



October 5, 2020

The Honorable 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
Submitted via: www.regulations.gov

Re: File Code CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 3, 2020).

Dear Administrator Verma:

The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 8,800 members, including most US physicians who are practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally-invasive, image-guided therapies. SIR appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies proposed rule.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic (section II.F.)

SIR appreciates the Agency's efforts to reduce the physician burden related to evaluation and management documentation and the willingness to work with the medical community through the AMA CPT/RUC process to update the evaluation and management codes. However, the anticipated -9% cut in interventional radiology (IR) reimbursement to offset the evaluation and management changes in RVUs for CY2021 are devastating. Interventional radiology is a small specialty and cannot continue to offer safer minimally invasive treatments, shorter recovery times, and more advanced and cost-effective care to Medicare beneficiaries when repeated cuts to reimbursement are imposed by the Medicare payment system. Predictability and stability over time should be guiding principles of the Medicare payment systems. In the CY2020 MPFS Final

Rule CMS predicted a -6% impact for interventional radiology for CY2021 to offset the E/M changes. This proposed rule currently estimates the impact at -9% in IR payments and -11% in diagnostic radiology payments, which are services also provided by a large portion of our membership, to account for the E/M changes. Our physicians and their practices cannot withstand such drastic cuts, on top of the crushing losses encountered during the global pandemic.

TABLE 90: CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty					
(A)	(B)	(C)	(D)	(E)	(F)
Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact*
Total	\$96,557	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	\$497	-3%	-5%	0%	-9%

Recommendation: SIR urges CMS to refrain from implementing the -9% cut in reimbursement for our specialty and to also utilize its authority under the public health emergency declaration to waive budget neutrality requirements.

GPC1X

CMS is moving forward with their new add-on code 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 (Add-on code, list separately in addition to an evaluation and management visit)*. The Agency has received numerous requests seeking clarification on the (1) intended use of this code and (2) estimated utilization for the service. During prior rule making cycles the medical community expressed significant concern that the projected utilization for this code were too high. In this rule making cycle, not only did the Agency not provide the requested detail explaining the utilization numbers, their estimates in this proposed rule are even higher.

Recommendation: SIR urges CMS to (1) postpone the implementation of GPC1X, (2) work with the AMA CPT/RUC network to better establish the use of the code and (3) remove the estimated utilization numbers in the CY2021 formulas.

Global Periods

This proposed rule does not include any new proposals to apply the office visit increases to the visits bundled into global surgery payment. The medical specialty societies reject CMS’ establishment of a two-tiered system for evaluation and management services. We are disappointed by CMS’ ongoing argument that they do not believe physicians are performing follow-up care with their patients. Stakeholders have articulated in great detail the fatal flaws

with the RAND study, which CMS uses to defend their position that physicians are not seeing patients for follow-up care.

Recommendation: SIR urges CMS to apply the RUC recommended values to the bundled post-operative office visits.

Practice Expense Methodology AND Potentially Misvalued Services Under the PFS (RVUs – section II.B.)

SIR feels strongly that the RAND initiatives continue to have fundamental flaws, particularly the Phase II Rand Report discussing the use of hospital outpatient costs as the basis to re-establish PE RVUs. The Agency has received countless comments over the years from stakeholders identifying egregious irregularities in the outpatient cost data. So often hospitals use APC payments to quantify their costs, which is a circular methodology and highlights the unreliability of those data. It is inappropriate for the Agency to abandon the bedrock of the Medicare Fee Schedule, relativity.

Practice Expense Payments made under the MFS reflect physician work, professional liability insurance, and practice expense (PE) components. The current PE methodology for setting rates relies in part on data collected in the Physician Practice Information (PPI) Survey. In the current system, PE is broken into *direct* and *indirect* components. Direct PE includes nonphysician clinical labor, disposable medical supplies, and medical equipment that are typically used to provide a service. Indirect PE relates to such expenses as administration, rent, and other forms of overhead that cannot be attributed to any specific service. CMS stated that they are interested in refining the PE methodology and updating the data used to make payments under the PFS. They go on to say *they believe that potential refinements could improve payment accuracy and strengthen Medicare*. While those goals are laudable, the data/results included in the *Practice Expense Methodology and Data Collection Research and Analysis Interim Phase II Report (RAND)* are alarming. Table 7.3. *Impact of Using Outpatient Prospective Payment System–Based Relative Values for Total Practice Expense Relative Value Units, by Specialty* illustrates wild shifts in potential impacts to specialties (i.e. interventional radiology -23%, radiology -15% and vascular surgery -27%).

CMS also states in the proposed rule that they would like to “obtain[ing] the data as soon as practicable.” There is also a discussion in this proposed rule, within the AMA, to conduct another PPI survey to update physician and practice costs.

Recommendation: SIR implores the Agency to decelerate and work closely with stakeholders to analyze alternatives and/or modifications to the PE methodology. While CMS notes that they are *interested in hosting a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders*, it is critical to the success of the project that the Agency make informed decisions from the information collected in those Town Hall meetings as well as Technical Expert Panels (TEP). Holding them only in name is disingenuous and will lead to uninformed policy. If a new PPI survey is to be conducted it is imperative that the Agency and the AMA work closely with specialties to determine the most cost effective and thorough way to update their practice costs.

Recommendation: If the supplementary survey option is implemented by CMS, then SIR and other specialty societies will likely need to conduct supplemental surveys due to the complicated nature of their specialties. In this time of devastating cuts in reimbursement to practices and the global pandemic, specialty societies will need assistance in covering the costs to conduct supplemental surveys. In regard to PE RVUs, SIR strongly requests that CMS implement the RUC process and recommendations instead of relying on a flawed system, such as RAND.

Valuation of Specific Codes (section II.H.)

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 by the AMA through a screen of code pairs that are reported on the same day, same patient and same NPI number at or more than 75 percent of the time. The CPT Editorial Panel deleted CPT code 32405 and replaced it with 324X0 (Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed).

CMS disagrees with the RUC recommended median work RVU of 4.00 for 324X0 and is proposing a work RVU of 3.18 for code 324X0 based on the sum of the work RVUs of deleted code 32405 (work RVU = 1.68) and imaging code 77012 (work RVU = 1.50). SIR disagrees with CMS using an alternate approach in lieu of survey data, strong reference codes, and input from the RUC, radiologists, and interventional radiologists, a majority of which have experience performing this service in the past 12 months. CMS does not provide any supporting rationale or clinical information for their proposed work RVU of 3.18 other than debating survey times, primarily the intra-service time and total time ratio for this service, then justifying their proposed work RVU with the work RVU sum of deleted code 32405 and imaging code 77012. Combining the exact times of codes 32405 and 77012 is not an appropriate methodology for code valuation and would not be accepted by CMS if the combination of two bundled codes resulted in increased valuation. The specialty societies and the RUC worked together to value the code based on valid surveys, in depth discussion, and evaluation of comparator codes.

Recommendation: SIR strongly discourages CMS' methodology in valuing services by time-based ratios. This methodology is flawed and inaccurately treats all components of the physician time as having identical intensity. In addition, it lacks the rigor of the survey process and RUC panel evaluation.

The Proposed Rule text did not discuss the RUC's compelling evidence rationale for why this service was presently mis-valued, which suggests the Agency may have not considered this rationale. Since the deleted lung biopsy code 32405 was last RUC valued in 2010, cancer treatment protocols have evolved significantly to require more definitive tissue diagnosis including biomolecular marker profiles. Radiologists must now acquire a larger number of tissue samples for biomarker profiles that will guide initial or ongoing treatment decisions in these patients. Currently, radiologists typically obtain 3 or more core biopsy samples compared to 1-3 passes when this code was previously valued in 2010. As such, the societies requested, and the

The RUC approved these compelling evidence arguments. The increased tissue requirement (either in size or number) increases the risk for pneumothorax and other procedural complications. This requirement is similar for other organ lesions as well (e.g. hepatocellular carcinoma) as molecular based diagnoses influence treatment options. In current clinical practice lung cancer screening CT now identifies smaller-sized nodules requiring biopsy, typically in patients with emphysema and history of tobacco abuse. Advances in chemotherapy agents and treatment protocols in the past 5-8 years now require specific tissue diagnoses, which has impacted the risk/benefit ratio for sicker, more complex patients in whom a biopsy may have been deferred in the past when the results would not have effected management of the patient's treatment. These factors have resulted in more requests to biopsy smaller and/or increasingly challenging lung lesions. Overall, the work of performing a typical CT guided lung biopsy has become significantly more complex, challenging, and intense. The new code 324X0 has increased the total time and the intensity/ complexity, warranting the RUC recommended work RVU of 4.00.

The RUC recommendation for CPT code 324X0 was based on the median work RVU from robust survey results (30 minutes of pre-service evaluation, 5 minutes of pre-service positioning, 6 minutes of pre-service scrub/dress/wait, 40 minutes of intra-service time, and 20 minutes of post-service time) and favorable comparisons to MPC code 49405 *Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous* (work RVU= 4.00, intra-service time of 40 minutes and total time of 95 minutes) and CPT code 31288 *Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus* (work RVU= 4.10, intra-service time of 40 minutes and total time of 96 minutes). The RUC also compared CPT code 324X0 to the second key reference service (KRS) code 32550 *Insertion of indwelling tunneled pleural catheter with cuff* (work RVU= 3.92, intra-service time of 30 minutes and total time of 85 minutes). Image guided lung biopsy is more technically challenging and riskier than insertion of indwelling tunneled pleural catheter with cuff and the risk of pneumothorax is significantly higher. CPT code 324X0 is more intense and complex than code 32550, warranting the slightly higher work value. SIR urges CMS to accept a work RVU of 4.00 for CPT code 324X0.

Recommendation: SIR appreciates that CMS is proposing the RUC-recommended direct PE inputs for CPT code 324X0.

Medical Physics Dose Evaluation (CPT code 7615X)

The CPT Editorial Panel created CPT code 7615X (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report), which is a new PE-only code. Because of the high amount of clinical staff time and the fact that there are not analogous services, the PE Subcommittee requested that the specialty societies conduct a PE survey. In addition, they stated that the service is stand-alone, meaning that the medical physicist works independently from a physician and there are no elements of the PE that are informed by time from a physician work survey. Following the meeting, the specialty societies developed a PE survey, which was reviewed and approved by the Research Subcommittee.

Recommendation: SIR appreciates that CMS is proposing the RUC-recommended direct PE inputs for CPT code 7615X without refinement. However, SIR is concerned that CMS included CPT Code 7615X in the CY2021 PFS proposed-rule-outpatient-cap-list (codes subject to DRA cap). The Deficit Reduction Act (DRA) caps Medicare payment amounts for certain imaging service at the amount paid to hospitals under the Hospital Outpatient Prospective Payment System (OPPS). CPT Code 7615X describes medical physics dose evaluation for radiation exposure that exceeds the institutional review threshold. The code describes the work of clinical staff performing an evaluation following the procedure where the threshold of exposure was met. The service recreates the procedure to accurately determine organ specific doses resulting from radiation exposure during the procedure. We urge CMS to remove CPT Code 7615X from the DRA cap list.

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

CMS erroneously double-counted the utilization for new codes that had image guidance bundled, causing the Agency to incorrectly assert that the RUC was recommending a 20 percent increase in physician work for the Fine Needle Aspiration code family. After correcting for double counting the utilization for the newly created bundled codes, the work pool based on the RUC recommended values would have been instead resulted in a decrease by 15 percent using the CMS utilizations from the CY 2019 NPRM.

In the CY 2021 NPRM, CMS notes that they will "...welcome the submission of new information regarding these services that was not part of the previous CY 2019 review of the code family." Actual claims data from CY 2019 are now available. CMS' projected RVU pool for CY 2019 for the updated FNA code family is over twice as high as what actual claims data demonstrate for 2019; utilization of the newly created codes is largely identical to the source utilization from 10021 and 10022 immediately prior to their removal from the code set.

Recommendation: Based on the new information highlighted above and our further clarification on the misunderstanding, SIR urges CMS to accept a work RVU of 1.20 for CPT code 10021, a work RVU of 1.63 for CPT code 10005 and work RVU of 2.43 for CPT code 10009.

Venography (CPT codes 75820 and 75822)

The review of CPT code 75820 (Venography, extremity, unilateral, radiological supervision and interpretation) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 20,000 claims in a year. CPT code 75820 currently has a work RVU of 0.70 with 14 minutes of total time. This service involves the supervision and interpretation of a contrast injection and imaging of either the upper or lower extremity. For CPT code 75820, the RUC recommends 12 minutes preservice time, 20 minutes intra-service time, 10 minutes post-service time and 42 minutes of total time. The specialty societies' survey at the 25th percentile yielded a 1.05 work RVU, and it is the RUC's recommended work value. CMS is proposing the RUC recommended value for CPT code 75820.

CPT code 75822 (Venography, extremity, bilateral, radiological supervision and interpretation) was reviewed as part of the family of codes included with CPT code 75820. CPT code 75822 has a current 1.06 work RVU and 21 minutes of total time. The RUC recommended 15 minutes

preservice time, 30 minutes intraservice time, 12 minutes postservice time and 57 minutes of total time, and the survey's 25th percentile work RVU of 1.48. The service is similar to CPT 75820, except that this CPT code is bilateral, involving the supervision and interpretation of contrast injection and imaging of both of either the upper or lower extremities. The RUC recommended 1.48 work RVU and 57 minutes of total time for CPT code 75822. CMS is proposing these RUC recommended values for CPT code 75822.

Recommendation: SIR appreciates that CMS is proposing the RUC-recommended values for CPT Codes 75820 and 75822 as well as the direct PE inputs without refinements.

Introduction of Catheter or Stent (CPT code 75984)

The RUC recommended reviewing CPT code 75984 (Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess) radiological supervision and interpretation) after more utilization data was available, which resulted in this service being surveyed and reviewed for the April 2019 RUC meeting. SIR appreciates that CMS is proposing the work RVU of 0.83 as recommended by the RUC as well as the direct PE inputs without refinements.

Proposal to Establish New Code Categories (section III.N.) and Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS code G2170 and G2171)

For CY 2019, based on two new technology applications for arteriovenous fistula creation, CMS established two new HCPCS codes to describe the two modalities of this service. Specifically, CMS established HCPCS code C9754 (Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)) and HCPCS code C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed).

The HCPCS codes CMS created were for institutional payment systems, and thus did not allow for payment for the physician's work portion of the service. Stakeholders have stated that the lack of proper coding to report the physician work associated with these procedures is problematic, as physicians are either billing an unlisted procedure code, or are billing other CPT codes that do not appropriately reflect the resource cost associated with the physician work portion of the service. Stakeholders stated that separate coding for physician payment will allow billing when the procedures are furnished in either a physician office or an institutional setting, and be paid under the respective payment systems, as appropriate.

CMS has recognized that the lack of appropriate coding for this crucial physician service has become an even greater burden given the PHE that was declared effective January 27, 2020 for the COVID-19 epidemic. In order to mitigate potential health risks to beneficiaries, physicians and practitioners as a result of having this procedure performed in an institutional setting, CMS created two HCPCS G codes for percutaneous creation of an arteriovenous fistula (AVF). CMS stated that the codes went into effect July 1, 2020 and will be contractor priced. CMS argued

that this change *will allow for more accurate billing and coding of a crucial physician service that could then be performed in both institutional and office settings, thus mitigating unnecessary risk to beneficiaries, physicians and practitioners caused by disease transmission.*

The HCPCS G codes are described as follows:

- HCPCS G code G2170 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed.)
- HCPCS G code G2171 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, CMSn performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed.)

Medicare Administrative Contractors (MACs)

National Government Services (NGS) published a proposed local coverage determination (LCD) regarding Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis (DL38573) which included these two new G Codes on June 24th, 2020 with the comment period ending July 18th, 2020. In the LCD NGS stated “Coverage of the WavelinQ system must await resolution of ongoing safety issues as well as longer-term data” thus eliminating reimbursement for a service that has been covered in the hospital outpatient setting since 2019 under CMS’ HCPCS codes.

Recommendation: If CMS’ intent was to provide expanded access to this “*crucial physician service*,” then SIR is urging CMS to correct this critical oversight and clearly communicate that intent with their MACs. CMS’ change effectively eliminated coverage for this service to thousands of Medicare beneficiaries during a global health crisis, requiring America’s seniors to pay out of pocket for this “critical service”.

Updated Supply Pricing for Venous and Arterial Stenting Services

The use of the “stent, vascular, deployment system, Cordis SMART” (SA103) supply is no longer typical in CPT codes 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein) and 37239 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein). A new venous stent system has become the typical standard of care for these services, and a stakeholder supplied ten invoices for use in pricing this supply. As such, CMS is proposing to remove the SA103 supply item from CPT codes 37238 and 37239. CMS is proposing to replace it with a newly created “venous stent system” (SD340) at the same supply quantity. CMS is proposing a price of \$1,750.00 for the venous stent system.

Recommendation: SIR supports the proposed change to replace the stent for CPT Codes 37238 and 37239.

Market-Based Supply and Equipment Pricing Update

For CY 2021, CMS received invoice submissions for approximately a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. The submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. CMS reviewed the invoices as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. SIR has concerns with the updated pricing for several interventional radiology supplies, as outlined below.

SD136 vascular sheath

The proposed price for the vascular sheath (SD136) was determined by removing the sheath from the eight submitted kit invoices and then averaging the resulting price together with the single standalone sheath invoice. SD136 can be found in over 70 CPT codes, not just RF services. SIR does not support this proposed pricing methodology. The current pricing of \$52.80 is more representative of the sheaths used in the variety of procedures with SD136 as a direct supply.

Recommendation: SIR requests that CMS maintain the current pricing for SD136 of \$52.80.

SD155 catheter, RF endovenous occlusion

The proposed price for the RF endovenous occlusion (SD155) was also determined by removing the catheter from the eight submitted kit invoices and then averaging the resulting price together with the single standalone catheter invoice. This methodology results in CMS proposing to establish a price of \$382.50 for SD155. SIR believes the methodology outlined significantly undervalues SD155. Attached to this comment letter is documentation to support \$475 as a more appropriate reimbursement rate for SD155.

Recommendation: SIR requests that CMS update the pricing for SD155 to \$475

SD089 guidewire, hydrophilic

CMS is proposing an updated price of \$13.35 for SD089 for CY2021. Attached to this comment letter is documentation to support \$27.76 as a more appropriate reimbursement rate for SD089.

Recommendation: SIR requests that CMS update the pricing for SD089 to \$27.76.

Technical Corrections to Direct PE Input Database and Supporting Files

Recommendation: SIR requests that CMS update the unit type for SA122 clarivein kit to “kit” in the CMS database.

Proposal to Remove Selected National Coverage Determinations (section III.J.)

SIR appreciates CMS' effort to consider requests to remove established National Coverage Determination (NCD) or reconsideration of an existing NCD and established an expedited administrative process, using specific criteria, to remove NCDs older than 10 years. SIR sent a letter to CMS on November 20th, 2019 requesting for the expedited removal of National Coverage Determination (NCD) for Transvenous (Catheter) Pulmonary Embolectomy (240.6). However, upon reviewing the CY2021 MPFS, the Society noticed that NCD 240.6 was not on the list of removed NCD. SIR urges CMS to remove this NCD immediately because this particular policy had not been reviewed or updated since 1987. In the original analysis of the policy, CMS indicated that the procedure was experimental with little to no supporting evidence qualifying it medically necessary for coverage. However, within the last 30 years, there has been substantial evidence that proves the procedure as a concrete, medically necessary procedure to treat pulmonary embolism (PE).

Recommendation: SVS urges the Agency to add NCD 240.6 to the list of outdated/obsolete NCDs being considered for removal for CY2021.

Care Management Services and Remote Physiologic Monitoring Services (section II.E.); Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule (section III.M.)

CMS is proposing to add eight new codes, HCPCS code GPC1X and CPT codes 99XXX, 96121, 99483, 99334, 99335, 99347, and 99348, to the list of Medicare telehealth services list for CY 2021. The Agency is also proposing to add the following services provisionally on a category 3 basis: CPT codes 96130, 96131, 96132, 96133, 96136, 96137, 96138, 96139, 99281, 99282, 99283, 99315, 99316, 99336, 99337, 99349, and 99350.

Recommendation: SIR appreciates CMS' initiative to expand telehealth services to benefit patients all over the country; especially those in rural communities. SIR applauds CMS' efforts and urges the Agency to extend these measures indefinitely.

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.F.); Medicare Shared Savings Program (section III.G.); Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 (section III.I.); CY 2021 Updates to the Quality Payment Program (section IV.); Collection of Information Requirements (section VI.) CAHPS for MIPS Patient Assignment; Regulatory Impact Analysis (section VIII.) - Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA)

CMS proposal that QCDR measures approved for the 2022 performance year with face validity must be fully tested prior to being self-nominated for any subsequent performance periods to be considered for inclusion in the MIPS program.

Recommendation: SIR believes this is creating a burden for QCDRs. Because data to fully test an SIR quality measure for validity is difficult to capture, we cannot support requirements that each measure be tested for validity beyond face validity.

CMS proposes to permit QCDRs (and qualified registries) to support the reporting of MVPs beginning with the 2022 performance period. This timeline is problematic because QCDRs and QRs must submit their self-nomination application prior to the publication of the final rule for the next performance year.

Recommendation: SIR encourages CMS to establish a process to allow QCDRs (and qualified registries) to select which MVPs they can support following the publication of the final rule.

Current policies allows CMS to remove measures at the reporting year because they are topped out or that there was not enough clinicians reporting the measure. CMS policies to approve QCDR measures for two years ensures stability in the program and allows QCDRs and measure developers adequate time to prepare for measures to be retired or replaced We do not support CMS removing a measure before its second year for it being topped out or duplicative of a more robust measure. The auditing requirements proposed by CMS makes it necessary to collect additional PHI to meet those requirements. SIR aims to collect only PHI necessary to conduct its work. These additional audit requirements makes it difficult for SIR to meet this aim.

Recommendation: Significant amount of time has been spent developing QCDR measures. SIR believes these measures should be included MVPs.

CMS proposes that stakeholders consult patients and/or patient representatives as part of the MVP development process as a pre-requisite for CMS to consider the candidate MVP and must include the full set of Promoting Interoperability measures in their MVP.

Recommendation: SIR requests further guidance on this requirement.

SIR appreciates the opportunity to provide feedback on the proposed rule. If additional information is required, please contact Erica Holland, Interim SIR Executive Director at eholland@sirweb.org.

Sincerely,



Michael Dake, MD
President, SIR

cc: Erica Holland, Interim Executive Director, SIR
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