September 10, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2019 Medicare Physician Fee Schedule (MPFS) Proposed Rule.

In this comment letter, we address the following important issues:

Payment Provisions

- Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS)
- Determination of Practice Expense (PE) Relative Value Units (RVUs)
- Standardization of Clinical Labor Tasks
- Updates to Prices for Existing Direct PE Inputs (DPEI)
- Breast Biopsy software (EQ370)
- Potentially Misvalued Services
- Valuation of Specific Codes
- Radiologist Assistants (RA)
- Evaluation and Management (E/M) Visits
- Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services
- Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information
Quality Payment Program

- Small Practice Bonus
- Identifying Merit-Based Incentive Payment System (MIPS) Eligible Clinicians (EC)
- MIPS Determination Period
- Facility-Based Measurement
- Performance Period
- MIPS: Quality Performance Category
- MIPS: Improvement Activity (IA) Performance Category
- Final Score Methodology
- MIPS: Qualified Clinical Data Registry (QCDR)
- MIPS: Promoting Interoperability Performance Category
- MIPS: Cost Performance Category
- Advanced Alternative Payment Models (APMs)

PAYMENT PROVISIONS

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS)

The proposed rule outlines CMS’ continued plan for implementing Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA), establishing a program to mandate the use of AUC for ADIS. The ACR greatly appreciates CMS’ continued willingness to engage stakeholders in this process and for the consideration of our input during this rulemaking cycle. We look forward to continued collaboration as the program moves closer to implementation.

Expanding Applicable Settings

Proposals

CMS proposed to revise the definition of applicable setting to include independent diagnostic testing facilities (IDTFs). The agency believes that the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across outpatient settings in which outpatient ADIS are furnished and would appropriately and consistently apply the program. CMS also points out that the application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the MPFS, Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment systems).
ACR Perspective and Comments

The ACR supports the proposal to add IDTFs to the definition of applicable setting for the AUC program. The College appreciates CMS’ efforts to ensure there is no confusion on the applicability of the program to all outpatient settings in which ADIS are performed.

Consultations by Ordering Professionals

Proposals

In response to comments in the 2018 rulemaking cycle seeking clarification on who is required to perform the consultation of AUC through a qualified clinical decision support mechanism (CDSM), CMS proposed that the consultation may be performed by “clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law.” While this is the language in the preamble, the specific proposed regulation text at 42 C.F.R. § 414.94(j)(2) states the consultation could be performed by “auxiliary personnel (as defined in § 410.26(a)(1) of this chapter) under the direction of, and incident to, the ordering physician or non-physician practitioner’s professional service.”

CMS recognizes that the statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional. However, the agency is making efforts to seek ways to minimize the burden of this new program. The rule states that it is important to note that ordering professionals are ultimately responsible for the consultations as their national provider identifiers (NPI) are reported by the furnishing professionals on the claims for the applicable imaging services and that it is the ordering professionals who could be identified as outlier ordering professionals and become subject to prior authorization based on their ordering patterns.

ACR Perspective and Comments

The ACR understands that CMS has heard concerns from some stakeholders about the potential burden of the AUC program. We appreciate the need to address these concerns by allowing some flexibility. The statute is clear that the ordering professional is required to consult the AUC, which we believe requires the ordering professional to meaningfully interact with the CDSM program. CMS should not lose sight of Congress’s intent to educate ordering professionals in the optimal use of ADIS. This education cannot take place if the ordering professionals have no contact with the AUC themselves.

The ACR supports flexibility for ordering professionals to delegate the AUC consultation to certain clinical staff with appropriate training (e.g., nurse practitioners, registered nurses, licensed vocational nurses, physician assistants, medical assistants), but not to non-clinical personnel. We recommend that CMS revise its proposal to reflect language used in the preamble, “clinical staff,” rather than “auxiliary personnel.” Additionally, the ACR recommends that CMS require that the clinical staff be required to confer with the ordering professional and document in the patient’s medical record should the AUC
consultation result in “not adhere” feedback. This would maintain the educational aspect of the program while allowing some flexibility for ordering professionals to delegate the AUC consultation to their clinical staff. We recommend that CMS revise 42 C.F.R. § 414.94(j)(2) to state:

(2) The AUC consultation specified in this paragraph (j) may be performed by clinical staff, subject to applicable state licensure and scope of practice law, working under the direction of, and incident to, the ordering professional’s services.

The ACR has heard concerns from members that office-based practices may be disadvantaged by hospitals that may, as furnishing providers, perform the AUC consultation on behalf of the ordering providers. To address these concerns, the ACR requests that CMS clarify that regardless of practice setting, the consultation must be performed by the ordering physician or his or her clinical staff, not by the furnishing professional or furnishing professional’s staff.

Reporting AUC Consultation Information

Proposals

When CMS initially codified the AUC consultation reporting requirement through rulemaking in the CY 2018 MPFS final rule, the agency specified only that “furnishing professionals” must report AUC consultation information on claims for applicable imaging services. This led some stakeholders to believe that AUC consultation information would be required only on claims for professional services. To better reflect the statutory requirements, CMS proposed to revise the regulations to clarify that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (including both the professional and technical components).

ACR Perspective and Comments

The ACR agrees that this is consistent with the PAMA statute and supports the proposal.

Claims-Based Reporting

Proposals

In the CY 2018 MPFS proposed rule, CMS proposed using a combination of G-codes and modifiers to report the required AUC consultation information on the Medicare claim. In response to numerous public comments objecting to this potential solution, the agency considered additional approaches to reporting AUC information, including reporting of a unique consultation identifier (UCI) that ACR suggested as a less burdensome approach.

CMS had the opportunity to engage with stakeholders in the months since the publication of the CY 2018 MPFS final rule and understands that there are continued challenges with the UCI
approach. Specifically, there are issues with the use of a UCI when more than one Current Procedural Terminology (CPT®) code is reported on a claim.

After exploring the UCI option, CMS concluded that it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims form, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying issue that the UCI seems limited to claim-level reporting in time for the January 1, 2020 implementation date. Therefore, CMS proposed to use G-codes and modifiers to establish reporting requirements, allowing for implementation to proceed on January 1, 2020. The agency will consider future opportunities to use a UCI and will continue to engage with stakeholders.

Under the proposal, each qualified CDSM would be assigned a G-code with a code descriptor containing the name of the qualified CDSM. Three modifiers would be developed to report the result of the AUC consultation as: 1) the imaging service would adhere to the applicable AUC, 2) the imaging service would not adhere to the criteria, or 3) such criteria were not applicable to the imaging service ordered. These modifiers, when placed on the same line with the CPT code for the ADIS, would allow the information to be easily accessed in the Medicare claims data and matched with the imaging service.

**ACR Perspective and Comments**

The ACR appreciates CMS’ willingness to work with providers to implement the AUC program as expeditiously as possible. **While we continue to believe that the most effective way to implement the AUC program is to require reporting UCI on the claim, the College appreciates the challenges when multiple codes are reported on a single claim and we support the G-code and modifier proposals as a temporary, short-term solution.** We look forward to continuing to work with CMS to develop a way to report a UCI on claims for ADIS in the future.

Not only will a UCI link to the information that PAMA requires, but it also will provide information on the outcome of the consult prior to the determination that a study was or was not adherent. In particular, analyses can be performed for circumstances when the ordering professional, as a result of the consultation, decided not to order any ADIS test -- which the ACR understands is the most common "change" made in physician orders as a result of consultation and, in fact, contributes the highest value of that consultation. Since the goal is to reduce or eliminate inappropriate imaging, this information is essential in evaluating the success and budgetary impacts of the AUC program. Additionally, this information may also be used in the implementation of the future outlier policy.

Requiring a UCI on the claim will assure that during market implementations, this evidence of consultation will be provided to the furnishing provider so that they may confidently attest that a consultation has taken place. We believe that program integrity will be improved as verification of a consult via the UCI increases program reliability. Through additional rulemaking, CMS can require qCDSMs to record and store richer AUC consultation data and provide access to CMS for analysis and audit.
The ACR does not believe there to be any taxonomy requirements contemplated in the regulation related to qCDSM functionality, and does not believe there to be any need to ‘encode’ information within the UCI. The qCDSM G-Code, together with the UCI are globally unique to the program and traceable to a unique consultation. When CMS implements an approach leveraging the UCI, the only taxonomy requirement should be field length, such that the UCI can be rendered ‘as is’ on the claim.

The ACR asks that CMS specify instructions for communication of the pertinent information from the ordering professional to the furnishing professional. The furnishing professional is expected to report the appropriate G-codes and modifiers with the required information, but as proposed, there is no guidance on how the furnishing professional will receive this information.

**Significant Hardship Exception**

*Proposals*

CMS proposed the following as situations where an ordering professional would not be required to consult AUC using a qualified CDSM when ordering ADIS:

- Insufficient internet access;
- Electronic Health Records (EHR) or CDSM vendor issues (including temporary technical problems, installation or upgrades that impede access or CMS de-qualification of a CDSM vendor); or
- Extreme and uncontrollable circumstances (including natural or manmade disasters).

The agency proposed that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an ADIS order and such attestation be supported with documentation of the significant hardship. Ordering professionals would communicate the information to the furnishing professional with the order and it would be reflected on the furnishing professional’s and furnishing facility’s claims by appending a Healthcare Common Procedure Coding System (HCPCS) modifier. Claims that include the significant hardship modifier would not be required to include AUC consultation information.

*ACR Perspective and Comments*

The ACR agrees with CMS’ position that this proposal is more straightforward and less burdensome than linking the significant hardship exceptions to other programs such as the EHR Incentive Program and/or MIPS.

In the case of the AUC consultation requirement, the hardship event may be simultaneous with the ordering activity, and quickly followed by study performance and claim submission. In many cases, it will not be possible for the clinician performing the imaging study or its interpretation to have the ability to validate that the ordering professional actually experienced a hardship. For this reason, the ACR requests CMS clarify that a rendering or interpreting provider (the
furnishing provider) who relies in good faith on a representation by the ordering provider that it experienced a hardship event (e.g., a connectivity problem or vendor issue) would not lose payment of their Medicare claim were it to be subsequently determined that the terms and conditions of the hardship exception had not actually been met.

Other Comments

With regard to the education and testing period, the CY 2018 MPFS final rule indicated that the ordering professionals would be required to consult AUC and the furnishing professional required to report the appropriate information on the claim without penalty for incorrect reporting. The ACR is aware that there is still confusion on whether there would be a penalty if AUC is not consulted and/or reported on the claim at all. Some are interpreting the education and testing period to mean that AUC consultation and reporting in 2020 will be optional. The ACR asks CMS to clarify that AUC must be consulted and reported in 2020, but claims that contain incorrect information on the consultation will still be paid.

Determination of Practice Expense (PE) Relative Value Units (RVUs)

Low volume services

Proposals

For CY 2019, CMS proposed to add 28 codes that have been identified as low volume services to the list of codes for which the expected specialty is assigned. Based on CMS’ own medical review and input from the American Medical Association’s (AMA) Relative Value Scale Update Committee (RUC) and specialty societies, the agency proposed to assign expected specialty codes as listed in Table 1 of the proposed rule.

ACR Perspective and Comments

The ACR agrees with diagnostic radiology as the expected specialty as indicated in Table 1 with some exceptions. We would note that many codes (e.g., x-ray of fallopian tube) may fall into the low volume category simply due to the nature of the older Medicare patient population. The ACR offers the following comments on the specialty assignments of the new low volume services.

- CPT codes 70557 (Magnetic resonance (e.g., proton) imaging, brain (including brain stem and skull base), during open intracranial procedure (e.g., to assess for residual tumor or residual vascular malformation); without contrast material) and 70558 (Magnetic resonance (e.g., proton) imaging, brain (including brain stem and skull base), during open intracranial procedure (e.g., to assess for residual tumor or residual vascular malformation); with contrast material(s)) are intraoperative exams and most often performed by neurosurgeons.
• 74235 (Removal of foreign body(s), esophageal, with use of balloon catheter, radiological supervision and interpretation) is a diagnostic radiology code rather than gastroenterology.
• 75810 (Splenoportography, radiological supervision and interpretation) should be assigned to interventional radiology rather than diagnostic radiology.
• 78282 (Gastrointestinal protein loss) and 79300 (Radiopharmaceutical therapy, by interstitial radioactive colloid administration) should be assigned to nuclear medicine rather than diagnostic radiology.

Standardization of Clinical Labor Tasks

Proposals

In the proposed rule, CMS stated that “3 minutes of clinical labor time traditionally assigned to the “Prepare room, equipment and supplies” (CA013) clinical labor activity were split into 2 minutes for the “Prepare room, equipment and supplies” activity and 1 minute for the “Confirm order, protocol exam” (CA014)”. The ACR believes that this statement is inaccurate, as “Prepare room, equipment and supplies” (CA013) has always had 2 minutes of standard time.

ACR Perspective and Comments

The PE Subcommittee formed a Workgroup in October 2015 to revise and update the PE spreadsheet, implemented in 2017. Prior to the revision, the PE Spreadsheet for Imaging contained a line item for “Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocled by radiologist.” With the revised PE spreadsheet, the language for that clinical activity was a) streamlined to apply to a variety of services, b) divided into two separate line items with their own standard times, and c) split between the pre-service period and the service period, as outlined below.

• Pre-service period
  o CA007 - Review patient clinical extant information and questionnaire (1 minute)
• Service period
  o CA014 - Confirm order, protocol exam (1 minute)

The ACR supports the RUC’s request for CMS to remove the minute of clinical staff time that was added to CA013, in order to maintain a standard of 2 minutes for that clinical activity, and accept 1 minute of clinical staff time as originally recommended by the RUC for CA014, in order to maintain a standard of 1 minute for that clinical activity. We request that these changes be made wherever the refinement has been proposed throughout the RUC-reviewed codes for CY 2019.
Updates to Prices for Existing Direct PE Inputs

Proposals

CMS used its authority under section 1848(c)(2)(M) of PAMA to initiate a market research contract with StrategyGen to update the MPFS direct PE inputs (DPEI) supply and equipment pricing for CY 2019. StrategyGen submitted a report to CMS with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs, from which CMS is recommending updated pricing recommendations for 2,017 supply and equipment items.

StrategyGen used several primary and secondary resources to gather price data for the supplies and equipment. The resources included vendor survey, physician panel, General Services Administration system (GSA), aggregate health system buyers’ database, and Amazon Business and Cardinal Health.

Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, the agency proposed to phase in use of the new direct PE input pricing over a 4-year period using a 25/75 (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021) and 100/0 percent (CY 2022) split between new and old pricing. CMS notes that this transition period will not only ease the shift to the updated supply and equipment pricing, but will allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

ACR Perspective and Comments

The ACR appreciates CMS’ efforts to ensure price accuracy for the supplies and equipment. CMS stated that there has not been a comprehensive review of supply and equipment prices since 2004-2005. This is true, but a continual item-by-item update has occurred each time the RUC and its PE Subcommittee and the specialties review new and revised codes. This level of dialogue and collaboration between physicians and CMS should not be minimized in favor of expediency.

Regarding the data and methodology, we have concerns in the following areas:

Transparency:

Any repricing effort of this scale must be transparent. The subscription-based benchmark databases utilized by StrategyGen are not publicly available. Therefore, there is no means for stakeholders to analyze the data to validate their accuracy.

Data Sources:

Commercial prices for the supplies and equipment were gathered from subscription-based benchmark databases, operated by a nonprofit organization that represents more than 5,000 members. Some of the members included integrated health delivery systems, physicians,
hospitals and other providers. We are concerned that stakeholders cannot fully analyze the data
to check for pricing accuracy, as these databases are not publicly available. Further, we can
analyze the StrategyGen proposed supply and equipment prices specific to our specialty. But, in
general, we may not review and comment on the more general supplies and equipment which are
used by multiple specialties but could still have significant impact to our specialty. CMS also
needs to ensure that small practices are well represented in the repricing effort. There could be a
significant variability in the supply and equipment price from practice to practice.

StrategyGen used multiple sources, one of which is the Emergency Care Research Institute
(ECRI), which per their web site describes its database as representing “U.S. hospital types and
group purchasing organizations.” It is inappropriate to use this data source. The direct inputs
used in the MPFS for the non-facility setting involve, by definition, the physician office.
Therefore, it is unclear why hospital pricing is being used for comparison purposes. This data
skews the prices down without regard for practice size, practice type, procedural volume and
purchasing method, and geography, all relevant considerations. This risks underestimating the
actual prices available to smaller practices and individual physicians, who simply do not have
access to the same bulk pricing as larger physician groups, group purchasing organizations
(GPOs) or hospital contractual arrangements.

StrategyGen used the GSA system and acknowledges that “the GSA system by design provides
the lowest available prices to government purchasers...eligible physicians typically use sources
other than the GSA to purchase medical equipment.” Further, StrategyGen indicates their
“statistician found the GSA pricing to be significantly different than both the current CMS and
commercially research prices. Therefore, it was ill advised to integrate the GSA price into the
Recommended CMS Price for equipment items. In addition, the options that most heavily
integrate GSA pricing, relative to commercial pricing, tended to result in the lowest prices. The
ACR agrees that the GSA is not representative of the typical prices available to physicians.

Methodology:

StrategyGen acknowledges prioritizing equipment and supply research based on the current
share of PE RVUs attributable to that item. On the surface, this seems logical, but the
methodology ignores the fact that some services (and specialties) inherently require higher priced
equipment. Therefore, prioritization of this nature subjects those services (and specialties) to a
disproportionate scrutiny and impacts.

At the conclusion of the market research, StrategyGen provided five repricing options to CMS.
The StrategyGen recommendation was to use the “researched commercial price” when available
and if not, then the current CMS price. They also provided CMS with four additional options.
Instead of accepting StrategyGen’s recommendation, CMS decided to go with option 1, “The
researched commercial price, when available. If not available, then the GSA price. If the GSA
price is also unavailable, then the current CMS Price.” The ACR is concerned that CMS decided
to go with option 1 despite concerns regarding GSA found in the StrategyGen report described
above. We re-emphasize that GSA is not representative of the typical prices available to private
practice providers and should have no place in price determinations. The ACR recommends that
CMS reconsider StrategyGen’s recommendation to use the researched-commercial price when available and current CMS Price if not available.

Rates for Clinical Staff Labor

CMS believes that the rates for clinical labor staff needs to be updated to maintain relativity between the clinical labor, medical supplies and medical equipment portions of the practice expense methodology. CMS is seeking comments whether the update should take place during the four-year pricing transition for supplies and equipment or at the conclusion of the transition. The ACR believes it is reasonable to update the rates for the clinical staff labor if CMS continues to base them on the Bureau of Labor Statistics data.

Due to concerns around transparency, validity of data sources, chosen methodology and inherent bias, the ACR does not support the updates proposed by CMS. We recommend that CMS abandon or delay these updates and continue working with stakeholders on updates to ensure the accuracy of the CMS PE Database. However, if the updates are finalized, we encourage CMS to allow continued rule making comments on equipment supplies, which may include the submission of supportive data and invoices. This should continue throughout the proposed four-year phase-in and beyond.

At the same time, as new and revised CPT codes come before the RUC PE Subcommittee, we encourage CMS to allow updates by the specialty societies, where appropriate.

Breast Biopsy software (EQ370)

Proposals

After the publication of the CY 2018 MPFS final rule, a stakeholder contacted CMS to request that the price for the Breast Biopsy software (EQ370) equipment be updated. This equipment item currently lacks a price in the direct PE database, and when an invoice for the Breast Biopsy software was first submitted during the CY 2014 MPFS rule, CMS stated that this item served clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL008). Therefore, CMS did not create new direct PE inputs for this equipment item.

After reviewing the use of the Breast Biopsy software (EQ370) equipment in the six applicable CPT codes, CMS did not propose to update the price or add the software to these procedures. The agency continues to believe that equipment item EQ370 serves clinical functions similar to other items already included in the MR room equipment package (EL008), and that it would be duplicative to include this Breast Biopsy software as a separate direct PE input. CMS also noted that the RUC recommendations for the new CPT codes 77X51 and 77X52 do not include EQ370 in the recommended equipment for these procedures and they do not have any reason to believe that the inclusion of additional Breast Biopsy software beyond what is already contained in the MR room equipment package would be typical. CMS will however, update the name of the
EQ370 equipment item from “Breast Biopsy software” to the requested “Breast MRI computer aided detection and biopsy guidance software” to help better describe the equipment in question.

ACR Perspective and Comments

The ACR believes that the Breast Biopsy Software (EQ370) is a separate and additional input from the MR room (EL008). The biopsy software is not part of any standard MR room package available for purchase, as these are different equipment that are sold by different vendors. Regarding 77X51 and 77X52, the Breast Biopsy Software is not included since those codes are used for diagnostic MR. When an intervention is performed, that involves different CPT codes which would include EQ370. We request that CMS include EQ370 and allow updated pricing based on the invoices provided in 2014.

Potentially Misvalued Services

Proposals

For CY 2019, CMS received one submission that nominated several high-volume codes, including 70450 (CT of the head without contrast) for review under the potentially misvalued code initiative. In the request, the submitter noted a “systemic overvaluation” of work RVUs (wRVUs) in certain procedures and tests based “on a number of Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute report for CMS.” The submitter suggested that the times CMS assumes in estimating wRVUs are inaccurate for procedures, especially due to substantial overestimates of pre-service and post-service time, including follow-up inpatient and outpatient visits that do not take place. According to the submitter, the time estimates for tests and some other procedures are primarily overstated as part of the intra-service time. Furthermore, the submitter stated that previous RUC reviews of these services did not result in reductions in valuation that adequately reflected reductions in surveyed times. The submitter requested that the codes be reviewed as potentially misvalued.

ACR Perspectives and Comments

CPT code 70450 was surveyed for the October 2012 RUC meeting, and the value was supported by strong survey data. Non-contrast CT of the head fits appropriately within the CT code family, as well as maintains relativity within the larger resource-based relative value scale (RBRVS). The ACR does not feel that this code is potentially misvalued.

The ACR supports the RUC’s request for CMS to publicly share the comment letter that nominated the seven codes for re-review in order to establish transparency and guide future discussion regarding the potential misvaluation of the identified services.
Valuation of Specific Codes

Overall Comments

The ACR appreciates CMS explaining its methodologies and rationale for refining or adjusting RUC recommended values. We agree with CMS that valuation methodologies used by the agency to adjust RUC-valued codes (i.e. survey data, building blocks, increments, magnitude estimation, or crosswalks to key reference service (KRS) or similar codes) are technically appropriate. However, we are concerned that CMS has, in some instances, applied these methods in an inappropriate or unprecedented manner, or has adjusted code values based on a misunderstanding. We are also concerned that the mechanisms for these adjustments are not consistently applied and contradictory rationales exist for different codes in the same rule making cycle.

As a specialty society, our most significant point of contention with the methods used by CMS has to do with the treatment of time. We agree with CMS that the agency is “obligated under the statute to consider both time and intensity in establishing wRVUs for MPFS services,” as emphasized in different phrasing throughout the rule. However, many of the methods employed by CMS to arrive at alternative values do not consider intensity in the stated rationale. This is particularly the case when crosswalks are employed for unrelated procedures across different specialties that do not share much in common. Moreover, a specific approach adopted in this rule not previously used or endorsed by either the RUC or CMS (e.g., using the same RVU for multiple different procedures across different anatomic regions and with varying intra-service times) discounts the differences in clinical work and patient population in favor of an argument based on times being similar across the family of codes. These choices do not support the view put forward by CMS that time and intensity are each important in determining appropriate relativity.

In this letter, we will identify the code values for which we have concern with the approach taken by CMS, explain our rationale, and when needed, provide what we believe to be a more compelling justification for why the codes warrant a different value. For the ACR’s comments on individual refinements of direct PE inputs, please refer to the attached refinement table (Attachment A), filtered for radiology codes.

Fine Needle Aspiration (FNA, CPT 10021, 10X12 and 10X16)

The ACR disagrees with applying an incremental change in value from the adjusted RVU of 10021, a non-image guided code, to the bundled fine needle aspiration (FNA) codes that include imaging. While we concur that an increment methodology can be appropriate in some settings, we believe that applying it here is not appropriate. The dominant specialties performing 10021 are different than those performing the image-guided codes (previously 10022, and now 10X12 and 10X16). A work increment has more credence as a valuation methodology when the same physicians perform both services. The clinical work, set-up, patient complexity, and technical skill differences required to perform 10022 (now 10X12 and 10X16) compared with 10021 justify the intensity difference between the procedures. If radiologists performed 10021, we might concur with an incremental approach. However, we do not believe the incremental
methodology accounts for intensity differences between the procedures performed by different specialties in distinctly different circumstances. We strongly endorse the values recommended by the RUC as reflecting an appropriate RVU for the bundled services of FNA and modality-specific imaging guidance when considering both time and intensity.

The ACR respectfully disagrees with CMS’ argument that the work pool for a recoded family should be similar before and after the valuation of the new codes. This code set previously only included two codes, 10021 (FNA without imaging) and 10022 (FNA with imaging). Ultrasound, computed tomography (CT), and MRI-based imaging guidance were all reported separately along with 10022. By separating the modalities into their own codes, the appropriate time and intensity differences for these services are more accurately reflected in the recommended RVUs, and the work pool appropriately expands to reflect these differences. Specifically, 10022 could not account for the different patients receiving a biopsy using ultrasound (US) or CT. The reason the CT-guided code is valued higher is because the procedure itself is more challenging, the patients are more complex, and the imaging modality used requires a different set of technical skills and more time. Moreover, we disagree with CMS that imaging guidance does not warrant its own pre-service and post-service times. When these and similar codes have been valued, as was the case with 77021, those pre-service and post-service times specifically address only the imaging components of the procedure, including the assessment of which imaging modality is most appropriate, the use of radiation protection equipment and attire, and the reporting required specifically for certain imaging modalities as mandated by CMS for either documentation or quality control.

*Knee Arthrography Injection (CPT 27X69)*

The ACR disagrees with CMS that the survey times for this service, which is replacing 27370 due to miscoding issues, justify a decrease in value. The most important consideration here is that the work of 27370/27X69 has not changed. There is no technological change, patient population change, or equipment change that materially affects the physician work to justify a change in RVU for a service that was only brought forward based on miscoding as caught on a utilization screen, even if the times are different from the Harvard valued code (27370). Moreover, the crosswalk (29075) used to justify this lower valuation is not performed by the specialty performing 27X69, nor is it clinically similar work. An external application of a cast is not an appropriate comparison to injecting contrast into a joint. As a starting point, a review of RUC-surveyed codes performed by Radiology with intra-service times between 12 and 17 minutes and total times between 20 and 35 minutes shows a wRVU range of 0.69 to 1.50. As an invasive procedure, magnitude estimation would justify its placement further away from the bottom of this range, and more appropriate crosswalks to justify the current 0.96 wRVU would be 72240 or 78582.

We would also like to highlight two additional technical details. The original code is Harvard valued, and as such pre-dates the existence of pre-time packages. The service period time as listed also does not separate the time periods into pre-service, intra-service, and post-service. Without that separation, the ACR objects to the use of a “reverse building block” methodology because it cannot accurately account for the differences in value or intensity for the work accomplished in these time periods.
The ACR agrees with the comments submitted by the Society of Interventional Radiology with respect to these codes.

Of particular importance, the ACR feels that this is an example of applying a potentially valid methodology in an inappropriate manner. Specifically, using direct time comparisons between two clinically dissimilar services (36X72 and 50435) completely disregards the intensity differences between these two procedures. 50435 may be recently valued and have similar times as the survey for 36X72, but it is a catheter exchange procedure as opposed to establishing de novo vascular access. Additionally, 50435 is predominantly performed on adults, as opposed to 36X72, which by definition is performed on children under 5 years of age. Specific to this set of codes, these children are being referred for 36X72 when superficial venous access could not be established, so imaging guidance is needed to access deep veins.

With respect to code 36X73, we believe CMS has used similar inappropriate methodology in considering comparison to 36569. To value a code using imaging guidance the same or less than the same code without imaging guidance is specious and treats the use of imaging guidance as a negative work component when in fact there is additional work required in using imaging guidance. The patients undergoing 36X73 are by definition more complex than 36569 and the differences in value must be accounted for by higher intensity. For example, if a physician attempts 36569, it is reasonable to presume some time is spent attempting to locate and access the superficial vein. This typically requires more than one attempt. Therefore, a period of low intensity time occurs while searching for a vein and attempting to place a needle. A patient referred for 36X73 has typically failed 36569. The patient’s venous anatomy is assessed with ultrasound, a deeper vein is identified, and ultrasound is used to guide a needle into the vein. Fluoroscopy is used to manage the placement and positioning of wires in the central venous anatomy. The line is subsequently placed and secured. This work happens without low intensity time searching for venous access and is fundamentally different than the work of 36569. Image guidance makes the impossible procedure possible, and the challenging procedure achievable; but there is time and work intensity that must be accounted for in the valuation of these efforts.

X-Ray families including Spine, Sacrum, Elbow/Forearm, Heel and Toe (CPT 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, 72120, 72200, 72202, 72220, 73070, 73080, 73090, 73650 and 73660)

The ACR disagrees strongly with the approach used by CMS to suggest alternative values for these codes.

First, the statement that these codes were “all identified as potentially misvalued through a screen for CPT codes with high utilization” is incorrect. A few of these codes were caught on screens for codes with “CMS/Other” as a time and value source, and then the code families were voluntarily expanded by the specialties. The utilization of these codes is actually relatively low, which is why they had not previously been captured by a utilization-based screen.
Second, in deciding against the validity of using the crosswalk methodology to arrive at the RUC recommended values, the proposed rule states, “we have concerns about the quality of the underlying data used to value these CPT codes”. As an example, 73660 (X-ray of the toes, minimum 2 views) was crosswalked to 73140 (X-ray of the fingers, minimum 2 views). The finger X-ray code was surveyed for April 2016 with 93 respondents and the current value of 0.13 was approved by the RUC, which was below the 25th percentile survey value. This survey data was of high quality and recent. Comparing fingers to toes is anatomically appropriate and the clinical work is very similar. This is the archetype of a high-quality crosswalk.

In the rule, CMS expressed concern that using crosswalks for valuation provides “no new information about any of these CPT codes that would allow us to detect any potential improvements in efficiency of furnishing the service or evaluate whether changes in practice patterns have affected time and intensity.” For the reasons below, we find this line of reasoning incompatible with the specific codes being valued here.

- It discounts the work of the RUC, which has vetted both this concept in prior years, and which reviewed these codes in particular, both in committee and as a whole.
- The work of interpreting X-rays has not substantively changed in decades. When RUC surveys of X-ray codes have been performed in the last three years, the RUC has recommended maintaining the current values the majority of the time, though a few codes have been either slightly increased or decreased (+/- 0.02 wRVU). This was the case with all of the codes used to support crosswalks this past cycle, including the abdominal and chest radiograph families.

Third, the ACR finds the method used by CMS, while novel, to be wholly inappropriate for the valuation of physician services and a significant departure from accepted procedures. Within this proposed rule CMS has used crosswalks to support the work values of codes the agency has calculated using a variety of methodologies. It is inconsistent to then disavow the accuracy of the crosswalk methodology when used to support the work values for these particular codes. Additionally, we strongly disagree with the CMS contentions that these services cannot be differentiated based on time. CMS states that there are “very similar intra-service (3-5 minutes) and total times (5-8 minutes)” to justify a “utilization-weighted average” of RUC recommended RVUs for 20 different X-ray procedures across different anatomic regions. This reasoning is inconsistent with clinical practice, and is the equivalent of saying that codes with 30-50 minutes of intra-service time are very similar. Proportionally, these are the same argument. 50 minutes is 66 percent more time than 30 minutes, as 5 minutes is 66 percent more time than 3 minutes. RUC members are highly qualified to appreciate these relative differences when developing recommendations to CMS.

In summary, the ACR believes the methods used by CMS to suggest these alternative values for this group of X-ray codes to be fundamentally flawed. The rationale put forward by CMS renounces accepted valuation methodology based on incorrect clinical and methodological reasoning. The novel valuation method used by CMS (i.e., utilization-weighted average RVU) is not supported by the RUC, nor has it previously been used by CMS. This novel method is not supported by the clinical work of the codes in this X-ray group and represents a serious departure from the norms of the RBRVS. If put into the fee schedule, these values distort time and
relativity for any codes to which they are subsequently compared. Therefore, these new code values are not supported by either time or intensity comparisons and are prima facie invalid with respect to the RBRVS.

X-Ray Esophagus (CPT codes 74210, 74220 and 74230)

CMS seeks additional comment regarding the barium suspension used for these procedures. Codes 74210 and 74220 involve the use of barium and fluoroscopy to evaluate the pharynx and upper esophagus or the esophagus as a whole, respectively. The barium suspension quantity listed for 74210 prior to review was only 1mL. This is an insufficient quantity of barium for a procedure that requires viewing the patient during multiple swallows in different positions. Similarly, 74420 did not have barium suspension listed as a supply item, which is an obvious oversight. The expert panel agreed that a typical fluoroscopic evaluation of the esophagus could be accomplished with 100mL of barium in addition to the high-density barium suspension already included as a supply item. Specifically, for this exam, the patient is asked to swallow a small quantity of high-density barium to outline the esophagus. Then effervescent crystals and water are swallowed to distend the esophagus while additional high density and normal barium is swallowed to assess the mucosa. Multiple subsequent swallows of normal density barium (Polibar) are assessed under fluoroscopy from different angles to evaluate the esophageal anatomy and mucosa, with particular attention to the gastroesophageal junction. Then the patient is placed in a prone oblique position and multiple swallows of regular barium are viewed with fluoroscopy to assess esophageal motility and the presence of reflux or a hernia. Additional swallows of barium in other positions or with additional water are performed to highlight abnormalities previously identified or as a challenge to induce reflux. The overall quantity of barium consumed is usually more than the equivalent of a can of soda accounting for both the barium suspension (SH016) and high-density barium (SH013).

Contrast-Enhanced Ultrasound (CPT 76X0X and 76X1X)

The ACR disagrees with the contention by CMS that the 25th percentile survey value is the de facto correct value for a service. Moreover, the assumption by CMS that a code cannot be at the high end of the range of values for a given intra-service time is another example of discounting the importance of intensity in valuing physician services in favor of considering only time.

Contrast enhanced ultrasound (CEUS) is a new technology that requires more technical skill and time than other established ultrasound services. As a new technology, we will be resurveying this code after three years, and the expectation is that as the service is performed more frequently and physician experience increases, the time to perform the procedure and RVU may decrease. CMS discounts two important facts in their reasoning. First, the surveyed physicians indicated pre-service and post-service times of 10 minutes and 10 minutes, respectively. We disagree with the RUC changing these times to 5 minutes each based on the premise that this is an ultrasound procedure and other ultrasound codes have 5 minutes in these service periods. The surveyed physicians clearly indicated the presence of additional work in both service periods specifically related to the administration of the ultrasound-based contrast in addition to the work required to perform the ultrasound, and the RUC agreed. Second, the RUC was presented with the median survey value of 1.82 wRVU and a total time of 40 minutes.
Given these two considerations, the RUC-recommended crosswalk is supported by the range of codes in the RBRVS with intra-service time between 18 and 22 minutes and total time of 30-45 minutes. Recently valued codes (post 2012) within this range have RVUs between 1.35 and 1.80. The mid-point of this range is 1.67-1.68, so the RUC-recommended crosswalk of 1.62 RVU is actually lower than the median of value of similar codes (not at the high end) when accounting for the surveyed times. This is the basis for the crosswalk used by the RUC, since the median survey RVU for 76X0X was 1.82, which would have been the highest code in the range, and the RUC recommended value is more appropriately supported by the clinical work and the intensity of 76X0X.

In regards to practice expense, the supply item SL180 (phosphate buffered saline) can be replaced with normal saline. It is used to flush the intravenous lines before and after the injection of the contrast agent.

*Magnetic Resonance Elastography (CPT 76X01)*

The ACR disagrees with CMS’ reasoning for changing the RUC-recommended value. In expressing concern about the “relativity of this code in comparison with other imaging procedures that have similar intra-service and total times”, CMS has contradicted itself and inappropriately discounted the importance of clinical service intensity in favor of a time-based argument.

Within the set of radiology codes with intra-service time of 15 minutes and total times from 20-30 minutes, there is a range of RVUs from 0.67 to 1.50. The higher end of this range are MRI codes, including 70548 (MR angiography neck with contrast at 1.50) and 73718 (MRI lower extremity without contrast at 1.35). Both of these codes have higher values than that recommended for 76X01 at 1.29 wRVU. To decrease 76X01 to 1.10 based on a methodologically inappropriate time ratio creates rank order problems by valuing an intense MRI procedure less than a comparable CT procedure (e.g., 74160, CT abdomen with contrast at 1.27 wRVU).

There are two additional technical points that need consideration. The ACR is fundamentally opposed to using intra-service time ratios to value codes, as we have discussed in prior rulemaking letters, because it inappropriately discounts the importance of work intensity in favor of purely time-based arguments. An example of the negative consequences of using this method is detailed in the prior paragraph. Additionally, CMS states they are using 71250 as a “direct” crosswalk; however, the CMS recommended RVU is 1.10 and the RVU of 71250 is 1.16.

*CT Scan for Needle Biopsy (CPT code 77012)*

The ACR disagrees with CMS applying the radiology supervision and interpretation (RS&I) standard room time for angiographic rooms to CT guidance. The room time is included in CT guidance, as it is in US guidance (76942) because that is the room the procedure is performed in. The codes for which guidance is used, specifically the core biopsy codes, are organ specific and
do not have a standard room because they may be performed in the OR, or with various modalities.

We agree with CMS that other RS&I codes use the 9 minutes for room time as a precedent, but this is specific to angiographic rooms. Please see the language below from 2013 regarding angiographic rooms and RS&I codes:

*Rationale for Angiographic Room time Allocation*

To prevent double counting of room time between the procedure code and the S&I code the Practice Expense Advisory Committee (PEAC) approved the following time allocation criteria.

The S&I code should receive a base time of 9 minutes for the room, and all other time will be allocated to the procedure code.

Specifically, the procedure code time allocated to the room is equal to:

Intra-service time minus 9 minutes (allocated to the S&I code)  
+ prepare room  
+ sedate patient  
+ position patient  
+ clean room

*Breast MRI with Computer Aided Detection (CPT 77X49, 77X50, 77X51, and 77X52)*

The ACR strongly objects to the rationale proposed by CMS for decreasing the value of 77X49 from the recommended wRVU of 1.45 to 1.15. The basis for this change as proposed is a decrease in time compared to the deleted code 77058 (in the proposed rule this is misstated as 74177, which is actually the KRS).

The primary reason that the agency's argument is flawed is that the predecessor code 77058 cannot be used as a comparison for 77X49 because they are different procedures used on different patients. 77058 was used to cover a varied population of patients having either a unilateral breast MRI without contrast, a unilateral breast MRI with contrast, or a unilateral breast MRI with and without contrast. This set of patients has now been broken out into two different codes (77X49 and 77X51, which bundles in computer aided detection (CAD)). Therefore, the prior time is invalid not only because the procedure it is based upon is different than the one we are comparing it to now, but its values also date from the first 5-year review (1995). As such, it has only had a total time, with no indication of the service periods. The RUC does not consider these time comparisons directly comparable for valuing current services. As a result, these codes are not used in reference service lists (or, therefore, as key reference services).

The comparison code (77334) chosen by CMS is also incongruous. The two codes being compared, 77X49 and 77334, are performed by different physicians on entirely different patient populations. Moreover, 77334 has no pre-service time, is a code billed with multiple other
services (which is why it does not have pre-service time), and has a different intra-service time. The services performed in 77334 have varying intensity with significant low intensity time spent moving around the patient and positioned external equipment, as opposed to 77X49, which is similar to other radiological exams with its fairly uniform high intensity work throughout the intra-service period. For these reasons, it is reasonable for these two codes to have different values. It is apparent that 77334 was chosen only because the value was similar to that achieved by using a time ratio without consideration to its accuracy as a crosswalk.

The use of time ratios for valuing physician services is inappropriate and methodologically unsound because it discounts intensity in favor of an inappropriate solely time-based argument. Moreover, the work involved in the breast MRI code family has fundamentally changed, and met the compelling evidence standard at the RUC (based on change in technology and change in patient population), which represents further evidence that this time comparison is not supported.

Within the set of radiology codes with intra-service time of 25 minutes and total times from 30-40 minutes, there is a range of RVUs from 1.73 to 2.29. At the higher end of this range are MRI services, including 72157 (MR thoracic spine with and without contrast at 2.29). The lower end of the range includes 74177 (CT abdomen and pelvis with contrast at 1.82). Both of these codes have higher values than that recommended for 77X49 at 1.45 wRVU. To decrease 77X49 to 1.15 based on a methodologically inappropriate time ratio creates profound rank order problems by valuing this MRI procedure significantly less than other comparable MRI procedures (e.g., 72196, MRI pelvis with contrast at 1.73 wRVU).

For the reasons states above, the ACR believes the CMS proposed value for 77X49 is incorrect. Therefore, we believe the subsequently adjusted values for 77X50, 77X51, and 77X52, which were derived by increments from the adjusted value of 77X49, are also incorrect. The RUC-recommended values for this code family correspond well with the comparisons offered in the RUC rationale, and fit appropriately within the larger RBRVS based on time and intensity comparisons. The CMS-adjusted values for this code family would create disparities in the RBRVS by undervaluing these radiology procedures and disregarding their surveyed times and the clinical intensity of the work.

Practice Expense

CMS indicated that it did not receive invoices for the five new equipment items requested for 77X51 and 77X52: CAD Server (ED057), CAD Software (ED058), CAD Software - Additional User License (ED059), Breast coil (EQ388), and CAD Workstation (CPU + Color Monitor) (ED056). The ACR submitted invoices to the AMA during the October 2017 meeting. If the invoices were not submitted to CMS, this may have been an oversight, and we have enclosed them with this letter.

CAD Software (ED058) is actually synonymous with the “breast biopsy software” (EQ370), included in breast biopsy codes 19085 and 19086. In hindsight, the ACR should have been consistent in identifying the equipment item between the breast biopsy codes and the MR breast codes. We agree with CMS’ proposal to update the name for EQ370 to “Breast MRI computer aided detection and biopsy guidance software.”
Radiologist Assistants (RA)

Proposals

CMS proposed to revise the supervision requirements to specify that all diagnostic imaging tests may be furnished under the direct supervision of a physician when performed by an RA in accordance with state law and state scope of practice rules. Specifically, CMS proposed to revise the regulations to add a new paragraph to state that diagnostic tests performed by a registered radiologist assistant (RRA) or a radiology practitioner assistant (RPA) require only a direct level of supervision, when permitted by state law and state scope of practice regulations. The agency notes that for diagnostic imaging tests requiring general level of supervision, this proposal would not change the level of physician supervision to direct supervision.

ACR Perspectives and Comments

The ACR supports CMS’ proposal to revise its regulation at 42 CFR §410.32 to add a new paragraph (b)(4) to state that diagnostic tests performed by a RA require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations. This change will allow RAs supervised by radiologists to provide efficient, quality care to patients and align federal requirements with those of the states, thereby decreasing regulatory burden.

Currently, Medicare requires that some diagnostic tests be personally supervised by a physician even when performed by a qualified RA trained to perform the test. This means that a radiologist must be physically present in the same room as the RA for the RA to perform any test with a supervision indicator of “03”, including those tests which are within the RA’s state scope of practice. This CMS supervision requirement exceeds many states’ rules regarding appropriate physician supervision of RAs, which allows direct supervision. As CMS rightfully acknowledges in its proposal, this personal supervision standard is unduly burdensome and inequitable for Medicare patients.

The proposed modification will retain personal supervision for diagnostic tests currently assigned a supervision indicator of “03” but will allow direct supervision when these tests are performed by a qualified RA. In these circumstances, RAs would still require that a radiologist supervise and be physically present and immediately available in the same facility as the RA and the patient. It is also important to note that the RA is strictly prohibited from issuing a final interpretation on any examination in which they assist. However, under the direct supervision standard, RAs could assist the radiologist by performing services within their state scope of practice without a radiologist present in the room. This standard would allow radiologists to devote more time to performing more complex clinical functions which are uniquely within their scope of practice. For example, under this team model, radiologists can spend more focused time reviewing complex medical images and performing complex procedures, while still available to the RA as needed, thereby providing more timely diagnoses and consultations that result in efficient and safe medical treatment. Hospitals utilizing RAs will also likely benefit from
increased efficiency in the radiology department, leading to decreased lengths of stay and decreased cost per patient admission, while improving the quality of radiologic care.

If CMS’ RA proposal is finalized, the agency should operationalize the proposal starting January 1, 2019 by issuing a radiologist supervision indicator to recognize the RA under direct supervision rather than personal supervision when RAs provide Medicare services under their state scope of practice. CMS has created unique supervision indicators for special situations where the performing personnel have specialized capabilities to perform the diagnostic service. For instance, physician supervision does not apply to diagnostic services identified with supervision indicator “04” when performed by a qualified independent psychologist or a clinical psychologist or “05” when performed by a qualified audiologist.

Following the model for other indicators, we suggest a new supervision indicator when a diagnostic test or IR procedure is performed under the supervision of a radiologist by a registered radiologist assistant who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant who is certified by the Certification Board for Radiology Practitioner Assistants.

[XX]= Procedure may be performed under the direct supervision of a radiologist when performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants.

**Evaluation and Management (E/M) Visits**

*Proposals*

Potential misvaluation of E/M codes is an issue that CMS has been considering for several years. The agency notes that this code set represents a high proportion of MPFS expenditures, but has not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway to meet the Medicare population’s health care needs.

Stakeholders have long maintained that the E/M documentation guidelines are administratively burdensome and outdated with respect to the practice of medicine. Having considered public feedback to the CY 2018 MPFS proposed rule and other outreach efforts, CMS proposed several changes to E/M visit documentation and payment. The proposed changes would only apply to office/outpatient visit codes except where otherwise specified.

CMS proposed to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office. CMS welcomes public comment on this proposal, including any potential unintended consequences of eliminating the requirement.
CMS proposed to allow practitioners to choose, as an alternative to the current documentation framework, either medical decision-making or time as a basis to determine the appropriate level of E/M visit. This proposal would allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice.

In addition, the agency proposed a single payment amount for office/outpatient E/M visit levels 2 through 5 and a minimum documentation standard where practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or medical decision-making. CMS notes that practitioners could choose to document more information for clinical, legal, operational or other purposes.

Additionally, CMS believes that when a separately identifiable visit is furnished in conjunction with a procedure, there are certain duplicative resource costs that are not accounted for by current coding and payment. Therefore, CMS proposed the following adjustments to better capture the variety of resource costs associated with different types of care provided in E/M visits:

1. An E/M multiple procedure payment adjustment to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together;
2. HCPCS G-code add-ons to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits;
3. HCPCS G-codes to describe podiatric E/M visits;
4. An additional prolonged face-to-face services add-on G code that may be billed for an additional 30 minutes of time spent with the patient rather than 60 minutes required by the current CPT code; and
5. A technical modification to the PE methodology to stabilize the allocation of indirect PE for visit services.

CMS proposed to collapse payment for office visits included creating a new indirect practice cost indices (IPCI) solely for office visits, overriding the current methodology for these services by treating Office E/M as a separate Medicare Designated Specialty.

**ACR Perspective and Comments**

The ACR appreciates CMS’ effort to reduce paperwork burden by eliminating some of the onerous documentation requirements and supports moving forward with some of these proposals in 2019. These issues are especially important to our Radiation Oncology and Interventional Radiology members who bill E/M codes with some frequency. The ACR, however, finds the CMS proposals to collapse payment levels for E/M services unworkable and does not support adoption.

Further, the E/M related multiple procedure payment reduction (MPPR) is unnecessary. The RUC, national medical specialty societies, and other health care professionals have worked diligently to ensure that there are no duplicate resource costs imbedded in procedure codes.
typically performed with E/M services. The RUC’s Relativity Assessment Workgroup has conducted screening and reviewed all procedures where same-day E/M services are typically reported to account for duplicate work. AMA staff provides ongoing data analyses to specialties and the RUC in the development and review of both wRVUs and direct practice expense costs in preparation for RUC review. These analyses include information regarding the performance of E/M on the same date of each procedure code.

Regarding the creation of a new IPCI solely for office visits, the ACR is concerned about the downstream impacts of this proposal. This change would result in the exclusion of the indirect practice costs for office visits when deriving every other specialty IPCI. The proposed policy change would result in a large shift in the specialty-level IPCIs for CY 2019 for several specialties and large swings in payment for many services predominantly performed by those specialties.

The ACR opposes the implementation of this proposal because it could hurt physicians and other health care professionals in specialties that treat the sickest patients, ultimately jeopardizing patients’ access to care. We also urge that the new multiple service payment reduction policy in the proposed rule not be adopted as the issue of multiple services including E/M services on the same day of service was factored into prior valuations of the affected codes. The ACR also believes the development of a separate office IPCI distorts the relativity of the RBRVS and should not be implemented.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

Proposals

The Bipartisan Budget Act of 2018 (BBA) added a new paragraph that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act.

To implement these requirements, CMS proposed to create a new modifier that would be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. Practitioners would be responsible for assessing whether it would be clinically appropriate to use this modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners would be
indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke. CMS believes that the adoption of a service level modifier is the least administratively burdensome means of implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

In accordance with section 1834(m)(6)(B) of the Act, as added by section 50325 of the BBA of 2018, CMS also proposed to revise §410.78(b)(3) of its regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. CMS also proposed to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and are seeking comment on this definition, as well as additional information on how these units are used in current medical practice.

ACR Perspective and Comments

The ACR supports CMS implementing BBA provisions that remove the geographic restrictions for diagnosis, evaluation, or treatment of symptoms of an acute stroke delivered via telehealth (acute stroke telehealth services). This change will facilitate earlier recognition, triage and treatment of stroke patients. This includes controlling clinical factors such as hypertension and also pharmacological treatment in the field, such as tissue plasminogen activator (tPA) within the critical 4.5 hour window necessary for a favorable response and outcome. Further, prompt endovascular revascularization for large vessel occlusion is critical, which can be better enabled when telehealth contributes to prompt and proper triage to stroke centers with this capability.

The ACR also supports the modification of existing regulations to add mobile stroke units as an originating site for acute stroke telehealth services. These mobile units must be defined to ensure the proper resources and level of care are provided. To that end, the ACR recommends CMS define a mobile stroke unit as an entity that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke, and must include a computed tomographic (CT) scanner (or Magnetic Resonance Imaging Scanner) and a telehealth (audio and video)/teleradiology (picturing archiving and communications system (PACS)) connection to a radiologist or physician who is capable and experienced in the interpretation of CT or MRI scans of the brain remotely or in-person. Further, the telehealth interface should connect to a person able to prescribe an intravenous thrombolysis. The unit must also have a qualified health professional who is able to administer an intravenous thrombolysis if the physician interpreting the CT scan or MRI and/or prescribing the treatment does so via telehealth.

The ACR also advises CMS to include Emergency Medical Service (EMS) transports equipped with telehealth connection to stroke specialists as an originating site. This will allow faster access, diagnosis and triage. The ACR recommends that CMS establish different modifiers for the mobile stroke unit versus an EMS transport vehicle equipped with telehealth. This differentiation is important to allow comparisons of resource use and clinical efficacy.

While the College supports the changes to geographic and originating site restrictions related to the narrow focus of acute stroke care, the ACR continues to closely monitor all other efforts by Congress, CMS, national medical specialty societies, and other affected stakeholders to alter the
existing regulation of telehealth services. Telehealth presents a difficult challenge for the specialty of radiology to properly manage. Telehealth holds great promise in providing improved treatment, however, it also presents risks related to patients receiving subpar. We applaud that CMS does not alter any existing scope of practice issues or licensure requirements as it relates to telehealth and acute stroke care. **The ACR urges CMS, whether providing technical assistance to Congress or considering additional regulatory changes, to exercise caution and restraint when addressing telehealth regulation, in general.**

**Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information**

The ACR applauds the overarching effort by CMS to improve patient accessibility and usability of charge information hospitals are required to post on the Internet under Section 2718(e) of the Public Health Service Act. The College supports the new mandate to post this previously required hospital charge information in a machine-readable format, as well. Yet, the College questions any perceived connection between the need to increase hospital price transparency and alleviating so-called “surprise bills,” or patients receiving care from physicians, such as radiologists, who are out-of-network but located at in-network facilities. In short, the ACR believes that:

- Issues surrounding “surprise billing” are not a Medicare problem but rather a concept involving private insurance and, as a result, is best regulated by state legislatures;
- It is improper to place exclusive or even majority blame on the providers as the payers must have accountability for the products they are selling (without proper disclosure) and the aggressive contracting they employ;
- The term “surprise gaps in insurance coverage” is a better summary of the issue; and
- Any discussion of “surprise bills” is largely inapplicable to Medicare and outside-the-scope-of the MPFS rulemaking process.

More specific comments regarding these topics can be found below:

The ACR continues to favor steps to enhance transparency regarding the cost of health care, including advanced diagnostic imaging services, administered in the hospital and all other care settings. The ACR is supportive of provisions originally enacted via the CY 2015 Inpatient Prospective Payment System (IPPS) Final Rule (79 FR 50146) requiring hospitals to make public either a list of charges (either the charge master itself or in another form of their choice) for provided items and services or their policies for allowing the public to view prices in response to a patient inquiry. While this concept is not up for consideration in the CY 2019 MPFS proposed rule, the College also supports new provisions in the CY 2019 IPPS Final Rule mandating hospitals post the charges in a machine-readable format. The ACR shares CMS’ view that patients are more inclined to choose the most efficient setting for care if they are more conscious of its underlying expense. Choice, however, must remain a two-way concept and patients, in consultation with their treating physician, should retain the ability to pursue the care they feel best suits their clinical needs, even if it means selecting the more expensive setting.
Despite our support for greater price transparency, the College is perplexed why CMS included provisions in the 2019 MPFS Proposed Rule stating their concern that insufficient access to price transparency information is contributing to patients being surprised by out-of-network bills for physicians, such as radiologists, at in-network hospitals and other settings. **First and foremost, the ACR questions any true connection between the issue of “surprise bills” and Medicare.**

“Surprise bills” typically arise when an individual receives planned care from an in-network provider but other providers brought in to participate in the patient’s care do not participate in the same network. The ramifications for patients seeing out-of-network physicians at an in-network facility are typically higher cost-sharing (e.g., copayments, coinsurance, and deductibles) and balance bills, or treating providers billing individuals directly for the remaining cost of the service rendered above the negotiated rate assessed by the insurance company to in-network providers.

**The ACR, however, views “surprise bills” as an issue largely stemming from the actions of private insurers and not government payers.** In fact, Medicare classifies practitioners into three categories: participating, nonparticipating, or opt out/private contracting providers. According to briefs published on the web sites of the AARP and Kaiser Family Foundation, as many as 95 percent of Medicare physicians are participating providers. This classification means they agree to accept Medicare’s approved payment as payment in full (e.g., “accept assignment”) for the Medicare covered services they provide for all Medicare patients they see. In addition, they must also collect payment from services rendered directly from Medicare, rather than the patient. As a result, Medicare patients who see a “participating provider” are guaranteed to not be charged more than the published fee-schedule amount, nor will they face higher out-of-pocket cost-sharing above the standard 20 percent coinsurance for the service received. It is important to note that the coinsurance is assessed based off the Medicare discounted rate, as well.

Only a small percentage of providers, approximately 4 percent, are classified as nonparticipating Medicare physicians. Nonparticipating physicians only receive 95 percent of the Medicare payment reimbursed to participating providers. In addition, nonparticipating physicians can only balance bill patients based off payment rates that are no more than 115 percent above Medicare’s established fee-for-service rates. While patients seen by nonparticipating providers are still assessed a 20 percent coinsurance, it is calculated based off 95 percent of Medicare’s established fee-for-service amount. The stipulations placed on the amount nonparticipating providers can charge Medicare patients have successfully limited the negative impact of surprise out-of-}

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network bills. In fact, total out-of-pocket liability from balance billing declined from $2.5 billion in 1983 to $40 million in 2011⁴.

An even smaller percentage of providers, approximately less than 1 percent, are classified as opt-out or private contracting providers⁵. In 2016, of this 1 percent, 42 percent of opt out physicians were psychiatrists⁶. In fact, 2013 data indicates in the specialties of radiology/nuclear medicine, only 19 out of a possible 24,887 radiologists, were opt-out/private contracting providers within Medicare⁷. In other words, radiology and nuclear medicine only comprised 0.1 percent of the total opt-out/private contracting population in 2013. Although this category of providers are not bound by Medicare’s physician fee schedule in any way and are free to balance bill for the entire cost of the service, there are so few opt-out/private contracting physicians that it has an almost minimal impact on the current system.

Since the vast majority of providers are classified as “participating,” there is almost no tangible concern about “surprise” out-of-network bills from any physician, including radiologists, in Medicare. Additionally, the strict limitations on balance billing placed on nonparticipating Medicare providers, as well as the extremely small percentage of total opt-out/private contracting physicians, further lessens the concerns pertaining to this issue.

Finally, the College views the term “surprise bills” as overly biased against physicians and mischaracterizes the role of the insurer. Private payers are quick to shift the blame for excessive out-of-network bills to physicians when, in reality, “surprise bills” are “surprise coverage gaps” typically associated with cheap insurance plans and inadequate provider networks. As a result, it is more accurate to associate “surprise bills” with insurers preying upon consumers’ desire for low-cost insurance, as well as private payers failing to disclose potentially costly flaws in their plans.

In summary, the ACR questions the exposure of patients to surprise out-of-network bills within Medicare. Issues pertaining to out-of-network bills are the result of private payers and, as a result, any policy proposals are best dealt with at the state level. Furthermore, the ACR believes this policy concept is outside-of-the-scope of the IPPS proposed rule and we question the validity of trying to address any perceived problems in this manner.

QUALITY PAYMENT PROGRAM

Small Practice Bonus

Proposal

In the CY 2018 Quality Payment Program final rule, CMS added a small practice bonus of 5 points to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice and submit data on at least one performance category in the 2018 MIPS performance period. In the proposed rule, CMS proposed to remove the 5-point bonus from the final score and add a bonus of 3 points to the quality performance category score for MIPS eligible clinicians in small practices who have submitted data on at least 1 quality measure.

ACR Perspectives and Comments

The ACR advocates keeping the small practice bonus for as long as possible. As long as there are still considerations given to small practices, such as the special status for Improvement Activities and the option for hardship exemption for Promoting Interoperability, we support moving the bonus points from the final score to the Quality category. The ACR encourages CMS to continue to offer bonus points and other special scoring considerations for small practices since these practices often face significant reporting burdens.

Identifying MIPS Eligible Clinicians (EC)

Additional MIPS Eligible Clinicians

Proposal

CMS requested comments on modifying the definition of a MIPS eligible clinician. In previous years, CMS applied this definition to any of the following: a physician, physician assistant, nurse practitioner, clinical nurse specialist, or a certified registered nurse anesthetist. Beginning with the 2021 MIPS payment year, this would be expanded to include physical therapists, occupational therapists, clinical social workers, clinical psychologists, or a group that includes such clinicians. In the event that quality measures proposed for removal are not finalized, and each applicable eligible clinician type would have at least 6 MIPS quality measures to report, then CMS would also expand the definition of MIPS eligible clinician to include the following in the 2021 MIPS payment year: qualified speech-language pathologists, qualified audiologists, certified nurse midwives, and registered dietitians or nutrition professionals.

ACR Perspectives and Comments

The ACR believes that adding more clinicians would enable better understanding of healthcare data across other specialties, and agrees with CMS’ approach of adding these
clinicians only when there are available measures that could be reported to meet requirements.

Low-volume threshold

Proposal

For the 2020 MIPS payment year and future years, the low-volume threshold has already been defined as an individual eligible clinician or group that has Medicare Part B allowed charges less than or equal to $90,000 or provides care for 200 or fewer Part B–enrolled Medicare beneficiaries. Beginning with the 2021 MIPS payment year, CMS has proposed to modify the low-volume threshold (LVT) definition to apply to: an individual eligible clinician or group that furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals. These changes clarify that the low-volume exclusion for MIPS will now only be based on “covered professional services,” and not Medicare Part B medications and services billed separately from the Physician Fee Schedule.

ACR Perspectives and Comments

The ACR supports this proposal as it helps ease the burden on small and/or rural and practice physicians, who typically have limited resources with which to adequately participate in the MIPS program. However, we again suggest that CMS apply the same methodology and thresholds in determining patient-facing status; that is, if 75 percent of eligible clinicians in a group meet the low-volume threshold criteria, then the group would be considered a low-volume threshold group and not MIPS eligible.

Options for Participating in MIPS for LVT ECs and Groups

Proposal

CMS proposed that beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria, they may elect to report on applicable measures and activities under MIPS and will be treated as MIPS eligible clinicians for the applicable MIPS payment year and receive a payment adjustment. For APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable payment year.

Physicians who meet the criteria can opt-in in one of the following ways:

- Individuals/groups make an election on the QPP portal by choosing to opt-in (subject to payment adjustment) or voluntarily report (no adjustment). CMS proposed an active
election process rather than submission of measure data as an indication since some clinicians’ systems may automatically send data.

- Virtual group election would constitute an opt-in to MIPS for any member of a virtual group.
- APM entities in MIPS APMs that do not meet all LVT criteria must make a definitive choice at the APM entity level to opt-in/participate in MIPS, similar to the process for individual/group eligible clinicians.
- If an applicable eligible clinician is part of an APM that elects not to participate in MIPS, while their tax identification number (TIN) or virtual group does elect to participate, it does not mean that the clinician is opting-in on their own behalf or on behalf of their APM Entity. That clinician would still be considered excluded from MIPS participation as part of the APM Entity.

Once the election to participate in MIPS has been made, it cannot be changed for the applicable performance period.

**ACR Perspectives and Comments**

The ACR supports CMS’ proposal for allowing eligible clinicians, groups and APM entities with low volume threshold status these various options for participating in MIPS. We agree that choice should be an active election process to avoid unintentional participation based on measure data submission alone.

**Group Reporting – Subgroups**

**Proposal**

Although CMS is not making proposals at this time to allow a portion of a group to report as a separate sub-group, it has previously received a great deal of input on an option to allow a portion of a group to be assessed and scored based on the performance of the sub-group. CMS will consider use of a sub-group identifier in year four of the QPP. CMS states there are several challenges to implement sub-group reporting, including concerns of potential gaming opportunities. CMS requests comments on several aspects of this option as outlined below.

- Whether and how a sub-group should be treated as a separate group from the primary group (e.g., if there is one sub-group within a group, how would CMS assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the sub-group level);
- Whether all of the sub-group’s MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the sub-group’s final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level;
- Possible low burden solutions for identification of sub-groups (e.g., whether CMS should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt-in proposed in this rule); and
• Potential issues or solutions needed for sub-groups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group.
• Other approaches for sub-group reporting that CMS should consider.

ACR Perspectives and Comments

The ACR supports CMS’ consideration of allowing sub-groups. We agree that this would offer flexibility in reporting for MIPS.

The uniting feature of such sub-groups could be a logical commonality such as a common specialty or provider enrollment, chain and ownership system (PECOS) type (with a specialty-sponsored registry being the source of data), a clinical service line, common measures set, common patients or even a geographic area. However, there should be a minimum standard to ensure that sub-groups do not result in arbitrary alignments aimed simply at maximizing payment incentives or otherwise “gaming” the system. CMS could develop minimum standards to ensure that the members of a sub-group are caring for a common population, are responsible for decisions that could affect the group as a whole, or otherwise have a mutual interest in quality improvement.

This could be implemented similar to the structure and method used for a virtual group election – using TIN/NPI and assignment of a subgroup number. The subgroup identifier could be used for submission mechanisms and allow same methods of reporting as for group (GPRO) participation.

Additionally, the ACR is concerned shared savings inside accountable care organizations (ACOs) is not always distributed to subsets of participating clinicians based on merit, but instead based on specialty or internal discussions. Encouraging appropriate distribution of shared savings and losses inside an ACO would advance the agency's transformation goals by promoting active engagement of a wide variety of specialists.

The ACR encourages CMS to allow a subgroup to electively report into MIPS according to the generally applicable scoring criteria, even when the primary group is a single TIN participant in an ACO that is scored as a MIPS APM or Advanced APM.

Virtual Groups

Proposal

CMS proposed to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years. The continued proposal includes a definition of a virtual group being limited to TINs of ten or less ECs.
The ACR recommends that CMS consider revising the method of counting NPIs within TINs for the purpose of forming a virtual group. In cases where the same NPIs are part of more than one TIN, we do not think these NPIs should be “double counted” in determining virtual group eligibility. For example, a common practice in radiology is the use of multiple different TINs for a single group practice. These multiple TINs are often necessary because a group may practice in different settings including, hospitals, joint venture imaging centers, and privately owned imaging centers. Each of these practice settings may have different ownership structures requiring a separate TIN; however, the same radiologists work across all of these TINs. The proposed requirements of reporting MIPS or becoming a qualified APM at the TIN level or NPI/TIN level dictates that this single group or clinician would have to report multiple times based on each TIN. Allowing these TINs to combine under the virtual group option would lessen the complexity of reporting MIPS or qualifying for APMs across multiple TINs that share the same clinician NPIs. Meeting reporting requirements under multiple TIN/NPI combinations or arrangements is complex, burdensome, and may result in payment adjustments based on groupings of providers that are not necessarily reflective of team-based/coordinated care or appropriate for quality improvement.

**MIPS Determination Period**

*Proposal*

CMS proposed a change to the determination periods for MIPS eligibility in hopes of simplifying and standardizing the policies used to determine low-volume threshold, non-patient facing status, small practice status, hospital-based and ASC-based determinations. CMS proposed that beginning with the 2021 MIPS payment year, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) an initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

CMS did not propose to include the facility-based, virtual group or the rural and health professional shortage areas (HPSA) eligibility determination periods in this policy, as the facility-based and virtual group determinations require a different process or timeline that does not align with the other determination periods, and the rural and HPSA determination does not utilize a determination period. CMS invites public comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

**ACR Perspectives and Comments**

The ACR supports this proposal. Consolidation of the various special status determination periods will reduce complexity of the program and simplify tracking. We encourage CMS
to work towards also incorporating facility-based, rural/HPSA and virtual group eligibility determination periods into the same determination period.

Facility-based Measurement

Eligibility Determination

Proposal

In the CY 2018 final rule, CMS discussed, but did not finalize, a proposal for how an individual clinician or group could be identified as using facility-based measurement for the MIPS program, as facility-based measurement was not offered until the 2019 MIPS performance period. In this CY 2019 proposed rule, CMS proposed to specify a criterion for a clinician to be eligible for facility-based measurement: specifically, if a clinician furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-days claims run out. Note that this is different from the MIPS determination period in that only the first 12-month segment is evaluated.

CMS proposed to modify its determination of a facility-based individual in four ways:

- Add on-campus outpatient hospital (as identified by place of service (POS) code 22) to the settings that determine whether a clinician is facility-based.
- A clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room.
- If CMS is unable to identify a facility with a value-based purchasing (VBP) score to attribute a clinician’s performance, that clinician is not eligible for facility-based measurement.
- CMS proposed to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed earlier in this proposed rule.

ACR Perspectives and Comments

ACR supports the inclusion of the on-campus outpatient hospital code in the determination of eligibility for facility-based measurement. However, we strongly encourage CMS to include off-campus outpatient hospital (POS code 19) in the facility-based eligibility determination. Many MIPS eligible radiologists perform more than 75 percent of their work in a facility but primarily in hospital outpatient departments. Because the proposed definition for facility-based clinician excludes off-campus outpatients, these radiologists will not be considered facility-based. These MIPS-eligible radiologists would still be disadvantaged, as they require hospital resources for successful participation in MIPS.
With the inclusion of off-campus services (POS 19) the ACR strongly recommends that CMS use the quality measures in the Hospital Outpatient Quality Reporting (HOQR) program, in particular the HOQR Imaging Efficiency measures, which are relevant to radiology groups. Doing so would provide for more meaningful facility-based measurement for radiologists. Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may apply non-clinician measures such as measures for inpatient hospitals, for purposes of the physician quality and cost performance categories. The Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

Although the HOQR program does not include cost measures as the hospital value-based purchasing (HVBP) program does, this mirrors the current lack of MIPS cost measures attributable to radiologists.

No Election of Facility-Based Measurement

Proposal

CMS proposed an alternative approach of not requiring an election process but instead automatically applying facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement, if technically feasible, if the facility-based measurement score is higher than the quality and cost performance category scores based on data submitted.

In addition to this proposal, CMS notes that, much like in the MIPS program, clinicians will be scored as individuals unless they opt to submit data as a group. CMS proposed that although there are no submission requirements for individual clinicians in facility-based measurement, a group must submit data in the improvement activities or Promoting Interoperability performance categories to be measured as a group under facility-based measurement. If a group does not submit improvement activities or Promoting Interoperability measures, then CMS would apply facility-based measurement to the individual clinicians rather than the entire group.

CMS proposed that there are no submission requirements for individual clinicians in facility-based measurement but a group must submit data in the improvement activities or Promoting Interoperability performance categories as a group in order to be measured as a group under facility-based measurement.

CMS states that submission of data for improvement activities or Promoting Interoperability measures indicates an intent and desire to be scored as a group. Hence, CMS believes that the choice to submit data as a group can be used to identify a group in the context of facility-based scoring, which will preserve choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. CMS solicits comments specifically on this proposal and other means to achieve the same end.
The ACR supports CMS’ scoring approach to automatically use the higher of the following: the facility score or the quality and cost performance category MIPS submitted data. This provides the most flexibility, however we believe that most facility-based individuals or groups would want to continue to submit data for MIPS as a safety net, particularly initially, negating any potential burden reduction on the clinician’s part. We also seek clarification on data submission requirements for facility-based measurement. CMS states that there are no submission requirements for individuals in facility-based measurement but that groups must submit data on improvement activities (IA) and Promoting Interoperability (PI). Does this mean the requirements are less for individuals than groups being considered under facility-based measurement? If the only reason for requiring groups to submit for IA and PI is to determine their status as a group, then the ACR would recommend CMS reconsider an election process in which group reporting could be established.

Performance Period

Proposal

In an effort to provide as much transparency as possible so that MIPS eligible clinicians and groups can plan for participation in the program, CMS requests comments on their proposals that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. In addition, they request comments on the proposal that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

ACR Perspectives and Comments

The ACR supports the full calendar year approach for the quality and cost categories, as well as the 90-day minimum reporting period for improvement activities and promoting interoperability. Using a full year of quality data helps to more accurately capture the performance of MIPS clinicians, while still easing the burden of EHR reporting through promoting interoperability.
MIPS: Quality Performance Category

Data Completeness

Proposal

CMS proposed to keep the Quality measure data completeness requirement for qualified clinical data registry (QCDR) measures at 60 percent of an individual MIPS eligible clinician’s (or group’s) patients across all payers for the performance period.

ACR Perspectives and Comments

ACR supports the proposal to keep the data completeness requirement for Quality measures at 60 percent of all patients and we encourage CMS to continue maintaining this requirement at a reasonable rate. While we agree that high data completeness is essential for establishing the most accurate performance rate across measures, we acknowledge that it is very difficult for some clinicians to reach 100 percent completeness, especially if their clinical activities encompass several separate facilities, as is the case with many radiologists.

Radiologists rely heavily on the internet technology (IT) infrastructure purchased, maintained, and operated by our hospitals. Many hospitals are just beginning to support data collection for facility-based physicians while shouldering the burden of their own set of facility-based quality reporting requirements. As we have mentioned in previous communications, hospital consolidation has led to radiology group consolidation and new contracts in hopes of providing more uniform care across larger hospital networks. These complex mergers between radiology groups often result in a creation of a new TIN. It takes time to merge governance, best practice, culture, and MIPS reporting. Building the infrastructure within the new TIN to meet requirements to satisfy a threshold of greater than 60 percent would be very onerous to meet during one performance period.

The ACR strongly supports CMS’ proposal to maintain the 60 percent data completeness requirement and cautions against significant raises in the future.

Multiple Collection Types

Proposal

Although CMS provided a summary of how the existing policy for scoring submitted measures collected across multiple collection types will be scored using the new collection type terminology, CMS did not propose any changes to that scoring policy.
ACR Perspectives and Comments

The ACR strongly encourages CMS allow for scoring in the case where an individual or group uses multiple QCDRs. Allowance of reporting via multiple QCDRs in single TIN could serve as a pathway forward for greater specialist participation within multispecialty groups.

Incentives to Use Certified EHR Technology (CEHRT) to Support Quality Performance Category Submissions

Proposal

CMS proposed to continue to assign bonus points for end-to-end electronic reporting for the 2021 MIPS payment year, stating that this policy encourages electronic reporting. CMS also proposed to modify the end-to-end reporting bonus point scoring policy based on the proposed changes to the submission terminology so the bonus points can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule.

Additionally, CMS intends to consider in future rulemaking modifying its scoring policy to no longer offer end-to-end reporting bonus points after the 2021 MIPS payment year. However, the intention is to continue incentivizing and encouraging these reporting methods. CMS invites comment on other ways to encourage the use of CEHRT for quality reporting.

ACR Perspective and Comments

The ACR encourages CMS to maintain the end-to-end reporting bonus beyond the 2021 MIPS payment year. Clinicians are still transitioning to more automated and electronic reporting and should continue to be incentivized to do so. One way CMS could encourage higher use of electronic reporting would be to incorporate end-to-end reporting through QCDRs connected to electronic systems beyond only those that are CEHRT, and apply that bonus to registry reporters.

For example, most radiologists do not use CEHRT or certified health IT in their practices. The ACR enables end-to-end reporting for our registry participants by bridging radiology-specific, standardized health IT solutions (radiology information systems (RIS)/PACS, etc.) to ACR’s QCDR using our transfer of images and data (TRIAD™) software, or by submitting data to us through web services application programming interface (API) directly from the participant’s IT solution. However, none of the software used in our registry is certified under the office of the National Coordinator’s (ONC) health IT certification program. What would need to change for interfaces such as TRIAD to be considered end-to-end electronic reporting? The ACR holds that use of web services APIs to submit quality measure data directly from standardized, but not CEHRT, health IT solutions to the ACR registries from which data is submitted to CMS, all without a break in the electronic process meet the intent.
Incentives to Report High Priority Measures

Proposal

CMS proposed to maintain the cap on high priority measure bonus points for the 2019 reporting year as established in the 2017 QPP final rule. This bonus can be obtained by submitting additional high priority measures beyond the six required measures in the Quality category. Bonus points will remain capped at 10 percent of the denominator of the Quality performance category.

ACR Perspectives and Comments

ACR supports the proposal to continue offering bonus points for clinicians submitting additional high-priority measures and encourages CMS not to reduce the current cap of 10 percent. We believe the opportunity for bonus points encourages physicians to submit measures, which they may not have otherwise submitted, such as measures with lower performance rates, which therefore create a more realistic picture of a measure’s true average performance rate. The cap of 10 percent allows clinicians to receive a modest, but not negligible, bonus for going above and beyond the established Quality reporting requirements.

Claims Submission

Proposal

CMS proposed to limit the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and to allow clinicians in small practices to report claims as a group. CMS discusses its ongoing desire to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. While CMS would like to move towards the utilization of electronic reporting by all clinicians and groups, CMS realizes that small practices continue to face additional challenges.

ACR Perspectives and Comments

The ACR appreciates CMS’ desire to have the MIPS program primarily based on electronic data submission, reducing claims submission to a minimum but believes that it is premature to begin this restriction in the 2019 performance year (2012 MIPS payment year). The prematurity of this proposal is evidenced in CMS’ recently published “2016 Reporting Experience Including Trends (2007-2016) Physician Quality Reporting System (2018).” In 2016, 22 percent of participating PQRS eligible clinicians reported using claims, 25 percent participated as a GPRO (precluding the use of claims reporting). In 2016, 43,642 radiologists (85.7 percent of those eligible) participated in PQRS, of those 50 percent reported using claims.
While participation in MIPS using claims reporting may have decreased in 2017 and may continue to decrease in 2018, it is likely that a substantial portion of MIPS eligible clinicians including radiologists are still using claims reporting. The ACR has actively encouraged its members to move from claims reporting to qualified registries or QCDRs. Although the number of radiologists using the ACR QCDR increased by approximately 46 percent from 2016 to 2017, those using the ACR QCDR are still a minority (an estimated 5 percent - 6 percent) of radiologist MIPS eligible professionals.

Additionally, practices who are not determined to be a small practice and who currently use claims reporting would have limited time after finalization of the policy in late 2018 to adjust to using a different data collection type, such as QCDR, for 2019 reporting. If CMS finalizes this policy, it should not be implemented in such a short timeframe.

**Contribution to Final Score**

*Proposal*

CMS proposed to reduce the weight of the quality category to 45 percent in performance year 2019 (from 50 percent in performance year 2018) based on authority under the Bipartisan Budget Act (BBA) of 2018.

*ACR Perspectives and Comments*

**ACR supports the reduction of the Quality category weight to 45 percent.** As the Quality category’s weight is set to drop further as the Cost category receives progressively higher weight, we believe it is important to make this change incrementally.

**Removal of Quality Measures**

*Proposal*

In Table C of the proposed rule, CMS proposed to remove 34 previously finalized quality measures from the MIPS Program for the 2021 MIPS payment year and future years. These measures are discussed in detail below. The measure removal criteria consider the following:

- Whether the removal of the measure impacts the number of measures available to a specific specialty.
- Whether the measure addresses a priority area of the Meaningful Measures Initiative.
- Whether the measure is linked closely to improved outcomes in patients.

Further considerations to removal are given in the evaluation of the measure’s performance data, to determine whether there continues to be variation in performance. CMS has also made proposals this year on additional criteria that should be used for the removal of measures, such
as: extremely topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent.

**ACR Perspectives and Comments**

While the ACR acknowledges the importance of including measures only where there is an identified gap in care and opportunity for improvement, we encourage CMS to look at other factors in addition to a high benchmark when considering removal of a measure. Some measures that may be considered topped out by customary criteria are worthy of continued effort due to their critical position in clinical care pathways, and the integrity of other measures in MIPS or in other quality programs. Additionally, CMS’ calculation for topped out status does not consider the percentage of clinicians reporting a measure versus the percentage for whom the measure applies and could have reported it. In other words, top performers may be driving the performance score but represent only a small portion of all providers to whom the measure applies, potentially yielding an inaccurate assessment of topped out status.

We also suggest that CMS start the timeline for removal of topped out measures based on benchmarks derived from MIPS performance years rather than rely on data collected prior to MIPS because measure sets, reporting options, and overall incentives for participation were different in PQRS than under MIPS.

**Removal of Measures Specific to Radiology**

**Proposal**

In Table C of the proposed rule, CMS specifically proposed to remove two radiology measures due to their status as extremely topped out. These measures are #359 (Optimizing Patient Exposure to Ionizing Radiation (OPEIR): Utilization of a Standard Nomenclature for CT Imaging) and #363 (OPEIR: Search for Prior CT Studies through a Secure, Authorized, Media-Free, Shared Archive).

**ACR Perspectives and Comments**

The ACR recommends that CMS reconsider the proposed removal of measures #359 (Optimizing Patient Exposure to Ionizing Radiation (OPEIR): Utilization of a Standardized Nomenclature for Computerized Tomography (CT) Imaging) and #363 (Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies through a Secure, Authorized, Media-Free, Shared Archive). We strongly encourage CMS to keep both of these measures as they each promote network integration and image sharing via electronic exchange. Also, in keeping with CMS’ mission to ensure there are enough available MIPS measures for every type of MIPS eligible clinician, we believe these measures should remain. Removing them may affect some radiologists’ ability to meet quality measure requirements.
Electronic access to patients’ imaging history and radiology data by clinicians involved in those patients’ care would reduce unnecessary and duplicative imaging studies, thereby lowering health care costs for patients and payers and reducing patients’ exposure to radiation. Access to prior and complementary images and data by radiologists can also improve their services, thereby improving accuracy and generally enhancing early detection, diagnosis, and treatment.

Due primarily to non-technological factors and artificial barriers, a large amount of imaging data continues to be shared between disparate providers on antiquated CD and DVD optical disc storage media instead of via available electronic exchange methods. More could be done to address non-technological barriers to connectivity and to proliferate electronic exchange of medical images and corresponding data. Inclusion of these two OPEIR measures would support that effort.

The two OPEIR measures (#359 and #363) support the move to electronic image exchange and the ACR’s aggressive approach towards standardization for such purposes. These measures, as part of the Optimizing Patient Exposure to Ionizing Radiation set, currently focus on CT imaging only but the ACR is considering updating the measures to include other advanced imaging modalities.

The ACR urges CMS to maintain these in the MIPS program based on their continuing applicability as described below.

Measure #359

CMS’ stated rationale for removal of this measure is that it is duplicative of Measure #361: OPEIR – Reporting to a Dose Index Registry and is only intended to enable reporting to a dose index registry to allow comparison across radiology sites.

While the original primary purpose of the measure was as stated above, that is to standardize CT exam names to enable valid comparisons of radiation exposure; in practice, the measure promotes a fundamental step in creating a network of image sharing to reduce unnecessary or redundant exams or outcome comparison. A universal nomenclature is an essential building block for such endeavors.

Measure #363

CMS’ stated rationale for removal of this measure is that the quality action does not completely attribute to the radiologist submitting the measure and that CT studies are ordered and completed by referring providers without opportunity to complete the quality action by the radiologist. CMS additionally states that the measure does not require a quality action that links to improved outcomes when the search is completed prior to the study (i.e. comparison).

The ACR respectfully suggests that CMS fails to appreciate the process upon which this measure has impact. It is correct that referring providers place orders, but radiologists would complete the exams. The measure quality action is that prior to performing the ordered exam, the radiologist would search existing image exchanges across institutions or geographic area for existing prior
images for the patient. The potential improved outcome would be a reduction in patient exposure to radiation as well as a substantial reduction when duplicative imaging procedures are avoided. Additionally, broader access to existing imaging studies, including relevant prior images used for comparative purposes of patient history (of lesions for example) could improve diagnostic specificity and accuracy for radiologists and potentially further minimize recommendations for follow-up studies.

**Topped-Out Measures**

*Proposal*

CMS previously finalized a policy to remove a measure identified as topped out after having topped out status for 3 consecutive years. The previously finalized policy also applies a 7-point cap to measures identified as topped out for two consecutive years. CMS now proposes that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), they may propose the measure for removal in the next rulemaking cycle, regardless of whether it is in the midst of the 3-year topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Additionally, since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle, CMS proposed to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule. When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. Because QCDRs have more flexibility to develop innovative measures, CMS believes there is limited value in maintaining topped out QCDR measures in MIPS.

*ACR Perspectives and Comments*

ACR opposes CMS’ proposal to accelerate the removal of what it defines as extremely topped out measures. The ACR believes this does not give sufficient time to assess the actual performance rate of a measure. Many high-performing measures are still showing a low adoption rate among physicians and the reason for the high performance score may be a result of a small pool of high-performing individuals choosing to report measures on which they achieve a high score, skewing the average performance score to appear higher than it truly is across all providers. Additionally, as discussed below, ACR proposes that for QCDR measures, CMS consider benchmarks based on historical data inclusive of all registry participants, not just QCDR submitters, before determining whether a QCDR measure is topped out.
Categorizing Measures by Value

Proposal

CMS is seeking comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. Higher value measures that are considered “gold” standard could include outcome measures, composite measures, measures that address agency priorities and the CAHPS for MIPS survey. Measures that would be considered second tier, or at a “silver” standard, would be either process measures that have a gap for improvement or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures would be considered “bronze” measures.

ACR Perspectives and Comments

ACR supports CMS’ plan to categorize measures by value but we have some reservations. ACR agrees with CMS that some measures are more complex and require more effort to submit than others, and we would like our members to receive credit for putting in the effort to report more complex measures. We also note that CMS has taken a fairly aggressive approach to removing topped out measures as well as encouraging QCDR measures to combine into composite measures in order to capture more meaningful data. While ACR has concern regarding CMS’ logic for removing or changing measures, we support the concept of assigning higher weights to composite measures as a way to recognize associated increased effort and to offset the reduced number of measures available for reporting.

The ACR also strongly encourages CMS to consult with QCDRs and their relevant specialty societies when they endeavor to assign higher and lower weights to measures. ACR believes that, as these societies have experience with developing and collecting data for these measures, they would have valuable insight into how a measure is weighted.

MIPS: Improvement Activity (IA) Performance Category

Required Time Period for Performing an Activity

CMS does not propose any changes to the required period of time for performing an activity for the improvement activities performance category in this proposed rule.

ACR Perspectives and Comments

The ACR supports CMS’ decision to maintain the performance period requirement.

Application to Non-Patient facing MIPS Eligible Clinicians

CMS does not propose changes to the application of improvement activities to non-patient facing
individual MIPS eligible clinicians and groups for the improvement activities performance category in this proposed rule.

ACR Perspectives and Comments

The ACR supports CMS’ decision to maintain the current application of IA requirements to non-patient facing ECs.

MIPS: Final Score Methodology

Quality Measure Benchmarks

Proposal

In the CY 2018 QPP final rule, CMS solicited comments on how CMS could improve its method of benchmarking quality measures. Several commenters raised concerns and provided suggestions for changes to the methodology. When CMS developed the quality measure benchmarks, CMS sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements. For the 2019 MIPS performance period, CMS proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. CMS is seeking comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes.

ACR Perspectives and Comments

ACR strongly supports QCDR benchmarks based on historical data. To this end, ACR proposes that QCDRs be allowed to provide benchmarks to CMS based on historical or same year data for use in scoring the quality category. We believe this would provide timelier availability of benchmarks to enable QCDR participants to gauge their performance status earlier in the year and improve throughout the year.

The ACR urges CMS to review and improve its process and timeline for providing MIPS eligible clinicians with historical or performance period/same year benchmarks. The ACR has been frustrated with the inability to obtain benchmarks from CMS for our QCDR measures and with the lack of responsiveness and rationale for delay to our requests for the benchmarks. Of the 17 ACR QCDR measures that have sufficient reported data with which to develop a benchmark (20 reporters with at least 20 cases reported), CMS has only derived a benchmark for 3 of the measures currently in the program. We have been able to develop these benchmarks internally using the CMS approach for decile scoring, with benchmarks for QCDR submitters and for the registry participants as a whole.

Of particular concern is CMS’ inability to create benchmarks for our non-proportional or continuous variable measures; currently there are six of these (ACRad 15-19 and 25) that are
reported in high volumes by our QCDR participants. We engaged in a number of communications with CMS to discuss the approach for calculating benchmarks for these type measures. Yet we never received from CMS any confirmation regarding the approach or potential availability of historical benchmarks to be used for 2018 performance year reporting. We also were under the impression that CMS would use same year benchmarks for the 2017 performance year scoring. With the roll out of 2017 performance year reports in July 2018, we began receiving questions from ACR members/QCDR participants as to why the continuous variable measures that they reported were receiving a maximum of 3 points, with a note in the feedback report “this is a continuous variable or ratio measure. These measures are awarded three (3) points.” This approach to scoring continuous variable measures was never promulgated as a formal policy, not widely known to QCDR vendors, much less MIPS eligible clinicians reporting non-proportional measures. The ACR believes that this is inequitable and was avoidable. Due to this, hundreds of ACR QCDR reporters’ quality scores and resulting total score were compromised; for some, it affected their payment adjustment. We then discovered that not only did CMS not use a same year benchmark, that due to the xml specifications for reporting continuous variable measures to CMS through the QPP Portal, that the data fields in the xml file structure did not carry over to the fields in the csv files on the QPP portal. As such, the performance rate field was blank for these measures.

Consequently, we reached out to QCDR Vendor Support and were advised to submit Targeted Reviews for the clinicians. We have notified affected participants and have worked with a handful to submit a targeted review, but we urge CMS to work with the ACR to correct the base cause of the issues – correcting the file specifications for the non-proportional measures, confirming a benchmarking methodology and using it to create 2018 performance year benchmarks for our QCDR measures with sufficient data.

ACR strongly supports QCDR benchmarks based on historical data. To this end, ACR proposes that QCDRs be allowed to provide benchmarks to CMS based on historical or same year data for use in scoring the quality category. We believe this would provide more timely availability of benchmarks to enable QCDR participants to gauge their performance status earlier in the year and, therefore, improve throughout the year.

Assigning Points Based on Achievement

Proposal

For the 2021 MIPS payment year, CMS proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. CMS also seeks comment on an approach to develop QCDR measure benchmarks based on historical measure data. This may require QDCRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. CMS anticipates that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period.
ACR Perspectives and Comments

The ACR fully supports CMS’ proposal to require QCDRs to submit historical data in order to develop benchmarks. The feedback reports that we have historically provided to our clinical data registry participants include comparative benchmarking based on registry data. Additionally, for the last two years we have calculated and provided to participants during the performance year preliminary decile benchmarks based on the previous year MIPS reporters to give participants an indication of which CMS benchmark they may be assigned. To date, only three of our QCDR measures have CMS-calculated benchmarks. We would like to assist CMS in more consistently providing our participants with a published benchmark in a timely manner, as discussed in greater detail above.

Establishing the Performance Threshold

Proposal

CMS proposed a performance threshold of 30 points for the 2021 MIPS payment year. It is believed that a performance threshold of 30 points would be a modest increase over the performance threshold for the 2020 MIPS payment year (15 points), and would provide a gradual and incremental transition to the performance threshold we would establish for the 2024 MIPS payment year.

ACR Perspectives and Comments

The ACR supports the increase in the performance threshold, as 30 points is a reasonable increase from the 2018 performance period threshold of 15 points.

Additional Performance Threshold for Exceptional Performance

Proposal

CMS proposed to increase the exceptional performance threshold to 80 points for the 2021 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold.

ACR Perspectives and Comments

The ACR supports the increase in the exceptional performance threshold. This is a modest increase that will continue to motivate physicians to deliver quality care.
Definition of a QCDR

Proposal

Beginning with the 2022 MIPS payment year, CMS proposed to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. Specifically, a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In addition, an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR.

ACR Perspectives and Comments

The ACR supports CMS’ updated definition of a QCDR. However, we request clarification and more specificity as to what structure, arrangement or contractual relationship would meet the definition of “having clinical expertise in medicine and quality measure development.” We suggest that these characteristics must be inherent to its organizational mission and goals; it is not sufficient to only have a contractual, advisory or an otherwise adjunct relationship with clinical experts or quality measurement development professionals. The ACR strongly recommends that CMS consider revision of its QCDR definition based on the 21st Century Cures Act definition of a clinician-led clinical data registry. Having statutory precedence, the “Cures” Act describes major features that should be carried over to the MIPS. The element most pronounced in this definition is “clinician-led” as compared to the CMS proposal of “with clinical expertise.” The “Cures” definition is also more specific in that entities should be “devoted” to the care of a population defined by a particular disease, condition, exposure or therapy” and that the data collection is focused in these areas.

“Clinician-led” carries with it more weight than a clinical advisory component, instead emphasizing the importance of having the capabilities, body of knowledge, resources and commitment specific to an area of care – most typically the domain of professional and clinical specialty societies. A clinical society often includes as part of its mission a guideline development process and has an awareness of and pulse on/insight to changing practices, emerging technologies, and research influencing the profession. Such a society has infrastructure and expert resources, both staff and physician volunteers, who are dedicated to the development, maintenance of evidence-based guidelines and data standards upon which quality measures are based.

The purpose of such clinician-led clinical data registries is first and foremost for quality improvement, not simply reporting quality data to meet regulatory requirements. These clinician-led registries also have a commitment to collecting data on an ongoing, longitudinal basis;
gathering data across a clinical domain, not only to provide performance feedback to participants for improving patient care, but to also inform the profession and improve the practice. Continued and centralized accrual and accumulation of data allows for development of data-driven national level benchmarks, informed modification of practice guidelines or even paradigms of care.

Examples from the ACR experience include:

- Development of diagnostic reference levels (DRLs) and achievable doses (ADs) for the 10 most common adult CT examinations that will enable facilities to more effectively optimize their CT protocols for the wide range of sizes of the patients they examine and thus to appropriately reduce dose to patients.
- Imaging data in combination with pathology results/biopsy outcomes potentially may change cancer screening interval recommendations, identify preferable modalities for detection, or most efficacious treatment needs for advanced disease.

In order for the data used for this purpose to have truth, it requires a “systematic collection of data using standardized data elements and having procedures in place to verify the completeness and validity of those data.” It requires rigor and commonality in data collection, aggregation analytics and reporting. Again, we would like to highlight and emphasize the importance of data standardization based on ACR clinical registry experience (now in our 10th year). Upon initial implementation of our National Mammography Database (NMD), we began receiving data from participating sites using various mammography reporting system vendors. In design of their systems, most vendors used the ACR BI-RADS Atlas, a well-established lexicon and published guideline to enable breast imaging radiologists to issue unambiguous radiology reports. The Atlas contains a highly detailed chapter on follow-up and outcome monitoring using the BI-RADS assessment categories in describing measures that a practice should use. When NMD was implemented, we instituted a certification process to validate data adherence to the registry data elements consistently across vendors. Even with this guideline as a basis for auditing and the certification process, it became apparent that each vendor calculated the same measures in slightly different ways and NMD was critical to standardizing the calculation of audit measures. As NMD participation grew, we continued to identify variability in interpretation of data elements by vendors and we worked with them to reduce this variability and implemented additional requirements for certification.

The NMD data dictionary is now included as an appendix to the BI-RADS Atlas. We provide this example to emphasize the impact, capabilities and commitment to data truth typical of clinician-led societies.

We offer this discussion and our recommendations for CMS to consider in a redefinition of the intent and criteria for a qualified clinical data registry. The ACR is willing to meet with CMS to answer questions and provide feedback.
QCDR Self-Nomination Process

Proposal

CMS proposes to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1 for the CY 2020 performance period. This would allow for more communication about measure development between CMS and QCDRs.

CMS also proposed an update to the CY 2018 Final Rule to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to CMS.

ACR Perspectives and Comments

The ACR supports this proposal with the following reservations. We appreciate CMS giving QCDRs more time to discuss QCDR measures but urge CMS to expand on how they will be able to facilitate more discussion during this updated nomination period. While this updated nomination period does help give QCDRs more time to implement the measures before the January start date, this proposal does not necessarily aid QCDRs with measure development.

Selection of QCDR Measures

Proposal

In addition to the QCDR measure criteria previously finalized in the CY 2018 QPP Final Rule, CMS proposed to apply the following criteria under the Call for Measures process when considering measures for inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

ACR Perspectives and Comments

The ACR urges CMS to clarify the process on which a measure would be prioritized within these domains and greater transparency in rationale of assignment of domains or outcome status. We strongly recommend that CMS defer to the rationale and status identified by the QCDR, in particular for clinician-led registries.
QCDRs Seeking Permission from another QCDR to Use an Existing, Approved QCDR Measure

Proposal

In the CY 2018 QPP final rule (82 FR 53813), CMS finalized that beginning with the 2018 performance period, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. CMS states that some QCDRs charge a fee for the use of their QCDR measures unlike MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries without a fee for use.

CMS believes that approved QCDR measures should be generally available to other QCDRs, without a fee for use and proposed that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure’s approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. CMS has also proposed that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

ACR Perspectives and Comments

The ACR strongly opposes this proposal. Since the American Taxpayer Relief Act (ATRA) authorized CMS to allow the use of clinical data registries beginning in 2014 to meet participation requirements for the physician quality reporting system (PQRS) and now MIPS, there has been a proliferation of QCDRs, as was intended and desired.

In the last two years that growth has been significant with a current count of 150 QCDRs. Based on the ATRA legislation, the CMS definition and criteria of a QCDR are currently rather broad, resulting in a substantial influx of approved QCDRs that are owned by commercial entities. One impact of this growth is the expansion in numbers of QCDR measures. In 2017, CMS reviewed over 1400 QCDR measures for the 2018 MIPS performance year.

With that, CMS has voiced growing concern about the possible duplication or similarity of measures and has recommended that QCDRs build composite measures or harmonize similar measures across registries. Both of these recommendations are worth review and consideration. Building composites may in the end provide a better picture of quality for patients; however, construction of a composite measure is not as straightforward as combining 3-4 measures into one performance score. Harmonizing measures for efficiency is of utmost importance in reducing burden and also reducing confusion to patients and consumers. Doing so, however, requires careful consideration.
In its efforts to promote harmonization, CMS proposes to require QCDRs to license their measures to CMS so that any QCDR may use an approved measure without a licensing fee. Many societies created their clinical registries primarily and first/foremost for quality improvement. Development of the registry and the associated measures requires resources of the organization along with countless hours of dedicated and highly experienced physician volunteers. This work occurs on a continual basis, with updates and improvements to data collection methods and feedback reporting ongoing.

CMS should also consider the difference between MIPS and QCDR measures in terms of availability across registry vendors. For the most part, MIPS measures are currently freely available to vendors. MIPS measures are primarily specified using CPT, international classification of disease (ICD) and G-codes. One of the major benefits of QCDR measures and a primary reason for recognizing the value in allowing clinical data registries to serve as a mechanism for MIPS participation is the flexibility with which QCDR measures can be specified. They cannot be viewed in the same light as MIPS measures. This flexibility requires a greater degree of oversight in data collection, aggregation, analytics and reporting. If multiple vendors are allowed to obtain rights to implementing measures with broader data element definitions beyond traditional administrative code sets, there is a high likelihood of inconsistency and variance in measure reporting.

Requiring open, fee-free licensing of QCDR measures would inhibit measure development by QCDRs and potentially diminish use of clinical data registry measures in MIPS, as QCDR measures take an extensive amount of time and resources to develop and maintain.

The ACR has considered licensing QCDR measures to other vendors but only if the vendor completed our certification program to validate that our measures are collected and calculated in the same way. This is resource intensive. Thus, in considering licensing we would have required a fee. Additionally, as part of the licensing we would require submission of aggregated data to our registry so as to maintain the accrual of data to inform practice and benchmarks. To date, we have not entered into such an agreement for the reasons outlined above and in the QCDR Definition section of this comment letter.

The ACR reiterates its strong opposition to this proposal. As discussed in the “QCDR Definition” section above, there are numerous reasons that we find dissemination of clinical data registry measures concerning and problematic:

- Oversight by the profession and commitment to bettering its practice.
- Body of knowledge, capabilities and dedicated resources beyond the registry and measure development.
- Centralized accrual and accumulation of data for informing benchmarks and guidelines, practice recommendations and paradigms of care.
- Stewardship of standardization and validation of data element definition, collection and aggregation.
- Development and maintenance of a clinical registry and its associated measures requires extensive time and resources on the part of the organization.
The ACR also notes that CMS has notified current QCDR vendors of CMS’ licensing proposals and that if finalized, that it would be a requirement for approval of measures during the 2019 QCDR Self-Nomination. This is of great concern in that the self-nomination period closes before publication of the CY 2019 Final Rule for the Quality Payment Program. It is unreasonable to expect a proposal of this substance and complexity, with ramifications not yet fully realized by CMS and currently open to discussion, to be implemented by QCDRs measure stewards immediately after potential finalization of the policy – and certainly not before finalization. The ACR recommends that CMS also reconsider the suggested timeframe for this proposed change.

**MIPS: Promoting Interoperability Performance Category**

*Proposal*

CMS proposed no changes to the current methodology by which groups are determined to be “hospital-based.” Specifically, 100 percent of the MIPS eligible clinicians in the group would need to be determined hospital-based in order for that group to be automatically zero-weighted for the Promoting Interoperability performance category as a hospital-based group.

*ACR Perspectives and Comments*

The ACR recommends a more flexible hospital-based determination whereby groups with greater than 75 percent of MIPS eligible clinicians determined hospital-based would then receive the hospital-based special status as a group. This threshold reduction from 100 percent to 75 percent would address problematic scenarios in which a single outlier provider in a large hospital-located practice causes an inability for that group/TIN to receive a hospital-based determination. Such scenarios create additional administrative burden and unnecessary angst for the affected groups. Moreover, a 75 percent threshold would also align the hospital-based special status with the facility-based group definition and the group-based special status determination threshold for “non-patient-facing.”

*Proposal*

CMS is again collecting comments on a potential alternative method of reallocating Promoting Interoperability’s weight to other MIPS performance categories whereby 15 percent would go to Quality and 10 percent would go to Improvement Activities (as opposed to all 25 percent reallocated to Quality).

*ACR Perspectives and Comments*

The ACR strongly supports and recommends implementation of this alternative methodology. We believe this alternative scheme would appropriately share Promoting Interoperability’s weight across multiple categories, thereby reducing overemphasis on the Quality category, which is widely considered to be the most difficult MIPS performance category in which to obtain a perfect score.
Proposal

CMS proposed no changes to the current group reporting requirement for Promoting Interoperability that all MIPS eligible clinicians’ data must be aggregated into the group-reported data, including any individuals within the group who qualify for automatic zero-weighting based on special status determinations. CMS has argued it is less complex for groups if performance data from these individuals are mandatorily aggregated into the group dataset.

ACR Perspectives and Comments

The ACR recommends that groups and virtual groups be allowed to choose whether or not to include data from their “non-patient-facing” and/or “hospital-based” MIPS eligible clinicians in the aggregated dataset for Promoting Interoperability. The ACR’s underlying concern is that many radiology groups are comprised of physicians with disparate subspecialty interests serving in a variety of practice locations, sometimes with different levels of access to, and interactions with, certified EHR technology. Promoting Interoperability measures are not typically appropriate or relevant for radiologists and other clinicians with special statuses. Therefore, there is an increased likelihood of weaker performance data in this MIPS category from such individuals. Thus, CMS’ current aggregation requirement disadvantages participating groups that include clinicians with special statuses and is not consistent with the APM scoring standard.

MIPS: Cost Performance Category

Proposals

In the CY 2018 Quality Payment Program final rule, CMS established that the weight of the cost performance category would be 10 percent of the final score for the 2020 MIPS payment year. For the CY 2019 CMS proposed a modest increase to 15 percent, citing a recognition that cost measures are still relatively early in the process of development and that clinicians do not have a sufficient level of familiarity or understanding of these measures. CMS invites comment on whether alternative weights should be considered for the 2021 MIPS payment year.

ACR Perspective and Comments

The ACR supports this proposal and further easing of this category in future rulemaking cycles.

Medicare Spending Per Beneficiary Measure

Proposals

In the CY 2018 Quality Payment Program final rule, CMS established the total per capita cost measure and the Medicare spending per beneficiary (MSPB) measure for the 2018 MIPS
performance period and future performance periods. For the Medicare Spending per Beneficiary (MSPB) measure, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period.

**ACR Perspective and Comments**

Results from our members’ 2017 feedback reports confirm that many radiologists are being attributed patients under MSPB and that many of our members would be held accountable for cost particularly at the group level under the existing 35 beneficiary threshold. We are aware of ongoing revisions to the attribution methodology and we strongly support CMS’ commitment to improving the attribution process such that clinicians are held accountable for costs which are within their control. The ACR is always available to work with CMS if imaging expertise is needed.

Furthermore, the ACR is concerned that the lack of granular patient-level data in the MIPS performance report compared to what was provided in the Quality and Resource Use Report (QRUR) limits clinicians’ ability to make meaningful changes toward improvements in the cost performance category. The ACR has previously commented that clinicians need to understand the attribution and the scoring methodology and gain more familiarity with the measures through performance feedback so that they may be able to make the adjustments necessary to improve their performance. **The ACR requests that more detailed patient-level reports be made available for episode-based cost measures and for MSPB and total per capita cost (TPCC) measures, such as that previously provided with the QRURs, and that CMS institute an appeals process for cases of mistaken or faulty physician attribution.**

**Episode-Based Cost Measures**

**Proposals**

For CY 2019, CMS proposed the addition of 8 episode-based measures as cost measures for the 2019 MIPS performance period and future performance periods. These measures are calculated using Medicare Parts A and B fee-for-service claims data and are based on episode groups which represent a clinically cohesive set of medical services rendered to treat a given medical condition, aggregate all items and services provided for a defined patient cohort to assess the total cost of care and are defined around treatment for a condition (acute or chronic) or performance of a procedure. Episode-based measures are developed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode’s timeframe.

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), CMS finalized a reliability threshold of 0.4 for measures in the cost performance category and in that same rule finalized a case minimum of 20 for episode-based measures specified for the 2017 MIPS performance period. For CY 2019 Performance period, CMS proposed a case minimum of
10 episodes for proposed procedural episode-based measures and 20 episodes for proposed acute inpatient medical condition episode-based measures. As CMS states in this proposed rule, higher case minimums would increase the reliability of a particular measure.

For CY 2019, CMS is also seeking comment on extending the performance period for the cost performance category measures from a single year to 2 or more in future rulemaking which CMS states would allow the measurement of a larger number of clinicians.

**ACR Perspective and Comments**

The ACR is concerned that lowering the case minimum to 10 in effort to maximize inclusivity would meaningfully sacrifice the reliability of episode-based cost measures. In order to maximize reliability and consistency the ACR recommends a case minimum of 35 across all cost measures. In addition, the ACR is opposed to extending the cost performance period from 1 to 2 or more years as this would create additional complexity and increased physician burden.

**Advanced APMs**

**Increasing the CEHRT Use Criterion for Advanced APMs**

*Proposal*

For CY 2019 CMS proposed that in order to be an Advanced APM, that the APM must require at least 75 percent of its eligible clinicians to use CEHRT. The current required percentage is 50 percent. CMS believes that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. CMS also believes that most existing Advanced APMs already include provisions that would require participants to adhere to the level of CEHRT use specified in their regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

**ACR Perspective and Comments**

The ACR believes that CMS should keep the CEHRT threshold at 50 percent similar to the proposed 50 percent threshold that CMS proposed for the all-payer APMs. It is difficult for hospital-based specialties to meet the 50 percent threshold and we are concerned that 75 percent is unreachable. CMS should ease the requirements to insure that specialists have a continued opportunity to participate in multispecialty APMs.
Bearing Financial Risk or Monetary Losses

Proposal

CMS proposed to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for qualifying participant (QP) Performance Periods 2021 through 2024. However, CMS requests comments on whether they should consider raising the revenue based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later.

ACR Perspective and Comments

The ACR appreciates CMS keeping the revenue-based nominal amount standard at 8 percent and the expenditure-based amount at 3 percent for 2019 and future years. We believe that CMS should only raise the risk levels for APMs based on data that shows that they are prepared to participate at higher risk levels. For 2019, CMS also proposed that ACOs under the Medicare Shared Savings Program to begin to participate on a new Basic track which phases-in low levels of risk. CMS states that one of the goals of this proposal is for these ACOs to qualify as advanced APMs under the QPP. It is difficult to know if the revenue-based nominal amount of 10 percent and expenditure-based nominal amount of 4 percent will be an achievable goal by 2025. Specialists need more opportunities in the future to participate in APMs and offering ACOs a stable base of shared savings/losses that they can handle to stay engaged is vitally important.

Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Proposal

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) mandates that from 2019 through 2024, eligible clinicians that provide services to a sufficient number of Medicare patients through Advanced APMs receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. By 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent.

ACR Perspective and Comments

The ACR is concerned that no significant progress has been made in creating more opportunities for specialists to participate in APMs. The ACR requests that CMS continue to work with the
specialty societies and other stakeholders to develop new payment models that allow for radiologists and radiation oncologists to participate in APMs in the near future.

QP Determinations under the All-Payer Combination Option

Proposal

Responding to stakeholder input, CMS proposed to add an alternative under which TIN level determinations could be requested in addition to those at group or individual levels. The TIN level alternative would only apply when all clinicians who have reassigned their billing rights under the TIN to participate in the same (single) APM Entity. Use of the TIN level alternative would be further restricted to those instances in which the entire TIN (not just the individual) has met the Medicare threshold for the All-Payer option based upon its participation in a single Medicare-sponsored Advanced APM entity. CMS proposed to utilize the most advantageous QP outcome (individual, TIN, or APM Entity level). CMS believes this alternative would add to QP determination flexibility, increase the number of QPs, better reflects non-Medicare payer contracting practices, and reduce reporting burden.

ACR Perspective and Comments

The ACR supports CMS’ proposal to add a TIN level QP determination in addition to the group and individual level determinations. We agree that this adds further flexibility for APM participants.

Conclusion

The ACR appreciates the opportunity to provide comments on the CY 2019 MPFS proposed rule. We encourage CMS to continue to work with physicians and their professional societies through the rulemaking process in order to create a stable and equitable payment system. The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Kathryn Keysor at 800-227-5463 ext. 4950 or via email at kkeysor@acr.org.

Respectfully Submitted,

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Attachments