for reporting pre- and post-operative PROMs. We request additional guidance on how the removal of measure 375, if finalized, will impact these programs.

Request for feedback on whether third party intermediaries (e.g., Qualified Clinical Data Registries (QCDRs)) should have the flexibility to choose the measures they will support within the MVP

AAOS appreciates the opportunity to provide feedback on the question of whether third-party intermediaries, including QCDRs, should have the flexibility to choose the measures they will support within the MVP. Should this flexibility be granted, we would be in favor of choosing which MVP measures we support to ensure that sites are able to achieve data completeness and reduced burden in their reporting. Several of the measures finalized in the CY 2022 rule require updates to our QCDR's specifications, and sites may not have the resources to update their queries to match the necessary data elements in time to report for CY 2023. However, there are several measures which are already supported by our QCDR within the MVP that our participating sites are actively reporting data on and thus reducing the burden of participation in the MVP program. As we continue to move toward a more robust value-based care environment, AAOS supports continued consideration of the burden associated with these changes and the subsequent flexibilities to promote strong uptake.

CMS is proposing to again delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. In turn, QCDR measures that are approved for the CY 2023 performance year would not be required to have been fully developed and tested until CY 2024. New QCDR measures first proposed for the CY 2024 performance year would only be required to meet face validity and full testing at the clinician level would be required prior to the measure staying in the MIPS program after the first year. In summary, CMS is proposing that beginning with the CY 2022 performance period/CY 2024 payment year, CMS will approve QCDR measures with face validity. For the CY 2024 performance period/CY 2026 payment year and onward, QCDR measures approved for an earlier performance year will be required to be fully developed and tested, including complete testing results at the clinician level, prior to self-nomination. AAOS supports this delay and appreciates CMS' recognition of the resources required to complete full measure testing at the clinician level.

Remedial Action and Termination of Third-Party Intermediaries

AAOS appreciates the remedies CMS has provided for QCDRs to maintain engagement in the program through self-nomination participation plans in cases where performance data has not yet been submitted. However, we disagree with the proposal to terminate QCDRs that, beginning with the CY 2024 performance period, do not submit MIPS data for the performance period for which they self-nominated. In practice, as a specialty registry, having the ability to support MVPs will be our strongest path forward for reporting on behalf of our participants given that they typically report traditional MIPS measures outside of the orthopedic setting. Thus, until there is an opportunity for the MVP program to gain traction, we request that CMS delay the termination of QCDRs.

Further, there are additional reasons to retain QCDR status. Maintaining our QCDR status allows us access to Medicare claims data and serves as a vetting tool for our own data. Some registry participants may wish to use the registry to monitor and benchmark measures throughout the year and then submit via another method. We cannot force any participant to submit through our registries but stripping us of the QCDR status for non-

submission will undermine our efforts to increase quality measurement and reporting. CMS must delay termination of QCDRs until uptake has gained momentum post the pandemic.

Promoting Wellness MVP

AAOS is pleased to see the inclusion of ‘Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age’ measure in the proposed “Promoting Wellness” MVP. This MIPS quality measure assesses women, 65-85 years of age, who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.” While this is a good start with CMS acknowledging that osteoporosis is “*an important public health issue requiring attention as it can lead to co-morbidities and decreased quality of life*”, we join our colleagues in urging CMS to prioritize payment mechanisms in the Medicare program to support a proven coordinated, collaborative care model – Fracture Liaison Service (FLS) - that is recognized internationally as the “gold standard” for secondary prevention of osteoporotic fractures.⁴⁵⁶⁷⁸

Earlier AAOS signed on to a consensus “White Paper”⁹ (endorsed by 17 bone health stakeholders, including specialty societies in orthopedics, endocrinology, and geriatrics and led by the Bone Health and Osteoporosis Foundation [BHOF] and the American Society for Bone and Mineral Research [ASBMR]) outlining the significant care gaps in bone health that disproportionately impact women as they age, and outlining a pragmatic, actionable plan to reduce osteoporotic fractures by leveraging the Fracture Liaison Service (FLS) model in US health systems. The Quality Payment Program’s incentive/disincentive system is insufficient to create new FLS sites or sustain existing programs. CMS has several existing tools that can be used to create a payment mechanism for FLS including the creation of G-codes, similar to the approach the Agency took for pain management services to improve care for opioid use disorders. The White Paper, referenced above, has the detailed design of integrated care under the FLS model, as well as the episode-based payment codes required to reimburse providers for delivering coordinated, high-quality care. It also identifies a set of FLS quality measures that CMS and other payers could use for program evaluation and improvement. BHOF and ASBMR conducted interviews with FLS programs, including those within orthopedic surgery practices. Findings from those interviews underscored the substantial, uncompensated time and resources required from orthopedic surgery practices seeking to ensure that osteoporotic fracture patients receive appropriate follow-up. CMS could, for example:

⁴ Barton DW, Piple AS, Smith CT, Moskal SA, Carmouche JJ. The Clinical Impact of Fracture Liaison Services: A Systematic Review. *Geriatr Orthop Surg Rehabil.* 2021 Jan 11;12:2151459320979978. doi: 10.1177/2151459320979978. PMID: 33489430; PMCID: PMC7809296.

⁵ Javaid MK, Kyer C, Mitchell PJ, et al. Effective secondary fracture prevention: implementation of a global benchmarking of clinical quality using the IOF capture the fracture(r) best practice framework tool. *Osteoporos Int.* 2015;26(11):2573–2578.

⁶ Mitchell PJ. Best practices in secondary fracture prevention: fracture liaison services. *Curr Osteoporos Rep.* 2013;11(1):52–60.

⁷ Akesson K, Marsh D, Mitchell PJ, et al. Capture the fracture: a best practice framework and global campaign to break the fragility fracture cycle. *Osteoporos Int.* 2013;24(8):2135–2152.

⁸ Marsh D, Akesson K, Beaton DE, et al. Coordinator-based systems for secondary prevention in fragility fracture patients. *Osteoporos Int.* 2011;22(7):2051–2065.

⁹ <https://www.bonehealthpolicyinstitute.org/newsroom/2022/8/15/proposal-for-fls-reimbursement-mechanism-through-the-centers-for-medicare-amp-medicaid-services-cms>

- create separate payment codes for fracture repair generally and those services associated with a presumptive osteoporotic fracture to account for diagnostic, treatment planning, and follow-up services performed within the assigned global period
- identify a payment code that orthopedic surgery practices could report when coordinating their care with that of an FLS program to which they refer patients
- ensure that any FLS-specific payment code is reportable by an orthopedic surgery practice treating the acute episode, and payable regardless of the applicable global period for that acute episode

Thus, we urge CMS to create a reliable payment mechanism to support FLS programs to encourage preventive care for osteoporosis patients thereby simultaneously addressing a major public health problem and a high-cost area for the Medicare program.

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 2023 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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American Association for Hand Surgery
American Association of Hip and Knee Surgeons
American Orthopaedic Society for Sports Medicine
American Osteopathic Academy of Orthopedics
American Society for Surgery of the Hand
Arthroscopy Association of North America
Atlantic Orthopaedic Specialists

Campbell Clinic
Cervical Spine Research Society
Delaware Orthopaedic Specialists
Delaware Society of Orthopaedic Surgeons
EmergeOrtho
Florida Orthopaedic Society
Georgia Orthopaedic Society
Idaho Orthopaedic Society
Illinois Association of Orthopedic Surgeons
Iowa Orthopaedics Society
Limb Lengthening and Reconstruction Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Missouri State Orthopaedic Association
Musculoskeletal Tumor Society
Nebraska Orthopedic Society
New Jersey Orthopaedic Society
New Mexico Orthopaedic Associates
New York State Society of Orthopaedic Surgeons
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
OrthoForum
Orthopaedic Rehabilitation Association
Orthopaedic Trauma Association
OrthoSC
Peachtree Orthopaedics
Pediatric Orthopaedic Society of North America
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Resurgens Orthopaedics
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Virginia Orthopaedic Society