

October 2, 2020

Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1734-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244–1850

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

Dear Administrator Verma:

The American College of Radiology (ACR), representing nearly 40,000 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) 2021 Medicare Physician Fee Schedule (MPFS) Proposed Rule.

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

Payment Provisions

- Payment for Evaluation and Management (E/M) Services
- Proposal to Remove Selected National Coverage Determinations (NCDs)
- Telehealth
- Supervision of Diagnostic Tests by Certain Non-Physician Practitioners (NPPs)
- Outpatient Prospective Payment System (OPPS) Cap List
- Proposed Valuation of Specific Codes
- Update on Technical Expert Panel Related to Practice Expense (PE)



Quality Provisions

- Medicare Shared Savings Program (MSSP)
- Merit-based Incentive Payment System (MIPS) Value-based Pathways
- MIPS: Quality Performance Category
- MIPS: Improvement Activity (IA) Performance Category
- MIPS: Cost Performance Category
- MIPS: Qualified Clinical Data Registry (QCDR)
- Alternative Payment Models (APMs): APM Performance Pathway (APP)
- Advanced APMs

PAYMENT PROVISIONS

Payment for Evaluation and Management (E/M) Services

Proposals

Background and Previous Rulemaking

In the 2021 proposed rule, CMS reiterated its decision in the 2020 final rule to move forward with adoption of a new coding structure for the office/outpatient E/M codes as recommended by the American Medical Association (AMA) and the associated increased valuations of these E/M services.

In the CY 2020 MPFS final rule, for the office/outpatient E/M visit code set (Current Procedural Terminology® (CPT) codes 99201 through 99215), CMS finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework issued by the AMA's CPT Editorial Panel (see <u>https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management</u>), effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be used to select the level of code for office/outpatient E/M visits. Instead, an office/outpatient E/M visit will include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam will no longer apply. History and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate. Beginning with CPT 2021, except for CPR code 99211, time alone may be used to select the appropriate code level for the office/outpatient E/M visit.

The changes also include deletion of CPT code 99201 (*Level 1 office/outpatient visit, new patient*), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward medical decision making (MDM) and currently largely differentiated by history and exam elements.

Add-On Codes

Regarding prolonged visits, in 2020, CMS finalized separate payment for a new prolonged visit add-on CPT code (CPT code 99XXX), and discontinued the use of CPT codes 99358 and 99359 (*prolonged E/M visit without direct patient contact*) to report prolonged time associated with



office/outpatient E/M visits. CMS also finalized separate payment for HCPCS code GPC1X, to provide payment for visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

Other Related Codes

CMS identified and is proposing to revalue a group of code sets that include or rely upon office/outpatient E/M visit valuation, consistent with the increases in values finalized for E/M visits for 2021. These code sets include end-stage renal disease monthly capitation payment services, transitional care management services, maternity services, cognitive impairment assessment and care planning, initial preventive physical examination and initial and subsequent annual wellness visits, emergency department visits, therapy evaluations and psychiatric diagnostic evaluations and psychotherapy services.

ACR Perspective and Comments

The ACR continues to be deeply concerned about the sizable cuts this update will impose upon radiology and other medical specialties who do not frequently bill E/M codes, particularly in light of the COVID-19 public health emergency (PHE). This will have a devastating impact to the medical community and ultimately negative impacts to the patients.

As a result of confronting the novel coronavirus in hard-hit communities and mitigating its spread throughout the country, many practices face a myriad of economic hardships. COVID-19 has created substantial financial uncertainties for health care practices that will generate lasting impacts long after the immediate crisis ends, especially in the diagnostic imaging world. Radiology practices were forced to cease performing important services, including cancer screening and are now facing significant backlogs. For example, screenings for breast cancer were down 90 percent, which will inevitably result in delays in diagnosis and treatment of this disease.

New time-consuming safety protocols limit the number of patients that may be scheduled on any particular day. Safety protocols include physical distancing and masking of staff and patients, which by definition requires increased time spacing between appointments so that crowding of imaging suites is eliminated. Medicare policies, such as the 90 percent equipment utilization assumption assumes practice volumes that no longer can be achieved due to these changes to safety protocols that practices now have to implement. For instance, patient volume in one New Jersey practice was down 90 percent during the crisis and is now barely 70 percent of what it was earlier this year. According to an article in the Journal of the American College of Radiology (JACR), Impact of the Coronavirus Disease 2019 (COVID-19) Pandemic on Imaging Case Volumes, there has been significant decline for radiology procedures performed in hospital outpatient setting in 2020 compared with 2019 - mammography (94% reduction), nuclear medicine (85% reduction), magnetic resonance imaging (MRI) (74% reduction), ultrasound (64% reduction), interventional (56% reduction), computed tomography (CT) (46% reduction),



and x-ray (22% reduction). Imaging services will likely be reduced for the foreseeable future due to scheduling spacing out needs and disinfectant requirements on equipment. This drop in volume underscores a major flaw in the presumptions made in the reimbursement reduction soon to be implemented – assuming an equipment utilization formula of 90 percent. This efficiency is impossible to achieve in a post-COVID environment, even with an assumption that radiology offices work longer hours.

The ACR requests that CMS delay any changes to the E/M policy that will result in significant payment reductions to providers who are already financially strained by COVID-19. The E/M changes were developed in a very different reality than the one we live in today, and we hope that the Agency continues the flexibility it demonstrated in managing the pandemic, and reevaluates the necessity of going forward with any E/M changes that result in drastic budget neutrality adjustments. The already finalized outpatient E/M changes would have drastic impact on the MPFS, the magnitude and consequences of which are unknown. Before adding more uncertainty and potential instability to the fee schedule, CMS should collect data on changing one huge category of payments at a time. Even in the absence of the PHE, redistributing such a large amount of money in the MPFS at the expense of a few specialties who don't bill E/M is unwarranted and threatens the ability of those specialties to continue to provide accessible and high quality care for Medicare beneficiaries.

With regard to the new complex services add-on code GPC1X, the ACR continues to believe this new code is unnecessary. CMS' intent is to ensure payment for outliers to the typical patients described by the newly revised office visit codes. However, the revised office codes are designed to capture this complexity. For instance, the descriptor for 99215 is Office visit for an established patient with a chronic illness in a severe exacerbation that poses a threat to life or bodily function or an acute illness/injury that poses a threat to life or bodily function, which clearly describes the highest complexity of the code family. The descriptor for GPC1X [Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established], is poorly defined. For example, hypertension is a "single chronic condition". We are concerned that the ambiguity of this code and the implicit direction from CMS that it be added to every, or nearly every, office visit creates program integrity issues for CMS. For instance, CMS offers no information about how appropriate use will be determined (audited) or what documentation will be expected. If the intent is to capture services related to care coordination, the MPFS already includes CPT codes for chronic care management (99490 and 99491), transition care management (99495 and 99496), complex condition care management (99487 and 99489) and the proposed "Principal Care Management codes." In addition, since the selection of office/outpatient E/M codes (except for 99211) can be time based, the additional time for a visit resulting from the visit complexity will be incorporated into the appropriate office/outpatient E/M code selected for a visit.



Furthermore, the creation of this unnecessary code will needlessly redistribute another \$1.5 billion dollars between specialties at a time when those specialties that do not bill E/M codes face struggles with the massive redistribution triggered by the above-described office based E/M code increases.

The ACR strongly opposes the implementation of GPC1X, a code describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition.

Finally, with regard to the proposed revaluation of the group of code sets that include or rely upon office/outpatient E/M visit valuation, consistent with the increases in values finalized for E/M visits for 2021, the ACR opposes the revaluation of these codes outside of the resource-based valuation system.

In conclusion, it is unclear what the healthcare delivery system will look like after the PHE has ended, including the extent and duration for safety precautions related to COVID-19, and the ACR firmly believes that now is not the time to make such substantial and potentially devastating redistribution of funds within the MPFS. The College urges CMS to hold off on these changes until stakeholders have a better idea of what the "new normal" will look like for healthcare delivery in the United States.

Proposal to Remove Selected National Coverage Determinations (NCDs)

Proposal

CMS proposed to use the rulemaking process to use the criterion established in 2013 to regularly identify and remove NCDs that no longer contain clinically pertinent and current information; those items and services that no longer reflect current medical practice, or that involve items or services that are not used frequently by beneficiaries. CMS proposed this change of vehicle because removing a NCD changes a substantive legal standard related to Medicare coverage and payment for items and services under section 1871(a)(2) of the Act. Eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare, consistent with the NCD. Instead, coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). On the other hand, if the previous NCD barred coverage for an item or service under title XVIII (that is, national non-coverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may now be beneficial for some uses.

The Agency is also interested in whether the time-based threshold of "older" which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate.



ACR Perspective and Comments

The ACR supports the removal of the NCDs on Magnetic Resonance Spectroscopy (220.2.1) and FDG PET for Inflammation and Infection (220.6.16), allowing coverage to defer back to the MACs.

With regard to the 10-year threshold of "older" defined in 2013, with the rapidly evolving nature of healthcare, the **ACR believes this timeframe is too long and recommends reducing the threshold to 7 years**.

In addition, the ACR recommends the removal of the NCD for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N). This NCD was completed in May 2009 and is over 11 years old. Colorectal cancer is the second most common cause of cancer death in the United States. Local contractor discretion to make a coverage decision on the use of CTC for colorectal cancer screening would better serve the needs of the program in allowing beneficiaries access to another colorectal cancer screening option. The Balanced Budget Act of 1997, Pub. L. No. 105-33; § 4104 (1997), established coverage for colorectal cancer screening procedures under Medicare Part B, effective January 1, 1998, however, the outdated 2009 NCD for CTC denies Medicare beneficiaries access to an effective screening tool that for many patients is the best option.

Prior to the COVID-19 pandemic, approximately 30 percent of Medicare beneficiaries were not receiving recommended colorectal cancer screening tests. Since the pandemic, colorectal screening rates have dropped by 86 percent relative to averages prior to January 20, 2020.¹ In the time of the PHE, CTC offers additional administration benefits versus optical colonoscopy (OC). OC requires additional administration personnel as well as close patient contact. During this procedure, there are often times an anesthesiologist, gastroenterologist, nurse, and surgical technician. However, during a CTC procedure, a patient is in the CT scanner while a radiology technologist is protected by glass in a different room and an offsite radiologist interprets the results. Now more than ever, it is important to keep medical professionals and patients safe and with as minimum exposure as possible.

As the ACR firmly believes that the best screening test is the one that gets done, the more options patients have, the better. This is also consistent with the United States Preventive Services Task Force (USPSTF) recommendations. Therefore, the ACR requests that the NCD for Screening CTC for Colorectal Cancer be removed, allowing local Medicare Administrative Contractors the discretion to offer coverage of this lifesaving exam.

¹ Siegel RL, Miller KD, Sauer AG, et al. Colorectal cancer statistics, 2020. CA: A Cancer Journal for Clinicians. <u>https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21601</u>



<u>Telehealth</u>

Proposals

CMS is proposing to add 9 services to the Medicare telehealth services list on a Category 1 basis for 2021. These include: GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services), 99XXX (Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes), 90853 (Group psychotherapy (other than of a multiple-family group), 96121 (Psychological and neuropsychological testing), 99483 (Cognitive Assessment and Care Planning Services), 99334 and 99335 (Domiciliary, Rest Home, or Custodial Care Services), and 99347 and 99348 (Home visits, established patients).

During the PHE, CMS included audio-telephone E/M services on the Medicare telehealth service list and established a payment for these services. CMS is not proposing to continue this after the conclusion of the PHE, as they are unable to do so without a PHE declaration. However, CMS recognizes that the need for audio-only interaction could remain and is seeking comment on whether they should develop coding and payment for a service similar to the virtual check-in (a communications technology-based service) but for a longer unit of time and with an accordingly higher value. CMS is seeking input on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them.

ACR Perspective and Comments

The ACR recognizes the value of telehealth services, particularly in rural areas, however, the College believes that E/M telehealth services and communications technology-based services should be valued separately from in-person visits as the services are inherently different, and should be valued according to the resource-based methodology in place for all other healthcare services. As previously stated in our comments on the E/M policy changes, the ACR does not believe that now is the time to make significant changes to the Medicare program. Rather, CMS should hold off on these changes and re-evaluate how the delivery of healthcare will look like after the end of the PHE.

Supervision of Diagnostic Tests by Certain Non-Physician Practitioners (NPPs)

Proposals

In the May 1st COVID-19 Interim Final Rule with Comment (IFC), CMS established on an interim basis during the COVID-19 PHE, a policy to permit physician assistants (PAs), nurse practitioners (NPs) and certain other non-physician practitioners (NPPs) to supervise diagnostic tests. CMS now proposes to make those changes permanent.

Prior to the COVID-19 PHE, physicians, NPs, clinical nurse specialists (CNSs), PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating a beneficiary for a specific medical problem may order diagnostic tests when they



use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests.

CMS is proposing to amend the rule to allow NPs, CNSs, PAs and CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or "incident to" their own professional services, to the extent authorized under state law and scope of practice.

ACR Perspectives and Comments

As stated in our comments on the May 1st COVID-19 IFC, the **ACR does not support the relaxation of supervision regulation to allow NP, CNS, PA, and CNMs to supervise diagnostic tests.** To prevent the spread of COVID-19 and provide the highest quality patient care, radiographic interpretations and supervision can be provided following appropriate social distancing measures via teleradiology/telecommunication. Allowing PAs and advanced practice registered nurses (APRNs) to supervise diagnostics tests would present unnecessary risks for patients and beneficiaries. These new policies would take major steps that move patient care away from a physician-led team and more towards allowing PAs and APRNS to work in independent practice. For radiological care, this could be very detrimental to patients. Supervision of diagnostic tests is a vital step in maintaining high quality. The skill set for selecting the most appropriate exam, protocoling that exam and evaluating the quality of a diagnostic tests should be primarily supervised by radiologists. Lastly, no NPP should ever be allowed to interpret images and none are meant to be trained to work in independent practice.

Loosening CMS' national policies on the supervision of NPPs and more broadly deferring to state law and scope of practice could detract from quality patient care. Currently, at the state level there are many laws that allow APRNs to perform and interpret X-rays under general supervision. From a medical training and malpractice perspective, this is a dangerous path to take regarding quality patient care and patient safety.

Outpatient Prospective Payment System (OPPS) Cap List

Proposals

CMS proposed to place new CPT code 7615X (*Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*) on the Deficit Reduction Act (DRA) OPPS cap list.

ACR Perspective and Comments

The 2007 Medicare Physician Fee Schedule final rule, which outlines the regulations for implementation of the Deficit Reduction Act, defines "imaging services" subject to the OPPS



cap as, "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), MRI, CT, and fluoroscopy, but excluding diagnostic and screening mammography"². CPT code 7615X is a practice expense (PE) only code to report the analysis of radiation exposure and itself is not an imaging service. The service describes the work of clinical staff performing an evaluation following the procedure where the threshold of exposure was met. Therefore, the ACR does not believe that 7615X should be subject to the DRA cap and requests that this code be removed from the OPPS Cap List.

Proposed Valuation of Specific Codes

Fine Needle Aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)

The fine needle aspiration (FNA) code family was finalized for CY 2019, with CMS accepting the AMA Relative Value Scale Update Committee (RUC)-recommended values for seven of the ten codes. The RUC provided comment that they believed CMS had double-counted the utilization for some of the new codes, leading to the refinement of some of the code values, though CMS disagrees with this contention. There is no need to continue the debate on whether a technical error in utilization estimation has been made or not. The underlying problem with the refinements finalized by CMS is the error in their rationale. CMS continues to use intra-service time ratios to revalue codes then apply inappropriate crosswalks to justify this logical fallacy.

For example, CMS noted that the recommended intra-service time for 10021 decreased from 17 minutes to 15 minutes (a 12 percent reduction); however, the RUC-recommended work relative value unit (RVU) is only decreased from 1.27 to 1.20, which is a reduction of just over 5 percent. In the case of CPT code 10021, CMS believed that it was more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 (*Push transfusion, blood, 2 years or younger*) to account for these decreases in the surveyed work time.

This continues a disappointing pattern for CMS of using inappropriate rationale and justifying it with inappropriate crosswalks. In this case, 36440 is an infusion code, which is then being compared to an invasive procedure. These two codes are not clinically similar, including the associated risks and required decision-making, other than the service times. Furthermore, this represents a rejection of current survey data. A review of the rationale from the 36440 database entry reveals that survey respondents also thought this code should have a value of 1.20 at the 25th percentile, but lacked compelling evidence to seek that value. This further supports current values obtained by the survey as consistent with the surveyed times.

Since the same refinement reasoning from code 10021 was used to decrease the values of 10005 and 10009, these two codes should also have their values reconsidered and changed to the prior RUC recommendations.

² 42 CFR Parts 405, 410, et al. Medicare Program; Revisions to Payment Policies, etc.; Final Rule



CMS is proposing refinements to the equipment times for CPT codes 10021, 10005, 10007, and 10009 based on the appropriate equipment formula. The ACR disagrees with several of the PE refinements to the FNA imaging codes. Please see the enclosed Table 25 NPRM PE Refinements spreadsheet for our specific comments.

Lung Biopsy-CT Guidance Bundle (CPT code 324X0)

CPT codes 32405 (*Biopsy, lung or mediastinum, percutaneous needle*) and 77012 (*Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) were identified on a screen for codes reported together 75 percent or more of the time. The CPT Editorial Panel then created a new code, 324X0 ((*Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*)), bundling these services, CMS disagrees with the RUC-recommended 4.00 RVU for CPT code 324X0, indicating that the value overstates the increase in intensity given the decrease in time. CMS believes there is some overlap in physician work that is not reflected in the RUC-recommended RVU, but provides no insight as to why this may be the case. Instead, CMS has proposed 3.18 RVU for CPT code 324X0, which is the sum of the current RVUs for the component codes: 32405 at 1.68 RVU and 77012 at 1.50 RVU.

The ACR disagrees strongly with the value recommended by CMS and their rationale for doing so. The work in the base code 32405 has changed since it was last valued in 2010 based on changes in clinical needs and tissue pathology to guide oncologic therapy. This was discussed in detail at the RUC and was included in the rationale. For this reason, the survey data and code comparisons are the most appropriate method of assessing the work in the current code bundle, not the values of the component codes. The Multi-Specialty Points of Comparison (MPC) and key reference service (KRS) comparisons for the new code 324X0 clearly supported the RUC valuation of 4.00 work RVU.

We would appreciate CMS reconsidering their recommendation of a decreased value of 324X0 in favor of the well-supported RVU recommendation from the RUC.

The ACR appreciates CMS' proposal to accept the PE inputs without refinement.

<u>Screening CT of Thorax (CPT codes 71250, 71260, 71270, and 712X0)</u>

HCPCS code G0297 (*Low dose ct scan (ldct) for lung cancer screening*) was identified on a CMS/Other screen for codes with 2017 Medicare utilization over 30,000. The RUC referred the code to the CPT Editorial Panel, which created a new CPT code for this procedure, 712X0 (*Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)*). CT chest codes 71250 (*Computed tomography, thorax; with contrast material(s)*), and 71270 (*Computed tomography, thorax; with contrast material(s)*), and 71270 (*Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections*), were also addressed as part of the larger code family.



We strongly disagree with the CMS rationale for adjusting the values throughout this family based on time ratios. This disregards the survey data regarding intensity of the services presented and the recent survey data, which was from 2016. A one-minute difference in the intra-service times between the current and a very recent 2016 survey is hardly a justification for significant valuation changes when the work has not fundamentally changed. All of the current and recommended values were at or below the 25th percentile survey values. The KRS selections (CT Abdomen family) of the survey respondents clearly indicate the times and values recommended for the CT Thorax family to be consistent across the CT family of codes (see chart below).

CPT Code	Descriptor	wRVU	Pre Time	Intra Time	Post Time	Total Time	IWPUT	Source	RUC Meeting Date
71250	Computed tomography, thorax, diagnostic; without contrast material	1.16	3	14	3	20	0.073		October 2019
712X0	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	1.16	3	15	3	21	0.068		October 2019
74150	Computed tomography, abdomen; without contrast material	1.19	3	12	5	20	0.084	RUC	April 2014
71260	Computed tomography, thorax, diagnostic; with contrast material(s)	1.24	4	15	3	22	0.072		October 2019
74160	Computed tomography, abdomen; with contrast material(s)	1.27	3	15	5	23	0.073	RUC	April 2014
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections	1.38	5	18	4	27	0.065		October 2019



74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections	1.40	5	18	5	28	0.065	RUC	April 2014	
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We request that CMS reconsider their adjustments to the CT Thorax family of codes based on the flawed intra-service time ratios in favor of the survey data and appropriate comparisons to other CT family codes.

Additionally, the RUC requested deletion of G0297, which CMS does not specifically address in the proposed rule. In the event this G-code is not deleted, the ACR supports the RUC request that G0297 be crosswalked to 712X0 and the same value and inputs be assigned.

The ACR disagrees with the PE refinements to the 712X0 CPT code. Please see the enclosed Table 25 NPRM PE Refinements spreadsheet for our specific comments.

X-Ray Bile Ducts (CPT codes 74300, 74328, 74329, and 74330)

CPT codes 74300 (Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation) and 74328 (Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation) were identified on a CMS/Other screen for codes with 2017 Medicare utilization over 30,000. The code family was expanded to include CPT codes 74329 (Endoscopic catheterization of the pancreatic ductal system, radiological supervision and 74330 (Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation), and all four codes were surveyed.

CMS disagrees with the RUC-recommended 0.32 RVU for CPT code 74300 and is proposing 0.27 RVU based on a crosswalk to CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*). This code comparison is inappropriate to use as a crosswalk due to the service time differences between the codes. 74021 has 1 minute each of pre-service and post-service time compared to 2 minutes each for 74300. Additionally, 74300 has 5 minutes of intra-service time compared to 4 minutes for 74021. The value differential between the two codes is supported by both the survey data and relative time comparisons. Moreover, the work of the two codes is different, as there are typically many more images to assess in 74300 while using that information to guide an invasive procedure as opposed to 74021, which typically has 3 images.

The ACR agrees with CMS' decision to accept the RUC recommendation for CPT code 74328 at 0.47 RVU.



CMS disagrees with the RUC-recommended 0.50 RVU for CPT code 74329 and is proposing 0.47 RVU, based on a crosswalk to CPT code 74328. Both codes have identical times, and CMS states that they believe "the work involved in the biliary ductal and pancreatic ductal systems is similar." While the work may be similar, the survey respondents indicated that the work associated with assessing the pancreatic ductal system (74329) is more intense than the biliary system (74328). We recognize that these differences are small, but this is an issue that has been discussed many times before with plain radiographs and other procedures that have fewer than 10 minutes of intra-service time. The survey requires whole integer times while allowing RVU recommendations in the hundredths. **The ACR sincerely requests that CMS respect the clinical experience and recommendations of the surveyed physicians when they reliably indicate small work differences for these codes with low intra-service times given these limitations.**

CMS disagrees with the RUC-recommended 0.70 RVU for CPT code 74330 and is proposing 0.56 RVU using a time ratio methodology applied to CPT code 74328. We fundamentally disagree with using time ratios for code valuation in lieu of survey data, as we have discussed in multiple comment letters including this one. We request CMS respect the experience of the surveyed physicians and reliability of simultaneously conducted surveys when those same physicians are indicating the increased intensity required to perform an evaluation of both the biliary and pancreatic ductal systems as opposed to one or the other. For these reasons, we believe the RUC-recommended values for 74330 are accurate and should be adopted.

Update on Technical Expert Panel Related to Practice Expense

The PE methodology currently relies on 2006 data collected from the Physician Practice Information Survey (PPIS). CMS has contracted with the RAND Corporation to revisit the PE methodology, to potentially update, improve, or refine the data collected in an effort to "improve payment accuracy and strengthen Medicare."

The ACR appreciates the opportunity to provide comments regarding the RAND Corporation report on "Practice Expense Methodology and Data Collection Research and Analysis – Interim Phase II Report." We are committed to helping to guide this discussion to ensure the ongoing clinical appropriateness of any future PE reimbursement methodology. We encourage CMS to work closely with stakeholders in the data collection process and to analyze alternatives or modifications to the PE methodology. If there are plans for a new PPIS survey, it is imperative that the specialties are involved in order to determine the most effective and appropriate methods for updating their practice costs.

Below are our thoughts pertaining to the key issues RAND focused on:

1. Updating Practice Expense Data Through Survey-Based Data Collection

The ACR strongly agrees that the input data should be improved. We have consistently commented that the current practice expense per hour (PE/HR) assigned to Radiology



specialties is inappropriately low due to flawed data collection and aggregation in the original PPIS, particularly in the non-facility (physician office) setting. The original data were based on groups with inappropriately low, or zero, practice expenses related to performing radiological examinations in the non-facility setting, and was not representative of the typical radiology practices performing in-office radiological examinations. Additionally, the survey was not representative of the typical group size at the time of the original survey.

We appreciate the work that CMS has put into assembling the comprehensive list of PE components: staffing; clinical services, supplies, and equipment; office space; office supplies and services; and professional services. These are important considerations in the updating of the PE methodology.

2. An Alternative Framework for Allocating Indirect Practice Expense

The ACR agrees that the current indirect cost allocation process could be refined and that this process would be best accomplished by the AMA RUC. Any update to the PPIS must address the flaws in the initial data collection and aggregation by including a sample that is widespread and representative of current physician practices, particularly regarding the outpatient setting. This will require data collected at the practice level, appropriately stratified, and statistically valid. Analysis and refinement of any collected data will require meaningful clinical input that can only be accurately provided by the individual specialties, such as through the RUC representative process.

3. Using Outpatient Prospective Payment System (OPPS) Costs to Determine Practice Expense Values

The ACR strongly disagrees with the RAND contention that the OPPS could be used to inform any reasonable approximate of practice expense costs unless the quality and veracity of the OPPS reported data is significantly improved. The Agency has received countless comments over the years from stakeholders identifying egregious flaws in the outpatient cost data. So often hospitals use ambulatory payment classification (APC) payments to quantify their costs, which is a circular methodology and highlights the unreliability of those data. As Radiology is one of the first specialties to experience the convergence of the MPFS and OPPS rates, as specifically cited in the Phase I RAND report (pg. 7), we have consistently commented that the current data is not an accurate representation of actual costs due to flawed collection and significant confusion by reporting entities. For example, internal data shows that only half of the data submitted to CMS complies with the new CT/MR cost center methodology as opposed to the prior square foot allocation process.

Finally, the Phase I RAND report acknowledges that "these differences in cost structures suggest that the OPPS data might not be appropriate for the entirety of services in the MPFS" (pg. 74) and we agree. At this time, OPPS data cannot be accurately nor effectively applied to the outpatient office setting and we strongly oppose any such efforts.



We appreciate the opportunity to work with CMS to develop appropriate goals and processes to address the issues detailed in this RAND report and are happy to provide additional comments or data as needed.

QUALITY PROVISIONS

Medicare Shared Savings Program (MSSP)

<u>Alignment of MSSP Quality Performance Standard with Proposed Alternative Payment Model</u> <u>Performance Pathway (APP)</u>

Proposals

In an effort to improve alignment and integration with the Quality Payment Program policies and operations and increase participation in Alternative Payment Models (APMs) and Advanced APMs by reducing reporting burden, CMS is proposing to revise the MSSP quality performance standard starting in performance year (PY) 2021. CMS proposes to align the MSSP quality performance standard with the proposed APP where MSSP participants would be required to report quality via the APP. The APP would replace the current MSSP quality measure set to streamline quality reporting for MSSP Accountable Care Organizations (ACOs) complementary to MIPS Value Pathways.

Under this new proposal, ACOs would only need to report one set of quality metrics that would satisfy reporting requirements under MIPS and MSSP. Additionally, under these proposed changes, ACOs would be assessed on a smaller measure set: the measures ACOs would be scored on would decrease from 23 to 6 and the number of measures on which ACOs would be required to actively report would be reduced from 10 to 3.

CMS is also seeking comment on an alternative approach, in the event that the 3 measures ACOs are actively required to report upon are not applicable to their beneficiary population and there are more appropriate measures under MIPS. CMS proposes that under this alternative, ACOs may opt out of the APP and report to MIPS as APM entities.

ACR Perspective and Comments

The ACR supports CMS' proposal to improve alignment within the Quality Payment Program (QPP) and reduce reporting burden for ACOs, and therefore supports the integration of the proposed APP into MSSP ACOs for quality reporting. Additionally, the ACR supports the alternative approach of ACOs reporting to MIPS as APM entities if the 3 APP measures are not applicable.



Extreme and Uncontrollable Circumstances

Proposals

CMS proposes to update its extreme and uncontrollable circumstances policy under the MSSP consistent with their proposal to align quality reporting under the proposed APP. CMS proposes to set the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances equal to the 40th percentile MIPS Quality score. If the ACO is able to report quality data and meet data completeness, CMS would use the higher of the ACO's MIPS quality score or the 40th percentile; while if an ACO is unable to report quality data and meet data completeness, CMS would apply the 40th percentile MIPS Quality performance score.

CMS is soliciting comment on a potential alternative to extreme and uncontrollable circumstances starting in PY 2022. This alternative would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or are unable to complete quality reporting. Under this proposal, CMS would determine shared savings by multiplying the maximum shared savings the ACO would be eligible for by the percentage of total months impacted and percentage of beneficiaries affected.

CMS also proposes a policy to allow ACOs a one-time opportunity to decrease the amount of their repayment mechanism. Under this proposal, an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount. CMS proposes that CMS would notify the ACO in writing of this opportunity.

ACR Perspective and Comments

The ACR supports CMS' proposed changes to extreme and uncontrollable circumstances. Additionally, in light of the COVID-19 PHE, the ACR supports CMS' proposal to allow ACOs a one-time opportunity to decrease the amount of their repayment.

MIPS Value-based Pathways

The ACR asks CMS to consider an automatic hardship exemption from MIPS for 2020, in keeping with the exemption policy offered in 2019. The PHE significantly impacts practices' ability to collect measures, distorts many practices cost data, and usurps resources that would otherwise be used to participate fully in the MIPS. These challenges are even more pronounced for 2020 than the reporting challenges faced by practices in 2019. Requiring practices to apply for a hardship exception is an unnecessary burden. If automatic exemptions are allowed, the ACR would also like clarification on whether facility based scoring would be automatically applied to eligible practices who do not report MIPS data. The ACR suggests that CMS take the higher of the facility-based score or the neutral score assigned to practices who are unable to submit their own MIPS data for 2020.



Transforming MIPS: MIPS Value Pathways

Proposals

CMS proposes updates to the MIPS Value Pathways (MVP) plans, including revisions to the guiding principles, MVP development criteria, and processes that would guide MVP implementation beginning with the 2022 MIPS performance period/2024 MIPS payment year.

CMS further states the intention to move forward with an initial set of MVPs and associated policies in the CY 2022 rulemaking cycle. CMS plans to implement the MVPs while maintaining the MIPS participation options established through rulemaking for MIPS performance years one through five (i.e., "traditional MIPS").

CMS proposes the following updates to the MVP guiding principles (changes delineated by italics):

- 1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* scoring, and lead to sufficient comparative data.
- 2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.* MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included,* to encourage performance improvements in high priority areas.
- 3. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.
- 4. *MVPs should support the transition to digital quality measures.*

CMS describes their intention to form MVPs to grow the number of available MVPs using the processes described in this proposed rule.

ACR Perspectives and Comments

The ACR continues to support CMS' efforts to reduce burden and improve participation in the QPP by making it more relevant and useful for both patients and clinicians. As such, the ACR sees MVPs as a theoretical move in the right direction. However, we remain concerned by the vagueness regarding the proposed guidance for the development, implementation, and participation in MVPs. **The ACR continues to recommend that the MVP implementation process encourage collaboration with specialty society-stakeholders**. We further appreciate the ability to continue participating in traditional MIPS until radiology-appropriate specialty or sub-specialty MVPs are implemented. The ACR also supports the proposed updates to the MVP guiding principles. These updates will support the goals envisioned by CMS of building a more cohesive and less burdensome program.



Though included during the 2020 MPFS proposed rule, CMS did not address the MVP assignment method or MVP composition within this proposed rule. As included in our comments last year, the ACR recommends that clinicians and groups self-select or opt-in to a specific MVP rather than be assigned to one by CMS based on default by specialty designation or previous MIPS participation. Further, the ACR recommends that CMS be more transparent regarding the elements contained in MVPs, such as the number of measures and activities. Both of these considerations would impact the scoring methodology and participant buy-in for specific MVPs compared to others.

MVP Development Criteria

Proposals

CMS proposes to develop and select MVPs for the 2022 MIPS performance period by applying criteria that would require MVP developers to establish meaningfulness of candidate MVPs for their specific MIPS participant and closely aligns with the guiding principles previously described.

To demonstrate that candidate MVPs meet the proposed criteria, developers must rationalize and justify that each measure and activity in a candidate MVP meets the MVP developers' designated intension. Further, MVP developers must ensure that the measures and activities for the Quality, Cost, and Improvement Activity performance categories are valid, scientifically sound, capture the patient voice, and are usable by rural and small practices.

CMS proposes incorporating (to the extent feasible) specialty- and sub-specialty- specific quality measures and cost measures into MVPs and incorporating broadly applicable (cross-cutting) quality and cost measures when a lack of specialty- and sub-specialty measures exist and are relevant to the measured clinicians.

ACR Perspectives and Comments

The ACR appreciates CMS' proposed criteria to inform developers on the formulation of MVPs and provide information on what CMS' decision-makers will consider in determining whether a candidate MVP is approved. **However, greater detail as to the MVP measure and activity criteria is needed for developers to fully understand what would be essential for CMS approval. The ACR recommends CMS specify the number of measures and activities necessary for an MVP to undergo the approval process. Further, given the ambiguity regarding the volume of measures and activities required of MVPs, the College is concerned by the lack of details described for the MVP scoring methodology.** It is unclear how CMS intends to award performance points to MIPS eligible clinicians participating in one particular MVP against those participating in a separate MVP.

Because of the lack of clarity, the ACR is concerned by CMS' proposed solution for MVP developers whose intended clinical specialty focus lacks the CMS-desired narrow-based and broad-based cost measures (if narrow-based cost measures do not exist for the clinicians measured under a particular MVP). Radiologists face challenges regarding the currently



approved total cost of care measures (e.g., MSPB and TPCC) in that they are not generally, attributed patients under these measures. Further, episode-based cost measures are not often applicable to radiologic care. We invite CMS to engage with ACR expert-stakeholders to develop an MVP pathway that promotes radiologists' participation and considers creative approaches to measuring cost and utilization, to the extent that statute allows.

Candidate MVP Co-Development, Solicitation Process, and Evaluation

Proposals

CMS proposes that beginning with the 2022 performance period, stakeholders may formally submit candidate MVPs utilizing a CMS-devised standardized template. In addition to MVP developers affirming that their MVP candidate meets the MVP development criteria, CMS exerts discretion on whether a candidate MVP is ready for inclusion in the upcoming MIPS performance period. CMS seeks comment on the implementation of a more transparent process for future program years. CMS is specifically interested in knowing whether the utilization of an advisory committee, technical expert panel, interdisciplinary committee (similar to the MIPS quality measures under the Call for Measures), or public process (such as the National Quality Forum (NQF) convened pre-rulemaking process) review of MVP candidates should be implemented.

Since the MPFS 2020 proposed rule, CMS has underscored the foundational layer of MVPs as consisting of Promoting Interoperability and population health administrative claims-based quality measures to provide data and feedback to clinicians while enhancing the information provided to patients. CMS plans to offer increased population health measurement data using administrative claims information while decreasing the volume of clinician-reported measurement data used for MIPS.

ACR Perspectives and Comments

The ACR appreciates CMS' emphasis on a consistent process that ensures stakeholder engagement and collaboration in the development of MVPs. However, we are concerned with CMS' proposal to develop a standardized MVP submission template without meaningful stakeholder input. Given the ambiguity associated with MVPs mentioned earlier, the **ACR supports a transparent and stakeholder-informed process for drafting and finalizing a submission template**. Such stakeholder engagement would ensure the development of a wellinformed template and submission process that is equitable and considers MVP participants' many unique characteristics.

The ACR acknowledges that a stakeholder-informed MVP-approval process is integral for MVPs to undergo rulemaking. However, we hesitate to immediately support the utilization of an advisory committee, technical expert panel, interdisciplinary committee (similar to the MIPS quality measures under the Call for Measures), or public process (e.g., the NQF convened pre-rulemaking process) to review candidate MVPs. The ACR is concerned that the current Call-for-Measures process lacks the efficiency to recommend a comprehensive as possible list of measures because of the limited inclusion of experts advising on the measures that undergo



rulemaking, particularly when the measures are outside of their expertise. Some medical specialties are not represented on these panels causing the inappropriate rejection or inclusion of measures. The ACR anticipates that implementing such a process would negatively impact rulemaking for candidate MVPs and their stakeholders.

According to CMS, there is a lack of additional resources to support well-rounded clinicianexperts' groups to address MVP approval. The ACR perceives this to mean that CMS cannot support altered modified Measures Application Partnership (MAP) process, to include broader expertise in concordance with each MVP undergoing review. As CMS has communicated it, the same volunteer groups participating in the MAP would also review MVPs. The ACR has continuing concerns regarding the MAP's level of transparency and consistency, as well as the limited range of clinical expertise to assess utility of measures under consideration. **The ACR recommends that experts review MVPs in the clinical areas that the MVPs address.** This is particularly important for specialties such as radiology that do not fit the typical CMS MVP framework. Should this type of method not be implemented, particular sets of clinicians will undoubtedly be unable to participate in MIPS through MVPs, despite their efforts to progress into more value-based payment models.

As the ACR noted in the 2020 MPFS proposed rule comment letter, we advocate for MVP measures to remain reportable by the various collection-types, since measures contained within an MVP may cross over collection types. The ACR requests clarification on whether a group or eligible clinician's performance on an individual measure in an MVP will be compared against the benchmarks for that collection type as it is done now in MIPS. We are also concerned about limiting MVP measures to certain collection types as small or rural practices may participate in an MVP through continued use of claims measures. Allowing multiple MVP measures to be submitted via multiple collection types would maintain consistency with CMS policy allowing clinicians to report MIPS measures via multiple collection types.

The ACR embraces CMS' effort to reduce measure reporting burden for clinicians. However, we are concerned that the administrative claims measures currently in existence cannot accurately capture meaningful performance information, particularly for radiologists. These measures are not universally applicable.

Incorporating QCDR measures into MVPs

Proposals

CMS describes MVP development plans for the 2022 performance period and future years, emphasizing the importance of considering the opportunity to include QCDR measures within MVPs.

ACR Perspectives and Comments

The ACR appreciates CMS' focus on integrating the use of QCDR measures into the MVP framework. QCDR measures are developed and stewarded by entities such as medical specialty



societies that convene multi-stakeholder technical experts responsible for prioritizing metrics considered meaningful to a specialty. The ACR is encouraged that MVP measures reported into QCDRs are distinct for the clinician-group intended to participate in a given MVP.

However, we request clarification of whether MVPs may contain both MIPS and QCDR measures. This could limit MIPS eligible clinicians' choices, meaning that QCDRs may need to obtain licensing for QCDR measures developed by and contained in another MVP. Should QCDRs mutually fail to agree to copyright and licensing fee agreements, some MIPS eligible clinicians may have to transition to a new QCDR and potentially lose years' worth of benchmarking data collected using the former-QCDR's measure benchmarks.

The ACR is concerned by problems regarding QCDRs' capability to adopt other QCDRs' measures. Eligible clinicians reporting measures in their appropriate MVP through QCDRs are unaware of potential data integrity problems with the data submitted to CMS for MIPS. Further, QCDR measure developers/stewards will face burdens, like the need for more resources to address the other QCDR users' customer service requests (such financial and human resources are not necessarily available). In light of the data integrity concerns, the ACR perceives that such issues pose barriers to comparing MVP participants' performance within a particular specialty and sub-specialty and MIPS scoring for MVPs across MIPS.

MIPS: Quality Performance Category

Quality Category Weighting

Proposals

For MIPS 2021, CMS proposes maintaining the Cost performance category at 20 percent, the Quality performance category weight at 40 percent, and the Promoting Interoperability (PI) and Improvement Activity (IA) performance categories at 25 and 15 percent, respectively. CMS intends to alleviate the stress of the COVID-19 PHE affecting many clinicians in 2020. For the 2022 performance year, CMS proposes to lower the Quality performance category to 30 percent, increase the Cost performance category to 30 percent, and maintain PI and IA performance categories at 25 and 15 percent.

ACR Perspectives and Comments

The ACR supports the decision to maintain the 2020 category weights for 2021; for many nonpatient-facing physicians, the Quality and IA categories represent the bulk of their MIPS score. **The ACR recommends that CMS continue to make allowances for physicians who are exempt from Promoting Interoperability and Cost by allowing them to receive a higher weight to their Quality and/or IA scores.**



Data Completeness

Proposals

CMS does not propose changes to the quality measure data completeness rate of 70 percent, as established for the 2020 performance year.

ACR Perspectives and Comments

The ACR appreciates that CMS has not raised the data completeness requirement, but emphasizes that the 70 percent completeness rate may be too burdensome for some physicians to meet, especially in small and rural practices, due to technological limitations.

The ACR recommends that CMS reduce the data completeness criteria from 70 percent back to 60 percent, specifically for the 2021 performance year to allay reporting difficulties due to the COVID 19 public health emergency, as well as for future performance years.

CMS should thoughtfully consider the following factors related to the data completeness threshold:

- Small and rural practices particularly have difficulty meeting the 70 percent threshold, placing substantial burden on such practices.
- As ACR has stated in previous years, the increased data completeness threshold is difficult and burdensome for many radiology groups, as is true of other hospital-based specialties. Most practices rely on the hospital(s) for which the group provides services to assist in data extraction for MIPS measure reporting from the hospital systems. In many cases, the hospital does not have the same motivation to enable MIPS data collection and reporting. Based on the number of hospitals where a group practices, this issue is exacerbated; the more facilities with which a practice works, the more difficulty in attaining a 70 percent completeness rate across all sites that a TIN practices.
- If a group begins providing services to a new hospital or facility during the reporting year it can be difficult and burdensome to develop processes for reporting for that year. This factor alone could prevent a group from meeting a 70 percent threshold.
- The time it takes to implement new measures or updates to measures into practice workflow discourages practices from reporting on new measures. EHR or other technology vendors often charge for any requested changes.

Because of these factors and typical circumstances for radiology groups, the ACR urges CMS to lower the data completeness threshold in future years to a maximum of 60 percent.

<u>Quality Measures Proposed for Removal</u>

Proposals

CMS proposes removing two measures previously reportable by radiologists or interventional radiologists.

• MIPS Quality ID 146: Inappropriate Use of 'Probably Benign' Assessment Category in Screening Mammograms



• MIPS Quality ID 437: Rate of Surgical Conversation from Lower Extremity Endovascular Revascularization Procedure

ACR Perspectives and Comments

The ACR does not support removing these two measures since reporting difficulties created by the COVID-19 pandemic may limit relevancy of some measures due to reduced services provided. Additionally, CMS' proposal to use performance period benchmarks for the 2021 performance year introduces uncertainty in measure selection, thus the ACR strongly encourages delayed removal of these measures from the MIPS program. Given the limited number of measures available to radiologists for MIPS reporting, in particular dedicated breast imagers, the removal of these two measures would reduce their pool of measures even further. Many radiology groups' business models carve out mammography services into separate TINs, thus group reporting does not broaden the list of available measures for these specialists. In addition, this measure could be useful as part of a measure set for a breast imaging MVP.

MIPS Performance Threshold

Proposals

The Bipartisan Budget Act of 2018 allows CMS flexibility to set performance thresholds until 2021. The statutorily required performance threshold is based on the mean or median of final scores from a prior period. Although a 60-point MIPS performance threshold for the 2021 MIPS performance year was previously finalized, **CMS proposes to lower the performance threshold to 50 points for 2021,** due to the COVID-19 PHE. CMS is not proposing revisions to the previously finalized exceptional performance threshold, set at 85 points for 2021.

ACR Perspectives and Comments

The ACR agrees with the proposal to lower the performance threshold to 50 points **but disagrees with setting an exceptional bonus threshold set beyond 80 points for 2021. The ACR recommends setting the exceptional bonus threshold year-by-year, based on the previous performance year's results, rather than setting an arbitrary threshold for a future program year.** The removal of quality measures affects clinician's performance in the program and is a contributing factor to performance scores. It would be more equitable to see how performance scores average out for each program year before setting a threshold.

Quality Measure Benchmarking

Proposals

Due to the decreased number of MIPS submissions for the 2019 performance year, CMS acknowledges that there may not be an adequate data set to establish quality measure historical benchmarks for use in 2021. Therefore, CMS proposes to use 2021 performance data to establish benchmarks for the 2021 performance year rather than historical benchmarks based on the previous year's (2019) data.



As an alternative, CMS proposes and seeks feedback on using 2018 historic benchmarks for both performance years 2020 and 2021. This option would provide clinicians with a clear performance goal for the 2021 performance period. CMS acknowledges that use of the "outdated" data set could potentially distribute scores that no longer reflect standard of care.

ACR Perspectives and Comments

The ACR believes use of 2021 performance period benchmarks is preferable to relying on the 2018 historic benchmarks. However, we acknowledge that this may create difficulty for many MIPS participants in determining which measures to submit. If 2021 benchmarks are based on 2021 performance, the ACR recommends that CMS consider removing the topped-out status and the seven-point cap from as many measures as possible during the 2021 performance year due to the uncertainty of the benchmarks.

Topped Out Measures

Proposals

As mentioned above, CMS proposes to use 2021 performance period benchmarks, rather than historical benchmarks, for the 2021 performance year out of concern that the COVID-19 PHE could skew benchmarking results. As a result, clinicians may not necessarily know whether a measure will continue to be considered topped out and subject to the 7-point scoring cap. Regarding their methodology for scoring topped out measures, CMS proposes that for a measure to be point-capped in the 2021 performance year, it must have been topped out for two consecutive years before 2021 and topped out at the conclusion of the 2021 performance year, giving clinicians an idea of whether a measure could become point-capped while allowing for the possibility that the measure may no longer be considered topped out for 2021.

ACR Perspectives and Comments

The ACR appreciates CMS' willingness to reconsider a measure's topped-out status if data received during 2021 differs from previous years. As stated in our above comment, many physicians will have difficulty selecting measures during the 2021 performance year if they are unable to know the benchmark by which they will be scored. **The ACR recommends that CMS remove the seven-point cap altogether for the 2021 performance year due to these uncertainties.**

MIPS: Improvement Activities Performance Category

Annual Call for Activities

Proposals

CMS proposes flexibility when submitting new improvement activities to the Annual Call for Activities, which is currently open from February 1st through June 30th, in the event of PHEs such as the COVID-19 crisis. This proposal would allow stakeholders to submit new improvement activities outside of the established five-month timeframe in the event of a PHE.



Similarly, CMS proposes a process to allow activities nominated by the Department of Health and Human Services (HHS) to be considered year-round for addition to the improvement activities inventory.

ACR Perspectives and Comments

The ACR agrees with CMS that under certain circumstances, such as the COVID-19 crisis, it may be beneficial to allow the addition of IAs to the MIPS program outside of the established Call-for-Activities window. We do not see a problem with adding new IAs to the program throughout the year, if introduction of a new IA allows for a 90-day performance period with a reasonable "ramp-up" period. However, we recommend that CMS concurrently provide data validation guidance for all new activities once added to the program since QCDRs are required to conduct audits of measures and IAs throughout the year.

MIPS: Cost Performance Category

Performance Category Weighting

Proposals

CMS proposes maintaining the 20 percent Cost performance category weight during the 2021 performance year, with plans to increase it to 30 percent for performance year 2022 and beyond. As mandated by statute, CMS will increase the Cost performance category weight to 30 percent for the 2022 performance year. However, comments are sought as to whether CMS should raise the weight to 22.5 percent for 2021 to promote a seven-and-a-half percent increase for the two consecutive years.

ACR Perspectives and Comments

The ACR agrees with CMS' proposal to maintain the Cost performance category's weight at 20 percent for the 2021 performance year. We believe it is beneficial to maintain the same weights as 2020 due to the additional burdens created by the COVID-19 emergency.

Addition of Telehealth Codes

Proposals

For the 2021 performance period and beyond, CMS proposes that telehealth services costs are included in the cost measures list. These telehealth services codes are directly relevant to each appropriate measure (e.g., E/M, follow up consultation following hospital discharge). CMS does not consider adding these cost codes to alter the measures' intent or capture a new category of costs.

ACR Perspectives and Comments

The ACR supports the proposal to add telehealth services directly correlated to existing cost measures to the list of cost measures.



MIPS: Qualified Clinical Data Registry (QCDR)

In this proposed rule, CMS proposes to update the content of the policies related to QCDR data validation audits and targeted audits and measure requirements.

Data Validation Audit and Targeted Audit Requirements

Proposals

CMS proposes to codify at § 414.1400(b)(2)(iv)(A), that QCDRs must conduct data validation for the payment year before submitting any data for that payment year to CMS for purposes of the MIPS program. CMS also proposes to refer to this audit as the "data validation audit" to ensure clarity regarding expectations that QCDRs will construct a sample and conduct an audit that complies with specific regulatory requirements and also distinguishes such audits from the targeted audits proposed at § 414.1400(b)(2)(v).

CMS seeks to codify at § 414.1400(b)(2)(iv)(C), that the QCDR must conduct data validation on data for each submitter type for which it will submit data, including (if applicable) MIPS eligible clinicians, groups, virtual groups, and voluntary and opt-in participants. Further proposals would require that the data validation audits account for all types of submitters utilizing the QCDR to submit data to CMS for MIPS. CMS also proposes to codify at § 414.1400(b)(2)(iv)(D) that QCDRs must collect clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured occurred or was performed.

ACR Perspectives and Comments

The ACR agrees with CMS that it is important for QCDRs to conduct validation audits to identify and correct data accuracy issues before submitting the data to CMS. Such validation audit timing would increase data reliability and accuracy, promoting compliance with CMS' requirement that data is true, accurate, and complete. The ACR also recognizes the importance of accurate data submissions to CMS regardless of participation/eligibility status (i.e., opt-in or voluntary). However, we are concerned that the requirement to audit per performance category or submitter type will significantly burden the National Radiology Data Registry (NRDR) QCDR participants as well as our operational resources.

If finalized, QCDRs like NRDR would become responsible for collecting additional clinical health information necessary to validate the IA and PI performance categories beyond that which NRDR traditionally accepts for registry and MIPS reporting purposes. This could potentially increase the risk of disseminating PHI outside recognized exceptions, e.g., via e-mail rather than secure box. Additionally, the ACR cautions CMS on the finalization of validating data for all submitter types regardless of their use for payment or public reporting. While we acknowledge impact on data integrity, we are concerned with the proposed IA data collection audit burden and limitations imposed on NRDR QCDR participants and staff responsible for participating in and conducting random audits. Our concerns lie with those participants who are categorized into specific submitter profiles, typically less utilized, such as



virtual groups that increase those submitters' likelihood of continually being selected to participate in the audit—thereby removing the random nature of the audit.

The ACR is concerned by CMS' proposal to initiate routine and targeted audits, as it would place a significant burden on NRDR's QCDR participating groups and business structure. There is an increased burden imposed during auditing, which typically occurs between January and March of the following reporting year. This burden increases particularly because these audits occur parallel to when QCDR groups are finalizing their CMS submissions and particularly when participants finish IA selections at year-end. The College's experience with NRDR QCDR registry participants is that they typically finalize data submissions later in the performance year, which already burdens QCDR staff resources at the end of the performance year and during the submission period.

<u>OCDR Measure Testing Requirements</u>

Proposals

CMS proposes at § 414.1400(b)(3)(v)(C)(1) that for approval for the 2024 MIPS payment year, a QCDR measure must be fully developed and tested, including face validity. Further, for QCDR measures to gain approval for the 2025 MIPS payment year and future years, it must maintain its face validity and demonstrate that is has undergone full testing as defined by the MMS Blueprint. As such, CMS proposes to revise § 414.1400(b)(3)(v)(C) to account for an incremental approach to require fully tested QCDR measures.

ACR Perspectives and Comments

The ACR appreciates the delay to the QCDR testing requirement finalized in the 2020 rule. We agree QCDR measures must demonstrate empirical validity. Such testing establishes the integrity of the measures' individual performance rates and benchmarks. Although we recognize the delay of the empirical testing requirement as part of CMS' COVID-19 flexibilities, we request a continued testing delay beyond the 2023 QCDR self-nomination period. Our concerns lie in QCDR-users' measure reporting limitations resulting from the PHE. The CMS-approved 2020 QCDR measures implemented in the NRDR QCDR are collecting data based on non-routine practice. The data collected for these QCDR measures will likely not reflect routine practice for the performance year 2021, either.

APP: APM Performance Pathway

Proposals

CMS proposes beginning January 1, 2021, an optional MIPS reporting and scoring pathway, the APM Performance Pathway (APP). APPs would provide a predictable and consistent MIPS reporting standard for eligible clinicians in Advanced APMs who are subject to MIPS (because they are Partial Qualified Participants (QPs) for a year who elect to participate in MIPS or because they fall below the applicable Partial QP threshold for a performance year). The goal of APPs for Advanced APM MIPS eligible clinicians is to reduce reporting burden and encourage continued APM participation.



Further, CMS proposes that beginning in the 2021 performance period, MIPS eligible clinicians scored under the APP would be scored on the six-quality measure set finalized for a MIPS performance period.

ACR Perspectives and Comments

The ACR appreciates the opportunity for MIPS eligible clinicians in Advanced APMs to benefit from reduced reporting burden through participation in the APP. However, the six quality measures proposed for use beginning on January 1, 2021, are limited to primary care-focused clinicians.

While currently there is no Advanced APM for radiology, radiologists who are MIPS eligible clinicians practice in multispecialty groups and other practices that participate in Advanced APMs. There are likely MIPS eligible clinicians who are capable of participating in the quality measures currently proposed for the 2021 APP performance year. We are concerned for radiologists in Advanced APMs who are the sole MIPS-eligible clinicians for a radiology practice. **The ACR requests more clarity on plans for APP measure sets. For instance, should a radiology Advanced APM become available, would there also be an APP quality measure set specific to radiological care?** The College acknowledges the shift toward population health and patient outcomes. However, given the limited nature of the proposed APP quality measure set, the ACR questions how physicians would demonstrate their individual improvement with measures that assess care for which they are not accountable.

Advanced Alternative Payment Models

Targeted Review

Proposals

CMS is proposing that starting in the 2021 QP Performance Period, CMS would accept Targeted Review requests when an eligible clinician or APM Entity believes in good faith CMS has made a clerical error such that an eligible clinician(s) was not included on a Participation List of an APM Entity participating in an Advanced APM for purposes of QP or Partial QP determinations.

ACR Perspective and Comments

The ACR supports the proposed establishment of a targeted review process for QP determinations. This would be beneficial to both CMS and clinicians.

<u>Attribution</u>

Proposals

CMS proposes to establish a revised approach to identifying the Taxpayer Identification Numbers (TINs) to which they make the APM Incentive Payment: this approach would involve looking at a QP's relationship with their TIN(s) over time, as well as considering the relationship



the TIN(s) have with the APM Entity or Entities through which the eligible clinician earned QP status, or other APM Entities the QP may have joined in the interim.

ACR Perspective and Comments

The ACR agrees with CMS' operational revisions surrounding attribution, as this revised approach will help CMS to more accurately identify TINs in which QPs are currently receiving Medicare payments, and therefore make APM incentive payments.

Conclusion

The ACR appreciates the opportunity to provide comments on the CY 2021 MPFS proposed rule. We encourage CMS to continue to work with physicians and their professional societies throughout the rulemaking process in order to create a stable and equitable payment system. The ACR looks forward to continued dialogue 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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William T. Thorwarth, Jr, MD, FACR Chief Executive Officer

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