September 8, 2015

Mr. Andrew M. Slavitt, MBA
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: [CMS-1631-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule

Dear Acting Administrator Slavitt:

Representing more than 18,000 board-certified orthopaedic surgeons, the American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) CY 2016 Proposed Rule [CMS-1631-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B.

The AAOS commends CMS’ continuous efforts to administer and improve payment systems for physicians and non-physician providers while improving the quality of and increasing access to care for Medicare beneficiaries. We have identified several provisions of the proposed rule (PR) where solicited comments are most relevant to AAOS and present our responses below. Thank you in advance for your attention to these comments and concerns.

Valuing New, Revised, and Potentially Misvalued Codes

In the proposed rule, CMS indicates they will continue to publish all available Healthcare Procedure Code System (HCPCS) codes in the annual proposed rule rather than in the final rule as interim. The AAOS appreciates CMS’ recognition that the former process, whereby all new, revised, and potentially misvalued codes were published in the Medicare Physician Fee Schedule (MPFS) Final Rule (FR) publication on or around November 1st of the preceding year, was and continues to be flawed. The main issue with this approach is that it severely and unfairly limited stakeholder input on proposed values; when values are published in a final rule versus a proposed rule, the values immediately become final for the next fiscal year and remain in place for that entire year. Stakeholders were limited to requesting review over the course of the year, while the values were already in effect, and the review process utilized by CMS was
ineffective and opaque. This process is limiting and much less effective than publishing values in the MPFS proposed rule in the summer preceding the fiscal year, and it also runs in direct contrast to the agency’s statutory obligation for transparency and public input into regulatory matters. Therefore, the AAOS is pleased by CMS’ willingness to revise their approach and increase transparency and public input by publishing proposed values in the proposed versus the final rule. We support the agency’s efforts and continuation of this policy.

CMS also announced in the proposed rule their intention to no longer utilize the refinement panel process to solicit stakeholder input and review of proposed values. The AAOS continues to support eliminating the refinement panel, in light of the continued use of the proposed rule to publish proposed values and solicit and respond to stakeholder input.

**Target for Relative Value Adjustments for Misvalued Services**

The Protecting Access to Medicare Act of 2014 (PAMA), enacted on April 1, 2014 established an annual target for reductions in Medicare Payment Schedule expenditures resulting from adjustments to relative values of misvalued codes. Soon thereafter, the Achieving a Better Life Experience Act of 2014 (ABLE), enacted on December 19, 2014, accelerated the application of the expenditure reduction target, setting a 1% target for CY 2016 and a 0.5% target for CYs 2017 and 2018. With estimated total allowed charges of $88.4 billion for CY 2016, 1% would roughly equate to a net reduction target of $884 million. According to the regulatory impact section of the Notice of Proposed Rulemaking (NPRM), CMS estimates a net reduction of approximately 0.25% of expenditures under the Medicare Payment Schedule for codes under review by CMS under the NPRM timeline.

The AAOS recommends that CMS take several steps towards establishing a transparent calculation process. First, the Agency should publish the dollar figure estimate in each year. In this NPRM, CMS simply publishes an estimated target reduction of 0.25%. Second, CMS should publish each issue’s estimated impact on the net target reduction. CMS could publish this information per CPT code, or identify each family of services and publish a combined impact. While estimating the impact of existing services is straightforward, new codes resulting from the revision of large families of services can be difficult to assess. To ensure the stakeholder community can fairly and accurately calculate the published reduction, CMS should publish the exact target reduction number and individual service-level impacts for each year.

The AAOS agrees with the CMS proposal to include all services that receive revised input values. This approach is especially appropriate given the amount of work the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) Practice Expense Subcommittee has done recently to update practice expense inputs, including the film-to-digital migration for imaging services and moderate sedation monitoring time. While the AAOS supports the overall proposal, the AAOS does not agree with CMS on its proposal related to large volume changes occurring due to new coding structures. These volume changes could...
result from coding changes to large families of services and/or the deletion of obsolete codes. Under the current proposal, these existing codes would not be included in the target reduction because their inputs would remain. However, the utilization of these services is changing and should be included as they are related to the activity of either the misvalued code project and/or the CPT Editorial Panel. CMS should include existing codes which are either being deleted or having utilization changes as a result of the misvalued code project and/or the CPT Editorial Panel process.

Additionally, CMS discusses the challenges presented by calculating an annual target when changes in values take place over three years: the original value in the first year, the interim final value in the second year, and the finalized value in the third year. CMS proposes to exclude code-level input changes from CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision. The AAOS agrees with this proposal. As CMS notes, the year two to year three changes represent an incomplete picture from the review of misvalued services. These changes largely represent increases in value to services that, after receiving public comment, CMS had previously proposed to decrease. The vast majority of redistribution happens between years one and two, where the RUC recommendations are initially reviewed and receive interim final values. Second, because of the nature of these changes, reductions that occurred on an interim final basis for CY 2015 were not counted towards target achievement. Thus, accepting changes resulting from CMS’ decision to modify CY 2015 interim final recommendations would distort the overall net impact of the RUC and CMS work on the service level input changes for CY 2015. CMS states the requirement to calculate net reductions implies that both decreases and increases must be considered and while we agree, we note that increases are rare to non-existent. CMS also notes this is the only practical approach given that revising families of services can often lead to both increases and decreases within the same family (e.g., splitting one code into two codes, simple and complex).

CMS also proposes a methodology to implement Section 220(e) of PAMA, which states that if the RVUs for a service in one year would be decreased by 20% or more compared to the RVUs for the same service provided in the previous year, CMS must phase-in the reduction over two year period refinements that result in a year-over-year reduction in total RVUs of 20% or more. We commend CMS for taking steps to implement the requirements of PAMA to avoid reductions to all PFS services. However, we are concerned with CMS’s proposal to apply a 19% reduction in the first year and the remainder of the second. This reduction is sure to have a negative impact on the physicians and facilities performing these services. CMS notes that for codes with drastic reductions greater than 20%, the majority of the reduction would occur in the second year of the phase-in, still resulting in an extreme reduction with negative implications for physicians and facilities in a single calendar year. In recognition of such an impact and in the spirit of fairness, AAOS recommends that CMS instead adopt a 50-50 phase-in approach. We are certain that Congress intended the reduction to be phased-in to avoid huge drops in payment in a single year.
Valuation of Specific Codes under the 2016 Medicare Physician Fee Schedule

Bone Biopsy Excisional (CPT Code 20240)

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Descriptor</th>
<th>RUC Rec RVU</th>
<th>CMS Proposed RVU</th>
<th>CMS Work RVU Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>20240</td>
<td>Biopsy, bone, open; superficial (eg, ilium, sternum, spinous process, ribs, trochanter of femur)</td>
<td>3.73</td>
<td>2.61</td>
<td>Disagree</td>
</tr>
</tbody>
</table>

The AAOS disagrees with the CMS recommendation noted above and strongly suggests that CMS reconsider its decision to not accept the RUC recommendation for CPT code 20240. The RUC identified CPT code 20240 as a family code related to a potentially misvalued code. Subsequent to this identification, the RUC also requested, and CMS approved, a change from a 10-day to a 0-day global period. CMS stated they do believe the RUC recommendation accurately reflects the work involved in this procedure and is proposing a work RVU of 2.61 for CPT code 20240 based on the reductions in time for the service.

The Summary of Recommendation form submitted with other materials to CMS indicated that code 20240 was a Harvard-based code with intra-service time estimated by seven orthopaedic surgeons. Currently, orthopaedic surgeons represent only 10% of the utilization of this code and clearly are not the dominant provider compared to podiatrists. In addition, the current post-operative visits were imputed and not surveyed. Although there are changes to the time and visits for this service, the total time for the 0-day global service (118 minutes) is greater than the total time for the Harvard-based 10-day global service (116 minutes). The RUC recommendation of a work RVU of 3.73 takes into consideration the compelling evidence that the service was previously reviewed by the wrong specialty and the work estimate undervalued.

The CMS proposed work RVU of 2.61 results in an intra-service intensity of 0.028, which is essentially equal to the intensity of a nursing visit (code 99211), and significantly undervalues this procedure. A review of 0-day services recently evaluated that have 30 minutes of intra-service time and are typically performed in a facility setting under anesthesia provide further support that the proposed value is not “relative” to other similar services in the MPFS. Similarly, in this proposed rule, CMS proposes work RVUs significantly greater for 0-day global colonoscopy codes with less intra-service time and with little or no inpatient utilization. We urge CMS to maintain the relativity of code 20240 with other 0-day global codes and accept the RUC recommended work RVU of 3.73.
Spinal Instability (CPT code 7208A, 7208B, 7208C, and 7208D)

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</thead>
<tbody>
<tr>
<td>7208A</td>
<td>Radiologic examination, spine, entire thoracic and lumbar, including skull, cervical and sacral spine if performed (eg, scoliosis evaluation); one view</td>
<td>0.3</td>
<td>0.26</td>
<td>Disagree</td>
</tr>
<tr>
<td>7208B</td>
<td>2 or 3 views</td>
<td>0.35</td>
<td>0.31</td>
<td>Disagree</td>
</tr>
<tr>
<td>7208C</td>
<td>4 or 5 views</td>
<td>0.39</td>
<td>0.35</td>
<td>Disagree</td>
</tr>
<tr>
<td>7208D</td>
<td>Minimum of 6 views</td>
<td>0.45</td>
<td>0.41</td>
<td>Disagree</td>
</tr>
</tbody>
</table>

The AAOS recommends that CMS reconsider its decision to not accept the RUC recommendation for CPT codes 7208A, 7208B, 7208C, and 7208D listed above and instead accept the RUC recommended values. To justify the values CMS recommends, it used deleted code 72069 *Radiologic examination, spine, thoracolumbar, standing (scoliosis)*, which was last reviewed by the RUC and CMS in 1995, as the basis for deriving their proposed work RVUs for these four new CPT codes. 72069 will be deleted for CY 2016 as it has no practical use in modern imaging in spinal instability. Part of the reason for the code deletion stems from a change in the patient population and technology for treating spinal instability as stated during the original RUC presentation by the AAOS and ACR. Additionally, CMS deems 72069 to be the closest code correlating to 7208A; however, 7208A includes skull, cervical spine, and pelvis “if performed,” making the deleted code a poor crosswalk. Also, the deleted code is used for scoliosis, but not necessarily other spinal instability determinations which are inherent to the newly created codes. For example, 7208A may be used to assess coronal imbalance and all of the codes in this new family may be used for complex post-operative evaluation and pre-operative planning.

The current time source for 72069 is “CMS/Other,” meaning the methodology used to determine the physician time is not a valid source as it was simply assigned by CMS in the early 1990s using unknown methodology. Furthermore, only total time is provided for “CMS/Other” codes. The breakdown of existing pre-service, intra-service, and post-service time and intensity is not available. The AAOS strongly recommends CMS avoid using existing times and RVUs from “CMS/Other” codes as the basis for any future valuation decisions. The AMA RUC Relativity Assessment Workgroup has employed many misvalued code screens based on whether a service is “CMS/Other” and CMS has concurred this represented valid criteria for discovering potentially misvalued services.

Therefore, the AAOS believes the RUC recommended values, which are also the 25% survey values, are the correct values to maintain relativity to other similar radiological services, and
urges CMS to accept its original recommendations of 0.30 RVUs for CPT code 7208A, 0.35 RVUs for CPT code 7208B, 0.39 RVUs for CPT code 7208C, and 0.45 RVUs for CPT code 7208D.

**Physician Compare Website and Open Payments Data**

The Affordable Care Act (ACA) required CMS to develop what they called the “Physician Compare” website – launched in late 2010 – to provide public information on Medicare-enrolled physicians. The ACA also mandated CMS to implement a plan no later than January 1, 2013, to expand the site’s contents and provide information on variables including performance, eligible professionals (EPs) who satisfactorily report under PQRS, as well as those who participate in the Medicare EHR Incentive Program.

In the CY 2016 Proposed Rule, CMS proposes to continue expansion of the data available on the Physician Compare website to include a five-star rating of each physician or group practice to reflect performance compared to a performance benchmark established by CMS under PQRS. In addition, Physician Compare would continue to include information on whether physicians and group practices successfully reported under the PQRS and/or received a Medicare payment adjustment under the PFS based on performance-related methodology using the Value-Based Payment Modifier (VM). Payment adjustments under the VM will continue to be implemented through the end of CY 2018, when, like the PQRS, it will sunset and be replaced by the MIPS, pursuant to MACRA, on January 1, 2019.

CMS also discusses its consideration of a formal proposal to make Open Payments data available on Physician Compare. CMS states that prior to considering a formal proposal, it will test these data with consumers to establish the context and structure required to ensure these data are accurately understood and depicted in a manner amenable to consumer decision making. Although these data are already publicly available on an alternative CMS website, [http://www.cms.gov/openpayments/](http://www.cms.gov/openpayments/), CMS seeks comments on whether or not it should make Open Payments data available on Physician Compare. According to CMS, consumer testing has indicated that access to this information on Physician Compare would increase consumer ability to locate, better understand, and evaluate the information on Open Payments data when presented on the Physician Compare site.

AAOS believes CMS’ plans to establish a formal proposal to make Open Payments data available on Physician Compare ignores important differences between the two databases. Open Payments and Physician Compare are entirely separate databases with their own distinct purposes. Open Payments provides data regarding financial relationships physicians and hospitals have with healthcare manufacturing companies, whereas Physician Compare assists Medicare Beneficiaries in identifying physicians and group practices that accept Medicare and participate in Medicare quality programs.
AAOS does not believe it would be helpful to patients to provide Open Payments data on Physician Compare. The information on Open Payments is unrelated to the quality or value of care provided to Medicare beneficiaries, which is likely to lead to confusion among beneficiaries and ultimately impede their ability to select a healthcare provider. Therefore, we recommend that CMS refrain from further pursuing any proposal to make Open Payments data available on Physician Compare.

**Changes to the Individual Eligible Professional (EP) and Group Practice Qualified Clinical Data Registry (QCDR) Measure Reporting**

The AAOS agrees with the Proposed Rule provision that CMS should continue to make available for public reporting on Physician Compare all individual EP level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year. We also agree that group practice level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year be available for public reporting.

**Changes to the Individual Eligible Professional (EP) and Group Practice QCDR Measure Reporting**

The AAOS appreciates that CMS is focusing on aligning QCDR measure reporting across all eligible professionals and group practices. AAOS agrees that QCDRs shall publicly report data annually in the year following the year the measures are reported and that QCDR PQRS and non-PQRS measures that have been collected for less than a full year are not subject to public reporting.

**Changes to the Requirements for Qualified Registries and the QCDR Program**

The AAOS is appreciative of CMS’ focus on aligning various physician payment, efficiency, and quality improvement reporting programs to reduce the burden on eligible professionals and group practices that participate in those programs. Improvements and increased flexibilities should encourage more widespread physician participation in the PQRS and related Medicare quality measure improvement programs for years to come.

The AAOS agrees that CMS should require QCDRs to provide specified information to CMS at the time of self-nomination to ensure QCDR data is valid. AAOS urges CMS to evaluate the requirements for entities to become QCDRs. We are concerned about what entities can apply to be a QCDR, whether the requirements for self-nomination are sufficient, and if this process is monitored by CMS. Our focus is patient safety and collecting accurate data. We want to ensure there are no inappropriate organizations collecting data.
Submission of Quality Measures Data for Group Practices

We are pleased CMS has responded to stakeholder feedback and has proposed to allow QCDRs the ability to submit quality measures data for group practices. The AAOS supports the MACRA legislation allowing Qualified Clinical Data Registries access to Medicare claims data granted upon request, and at no charge, for purposes of linking Medicare data with clinical outcomes data to perform risk-adjusted, scientifically valid analyses and research to support quality improvement, patient safety, and reduced costs to the Medicare program. We urge CMS to ensure that QCDRs be provided access to Medicare claims data, as required by law, on July 1, 2016 and that the process for obtaining these data be convenient, timely, and affordable.

Changes to Stark and Physician-Owned Hospital Ownership Provisions

In the proposed rule, CMS outlines some updates to the Stark provisions that do not allow physicians or other providers to self-refer patients for services other than those being immediately provided. CMS proposes to increase disclosure requirements for physicians in the proposed rule, which in and of itself is commendable. However, the AAOS recommends that CMS carefully consider the future consequences of such minor adjustments to existing regulations such as Stark in light of the future statutory requirements related to the Merit-Based Incentive Payment System (MIPS) under MACRA. Specific to the proposed Stark regulation revisions, we recommend that CMS delay any changes until they can ensure these changes will not increase efforts for physicians to participate in alternative payment models (APMs) in order to satisfy the MACRA requirements for the MIPS payments. CMS should make every effort to make the process as transparent and simple as possible, and we are concerned the proposed Stark revisions could render the process more burdensome than necessary.

In the CY 2011 OPPS/ASC Final Rule, CMS codified the physician-owned hospital (POH) bona fide investment requirement which states the percentage of the total value of the ownership or investment interests held in a POH, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate (the “Bona Fide Investment Level”) does not exceed such percentage as of March 23, 2010 (the “Baseline Bona Fide Investment Level”). In the OPPS/ASC Final Rule, CMS also established a policy that a POH need not consider non-referring physicians, including physicians who no longer practice medicine, in calculating the Baseline Bona Fide Investment Level. CMS is now proposing to revise its current policy and the accompanying interpretation to require the Baseline Bona Fide Investment Level and Bona Fide Investment Level include direct and indirect physician ownership and investment interests, regardless of whether such physicians are referring physicians. Accordingly, any interest held by a “physician,” as defined under Section 1861(r) of the Social Security Act and 42 CFR §411.351, would need to be included in a POH’s Bona Fide Investment Level and Baseline Bona Fide Investment Level calculations, even if such physician does not refer to the hospital and/or no longer practices medicine.
The proposed policy would make non-referring and/or retired physicians relevant, which diverges from the intent of the Stark law. The reversal, if implemented, would also necessitate ownership restructuring that will likely result in financial hardship for any non-referring or retiring physicians forced to sell his/her ownership interest at the current fair market value to allow the POH to comply with the new policy. It would also require burdensome and costly governance restructuring if implemented. The AAOS disagrees with the policy, and recommends that CMS maintain the current requirements and not change the baseline definitions.

**Implementation of Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) under MACRA**

In the Proposed Rule, CMS seeks comments on various aspects of its plans for future implementation of major reforms under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requiring CMS to establish a new payment system – MIPS – which will incorporate and replace existing physician quality programs as well as separate payment adjustments for Meaningful Use for items and services provided on or after January 1, 2019. Notably, the Proposed Rule excludes any specific proposals on implementing the MIPS but rather is requesting comments and seeking stakeholder input on particular aspects of the program as noted below.

Under the MIPS, a provider’s performance will be assessed according to established performance standards and used to determine an adjustment factor that is applied to the professional’s payment for per year based on a composite performance score and a MIPS adjustment factor, yet to be precisely defined. To aid in the planning and implementation of the MIPS, CMS specifically asks for public input on: 1) the low-volume threshold for purposes of excluding certain professionals from the program; and 2) the definition of clinical practice improvement activities, which is one of the performance categories used in determining the composite performance score. In addition, CMS is seeking comments on particular activities that could be classified as clinical practice improvement activities for purposes of the MIPS.

AAOS commends CMS for seeking early comments on its plans to implement the MIPS. However, in order to ensure CMS’ proposals are appropriate, AAOS believes CMS must work closely with AAOS and other specialty societies throughout the drafting process. Furthermore, AAOS recommends that CMS provide information on its policies to implement the MIPS prior to the release of the CY 2017 MPFS Proposed Rule, such as in the CY 2016 interim final rule or a separate rule specific to the MIPS.
“Incident-to Services”

In the Proposed Rule, CMS proposes additional requirements for physicians or other practitioners to bill for services rendered by auxiliary personnel “incident to” services provided by a physician.

Current regulations state the physician or other practitioner supervising auxiliary personnel need not be the same physician or other practitioner upon whose professional service the “incident to” service is based. However, CMS is now proposing that the physician or other practitioner who bills under the PFS for “incident to” services must have directly supervised the auxiliary personnel who provided the services.

The AAOS believes the current regulations for “incident to” billing are sufficient to ensure appropriate physician supervision and we do not believe the regulations require the proposed changes. We recommend CMS abandon its proposed changes and maintain its current rules and regulations for “incident to” billing. This is especially important in light of CMS’ efforts to increase coordination of care between physicians and non-physicians. The revisions proposed by CMS would likely decrease care coordination among health care practitioners and ultimately reduce the overall quality of care delivered to Medicare patients.

Thank you for your time and for considering the concerns, comments, and recommendations of the American Association of Orthopaedic Surgeons (AAOS) on this important proposed rule which primarily addresses revisions to payment policies under the Medicare Physician Fee Schedule. Should you have questions on any of the above comments, please do not hesitate to contact AAOS’ Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,

David D. Teuscher, MD
President, American Association of Orthopaedic Surgeons

cc: Karen Hackett, FACHE, CAE, AAOS Chief Executive Officer
    William O. Shaffer, MD, AAOS Medical Director
    Graham Newson, AAOS Director of the Office of Government Relations
Additional signatories to AAOS’ comments on CMS’ CY 2016 Revisions to Payment Policies Under the Medicare Physician Fee Schedule and Other Revisions to Part B Proposed Rule [CMS-1631-P] include the following organizations:

Scoliosis Research Society
J. Robert Gladden Orthopaedic Society
Pediatric Orthopaedic Society of North America
Orthopaedic Trauma Association
American Orthopaedic Society for Sports Medicine
Arthroscopy Association of North America
American Orthopaedic Foot and Ankle Society
American Spinal Injury Association
American Society for Surgery of the Hand