AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

September 27, 2019

Seema Verma, MPH
Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

Subject:[CMS-1715-P] Medicare Program; CY 2020 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1715-P) published in the Federal Register on August 14, 2019.

Proposed CY 2020 Work RVUs for New, Revised, and Potentially Misvalued Codes

Drug Delivery Implant Procedures (CPT Codes 11980, 11981, 11982, 11983, 206X0, 206X1, 206X2, 206X3, 206X4, and 206X5)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	1.10	1.10

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11981	Insertion, non-biodegradable drug delivery implant	**1.14**	**1.30**
11982	Removal, non-biodegradable drug delivery implant	**1.34**	**1.70**
11983	Removal with reinsertion, non-biodegradable drug delivery implant	**1.91**	**2.10**
206X0	Manual preparation and insertion of drug delivery device(s), deep (e.g., subfascial) (List separately in addition to code for primary procedure)	**1.32**	**1.50**
206X1	Manual preparation and insertion of drug delivery device(s), intramedullary (List separately in addition to code for primary procedure)	**1.70**	**2.50**
206X2	Manual preparation and insertion of drug delivery device(s), intra-articular (List separately in addition to code for primary procedure)	**1.80**	**2.60**
206X3	Removal of drug delivery device(s), deep (e.g., subfascial) (List separately in addition to code for primary procedure)	1.13	1.13
206X4	Removal of drug delivery device(s), intramedullary (List separately in addition to code for primary procedure)	1.80	1.80
206X5	Removal of drug delivery device(s), intra-articular (List separately in addition to code for primary procedure)	2.15	2.15

In the 2020 Medicare Physician Fee Schedule, CMS reviewed codes for insertion and removal of drug delivery implants. The issue was originated by a RUC screen related to 11981, Insertion, non-biodegradable drug delivery implant being surveyed. 11981 had been surveyed in 2002 by Otolaryngology and Plastic Surgery but was being used predominately by Orthopaedics. Orthopaedics, Otolaryngology, Plastic Surgery, and Obstetrics-Gynecology developed a code change proposal to revise the existing codes 11981-11983 for use for Plastics, Head/Neck, and

Gynecology, and created six new codes (206X0-206X5) to describe the insertion and removal of drug delivery devices for musculoskeletal conditions. All nine codes were surveyed for the October 2018 RUC meeting, with the three societies minus Orthopaedics surveying 11981-11983, and Orthopaedics surveying 206X0-206X5.

In the proposed rule, CMS significantly reduced the proposed RUC values for several of the procedures in the families. AAOS strongly objects to the changes and believes several of the incorrect proposed values are based on a fundamental misunderstanding of the series of codes. CMS states in the proposed rule that codes 206X0-206X5 are intended as add-on (ZZZ) codes for the codes 11981-11983. This is fundamentally and factually incorrect. 206X0-206X5 are ZZZ codes, but specifically are not add-on codes for 11981-11983. These procedures are add-on codes for major reconstructive musculoskeletal procedures such as radical bone resection procedures, major joint arthroplasty, and other major musculoskeletal procedures that require the use of drug-delivery implants to address defects and prevent infection in patients. 206X0-206X5 would not be add-on to 11981-11983. We believe that a correct understanding of the codes that 206X0-206X5 are used with will allow CMS to adopt the correct RUC recommended work RVUs for the family of codes which were reviewed and understood by the RUC to not be add-on to 11981-11983. The RUC recommended values reflect the correct and appropriate rank order for all codes in the family, and we implore CMS to adopt these values for the CY 2020 Medicare Physician Fee Schedule.

11981

CPT code 11981 was identified as being performed by a different specialty than who originally surveyed this service. RUC referred CPT codes 11980-11982 to CPT to better define these services and differentiate between their use in musculoskeletal procedures and use in urological or gynecological procedures. The CPT Editorial Panel approved the addition of six add-on codes to describe orthopaedic drug delivery to differentiate the service from the service described in code 11981.

CMS disagreed with the RUC recommended work RVU of 1.30 for CPT code 11981, stating that since CPT code 11981 incurs a 23% reduction in the new total physician time (30 minutes) and with reference to CPT code 67500 *Retrobulbar injection; medication (separate procedure, does not include supply of medication)* (work RVU = 1.18 and 33 minutes total time) CMS is proposing a work RVU of 1.14, and accepts the survey recommended five minutes for intra-service time and 30 minutes of total time.

The current source of time for CPT code 11981 is CMS/Other. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS/Other, implying that the time was merely cross-walked or selected by a single CMS staffer some time ago.** CMS should not compare the valid survey

time to the initial CMS/Other time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. CMS continuously applies this erroneous methodology and, if finalized, will compromise the integrity of this resource-based relative value scale system.

Based on valid survey data, the RUC recommended the survey 25th percentile work RVU of 1.30, which is a 12 percent decrease and is supported by codes 67515 *Injection of medication or other substance into Tenon's capsule* (work RVU = 1.40), 12013 *Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm* (work RVU = 1.22) and 12004 *Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm* (work RVU = 1.44). CPT Code 11981 requires surgically defining an area for device placement, preparing the tissue bed for device placement, accurately placing the device so it does not cause harm or disturb nearby tissues or structures, taking an assessment of what was placed (so that no part of the device is left behind when it is removed), and sometimes closing tissues around the device to ensure against unwanted device migration.

As proposed, 11981 will only be 0.04 more than CPT code 11980. The RUC noted that CPT code 11981 is a different procedure compared to 11980. CPT code 11980 is the subcutaneous implantation of a biodegradable compounded pellet that can be placed anywhere in the body with a needle and trocar. Whereas, CPT code 11981 is the insertion of a non-biodegradable implant that must be placed in a specific location in the arm. CPT code 11981 is the placement of a silastic capsule with a trocar system and removal of the placement device. Therefore, the physician time and work are different. A 0.04 work RVU difference does not accurately depict the relativity of these two services. CPT Code 11981 requires surgically defining an area for device placement, preparing the tissue bed for device placement, accurately placing the device so it does not cause harm or disturb nearby tissues or structures, taking an assessment of what was placed (so that no part of the device is left behind when it is removed) and sometimes closing tissues around the device to ensure against unwanted device migration. This is dissimilar to a pre-constructed capsule that will fit anywhere and is easily injected in a subcutaneous location. CMS is not using a valid method to propose a work RVU for CPT code 11981. There is no direct crosswalk, only a calculation that is based on flawed time. AAOS implores CMS to independently review the surveyed time and work and not compare it to the invalidated CMS/Other source of the current time and work. The RUC urges CMS to accept a work RVU of 1.30 for CPT code 11981.

11982

CMS disagreed with the RUC recommended work RVU of 1.70 for CPT code 11982, stating that since CPT code 11982 incurs a 25 percent reduction in the new total physician time (33 minutes) and with reference to CPT code 64486 *Transversus abdominis plane (TAP) block (abdominal*

plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed) (work RVU = 1.27 and 35 minutes total time) CMS is proposing a work RVU of 1.34, and accepts the RUC recommended 10 minutes for intra-service time and 33 minutes of total time.

The current source of time for CPT code 11982 is CMS/Other. The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS/Other, implying that the time was merely cross-walked or selected by a single CMS staffer some time ago. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. CMS continuously applies this erroneous methodology and, if finalized, will compromise the integrity of this resource-based relative value scale system.

Based on a valid survey the RUC recommends the survey 25th percentile work RVU of 1.70 for CPT code 11982. This is supported by CPT codes 54150 *Circumcision, using clamp or other device with regional dorsal penile or ring block* (work RVU = 1.90) and 12004 *Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm* (work RVU = 1.44). These are the correct and appropriate reference codes, not the crosswalks proposed by CMS.

CMS reference codes are not appropriate for comparison and crosswalk. In the removal of these devices they must be localized, sometimes under fluoroscopy. They must then be adequately mobilized for safe extraction, ensuring no damage to local tissues or surrounding structures. An assessment needs to be made to ensure complete device removal. Finally, tissues mobilized during the removal must then be re-secured. This is completely different, much more extensive and intensive, work than code 64486.

CMS is not using a valid method to propose a work RVU for CPT code 11982. There is no direct crosswalk, only a calculation that is based on flawed time. CMS' proposals for CPT codes 11981, 11982 and 11983 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. AAOS implores CMS to independently review the surveyed time and work, and not compare it to the invalidated CMS/Other source of the current time and work. The RUC urges CMS to accept a work RVU of 1.70 for CPT code 11982.

11983

CMS disagreed with the RUC recommended work RVU of 2.10 for CPT code 11983, stating that since CPT code 11983 incurs a 42 percent reduction in the new total physician time (40 minutes)

and with reference to CPT code 62324 *Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance* (work RVU = 1.89 and 43 minutes total time). CMS is proposing a work RVU of 1.91, and accepts the RUC recommended 15 minutes for intra-service time and 40 minutes of total time.

The current source of time for CPT code 11983 is CMS/Other. The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS/Other, implying that the time was merely cross-walked or selected by a single CMS staffer some time ago. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. CMS continuously applies this erroneous methodology and, if finalized, will compromise the integrity of this resource-based relative value scale system.

Based on a valid survey, the RUC recommended the survey 25th percentile work RVU of 2.10 for CPT code 11983, which is a 36% decrease and is supported by CPT codes 55700 *Biopsy, prostate; needle or punch, single or multiple, any approach* (work RVU = 2.50), 54150 *Circumcision, using clamp or other device with regional dorsal penile or ring block* (work RVU = 1.90) and 52281 *Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female* (work RVU = 2.75). These are the correct and appropriate reference codes, not the crosswalks proposed by CMS.

The crosswalk codes proposed by CMS are not appropriate for comparison and crosswalk. In the removal of these devices they must be localized, sometimes under fluoroscopy. They must be then adequately mobilized for safe extraction, ensuring no damage to local tissues or surrounding structures. An assessment needs to be made to ensure complete device removal. Finally, tissues mobilized during the removal must then be re-secured. This is completely different and much more work than code 62324.

CMS is not using a valid method to propose a work RVU for CPT code 11983. There is no direct crosswalk, only a calculation that is based on flawed time. CMS' proposals for CPT codes 11981, 11982 and 11983 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. The RUC implores CMS to independently review the surveyed time and work, and not compare it to the invalidated CMS/Other source of the current time and work. The RUC urges CMS to accept a work RVU of 2.10 for CPT code 11983.

206X0-206X5
As described above, new add-on CPT codes 206X0 – 206X5 are not intended to be typically reported with CPT codes 11981 – 11983, with debridement or arthrotomy procedures as CMS stated in the proposed rule. As a result of the misinterpretation, CMS did *not* accept the RUC recommended work value (1.50) for code 206X0 (*Manual preparation and insertion of drug delivery device(s), deep (e.g. subfascial)*) and proposes a work RVU of 1.32, referencing code 64634 (*Destruction of upper or middle spinal facet joint nerves with imaging guidance).* CMS did not accept the RUC recommended work value (2.50) for code 206X1 (*Manual preparation and insertion of drug delivery device(s), intramedullary*) stating that the reference code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq. cm, or part thereof)* is suitable, but that they adjusted the work RVU to 1.70 to account for the 25 minutes of intra-service work time versus the reference code's 30 minutes. CMS also did not accept the RUC recommended work RVU (2.60) for code 206X2 (*Manual preparation and insertion of drug delivery device(s), intra-articular*) stating again that reference code 11047 is a suitable guide and proposed a work RVU of 1.80 which is 31% lower than the RUC recommended value.

We recommend adoption of the RUC recommended values for 206X0-206X2.
CMS proposes the RUC recommended RVU for codes 206X3 (*Removal of drug delivery device(s),* 206X4 (*Removal of drug delivery device(s), intramedullary*) and 206X5 (*Removal of drug delivery device(s), intra-articular*).

206X0
206X0 requires surgically defining an area for device placement, preparing the tissue bed for device placement, accurately placing the device so it does not cause harm or disturb nearby tissues or structures, taking an assessment of what was placed (so that no part of the device is left behind when it is removed) and sometimes closing tissues around the device to ensure against unwanted device migration. 206X0 describes the insertion of a fabricated structural allograft into the musculoskeletal system while 64634 describes the destruction of nerves on a facet joint, which is a completely different procedure. 64634 and its parent code (64633) do not require an incision or work within the musculoskeletal system, but rather are done under image guidance and with a needle. In addition, 206X0 has more total time than 64634, and the work of preparing the implant is a significant amount of work that does not have an equivalent with 64634.

Furthermore, patients receiving the implants require significant post-operative management that is above and beyond the work of the parent codes, while 64634 does not have additional immediate post-service work. 206X0 is a facility procedure that is highly intense and complex, while 64634 is performed predominately in a physician's office by interventional pain physicians. 206X0 is primarily done by oncology and trauma surgeons. Therefore, 64634 is a poor crosswalk for 206X0. The RUC recommended value is the 25th percentile survey value and

is already a lower value than the survey key reference code 11981, which has essentially identical total times, but a work RVU that is considerably higher than the RUC recommended value. At the CMS recommended value, the IWPUT is too low for a complex surgery like 206X0.

AAOS notes that CMS proposes to accept the RUC recommendations of the survey 25th percentile work RVUs for the three removal of drug delivery device codes 206X3, 206X4 and 206X5, but not for the manual preparation and insertion of drug delivery device codes 206X0, 206X1 and 206X2. CMS is not considering the appropriate increase in work required for the insertions. The insertions require more physician work and time because of the requirements for preparing materials and limited time of the hardening of the mediums used for the musculoskeletal drug delivery devices.

AAOS is concerned that CMS' proposed values for 206X0, 206X1 and 206X2 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. We request that CMS rely on valid survey data and the RUC's collective review of the relativity of these services. **AAOS urges CMS to accept a work RVU of 1.50 for CPT code 206X0.**

206X1

CMS did not provide any rationale as to why they did not accept the RUC recommended survey 25th percentile work RVU of 2.50 for CPT code 206X1. CMS references CPT code 11047 *Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq. cm, or part thereof (List separately in addition to code for primary procedure)* (work RVU = 1.80, 30 minutes of intra-service time and 1 minute of immediate post-service time) and then adjusted the proposed work RVU to 1.70 "to account for the 25 minutes, instead of CMS' reference code's 30 minutes of intra-service time (and the 32 minutes of total time), for CPT code 206X1."

There are two typos in the Proposed Rule for 206X1, the code CMS references as 11047. The RUC total time recommended for 206X1 is 32 not 38, and the total time for CMS reference code 11047 is 31 not 32. Both are listed correctly in the *CY 2020 PFS Proposed Rule Physician Time file.*

The RUC recommended five minutes evaluation pre-service time, 25 minutes intra-service time and two minutes post-service time, totaling 32 minutes for CPT code 206X1. **CMS does not explain how they calculated their "adjustment" to manipulate the proposed work RVU for CPT code 206X1. Regardless, the methodology of such a calculation is invalid, voids relativity, and is not resource-based.**

CMS is proposing a significantly lower work RVU, 32% lower, than the RUC recommended work RVU of 2.50, which is supported by a valid survey. The CMS proposed work RVU for 206X1 of 1.70 dramatically undervalues 206X1 and creates multiple rank order anomalies. 206X1 has more time than the key reference service of 11047 but would have a lower work RVU. At 1.70, it would also create a rank order anomaly with the relevant implant removal code 206X4, which CMS accepted at 1.80. The work involved in preparing and inserting the implants is considerably more than the removal, and the values should appropriately reflect this clinical differential. The RUC recommended work RVUs do this, while the CMS proposed work RVUs reverse the appropriate clinical order and create rank order anomalies. 206X1 requires surgically defining an area for device placement, preparing the tissue bed for device placement, accurately placing the device so it does not cause harm or disturb nearby tissues or structures, taking an assessment of what was placed (so that no part of the device is left behind when it is removed) and sometimes closing tissues around the device to ensure against unwanted device migration.

AAOS notes that CMS proposes to accept the RUC recommendations of the survey 25th percentile work RVUs for the three removal of drug delivery device codes 206X3, 206X4 and 206X5, but not for the manual preparation and insertion of drug delivery device codes 206X0, 206X1 and 206X2. CMS is not considering the appropriate increase in work required for the insertions. The insertions require more physician work and time because of the requirements for preparing materials and limited time of the hardening of the mediums used for the musculoskeletal drug delivery devices.

AAOS is concerned that CMS' proposed values for 206X0, 206X1 and 206X2 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. The RUC requests that CMS rely on valid survey data and the RUC's collective review of the relativity of these services. **AAOS urges CMS to accept a work RVU of 2.50 for CPT code 206X1.**

206X2

AAOS does not believe that CPT code 206X2 should be cross-walked to CPT code 11047 as recommended by CMS. 206X2 has significantly more time than the key reference service of 11047 but would have the same work RVU. At 1.80, it would also create a rank order anomaly with the relevant implant removal code 206X5, which CMS accepted at 2.15. The work involved in preparing and inserting the implants is considerably more than the removal, and the values should appropriately reflect this clinical differential. The RUC recommended work RVUs do this, while the CMS proposed work RVUs reverse the appropriate clinical order and create rank order anomalies. 206X2 requires surgically defining an area for device placement, preparing the tissue bed for device placement, accurately placing the device so it does not cause harm or disturb nearby tissues or structures, taking an assessment of what was placed (so that no part of the device is left behind when it is removed) and sometimes closing tissues around the device to ensure against unwanted device migration.

AAOS notes that CMS proposes to accept the RUC recommendations of the survey 25th percentile work RVUs for the three removal of drug delivery device codes 206X3, 206X4 and 206X5, but not for the manual preparation and insertion of drug delivery device codes 206X0, 206X1 and 206X2. CMS is not considering the appropriate increase in work required for the insertions. The insertions require more physician work and time because of the requirements for preparing materials and limited time of the hardening of the mediums used for the musculoskeletal drug delivery devices.

We are concerned that CMS' proposed values for 206X0, 206X1 and 206X2 dismiss the input from the physicians who perform these services and distorts the intensity and relativity among this family of services. The RUC requests that CMS rely on valid survey data and the RUC's collective review of the relativity of these services. The RUC urges CMS to accept a work RVU of 2.60 for CPT code 206X2.

206X3-206X5

CMS accepted the RUC recommended work RVUs for the removal codes 206X3, 206X4, 206X5. AAOS agrees with these recommended values but reiterates that by accepting these proposed values and not the RUC proposed work RVUs for the insertion codes 206X0-206X2, CMS has created a rank order anomaly. We recommend CMS use the correct, RUC recommended work RVU values for all the codes in this family.

Closed Treatment of Vertebral Body Fracture(s) Without Manipulation (CPT Code 22310)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
22310	**Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing**	**3.45**	**3.75**

Code 22310 *(Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing)* was identified through a screen of services with a negative IWPUT and Medicare utilization greater than 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. CMS disagrees with the RUC recommended value (3.75) and proposes a work RVU 3.45 cross-walking to CPT code 21073 (*Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e. general or monitored anesthesia care)*). CMS believes that this better accounts for the decrease in the

surveyed work time as the crosswalk code has an identical intra-service time and similar total time as those proposed by the RUC for code 22310. CMS is proposing to refine the equipment time for the power table (EF031) to follow their standard for non-highly technical equipment for the direct PE inputs.

The RUC compared 22310 to CPT code 21073 *Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care* (work RVU = 3.45, 20 minutes intra-service time), the same code that CMS is proposing as a direct crosswalk. Although 21073 is a helpful comparison, the RUC compared it to the survey code as a lower bracket relative to the RUC recommended work value of 3.75. The RUC recommended crosswalk code, CPT code 67914 *Repair of ectropion; suture* (work RVU = 3.75, 20 minutes intra-service time), which, like the CMS crosswalk code, has identical intra-service time and similar total time, is a more appropriate crosswalk. The intra-service work value per unit of time is appropriately aligned with the survey's 2nd key reference service, CPT code 27267 *Closed treatment of femoral fracture, proximal end, head; without manipulation,* which is also a closed treatment service.

AAOS urges CMS to consider that the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is Harvard, implying that the time was merely extrapolated and not measured directly. We urge CMS to accept a work RVU of 3.75 for CPT code 22310.

Tendon Sheath Procedures (CPT Codes 26020, 26055, and 26160)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
26020	**Drainage of tendon sheath, digit and/or palm, each**	**6.84**	**7.79**
26055	**Tendon sheath incision (e.g., for trigger finger)**	**3.11**	**3.75**
26160	Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger	3.57	3.57

CPT codes 26020, 26055, and 26160 were identified by the RUC through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. In the proposed rule, CMS stated they do not agree with the RUC recommended work RVU of 7.79 based on the survey median stating there is no compelling reason that the service would be significantly more intense to furnish than services with similar times/values. CMS is proposing a work RVU of 6.84 which is the survey 25th percentile and falls between the work RVUs of CPT code 28122 *(Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*) and CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*).

CMS does not agree with the RUC recommended increase to the work RVU of 3.75 for CPT code 26055 (*Tendon sheath incision (e.g., for trigger finger)*) and proposes to maintain the current work RVU of 3.11. CMS is basing this on a total time increment methodology between CPT codes 26020 and 26055. The total time ratio between the recommended time of 119 minutes and the recommended 262 minutes for code 26020 equals 45 percent, and 45 percent of CMS' proposed RVU of 6.84 for CPT code 26020 equals a work RVU of 3.10, which they believe validates the current work RVU of 3.11.

CMS proposes the RUC recommended work RVU of 3.57 for CPT code 26160 (*Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger*) noting that their proposed work RVU validates the RUC's contention that code 26160 is slightly more intense to perform than code 26055.

CMS is proposing to refine the quantity of the impervious staff gown supply (SB027) from two to one for CPT codes 26055 and 26160 for direct PE inputs. CMS believes the second staff gown supply is duplicative, as this same supply is included in the surgical cleaning pack (SA043). The surgical cleaning pack provides one standalone gown and a second gown that is worn by the practitioner and one assistant.

26020

The RUC identified code 26020 through the negative IWPUT and CMS/Other source code screens. A negative IWPUT is a clear indicator that either the time/visit data is incorrect, the work RVU is incorrect or a combination of both. Consequently, revaluation of the code should be based on a correct relative value that considers both time and visits.

For CPT code 26020 CMS does not agree with the RUC recommended work RVU of 7.79 based on the survey median. CMS does not see a compelling reason that this service would be significantly more intense to furnish than services of similar time values. CMS is proposing a work RVU of 6.84 which is the survey 25th percentile. CMS notes that code 26020 should be

valued similarly to CPT code 28289, *Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*, (work RVU = 6.90) noting they have the same intra-service time of 45 minutes. However, CMS ignores the fact that the total time for 26020 (262 minutes) is 20% greater than the total time for 28289 (210 minutes). This difference in total time is reflective of the difference in work required for the typical patient. Code 26020 requires significant and close inpatient monitoring of a patient that has a tendon sheath infection which can escalate and result in the loss of the digit. Consultations with infectious disease physicians, and additional bedside treatment including assessment and dressing changes reflect some of the necessary patient care that is greater than the care required for a patient undergoing bunion repair who is typically discharged the same day after surgery in the outpatient hospital or ambulatory surgery center. The differences in total time (20% greater) and additional inpatient care required for 26020 clearly indicate that 26020 should be valued greater than 28289.

CMS also referenced code 28122, *Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus* (work RVU = 6.76) as a comparator code. However, similar to the comparison with 28289, the total time and work for 28122 is less than 26020, reflective of the typical patient that is discharged the same day or after a less than 23 hour stay (i.e., outpatient).

The fact is that even at the survey median, the intraoperative intensity (0.027) is so low that there are no comparator codes with a lower work RVU. The five codes shown in the table below that have the same intraoperative time of 45 minutes and similar total time of 255-278 minutes (compared with 262 minutes for 20620) further support the survey median work RVU of 7.79.

CPT	**Long Descriptor**	**RVW**	**Total Time**	**Intra time**
45020	Incision and drainage of deep supralevator, pelvirectal, or retrorectal abscess	**8.56**	**255**	45
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir,	**13.20**	**257**	45

	external approach			
25606	Percutaneous skeletal fixation of distal radial fracture or epiphyseal separation	**8.31**	**260**	45
26020	Drainage of tendon sheath, digit and/or palm, each	**7.79**	**262**	45
27766	Open treatment of medial malleolus fracture, includes internal fixation, when performed	**7.89**	**266**	45
27829	Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed	**8.80**	**271**	45
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery	**13.94**	**278**	45

We also note that the RUC specifically stated in its recommendation to CMS that valuing code 26020 at the survey 25th percentile would vastly underestimate the physician work, resulting in an intraoperative intensity of 0.006 – or essentially zero. This further widens the gap and skews the relativity to the RUC referenced codes 26615 (IWPUT = 0.044) and 33207 (IWPUT = 0.047), and CMS referenced codes 28289 (IWPUT = 0.044) and 28122 (IWPUT = 0.033).

AAOS urges CMS to consider the clinical input of over 150 physicians who perform this service and the RUC's collective review of the relativity of these services. The RUC urges CMS to accept a work RVU of 7.79 for CPT code 26020.

26055

The RUC identified code 26055 through the negative IWPUT screen. A negative IWPUT is a clear indicator that either the time/visit data is incorrect, the work RVU is incorrect or a combination of both. Consequently, revaluation of the code should be based on a correct relative value that considers both time and visits.

For CPT code 26055, CMS does not agree with the RUC recommendation to increase the work RVU to the survey 25th percentile of 3.75 to more correctly value this procedure relative to other similar services in the fee schedule. CMS is proposing to maintain the current work RVU of 3.11. CMS supports this recommendation by considering the increment between 26020 and 26055.

CMS' statement that the reduction in time should correlate with a reduction in work RVU continues the flawed assumptions that have plagued this code since 2005. The current times are based on a 2005 survey, but the current work RVU is based on the Harvard studies (2.69, but currently 3.11 due to E/M increases in the global period). CMS should not compare the old times relative to the work RVU. This service should be examined de novo, hence the RUC's recommendation based on current survey data for physician time and work.

AAOS strongly disagrees with CMS' use of valuing the increment. CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC. Codes 26055 and 26020 are distinct 90-day global period codes, not a base code and add-on service that may more easily identify the differences in physician work. The fact is that the current work RVU results in an intraoperative intensity (0.011) that is so low that it is difficult to find another major procedure with such an intensity for comparison. This IWPUT is not negative, but an IWPUT of 0.011 does not reflect an open surgical procedure typically performed in a facility under moderate sedation.

We also note that a work RVU of 3.11 for 119 minutes of physician time over 90 days is significantly undervalued compared to the work RVU of 3.50 for 60-74 minutes of physician and other qualified health care professional face-to-face and non-face-to-face time on a single day as proposed by CMS for code 99205. The work per unit time (WPUT) of 0.026 for code 26055 if the work RVU is 3.11 clearly indicates that the value CMS is proposing is not relative. Even the work RVU of 3.75 results in a lower WPUT for 26055 (0.032) compared with the WPUT for 99205 (0.041). We would suggest that the intensity of work related to 99205 is not 28 percent greater than the intensity of work related to a major surgical procedure 26055.

The RUC maintains that survey 25th percentile work RVU of 3.75 appropriately values CPT code 26055. This recommended value is supported by CPT code 67914 *Repair of ectropion; suture* (work RVU = 3.75, 20 minutes intra-service time), typically performed in the outpatient setting. **AAOS urges CMS to accept a work RVU of 3.75 for CPT code 26055.**

26160
CMS proposed to adopt the RUC recommended work RVU of 3.57 for CPT code 26160. AAOS agrees with this proposed work RVU and recommends finalizing a work RVU of 3.57 in the CY 2020 final rule.

Practice Expense
CMS is proposing refinements to the RUC recommended direct PE inputs for the codes in this family. For the RUC's comments on individual refinements of direct PE inputs please see the attached refinement table.

Closed Treatment Acetabulum Without Manipulation (CPT 27220)

CPT Code	CPT Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
27220	**Closed treatment of acetabulum (hip socket) fracture(s); without manipulation**	**5.50**	**6.00**

The RUC identified CPT code 27220 through the negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is Harvard, implying that the time was merely extrapolated and not measured directly.**

For CPT code 27220, CMS stated they do not agree with the RUC recommended work RVU of 6.00, the survey median. CMS disagrees with the RUC's recommendation because they do not believe the reduction in work RVUs from the current value of 6.83, given a decrease of 19 minutes in intra-service time and 80 minutes in total time, is appropriate. CMS is comparing accurate survey time to Harvard time, which holds zero validity for comparison. The RUC urges CMS to use accurate survey data for physician time and not to adjust the work RVU based on instituting inaccurate comparisons. Further, CMS states that they "…understand that the RUC considers the Harvard study time values for this service to be invalid time estimations…" however, CMS fails to acknowledge the history of this code. In the June 1991 Proposed Rule, the

work RVU for 27220, based on the Harvard study, was 6.18. In the November 1991 Final Rule for the 1992 PFS, the work RVU was reduced to 5.54. In 1997, hospital and office visits were assigned by algorithm for practice expense purposes. In 2007, the work RVUs were adjusted to account for the increases in the Evaluation and Management services included in the global period of this service, and the work RVU was 6.72. In 2010, the work RVUs were adjusted slightly to account for CMS no longer covering the consultation codes, and the work RVU was 6.83. CMS' proposal to reduce the work RVU to 5.50 does not account for the value of the Evaluation and Management services included in the global period of this service or the consultation work associated with the service, but not separately reported. Further, CMS continues to look at the survey intra-service and total time as a reduction from "current." However, referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations is not appropriate. The Harvard study employed much less rigor when determining physician time relative to the modern RUC/CMS process.

The RUC compared 27220 to the survey key reference service, CPT code 27267 *Closed treatment of femoral fracture, proximal end, head; without manipulation* (work RVU = 5.50, 15 minutes intra-service time), the same code that CMS is proposing as a direct crosswalk. Although 27267 is a helpful comparison, the RUC compared it to the survey code as a lower bracket relative to the RUC's recommended work value of 6.00. CPT code 27267 should not be used as a direct crosswalk because it has significantly less pre-service time. Further, 62% of survey respondents indicated that the overall intensity and complexity of 27220 is greater than 27267.

AAOS again urges CMS to consider that the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is Harvard, implying that the time was merely extrapolated and not measured directly. The RUC urges CMS to accept a work RVU of 6.00 for CPT code 27220.

In addition, the crosswalk to 27267 is not an appropriate clinical crosswalk for 27220. CPT Code 27267 describes the closed treatment of the proximal end of a femoral fracture, whereas 27220 is the treatment of the fracture of the hip (acetabulum) and a much more complicated fracture to manage, with a much sicker, more co-morbid patient population. Thus, the work RVU for 27220 should be greater than it is for 27267. An equal value between the two services creates a rank order anomaly with an IWPUT for 27220 that is too low (.008). CPT Code 27220 was flagged for a negative IWPUT, and a work RVU of 5.50 gives it an IWPUT essentially equal to 0.00, which is what the identification of services on the screen was designed to correct. By assigning a work RVU equal to 5.50, CMS has reversed the purpose of the screen and has recreated the rank order anomaly that previously existed, whereas the RUC recommended work RVU of 6.00 sets the IWPUT at an appropriate level given the difficult management of the highly co-morbid

typical patient for 27220. **We recommend that CMS adopt the RUC recommended work RVU of 6.00 for CPT code 27220.**

98X00, 980X1, 980X2

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
98X00	*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes*	**.25**	**.25**
980X1	*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes*	**.50**	**.50**
980X2	*Qualified nonphysician qualified healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*	**.80**	**.80**

CMS is proposing separate payment for online digital assessments via three HCPCS G-codes that mirror the RUC recommendations for CPT codes 98X00-98X02 for CY 2020. AAOS would like to note that we believe there is an error in the MPFS proposed rule. We think CMS inadvertently listed the incorrect code numbers regarding proposed work RVUs for codes GNPP1, GNPP2 AND GNPP3. Please see the highlighted text below.

"For CY 2020, we are proposing a work RVU of 0.25 for CPT code GNPP1, which reflects the RUC recommended work RVU for CPT code 98X00. For HCPCS codes GNPP2 and GNPP3, we believe that the 25th percentile work RVU associated with CPT codes 98X01 and 98X02 respectively, better reflects the intensity of performing these services, as well as the methodology used to value the other codes in the family, all of which use the 25th percentile work RVU.

Therefore, we are proposing a work RVU of 0.44 for HCPCS code GNPP1 and a work RVU of 0.69 for HCPCS code GNPP2."

Office/Outpatient E/M Visit Revaluation (CPT codes 99201 through 99215)
AAOS appreciates the CMS proposal to reduce administrative burden associated with outpatient E/M visits. As currently proposed, the changes for the E/M office visits would be effective starting January 1, 2021. The CPT coding changes will retain five levels of coding for established patients; reduce the number of levels to four for new patients (by deleting 99201); and make changes to the code definitions and guidelines. A new CPT code for extended office visit time will also be implemented. History and physical exams will continue to be performed when appropriate; however, only medical decision making, or time will be considered for code level selection.

AAOS joined 51 other specialty societies in the AMA/RVS Update Committee (RUC) survey of the revised office visit E/M codes. Subsequently, we submitted a comment letter to the RUC stating that we did not agree with the work RVU and time recommendations being put forward by a subgroup of the specialty societies who participated in this survey because we did not believe that the criteria for compelling evidence had been met. AAOS wrote to the RUC that *"The short amount of time provided for input and review, the large number of societies involved, and the lack of opportunity to convene in a face-to-face fashion made the task of achieving consensus nearly impossible."* We believe the survey data and times are flawed because the survey respondents did not understand the new CPT coding structure that reduces documentation burden and were not informed in the survey of the CMS changes in documentation requirements for 2019.

We think a better approach would be to conduct a survey after at least one year of experience to collect more accurate data from providers who have already used the new coding and documentation requirements. This will also give valuable information on any shift in reporting that needs to be taken into consideration and will likely occur. **Hence, we urge CMS to delay adoption of these new survey times and values.**

Global Surgical Packages
If CMS decides to finalize the office/outpatient E/M visit revaluation, **we urge you to extend the updates to the global surgical codes.** Procedures with a 10- and 90-day global period have postoperative visits included in their valuation. CMS mistakenly states that the visits in the global package codes are not directly included in the valuation. Rather, the work RVUs for procedures with a global period are generally valued using magnitude estimation. We believe that CMS has conflated the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation requirement to review the number and level of visits in global codes with maintaining relativity across the fee schedule based on current data in the CMS work/time file. These two issues are not related.

Earlier in August 2019, we joined several surgical specialties in writing to you stating that not extending the E/M will disrupt the relativity in the physician fee schedule, create specialty differences and may even violate MACRA section 523(a) statutory requirements.

Review of RAND Reports

As part of the MACRA statute, Congress instructed CMS to collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. Accordingly, CMS contracted with the RAND Corporation and included three new RAND reports with this proposed rule. We would like to note that RUC will review knee and hip arthroplasty in October 2019 hence, the RAND review of hip arthroplasty may already be dated and not relevant.

RAND Report 1: Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods

Effective July 1, 2017, Medicare practitioners in nine states have been required to report on the postoperative visits they furnish during the global period of specified procedures using CPT code 99024. Due to the low participation by physicians and the seeming difficulty the CMS/RAND researchers have encountered in matching up procedures to CPT code 99024, AAOS believes that this report's findings cannot be generalized to the larger population. The low participation rates would imply low mean and median post-op visit reporting.

The report indicates that participation varied widely by both specialty and state. AAOS believes that there are many errors in the computation of reporting data. Per the AMA-RUC's estimates, *"If RAND utilized the robust reporters only; eliminated the ½ 99238 from the expected visits; and utilized the 2020 CMS time files, we compute that 51% of the expected visits were captured in the reporting of [CPT code] 99024."*

The claims-based reporting for this survey included data from only nine states. While the intention of including analysis limited to "clean" procedures (where the link to 99024 codes is clear) made sense in theory, a mere 60% of the procedures sampled met this criterion. Furthermore, the analysis of 90-day global periods with at least one post-operative visit were not included in the report. Combined, these factors limit the applicability of the results and call into question their universality across specialties.

AAOS does not agree with RAND's determination of robust reporters since it excludes any practitioners who only perform 10-day global procedures. Updating the definition of robust reporters would increase the number of reported visits as well.

Since all RAND analyses on 10-day global services are volume-weighted, the findings are dominated by three high-volume services (CPT codes 17000, 17004 and 17110 typically

performed by Dermatology specialists) and are not representative of the universe of 10-day global codes. For 90-day global codes, cataract surgery (codes 66982, 66984) and hip/knee arthroplasty (codes 27130, 27447) are the highest volume. It is to be noted that cataract surgery was recently reviewed by the RUC. The RUC is reviewing hip/knee arthroplasty in October 2019.

RAND Report 2: Survey-Based Reporting of Post-Operative Visits for Select Procedures with 10- or 90-Day Global Periods

The MACRA statute also required CMS to collect data on the level of post-operative visits for global service. CMS and RAND decided the survey would cover only three high-volume services, cataract surgery (only CPT code 66984), hip arthroplasty (only CPT code 27130) and complex wound repair (CPT codes 13100, 13101, 13120, 13121, 13131, 13132, 13151, and 13152).

Total hip arthroplasty was one of three procedures implemented as a proof of concept for assessing level of post-operative care. The survey had a small sample size of just 1,500 physicians surveyed for each of the three procedures, where each of these 1,500 physicians reported on not more than five post-operative visits that were either office-based or inpatient. With a 15.5% response rate from the 4,500 participants, approximately 697 physicians ultimately participated. Though the practitioner time spent in the average post-operative visit was seven minutes less than the expected time for total hip arthroplasty, the survey did not make clear whether physician assistant (PA) or nurse practitioner (NP) time was included in this. AAOS believes that RAND misinterpreted the findings of their survey data as they compared the survey physician time "on the day of the visit" to the CMS physician time file, where the pre-service and post-service time of E/M services is not specific to the date of the encounter, thereby inappropriately excluding nurse practitioner (NP) and physician assistant (PA) time from their visit time comparison analysis. Additionally, in 2019, time is not the only factor relevant in selecting a code level. The new coding structure makes this RAND report irrelevant.

RAND Report 3: Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods

This third study utilized the reverse building block methodology to estimate the change in Medicare payment based on RAND's summary data from the first study. The analysis included in this study is extremely flawed and disingenuous, as the researchers completely disregarded the "robust reporters" concept highlighted in the first study and made no attempt to filter out the 54% of eligible providers that did not participate in the data collection initiative. When 54% of eligible providers were assumed to never perform post-operative visits simply because they were not aware or were unable to participate in the data collection project, the median number of visits for many surgical global codes would be zero irrespective of what participating physicians reported. Also, as no specialty achieved a 100% participation rate, all codes included in the study would have been undercounted in the study to some extent. Moreover, this study incorrectly

included immediate post-service time as a part of post-operative visit time for the analysis. As CMS is aware, the 10-day global and 90-day global services include instant post-service time which is separate from the E/M postoperative visits in the hospital or office later.

AAOS is concerned that using this RAND report methodology would result in arbitrary reductions in total Medicare payment for many surgical specialties, which in turn is likely to restrict access to care for Medicare beneficiaries.

Opportunities for Bundled Payments under the PFS

In this proposed rule, CMS has requested information on opportunities to use bundled payment models to improve payments for services that are provided together. CMS notes that the statute requires the Agency to pay for physicians' services based on the relative resources involved in furnishing the service but otherwise allows considerable flexibility for developing payment structure under the RBRVS. As you are aware, codes with assigned global periods of 10 or 90 days have multiple distinct services bundled into one payment amount. The AMA/RUC and CPT Editorial Panel have considerable experience developing episodes of care for various medical specialties and diseases. Hence, we urge CMS to work with the RUC, CPT and medical specialties to develop such bundled payments.

Earlier this summer, we participated in listening sessions with the CMS Innovation Center and staff from your office at CMS to discuss longitudinal models for specialty care. **As the leaders in musculoskeletal care, we urge CMS to include orthopaedic surgeons and other specialists in designing bundled chronic care models.**

Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services

CMS is proposing to establish rules to govern Medicare coverage of, and payment for, OUD treatment services furnished in Opioid Treatment Programs (OTPs). We appreciate CMS' proposal for 'zero' copays for OTPs during this opioid crisis. We believe that removal of Part B copays for Medicare patients will improve access to crucial care to combat the opioid epidemic. We would urge CMS to work with Congress to consider removing the deductible and coinsurance payments as required by statute. It should be noted that OTPs are increasingly being provided in outpatient settings and statutory updates to deductibles and coinsurance amounts may be a barrier to patients seeking OTP.

Although AAOS is committed to the highest standards of patient safety, we are concerned that CMS believes that it has the ability to revoke Part B and Part D provider enrollment through rulemaking authority. The definition of "patient harm" as listed in the criteria for CMS consideration is ambiguous. Also, the proposal to have CMS authority extend beyond the reach of state oversight boards' decisions is concerning. **Hence, we urge CMS to share detailed criteria and guidance on how the Agency will determine "patient harm" and make subsequent decisions for impacted physicians.**

Quality Payment Program/Merit-based Incentives Payment System (MIPS) Program

AAOS is interested to learn more about the Merit-based Incentives Payment System (MIPS) Value Pathway (MVP) concept that CMS put forward in this proposed rule. AAOS agrees with CMS that the MIPS program needs to be simplified and made more meaningful to ensure that MIPS participants can thrive in a future value-based health care paradigm. The structural changes that CMS is proposing through its MVP framework has the potential to improve patient care and outcomes if MVPs are designed and implemented with relevant clinical specialty consultation and input. Any future implementation of MVPs will likely add additional burden on providers as they will have to continue to adjust to an ever-changing MIPS program. If CMS were to provide more consistency for participants and reduce some of the existing reporting requirements through participation in MVPs, this could be one step forward toward ameliorating these issues.

AAOS recognizes that this concept is being offered up for input and will reserve more detailed comments on the MVP proposal until it is developed more fully**. Likewise, AAOS urges CMS not to implement this proposal until, and after discussing with relevant medical specialty societies to ensure clinical significance and to prevent added burden on providers.**

Below are a few questions and thoughts AAOS would like to raise as CMS considers this proposal:

- Will participation in an MVP reduce burden for MIPS participants? AAOS believes that reducing burden is important for MVPs to be valuable and meaningful for MIPS participants.
- Will participation in an MVP be voluntarily? AAOS recommends that reporting on MVPs be voluntary, alongside traditional MIPS reporting requirements, until and unless there are sufficient MVPs available for each medical specialty and sub-specialty. AAOS notes that there is already a lack of adequate reportable measures for orthopaedic surgeons.
- How will MVPs be phased into the MIPS program? AAOS notes CMS' comments in the proposed rule that state they would like to establish a methodology that allows them to assign in advance, and require providers and groups to report, relevant MVPs that are selected by CMS. AAOS strongly opposes this future approach. Providers best understand what is clinically feasible, meaningful, and relevant for their practices. We believe preserving choices for providers will allow them to determine where they can have the most impact in improving patient care and outcomes.
- How will the MVP program be scored? Providers should not be intentionally or unintentionally disadvantaged by not reporting through an MVP. In fact, the effort and energy required to carry out and report on MVPs should be less than that of traditional reporting through MIPS, for corresponding point values. AAOS believes that this can be

accomplished while improving patient care and outcomes.

- What will the MVP development process look like? AAOS believes that CMS should develop a formal consultative process with relevant medical specialty societies for MVP development (e.g. musculoskeletal-specific MVPs should incorporate relevant medical specialty society input before implementation).

These are just some of the initial questions we have related to the MVP concept. Overall, AAOS believes that this has the potential to be a step forward, if implemented correctly and clearly, to prevent confusion and reduce burden. **AAOS urges CMS to move cautiously and deliberately before implementing this proposal.**

Quality Performance Category

AAOS is concerned about the proposal to remove MIPS quality measures that do not meet case minimum and reporting volumes for benchmarking if they have been in the MIPS program for two performance years. There is already a lack of available options for many specialties and sub-specialties. Clinicians may not be immediately aware of new measures as they are incorporated, and while reporting may be low for some measures that does not negate the potential clinical significance it may have for smaller specialties and sub-specialties. Opportunities should exist to promote meaningful measures that are not necessarily widely reported, but clinically significant.

AAOS notes that CMS is seeking to require MIPS quality measure stewards to link their MIPS quality measures to existing and related cost measures and improvement activities (IA) in the future and provide a rationale for how they are related. This is a significant undertaking for measure stewards, such as medical specialty societies, that expend substantial time, resources, and energy to develop quality measures. CMS should consider the burden that this proposal would put on measure stewards. Should this be implemented in the future, adequate education, guidance and time for measure stewards would be appropriate to help them adapt to any new requirements.

AAOS is also concerned that this proposal is being made without reference to the MVP concept that CMS also put forth in this proposed rule.

- Would these proposed changes be the first step toward developing an MVP?
- What happens if a quality measure is not able to be aligned with existing cost and IA measures?
    - Can measure stewards develop a quality measure and have it accepted with the intention to pursue aligned cost and IA measures in the future?
- Will existing quality measures have a lower scoring potential if they are not aligned with other cost or IA measures?
- What is the relationship between this proposal and the MVP proposal?

CMS should clearly convey its intention with this proposal and how it does or does not relate to the MVP program, given the overlap and considerable changes they would both place on the MIPS program. As more stringent requirements are placed on the MIPS program, there is a greater risk that fewer measures will be available to providers. As we mentioned earlier, currently there is not an adequate amount of reportable measures for orthopaedic surgeons. AAOS supports improvements to generate greater value and harmony within and across performance measure categories but cautions CMS to do this carefully and precisely. Providing flexibility for providers, enough time to adapt to changes, and proper incentives is critical for substantive changes such as these to make the intended impact they seek.

Osteoarthritis (OA): Function and Pain Assessment Performance Measure

To reduce duplicity, CMS proposes to remove the *Q109: Osteoarthritis (OA): Function and Pain Assessment* performance measure from the QPP program and identifies *Q182: Functional Outcome Assessment* as an alternative measure to replace Q109. AAOS strongly encourages CMS to reconsider this removal, as Q109 has been rigorously vetted and adjusted by orthopaedic surgeons since the measure came under the American Academy of Orthopaedic Surgeon's stewardship in 2017.

While we recognize that there are some similarities between Q109 and Q182, there are important differences and nuances worth noting. Denominator-eligible encounters are not completely duplicative and may adversely affect both the quality of reporting and resource use. Q182 calls for a functional outcome assessment and documentation of a care plan for deficiencies for all patients over the age of 18 who have an office visit during the reporting period. In contrast, Q109 calls for a pain and function assessment for patients with osteoarthritis who are over the age of 21 who have an office visit during the reporting period.

The potentially much larger denominator specification for Q182 could expand resource-use and impose additional and exponential costs on participants who already have the infrastructure in place to report on Q109. The replacement measure also loses the ability to effectively track and assess OA, the most common joint pathology in the United States. The clinical specificity of Q109 is of great value to orthopaedic surgeons and other relevant clinical specialties, especially given the lack of other meaningful, medical specialty-specific measures available for reporting. For these reasons, AAOS strongly encourages CMS to reconsider this proposal and would welcome an open discussion to discuss this issue further.

Cost Performance Category

AAOS appreciates that CMS is proposing to include the attribution methodology for each cost performance category measure in the measure specifications for this and all future proposed rules. This type of transparency will allow providers to better understand how performance is measured and allows for feedback to ensure that the methodology is clinically sound and rigorously validated.

Improvement Activities (IA) Performance Category
AAOS understands CMS' interest in changing the group reporting requirement from at least one clinician to 50% of the group and requiring at least 50% of a group's National Provider Identifiers (NPIs) to perform the same 90-day continuous activity for the 2020 performance year. However, AAOS is concerned that this may not be feasible for certain multi-specialty group practices with various medical specialty clinicians. Nor, is it necessarily best for a subset of clinicians to report on a measure that lacks clinical meaning for them simply because they must meet the 50% threshold. AAOS agrees that one clinician's reported IA activity should not constitute the performance of the entire group. An alternative concept could be to set a percent threshold across the group but allow for variability in measures selected by individuals so that clinicians can choose what is most clinically relevant to them.

Promoting Interoperability (PI) Performance Category
Query of Prescription Drug Monitoring Program (PDMP) Measure
AAOS appreciates CMS' recognition of the challenges clinicians face because of inadequate integration between PDMPs and electronic health records (EHRs). AAOS strongly supports standardization and interoperability of PDMPs as they provide pertinent information about patients. Unfortunately, many clinicians must log in separately to access their state's PDMP. For this reason, AAOS is glad to see that the Query of PDMP measure will remain optional for the 2020 performance period, is eligible for five bonus points, and would be changed from a numerator/denominator measure to a yes/no attestation response. This flexibility will continue to encourage PDMP participation and acknowledges both the challenges and benefits associated with current PDMP infrastructure. AAOS is interested to learn more from CMS as it implements the SUPPORT Act, which is believed to help address these issues.

AAOS supports minimum standards for all PDMPs, including a uniform electronic format for reporting, increased information sharing and disclosure, minimum standards for interoperability, and making information available to physicians in real time. By ensuring prescription information relating to opioids and other controlled substances is available in an easy-to read system, interoperable across state lines, and in a timely manner, prescribers will be able to access the most accurate and up-to-date information to help them make the best clinical decisions for their patients. A deliberate, step-by-step approach will be necessary to achieve optimal state PDMPs. Further, inter-state reporting is especially important in border state situations where state monitoring is deficient or non-existent such as Missouri. Federal health facilities, Veterans Administration (VA), Department of Defense (DoD), and Indian Health centers should also comply with PDMP reporting requirements.

Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category
In the proposed rule, CMS expresses interest in learning more about what potential new opioid

measures could be included in the PI performance category. On March 29, 2019 AAOS issued comments to the Department of Health and Human Services (HHS) Pain Management Task Force explaining that "pre-operative mental health and substance abuse screening has significant potential to reduce the risks of post-operative complications and addiction."[1] The letter also noted that "surgical patients using opioids preoperatively have higher complication rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery."[2] AAOS believes that this is important information that could be incorporated into new opioid measures to improve care and outcomes for patients.

Request for Information (RFI) on the Provider to Patient Exchange Objective

AAOS strongly cautions CMS against any future proposals to require MIPS eligible clinicians to make patient health information available immediately through an open, standards-based application programming interface (API) within one business day after it is available through their certified electronic health record technology (CEHRT). AAOS understands and supports efforts to move the health care ecosystem toward a truly interoperable landscape. However, a one-day timeline to do this is not feasible for many clinicians. While a CEHRT developer may install the appropriate functionality, that does not mean that the small rural practice provider will be able to integrate that into their business practices and operational procedures on day one. There will be additional burden on many smaller practices to implement this requirement, and therefore, an adequate, longer timeline should be proposed.

MIPS Performance Category Re-Weighting

AAOS recognizes the statutory requirements placed on CMS to re-weight the quality and cost performance categories so that they are aligned by performance year 2022. We continue to believe that incremental, progressive, and manageable re-weighting should occur on a year-to-year basis to reach that statutory requirement. AAOS appreciates CMS' proposal to re-weight the quality and cost performance categories by reciprocal 5%e increases in the quality performance category and corresponding 5% decreases in the cost performance category year over year, until they are aligned in 2022. This standardized approach, with notification well in advance of 2022, will help clinicians plan for required changes in the MIPS program.

MIPS Performance Thresholds

For the MIPS performance thresholds, CMS proposes to set the 2022 payment year at 45 points, the 2023 payment year at 60 points, and the 2024 payment year potentially at 74.01 points (the mean final score for the 2019 MIPS payment year). As stated in previous comments, AAOS continues to believe that CMS should have more gradual increases in the performance threshold year over year and wait until more data is accrued and analyzed before determining a 2024

[1] American Academy of Orthopaedic Surgeons, RE: Draft Report on Pain Management Best Practices: Updates. Gaps, Inconsistencies, and Recommendations. March 29, 2019.
[2] Ibid

payment year performance threshold. AAOS previously requested that CMS increase the additional performance threshold by a more modest five points, rather than the proposed 10 for payment year 2021, and appreciates that CMS finalized that five-point increase and is proposing similar increases for payment years 2022 and 2023.

Alternative Payment Models (APMs)

In the proposed rule, CMS clarifies that for episode-based payment models, expected expenditures refers to the episode target price. CMS also states that for their definition of 'expected expenditures', they would "not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of an APM."[3] AAOS believes this approach will provide greater clarity on the episode target price and allow APM participants to have a simpler understanding of what they need to focus on to reduce costs.

AAOS is also glad to see that CMS is building in more flexibility for those that are Partial Qualified Participants (QPs). The proposed rule would change reporting so that eligible clinicians will have their Partial QP status apply to their relevant TIN/NPI combination, while allowing them to report any other TIN/NPI combinations under the MIPS program for a potential positive payment adjustment. This policy will enable a more seamless transition for clinicians from the MIPS program to APM participation, ensure quality measurement and maintain opportunities for appropriate payment for clinicians.

AAOS also welcomes proposals by CMS to provide more flexibility to the Other Payer Advanced APM Criteria by proposing to change the marginal risk criteria so that the average marginal risk rate will be used when actual expenditures exceed expected expenditures for comparison to the marginal risk rate. CMS noted that there are entities that may exceed the 30% marginal risk requirement for normal and lower levels of losses but may be below the 30% marginal risk requirement for higher levels of losses, and because of this do not qualify for the Other Payer Advanced APM model. AAOS is encouraged to see that CMS is seeking ways for inclusion of these groups that are clearly taking on risk and working towards progress in this area. This recognition is important as many clinicians who participate in these models have a sincere interest in continuing to advance value-based care.

Qualified Clinical Data Registries

Requirement for QCDRs To Support All Three Performance Categories Where Data Submission Is Required

[3] Centers for Medicare and Medicaid Services (CMS), Proposed Rule: Medicare Program: CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc., Vol. 84, No. 157, Fed. Reg., CMS–1715–P, RIN 0938–AT72, Proposed Aug. 14, 2019.

Beginning with the 2021 performance period, CMS proposes requiring QCDRs to support submission of Quality, Improvement Activities, and Promoting Interoperability measures. As a part of the self-nomination process, QCDRs would have to attest to their ability to submit data for these three performance categories. AAOS appreciates CMS' movement to make reporting easier and more streamlined for clinicians. We believe that a more streamlined QPP will encourage meaningful participation and are pleased that CMS recognizes QCDRs as a preferred mechanism for meeting that goal. However, to collaborate more effectively, we ask that CMS provide more guidance on the criteria for approval in the final rule.

Specifically, we would appreciate clarification on the number of measures from each performance category that will be required for approval and whether the QCDR will be required to audit data submitted for all performance categories. Is one from each category enough to meet this requirement? In the proposed rule, CMS points out that many QCDRs already report on all three performance categories, which we recognize as well; however, it should be noted that the majority of QCDRs support only a handful of relevant measures from each category. Furthermore, it is unclear in the proposed rule if CMS will require QCDRs to audit data submitted for each category. If that is the intent, AAOS requests CMS reconsider, particularly for auditing Improvement Activity data. Currently, how improvement activities should be documented is not clearly defined, which makes demonstrating that an activity truly occurred unstandardized. In this way, auditing improvement activities becomes challenging at best and unfeasible at worst.

For these reasons, AAOS urges CMS to more clearly describe the requirements of this proposal in the final rule.

Requirement for QCDRs To Engage in Activities That Will Foster Improvement in the Quality of Care

By performance year 2021, CMS proposes requirements for QCDRs to provide educational services in quality improvement and lead quality improvement initiatives for their MIPS eligible users. These educational services are separate from Improvement Activity measures.

While AAOS agrees that quality of patient care is of utmost importance and should be a pillar of the QPP, we cannot support placing undue burden on QCDRs. There is no statutory or regulatory basis for the proposal as neither MACRA nor existing regulations impose a requirement for educational services on QCDRs. Developing and providing educational services is also potentially costly, which could be passed along to the consumer and discourage participation in MIPS.

Furthermore, it is arbitrary to single out QCDRs for this additional burden. Qualified registries, EHR vendors, and other third-party intermediaries serve as reporting mechanisms for the MIPS program, but are not subject to this requirement in the proposed rule.

AAOS asks CMS to delay implementation of this proposal indefinitely and instead search for alternatives that do not place disproportionate burden on a single reporting pathway.

Enhanced Performance Feedback Requirement
In addition to the previously established four-time per year performance feedback requirement, CMS is proposing a requirement for QCDRs to include feedback comparing clinicians or groups also reporting the same measure to the QCDR starting with the 2021 performance year. AAOS is pleased CMS recognizes the powerful analytic capabilities of QCDRs and believes inclusion of this feedback will promote quality improvement.

QCDR Measure Requirements
Currently CMS considers whether a QCDR measure is 1) beyond the concept phase of development and 2) addresses significant variation in performance during the approval process. Starting with performance year 2020, CMS proposes making these criteria requirements for measure approval. AAOS strongly supports the requirement for a measure to be beyond the concept phase of development. We also support the requirement for a measure to address significant variation in performance with the caveat that special consideration should be made to not retire a "topped out" measure without having an alternative measure in place.

QCDR Measure Availability
While we are pleased CMS has softened its approach to achieving measure harmonization through licensing, we remain concerned the proposed rule may still limit the intellectual property rights of QCDRs. As noted in our comment letter for the CY 2019 Proposed Physician Fee Schedule, QCDRs devote significant time and capital to develop, test, and get performance measures approved. Giving measure approval preference based on availability to other vendors devalues the work that goes into developing a new measure and discourages innovation.

The proposal also provides no mechanism for QCDRs to monitor or control who is an appropriate licensee or how the measure is used. We are concerned this lack of oversight may lead to measures being implemented incorrectly, which could result in inaccurate data collection and malign measure validity.

In the final rule, AAOS encourages CMS to affirm the measure developer's right to decide to whom their measures are licensed and how their measures are utilized.

QCDR Measures Meeting Benchmarking Thresholds
AAOS appreciates CMS giving QCDRs the flexibility to create participation plans to increase utilization prior to removing a measure due to low volume. It is important to note, QCDR measures may be created to meet the needs of a sub-specialty due to lack of meaningful measures. In this way, some measures may inherently have low reporting volume; however, that does not mean the measures are not necessary.

In the final rule, AAOS encourages CMS to specify when notice of low reporting volume will be given so that QCDRs may have ample time to develop and implement the participation plan. Ideally, notice will be given shortly before or after the first year of low volume.

Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP)

Starting with the 2021 performance year, CMS proposes that QCDR measures must be linked to a cost measure, improvement activity, and/or a MIPS Value Pathway (MVP) at the time of self-nomination. It is unclear whether CMS would require measures to be linked to one or all three because throughout the proposed rule "and" and "or" are used interchangeably. AAOS seeks further clarification regarding the linkage requirement.

Linkage to all three would be incredibly burdensome to QCDR measure developers because a meaningful link may not be apparent among all three, particularly to the MVP, which is not fully defined at this time. A linkage to just one of the three would be more feasible. We appreciate CMS recognizing that a direct link may not always exist and support a process where QCDR measure developers can request an exception.

Completion of QCDR Measure Testing

As a new requirement for QCDR measure approval, CMS is proposing measures must be completely tested at the clinician level by the time of self-nomination. While AAOS also believes that data integrity is of utmost importance; we think such a strict requirement for measure approval fails to recognize the burden to measure developers.

Testing at the clinician level is resource intensive and time consuming for not only the measure developer, but also the provider. First the QCDR must find a clinician or group willing to test the measure voluntarily, which can be a lengthy process. 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, so the staff member must find the time in his/her busy workday to do the auditing while juggling their regular responsibilities.

In this way, AAOS urges CMS to reconsider and withdraw this proposal.

Collection of Data on QCDR Measures

CMS proposes QCDRs must collect data on validity and clinician interest for new measures prior to submitting a measure during the self-nomination process. The amount of data is not mandated, though CMS recommends a year.

AAOS agrees data validity is integral to the QPP; however, the constraint of collecting data prior to self-nomination is unduly burdensome and unfeasible. QCDR measures are already created by subject matter experts and undergo rigorous testing prior to submission for approval. Requiring QCDRs to collect additional data would only serve to delay new measure development.

Additionally, it is unclear how a QCDR would prove clinician interest in a new measure. Would a survey be required? It should be noted that many specialty societies, such as AAOS, have created QCDRs to serve the interests of their members. In this way, it can be assumed all measures are developed with their membership in mind. Requiring QCDRs to attest to clinician interest in new measures would be redundant and unnecessary.

Duplicative QCDR Measures
AAOS understands the importance of removing duplicative quality measures and appreciates CMS' flexibility in allowing provisional approval of potentially duplicative measures for one year. However, we request clear guidance from CMS on the criteria that will be used to determine whether a measure is redundant. QCDRs develop measures using specific clinical rationale, which dictates how data collected on a measure should be utilized. Forcing measure harmonization without appropriate consideration of the technical specifications and applications of the resultant data potentially removes clinically useful measures. A formal appeal process for QCDRs to dispute harmonization is needed before this proposal moves forward.

Multi-Year QCDR Measure Approval
AAOS supports the proposal by CMS to extend the QCDR measure approval cycle to two years. This proposal rewards QCDRs that maintain good standing and reduces some burden of the self-nomination process. Furthermore, we appreciate the flexibility created by this proposal because it allows QCDRs to put in the time and resources to develop more valuable measures. In this way, we urge CMS to adopt this proposal.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We commend CMS on its continued efforts to improve care quality and access. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, FAAOS, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

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Alabama Orthopaedic Society
American Alliance of Orthopaedic Executives (AAOE)
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
American Society for Surgery of the Hand (ASSH)
American Spinal Injury Association (ASIA)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
J. Robert Gladden Orthopaedic Society (JRGOS)
Limb Lengthening and Reconstruction Society (LLRS)
Massachusetts Orthopaedic Association
Minnesota Orthopaedic Society
Michigan Orthopaedic Society
Musculoskeletal Infection Society (MSIS)
Musculoskeletal Tumor Society (MSTS)
New York State Society of Orthopaedic Surgeons, Inc.
North Carolina Orthopaedic Association
Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
Orthopaedic Rehabilitation Association (ORA)
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Ruth Jackson Orthopaedic Society (RJOS)
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association

The Hip Society (HIP)
The Knee Society
Virginia Orthopaedic Society
Washington State Orthopaedic Association
West Virginia Orthopaedic Society