

September 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–1715–P; Medicare Program: CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the 2020 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, published in the *Federal Register* on August 14, 2019 (84 Fed. Reg. 40482).

While there are numerous important proposals in this proposed rule which we provide comments on below, the AMA has been particularly focused on two issues. First, the AMA greatly appreciates CMS' proposal to align the previously finalized Evaluation and Management (E/M) office visit coding change with the framework adopted by the Current Procedural Terminology® (CPT®) Editorial Panel. We urge CMS to finalize the CPT codes, CPT guidelines, and AMA/Specialty Society RVS Update Committee (RUC) recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC.

Second, the AMA has worked extensively to provide CMS with suggestions on how to improve the Merit-Based Incentive Payment System (MIPS), and we commend CMS for responding to recommendations made to CMS by the AMA in its MIPS Value Pathways (MVP) track proposal. While we appreciate CMS' efforts to develop a high-level MVP framework, the AMA urges CMS to revise aspects of the MVP proposal, such as ensuring that participation in the MVP program is voluntary, structuring the MVP as a more holistic track for physicians, and providing a minimum point floor for those who report via the MVP track. We look forward to continuing to work with CMS on both of these proposals to ensure the final regulations improve care for patients while also reducing physicians' administrative burden. See below for our summary and detailed comments on each PFS and QPP issue.

The following outlines our principal recommendations on the 2020 proposed rule.

PFS

- The AMA greatly appreciates CMS' proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. We urge CMS to finalize the CPT codes, CPT guidelines, and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC. CMS should urge Congress to implement positive updates to the Medicare conversion factor to offset the justified increases to office visits.
- The AMA recommends that CMS implement the proposed increases to office visits to the visits included within the surgical global payment packages. The AMA also provides specific comments on the methodology issues included in the three RAND reports.
- The AMA fully supports and endorses the recommendations and comments of the RUC regarding potentially misvalued services. We also support the RUC's recommendations for valuation of specific codes.
- The AMA generally supports the proposed coverage changes for new codes relating to substance use disorder, remote patient monitoring (RPM), E-visits, and self-measured blood pressure monitoring. We recommend that CMS work with the CPT editorial panel to further promote the use of digital medicine in Medicare.
- The AMA supports CMS' attempts to improve data collection efforts for the determination of Professional Liability Insurance Relative Value Units (PLI RVUs), and encourages CMS to work with the RUC to make the PLI RVUs as accurate as possible for all specialties.
- The AMA commends CMS on several aspects of the proposed payment policies for office-based and opioid treatment program (OTP) management of Opioid Use Disorder (OUD) treatment, which are consistent with previous AMA policy recommendations, and urges that these proposals be finalized. The AMA recommends that CMS consider modifications to better account for patients who need a more resource-intensive bundle of services.
- The AMA is supportive of efforts to increase the utilization of care management services; however, CMS should inform Congress that positive updates to the Medicare conversion factor are needed to expand these services.
- The AMA urges CMS not to finalize its proposal that would place the burden on physicians to notify beneficiaries of coinsurance. Instead, CMS should eliminate any out-of-pocket costs associated with screening colonoscopies.

MIPS Value Pathways (MVPs)

The AMA greatly appreciates CMS' efforts to further improve the Merit-based Incentive Payment System (MIPS) program through MVPs and agrees with CMS that the goal of MVPs should be to reduce the complexity of the MIPS program and physicians' reporting burden. We commend CMS for incorporating feedback from the physician community as it works to improve the MIPS program.

While we are appreciative of CMS' efforts to develop a high-level MVP framework and recognize it is a first step in the right direction, we recommend that several policies included in the MVP framework outlined in the proposed rule be changed. Specifically, CMS should:

- Ensure participation in the MVP is voluntary by allowing physicians to opt-in to an MVP or continue in the existing MIPS program;

- Focus on measures that are meaningful to physicians rather than population health administrative claims measures;
- Make the MVP track more holistic, allowing physicians to be accountable for lower-cost, higher quality care for a specific health condition, procedure, or risk factor by permitting attestation in the Promoting Interoperability (PI) category and automatically applying credit for Improvement Activities (IAs) into MVPs to reduce reporting burden;
- Establish appropriate incentives for physicians to transition to a new QPP track and report on new measures;
- Engage with specialty societies to develop MVPs in a collaborative process similar to the process for developing specialty measure sets; and
- View the first few years of MVP implementation as a pilot testing period, as it will take time and effort to develop, refine, and educate physicians on this new QPP track.

QPP

Because 2020 is a transition period to MVPs, we believe it is especially important to provide stability in the MIPS program. CMS should continue to encourage participation while specialty societies and physicians shift their time and focus toward developing or preparing to report on MVPs to make the MIPS program more sustainable in the long run. Specifically, we urge CMS to:

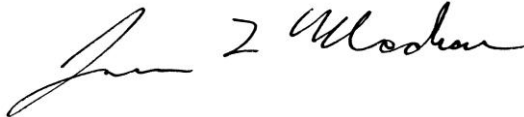
- Gradually increase the performance threshold in 2020 to 35 points to ensure continued high levels of participation in the program, to support small practices, and to be consistent with the size of the proposed increase in the exceptional performance threshold;
- Maintain the existing MIPS quality measures, to reduce burden, and allow for more measures to form the basis of MVPs. We also recommend that CMS not finalize the new measure removal factor;
- Maintain the data completeness threshold at 60 percent for all reporting mechanisms. However, the AMA continues to believe 50 percent is a sufficient threshold;
- Institute a manual+data driven approach to calculate measure benchmarks;
- Ensure licensing/sharing a measure with another Qualified Clinical Data Registry (QCDR) or Third-Party Intermediary (qualified registry or Electronic Health Record (EHR) is at the discretion of the QCDR measure steward and does not jeopardize data integrity. If the steward does not comply, they should not be subject to CMS automatically removing the measure(s) from the program;
- Not move to adopt global and population health administrative claims measures in MIPS, specifically we do not support finalizing the proposal to include the All-Cause Unplanned Admission for Patients with Multiple Chronic to the Quality Performance Category starting with the 2021 performance period;
- Focus opioid related quality or PI measures on how well patients' pain is controlled, whether functional improvement goals are met, and therapies used as opposed to the current approach of only focusing on preventing and/or reducing opioid use;
- Retain the cost category weight at 15 percent of the final MIPS score for at least 2020;
- Remove the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures that hold physicians accountable for costs outside their control;
- Maintain the existing participation threshold of requiring one clinician in a group to perform an IA for the Tax Identification Number (TIN) to receive IA credit to ensure consistency with program requirements and minimize burden. We support CMS' proposal for a 90-day performance period;
- Reduce the burden of health Information Technology (IT) measurement in the PI category by focusing on relevance of a measure to clinical practice and patient improvement, and eliminating any

additional electronic data collection that does not align with a physician's clinical workflow. CMS should move away from prescriptive PI measures tied directly to certified EHR (CEHRT) use and instead score measures based on a "yes/no" attestation; and

- Exercise greater flexibility in allowing Advanced Alternative Payment Models (APMs) and Other Payer APMs, including medical home models and capitation arrangements, to be counted for purposes of achieving QP status.

We thank you for the opportunity to provide input on this proposed rule. Our detailed comments on the proposed rule are located in the enclosed attachment. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and a stylized "M".

James L. Madara, MD

Enclosures

**2020 Physician Fee Schedule and Quality Payment Program Proposed Rule
Detailed Comments of the American Medical Association**

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I. PROVISIONS OF THE PROPOSED RULE FOR THE 2020 PHYSICIAN FEE SCHEDULE

A. Determination of Potentially Misvalued Services Under the Physician Fee Schedule and Valuation of Specific Codes

- **Recommendation:** The AMA fully supports and endorses the recommendations and comments of the RUC regarding potentially misvalued services. We also support the RUC's recommendations for valuation of specific codes.

The AMA urges CMS to reinstate the RUC recommendations for the potentially misvalued services as part of the 2020 PFS final rule. In addition, the AMA urges CMS to accept all of the RUC's recommendations for valuation of specific codes. CMS modified recommendations for 91 codes. The majority of these recommendations were unanimously approved by the RUC, meaning 29 physicians and other health care professionals, from a variety of specialties, agreed on the relativity of these specific services.

B. Updates to the Geographic Practice Cost Indices (GPCIs)

- **Recommendation:** The AMA understands that some localities will experience significant decreases in their GPCIs and recommends that CMS review comments from organizations representing physicians who practice in these localities closely to ensure that the data used in the GPCI updates are correct.

For CY 2020, CMS is conducting its statutorily required three-year review of the GPCIs. The proposed GPCIs do not include the 1.0 work GPCI floor, as the Balanced Budget Act of 2018 only extended the floor through the end of 2019. CMS has also made available a contractor report on the 2020 GPCI update providing more detailed information than is available in the proposed rule.

The contractor report describes how the contractor collected and summarized PLI premium data for use in updating the PLI GPCIs for the 2020 proposed rule, which generally changed more than the other GPCIs. There were some major swings in the PLI GPCIs but PLI accounts for a small share of average total payments, so these swings generally translate into fairly modest payment changes. The methodology used for the data collection appears similar to that used in previous years, with rate filings for insurers that in most states covered more than 50 percent of the market. Some localities that noted significant reductions in their PLI GPCI, such as Connecticut and Massachusetts, have noted that the contractor only looked at insurers representing about 30 percent of the market in that locality, even though Connecticut has relatively high PLI premiums when compared to the rest of the country.

Different GPCI issues drove the impacts in different states, with rural states like Montana and South Dakota facing GPCI reductions due to the expiration of the work GPCI floor, many localities seeing changes due to updated PLI GPCI data, and three California localities facing four percent payment reductions from 2019 to 2021 due to changes in the practice expense GPCI. The AMA urges CMS to give serious consideration to comments submitted by state medical societies and other organizations representing physicians who practice in localities facing GPCI reductions, and to ensure that the data driving these reductions are accurate.

C. Market Basket Supply and Equipment Pricing Update

- **Recommendation:** The AMA encourages CMS to continue to carefully consider all pricing data, including invoices and other supporting evidence that it receives from the specialty societies, and to move to an ongoing update process for supplies and equipment that is open to public comment through the rulemaking process.

In the CY 2019 PFS proposed rule, CMS used their authority under section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) to initiate a market research contract with a consulting firm, StrategyGen, to update the direct practice expense inputs for supply and equipment pricing. Based on the report from StrategyGen, CMS proposed to update pricing for 2,017 supply and equipment items currently used as direct practice expense (PE) inputs. Market research resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis. CMS proposed to update supply and equipment pricing over a four-year phase-in. The AMA appreciates CMS' careful consideration and additional price research for all instances where the accuracy of a supply or equipment code was questioned by commenters prior to finalizing the proposal in the 2019 PFS final rule.

In the CY 2020 PFS proposed rule CMS received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. The invoices were reviewed and researched by StrategyGen and based on this research CMS is proposing to update the prices of 36 supply and equipment items as listed in Table 9 of the CY 2020 proposed rule. The AMA takes this as indication that CMS is accepting comments, invoices, and additional pricing data from stakeholders throughout the four-year transition period. The AMA will continue to encourage the specialty societies to use the transition period as an opportunity to evaluate pricing updates and submit invoices and other pricing data as needed. The AMA believes this is extremely important as it is difficult for specialty societies to identify every supply and equipment item that might be inaccurately priced all at once. The AMA appreciates CMS' diligence in conducting further review of these 36 supply and equipment items. The AMA strongly encourages CMS to continue to carefully consider all pricing data, including invoices and other supporting evidence that it receives from the specialty societies throughout this comment period and the entirety of the four-year transition period.

The AMA agrees with CMS that there is a need for comprehensive review of supply and equipment pricing and, in general, supports CMS' efforts to this effect. However, the AMA has concerns that supply and equipment pricing will quickly become outdated once the transition to updated prices is complete in 2022. The AMA encourages CMS to move to an ongoing update process for supplies and equipment as well as clinical labor staff cost per minute that is open for public comment through the rulemaking process.

D. Determination of Professional Liability Insurance Relative Value Units (PLI RVUs)

- **Recommendation:** The AMA supports CMS' attempts to improve data collection efforts for the determination of PLI RVUs and encourages CMS to work with the RUC to make the PLI RVUs as accurate as possible for all specialties.

CMS is seeking comment on the proposed methodological improvements to the development of the PLI premium data. CMS contracted with the Actuarial Research Corporation and has provided the *CY 2020 Medicare PFS Proposed Update to the GPCIs and PLI RVUs Interim Report* as part of its supporting

documentation to the *Proposed Rule*. In the CY 2018 final rule for the PFS (CMS-1676-F), CMS indicated that it would not finalize its proposal for professional liability insurance relative value (PLI RVUs). Significant comments were submitted concerning the accuracy of the premium data collection. The AMA appreciates CMS' efforts to improve the data collection and methodology surrounding the PLI RVUs. The *Interim Report* describes how the process has been modified to increase the potential for obtaining premiums for historically underrepresented specialties and to reflect current understanding of the marketplace.

For CY 2020, CMS uses a broader set of PLI filings, available online from the System for Electronic Rates & Forms Filing (SERFF) Filing Access Interface and largest market share insurers in each state, to obtain a more comprehensive data set. This expansion of filing subtypes beyond those listed as "physician" and "surgeon" represents a welcome methodological change from the prior update, resulting in an expanded amount of premium data available for specialties that previously had insufficient data. There were some states (non-SERFF) that did not have expanded subtypes readily available and the AMA encourages CMS to request this from the state insurance departments in the future. CMS was successful in acquiring national premium data for 16 additional specialties that were formerly mapped entirely to another specialty. There is no longer mention of the arbitrary threshold that triggered the crosswalk methodology used by CMS in developing the PLI RVUs for specialties for which there was not premium data for at least 35 states.

Overall, we commend the CMS on its attempts to improve the premium data collection process. The AMA supports improvements in data collection efforts, and will continue to do so, such that updated premium data is obtained for all Medicare physician specialties, other health care professionals and facility providers, in all 50 states. The AMA also appreciates the opportunity to comment and to work together to make the PLI RVUs as accurate as possible for all specialties and other health care professionals. The AMA urges CMS to consider the more detailed suggestions offered in the RUC comment letter on this issue. Specifically, the AMA urges CMS to consider the RUC's input on five key areas of the PLI methodology, including: 1) non-physician health care professional, premium rates; 2) major vs. minor surgery service risk groups; 3) imputation, partial and total; 4) low volume services; and 5) technical component (TC) only services.

E. Digital Medicine

- **Recommendation:** The AMA generally supports the proposed coverage changes for new codes relating to substance use disorder, RPM, E-visits, and self-measured blood pressure monitoring. We recommend that CMS work with the CPT editorial panel to further promote the use of digital medicine in Medicare.

The AMA applauds the significant steps forward to advance digital medicine in the Medicare program. There remains a compelling need to modernize the Medicare program to enable practice transformations to ensure that Medicare is able to meet the needs of beneficiaries while improving patient health outcomes, increasing cost effectiveness, improving population health, enhancing care team experience, and promoting equity. The rapid advances in technology should be leveraged and deployed to achieve these essential goals. The AMA has detailed in the past three years the substantial commitment the organization has made to support practice transformations to address these challenges. The AMA's Digital Medicine Payment Advisory Group (DMPAG) continues to provide clinical expertise at the intersection of technology and medicine to identify additional technology-enabled services and provided helpful feedback incorporated below.

1. Telehealth

Telehealth, two-way audio-visual real time communications, continues to evolve. The AMA cautions against CMS' assumption that all services that can be delivered via telehealth have already been covered. Notably, the Veterans Health Administration and commercial insurers are deploying peripherals and diagnostic tools to support telehealth services that will enable increased data collection to aid an interactive session between a patient and their physician. The DMPAG is carefully considering and evaluating evolving technologies and norms in this area and expanded services that can be delivered via telehealth with peripherals by the DMPAG.

The AMA also strongly urges CMS to conduct demonstrations under existing waiver authorities by lifting geographic restrictions and originating site restrictions for Medicare beneficiaries across the board on a number of states to allow Medicare beneficiaries in urban locations to receive telehealth services. This will provide CMS with essential information on beneficiary outcomes and potential cost savings or cost neutrality.

The AMA also strongly urges CMS to issue guidance to state Medicaid directors concerning the changed coverage policies starting in 2019 and proposed for 2020 to ensure the dual eligible beneficiaries receive the benefit of the expanded coverage of these new technology-enabled services. And, the AMA strongly urges CMS to meet with the Federal Communications Commission to identify either joint or coordinated demonstrations under each agency's existing authorities to expand access to telehealth and other technology enabled services.

The AMA also strongly urges CMS to issue a comprehensive list of telehealth services along with comprehensive guidance that is user-friendly and easy to navigate to aid stakeholders to in identifying covered telehealth services that no longer have originating and geographic restrictions.

2. Substance Use Disorder Services

The AMA supports the proposed coverage of new Healthcare Common Procedure Coding System (HCPCS) II codes for substance use disorder via telehealth: GYYY1, GYYY2, and GYYY3.¹ The AMA agrees that components of HCPCS codes GYYY1-3 describing care coordination are commonly furnished remotely using telecommunications technology do not require the patient to be present in-person with the practitioner when they are furnished.

3. Remote Patient Monitoring and Management (RPM)

The AMA strongly supported the activation of and payment for CY 2019 for each of the three CPT codes developed to described services and technical components of remote physiologic monitoring: 99453,

¹ HCPCS code GYYY1: Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month; HCPCS code GYYY2: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month; HCPCS code GYYY3: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure)

99454, and 99457.² The AMA strongly supports the proposed activation for CY 2020 of a new CPT code 994X0 that reflects clinical practice.³ Furthermore, we also strongly support the related proposal to change the descriptor for 99457 to be ‘initial’ which is needed to reflect the addition of 994X0.

The foregoing RPM codes were developed through concerted and thoughtful deliberations with input from nationally recognized clinical experts in digital medicine services as well as coding, valuation, and coverage. The DMPAG in turn submitted applications for the creation of these new codes to the independent CPT Editorial Panel which approved the applications for new codes. The DMPAG aggregated and conducted in-depth interviews with national flagship health systems and providers deploying these systems and evaluated significant supporting meta-analysis of clinical trials establishing clinical benefit. An existing body of evidence exists, which was relied upon in making such recommendations, demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, and those facing access barriers due to geography, limited mobility, and who are medically fragile.

a. RUC Recommendations and Cost Data Submissions

We urge CMS to utilize the AMA’s RUC recommendations and cost data submission. We urge CMS to utilize this information for valuations of 99453, 99454, and 99457. Furthermore, the AMA urges CMS to utilize the RUC’s data for 994X0. CMS proposes to value an additional 20 minutes of the services described at an RVU lower than that for the same service for the first 20 minutes (99457). CMS’ rationale, using an analogy to CPT code 88381, is inapt and there is not an obvious reason as to why review by qualified health professionals is less valuable after 20 minutes aggregate each month. With more data and analysis of such data providing even greater insight into health trends for a patient, the analysis done in the additional 20 minutes is at least as valuable as the first 20 minutes (if not, in some cases, more valuable). We strongly urge CMS to adopt the RUC-recommended RVU of 0.61.

We also strongly urge CMS to not finalize the proposal to reduce the practice expense of code 99453 from 0.54 wRVU in CY2019 to 0.52 wRVU in CY2020, and to not reduce the practice expense of code 99454 from 1.77 in CY2019 to 1.71 in CY2020. CMS has not identified any changes in equipment, supplies, or staff which would justify a reduction in practice expense. We strongly encourage CMS to maintain the existing practice expense for these codes in CY2020.

b. General Supervision for “incident to” Billing of RPM

The AMA strongly supports the proposed change to allow general supervision for 99457 and 994X0 rather than requiring direct supervision. CMS is proposing to include 99457 and 994X0 as designated

² 99453 Remote monitoring of physiologic parameter(s) (e.g. weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment; 99454 Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days; and 99457 Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

³ 994X0 Remote physiologic monitoring treatment management services, clinical staff/physician /other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes).

care management services because such services can be furnished under general supervision. However, the AMA urges CMS to clarify that such codes are permitted for physiologic monitoring and are not limited to chronic conditions. In proposing the change from direct to general supervision for RPM, CMS effectively designates RPM as a “care management service,” stating: “because RPM services (that is, CPT codes 99457 and 994X0) include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely, we believe that CPT codes 99457 and 994X0 should be included as designated care management services.”⁴ CMS now appears to require that one or more chronic conditions be present in order for RPM services to be reimbursed which is contrary to CMS’ prior position on this issue. Furthermore, the code descriptors for CPT Codes 99453, 99454, and 99457 do not include any reference to chronic conditions, whereby code descriptors for Chronic Care Management services specifically require two or more chronic conditions for reimbursement. To clarify, these codes have descriptors for physiologic monitoring.

c. Clarification: RPM Codes Under Home Health Prospective Payment System and PFS

The AMA strongly urges CMS to issue guidance specifying when home health agencies are able to report costs under the Home Health Prospective Payment System (HHPPS) (and which costs) in the context of qualified health professionals billing the professional component for 99457 and 994X0 on the PFS. Guidance has not been proposed through rulemaking for CY 2020 despite multiple requests by the AMA. The lack of guidance invites confusion and inadvertent billing errors that can be easily remedied by CMS issuing subregulatory guidance as to the interplay between the activated codes on the PFS and the allowable RPM costs under the HHPPS. We strongly urge that CMS prioritize issuing a clarification.

4. Reimbursement for Online Digital Evaluation Services (E-Visits)

CMS proposes to cover six new non-in person codes to describe and reimburse for “patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office.” The AMA supports the activation and payment of CPT codes 98X00, 98X01, and 98X02, which are codes for practitioners who cannot independently bill E/M services. We recommend that CMS work with the CPT Editorial Panel to address issues with the descriptors by seeking technical corrections that could be effective by January 1, 2020. The creation of HCPCS Level II codes would create confusion and administrative burdens for providers responsible for using two different sets of codes depending on payer policy. We urge CMS to utilize the RUC valuation data and recommendations for the CPT codes and to utilize the RUC valuation data and recommendations for all six codes.

⁴ 84 FR 40482, 40555.

5. *Advance Beneficiary Consent*

CMS seeks comment on whether a single advance beneficiary consent can be obtained for certain communication-based technology services designated in the final 2019 PFS, including virtual visits (HCPCS 2012), remote evaluation of images (HCPCS 2010), and Interprofessional Internet Consultations (CPT Codes 99446-99449, 99451 and 99452). The AMA continues to receive reports from physicians that these notice requirements are a barrier to access and are overly burdensome. The AMA strongly urges a single annual notice that is both meaningful and clear. We urge CMS to develop as part of subregulatory guidance suggested models of both digital notice and consent as well as paper-based. In addition, the AMA strongly urges that documentation be made in a manner that is most appropriate as part of workflow, both administrative and clinical, and consistent with other program integrity documentation requirements.

6. *Self-Measured Blood Pressure Monitoring and Revised Ambulatory Blood Pressure Monitoring*

CMS proposes activation and coverage of Self-Measured Blood Pressure Monitoring and revised Ambulatory Blood Pressure Monitoring CPT codes, and proposes adoption of the RUC valuation recommendations and cost data for codes. The AMA strongly supports the activation, revision, and valuation of the codes as proposed by CMS. In September 2018, the CPT Editorial Panel created two new codes and revised four other codes to describe self-measured blood pressure monitoring services and to differentiate self-measured blood pressuring monitoring services from ambulatory blood pressure monitoring services.⁵

Improving high blood pressure control rates is a major priority for the AMA and the CMS proposal is an important step in advancing this work. The AMA strongly supports expanded coverage to provide patient-centered care utilizing new technologies. These codes represent an important advancement of efforts to address areas of high disease burden and cost with improved technologies available to beneficiaries and their health care team.

⁵ The foregoing CPT codes along with related ones include:

- 99X01 (Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration) and is a PE only code.
- 99X02 (Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings, one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient)
- 93784 (Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report)
- 93786 (Ambulatory blood pressure monitoring, recording only)
- 93788 (Ambulatory blood pressure monitoring, scanning analysis with report)
- 93790 (Ambulatory blood pressure monitoring, review with interpretation and report)
- 93784 is a composite code that is the sum of CPT codes 93786, 93788, and 93790.
- 93786 and 93788 are PE only codes

F. Bundled Payments for OUD Treatment

- **Recommendation:** The AMA commends CMS on several aspects of the proposed payment policies for office-based and opioid treatment program (OTP) management of OUD treatment which are consistent with previous AMA policy recommendations and urges that these proposals be finalized. The AMA recommends that CMS consider modifications to better account for patients who need a more resource-intensive bundle of services.

1. *Office-based OUD Treatment Payment Proposals*

In the 2019 PFS proposed rule, CMS sought comments on designing a new bundled payment for office-based management of patients with substance use disorders. In response, the AMA recommended that CMS focus the bundled payment policy on treatment for OUD rather than trying to craft something that would be appropriate for more broadly defined substance use disorders. AMA comments were based on a [concept paper](#) jointly developed by the AMA and the American Society of Addiction Medicine (ASAM), and recommended five major elements:

1. A payment to support the initial evaluation, diagnosis, and treatment planning for a patient with OUD and the initial month of medication-assisted treatment (MAT);
2. A monthly payment to provide MAT for as long as continued therapy is determined to be appropriate, including providing or coordinating the provision of counseling and social services;
3. Higher payments for patients with more complex needs;
4. Flexibility to support services of both primary care physicians and addiction medicine specialists, including consultation between them; and
5. Add-on payments to support integration of technology-based treatment and recovery support tools.

In the current rule, CMS proposes new codes that would provide monthly payments for a bundled episode of care, including development of a treatment plan, care coordination, individual and group therapy, and counseling for patients with OUD. The bundled payments would exclude medications approved by the U.S. Food and Drug Administration (FDA) for use in the treatment of OUD. There would be separate payments for the first month of treatment to cover induction and development of the treatment plan, payments for subsequent months of treatment (with no limit on duration of treatment), and an add-on code to cover patient circumstances that require substantial extra resources to manage.

The AMA particularly commends CMS for proposing separate payments for the induction and maintenance phases of OUD treatment. Addiction medicine and many other specialties that have been working to develop alternative payment models have identified the lack of adequate financial support for the services patients should initially receive—a complete diagnostic work-up, development of an initial treatment plan, and educating patients about their condition and how best to manage it at home—as a serious shortcoming in the fee-for-service system. The AMA also commends CMS for stating that the monthly maintenance payments may continue for as long as the patient’s OUD treatment continues. Arbitrary limits on OUD management with MAT have been a major problem in many health plans.

The total relative value units proposed in Addendum B would yield 2020 national average payment rates of about \$412 for the induction code (GYYY1), \$367 for the maintenance code (GYYY2), and \$70 for the add-on code (GYYY3). These payment amounts may serve as a good starting point in comparison to payments that would have been available for individual services under the Medicare physician payment

schedule, and we believe they would enable more physicians to offer OUD treatment to their patients. The AMA recommends several refinements to the current proposal:

- As the AMA recommended in last year's comment letter, payment amounts should be risk stratified to reflect patients who need more services or more resource-intensive services. For example, some patients may need the services of a typical care manager but others will need a trained behavioral health specialist. The current proposal allows only for an add-on code based on additional minutes of service provided but that is inadequate to recognize real differences in patients' needs and the different mix of services that may be required to address those needs, not just differences in the amount of time. If the payment amounts for the initial and ongoing service bundles are stratified into at least two categories reflecting different levels of patient need, using the criteria that ASAM has defined for different levels of services, the add-on code could then serve as an outlier payment. After there is more experience with the bundled payments, the relative values should be reviewed to ensure they reflect the actual resources needed to provide the services.
- As also noted in last year's comments, payment amounts should recognize different types of practice arrangements. Some practices will include addiction specialists and behavioral health counselors and be able to directly provide all the services in the bundle, but some practices may need to consult with specialists and/or refer patients for counseling, a social worker, or other support services outside the practice. The cost of the consultation must be reflected in the payment amounts to ensure that small practices and practices in rural areas will be able to offer these critical services.
- CMS should consider how its proposed policies could be best applied or modified to address patients transitioning from a different treatment setting to office-based OUD treatment. This could occur, for example, if a patient begins treatment for OUD with methadone and then transitions to office-based treatment with buprenorphine, or in other cases where a patient might need to move to office-based treatment after being in a facility setting.

2. *OTP Payment Proposals*

CMS also provides an extensive and detailed proposal to implement the new Medicare Part B benefit for OTPs that was established by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, including definitions of terms such as OUD and OTP, a methodology for determining Medicare payment for services and drugs provided by OTPs, and Medicare enrollment requirements for OTPs. The SUPPORT Act provides for payments to OTPs accredited by the Substance Abuse and Mental Health Services Administration to cover: medications used in the treatment of OUD, including oral, injected, and implanted buprenorphine, methadone, and naltrexone; medication dispensing and administration; counseling; individual and group therapy; toxicology testing; and other services deemed appropriate. While the new payments for office-based OUD treatment would be monthly, the OTP services would be defined on a weekly basis.

The proposed payment policies for OTPs are consistent with the proposed payment policies for office-based treatment of OUD, except where the statute requires differences, such as including medication and laboratory test costs in the OTP bundled payments. The AMA recommends that similar modifications be made in the OTP policies as are recommended above for the office-based OUD treatment services. For example, although the proposed rule notes that CMS recognizes "that there is a range of service intensity

depending on the severity of a patient's OUD," it has not actually proposed variations in the weekly payment bundles to reflect differences in severity.

G. Physician Supervision for Physician Assistant Services

- **Recommendation:** The AMA recommends maintaining the current regulations on physician supervision for physician assistant services because current regulation is consistent with the vast majority of state scope of practice laws. Alternatively, if CMS finalizes the proposed changes, AMA recommends that CMS further revise the regulation to ensure physicians maintain the ultimate responsibility for coordinating and managing the patient's care.

The AMA recognizes the desire for CMS to align its regulation with state scope of practice laws. Under state scope of practice laws, no state allows physician assistants (PAs) to practice independently without any physician supervision or collaboration. Moreover, with the vast majority of states—more than 40—requiring physician supervision of PAs, the AMA believes that current Medicare regulations are consistent with the majority of state laws. Even PA state scope of practice laws that allow physician collaboration instead of supervision, still require the PA to provide patient care largely within a dependent relationship with a physician and within the context of a physician-led health care team. For example, in Indiana, PAs may only practice within a dependent collaborative relationship with a physician.⁶ Therefore, we recommend that CMS maintain the current regulations on physician supervision for physician assistant services.

The AMA supports PAs working under the direction of and supervision of a physician and within the context of a health care team and state prerogative on PA scope of practice. As such, we support the concept of state prerogative in the proposed rule; however, if CMS finalizes the proposed changes, we recommend CMS include language to require PAs to work within a health care team led by a physician.

We also strongly urge CMS to remove the proposed regulatory language: "In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services." As stated earlier, most, but not all states require physician supervision. Some states require physician collaboration, which still requires that physicians maintain the ultimate responsibility for coordinating and managing the patient's care. Yet, this proposed language could be interpreted to preempt these state laws to, in effect, have the unintended consequence of eliminating any physician oversight of physician assistants, opening the door for independent practice of PAs.

⁶ Collaboration is defined as "overseeing the activities of, and accepting responsibility for, the medical services rendered by a physician assistant and that one of the following conditions is met at all times that services are rendered or tasks are performed by the physician assistant. (a) the collaborating physician or the physician designee is physically present at the same location at which the services are rendered or tasks performed by the physician assistant. (2) When the collaborating physician or physician designee is not physically present at the location at which services are rendered or tasks are performed by the physician assistant, the collaborating physician or the physician designee is able to personally ensure proper care of the patient and is: (A) immediately available through the use of telecommunications or other electronic means; and (B) able to see the patient within a medically appropriate time frame for consultation, if requested by the patient or physician assistant." (Indiana Code 25-27.5-2-4.9)

Accordingly, the AMA recommends that CMS revise § 410.74(a)(2)(iv) to require that a PA “performs the services in a health care team led by a physician and in accordance with state law and regulations governing physician assistants in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed.” This amended language would ensure that the statutory physician supervision requirement for PA services at § 1861(s)(2)(K)(i) of the Social Security Act are met.

H. Review and Verification of Medical Record Documentation

The AMA supports the proposal to establish a general principle to allow the physician who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or other members of the medical team. The AMA seeks confirmation from CMS that only physicians are responsible for signing and verifying the documentation of the residents and medical students. Eliminating and streamlining reporting, monitoring, and documentation requirements will improve the health care delivery system by reducing unnecessary burdens for physicians and making the health care system more effective, simple, and accessible. We also agree that this general principle should be applied across the spectrum of all Medicare-covered services paid under the physician fee schedule.

I. Care Management Services

- **Recommendation:** The AMA is supportive of efforts to increase the utilization of care management services; however, CMS should inform Congress that positive updates to the Medicare conversion factor are needed to expand these services.

The AMA is supportive of efforts to increase the utilization of these services and expand care management to additional patients. However, asking physicians to pay for these newly described services by redistributing money away from other important physician services is unfair. CMS must account for the savings for these services in decreased hospital visits and emergency visits to offset the cost of new and expanding coverage of care management services. CMS should also inform Congress that positive updates to the Medicare conversion factor are critical to expand these services, while maintaining the integrity of the valuation within the Resource-Based Relative Value System (RBRVS). The AMA supports the use of CPT to describe all physician services and recommends that CMS work with the CPT Editorial Panel to implement changes in coding to describe care management.

1. Transitional Care Management (TCM)

CMS examined studies that conclude that patients who receive TCM services have lower hospital readmission rates, lower mortality, and incur lower costs. Based on these findings, CMS seeks to increase the utilization of TCM services and expand payment for care management. To incentivize additional utilization, billing requirements will be modified to allow TCM codes to be reported concurrently with other codes. The AMA appreciates that CMS also proposes to increase payment for the two TCM codes as recommended by the RUC. The AMA recommends that CMS finalize the RUC recommendations for TCM.

CMS proposes to disregard the current CPT guidelines⁷ and allow the codes listed in the guidelines to be reported, if performed, in conjunction with TCM. CMS should work with the CPT Editorial Panel to align reporting rules. In general, it adds confusion and administrative burden when CMS implements policy changes that differ from CPT. In addition, the AMA notes that the following codes have either never been surveyed or have not been recently reviewed, making it difficult to fully assess if a potential overlap exists in the services: 99091, 99358, 99359, G0181, and G0182. If CMS finalizes a policy to allow additional reporting of concurrent care management codes, CMS should issue very clear guidance that physicians should not use multiple codes to describe the same service. For example, when reporting time-based codes, the same minute should only be counted once.

2. Chronic Care Management (CCM)

CMS is also proposing to adopt new add-on codes for CCM, which will allow providers to bill incrementally to reflect additional time resources that are required in certain cases. CMS requests comment on whether to implement G codes for these expanded CCM codes for 2020 or wait for anticipated changes to CPT in 2021. CMS also proposes to clarify the language describing the comprehensive care plan required for CCM codes.

The AMA and the RUC have consistently commented that CMS should work with the CPT Editorial Panel to create CPT codes, rather than G codes. Transitioning back and forth between CPT and G codes is administratively burdensome. The CPT Editorial Panel is considering an application for new add-on codes for CCM in September 2019 for the CPT 2021 publication. Clarifications regarding the patient care plans are also part of the proposal to the CPT Editorial Panel. The AMA strongly supports CCM services and we are encouraged that the initial CCM code 99490 has increased from 1 million in claims in 2015 to 4 million in claims in 2018. Additional codes and changes to CCM may be warranted; however, we encourage CMS to work with the CPT Editorial Panel to describe the services and consider data from the RUC on appropriate valuation.

3. Principal Care Management (PCM)

CMS proposes to create two new codes for PCM services, which would pay physicians for providing care management to patients with a single high-risk disease. The current CCM codes require patients to have two or more chronic conditions. CMS estimates an additional \$125 million in annual spending for these services, offset by reductions to the Medicare conversion factor.

This proposal deserves serious consideration and discussion and is best reviewed by the CPT Editorial Panel. CMS proposes this time-based code at the same time it is proposing an add-on code to each office visit code for a very similar patient. In addition, there may be other codes that describe the work performed for these patients, including the office visit codes, just revalued to include time spent three

⁷ CPT 2019 Guidelines: A physician or other qualified health care professional who reports codes 99495, 99496 may not report care plan oversight services (99339, 99340, 99374-99380), prolonged services without direct patient contact (99358, 99359), home and outpatient INR monitoring (93792, 93793), medical team conferences (99366-99368), education and training (98960-98962, 99071, 99078), telephone services (98966-98968, 99441-99443), end stage renal disease services (90951-90970), online medical evaluation services (98969, 99444), preparation of special reports (99080), analysis of data (99091), complex chronic care coordination services (99487-99489), medication therapy management services (99605-99607), during the time period covered by the transitional care management services codes.

days prior and seven days following each office visit. It is important that the service be appropriately described without overlap with other services. We recommend that the specialty society who presented these codes to CMS prepare a CPT coding application to be considered by the February 2020 CPT meeting and, if adopted, survey for resource costs for the April 2020 RUC meeting. CMS should include these recommendations for comment in the 2021 PFS proposed rule.

Due to the similarity between the description of the PCM and CCM services, CMS proposes that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. The AMA also supports requiring that the treating practitioner obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record. However, CMS should provide an exception to this requirement where the treating practitioner documents that advance consent was not possible either due to emergency conditions or other exigent circumstances where a delay could result in negative patient health outcomes.

J. Coinsurance for Colorectal Cancer Screening Tests

- **Recommendation:** The AMA urges CMS not to finalize its proposal that would place the burden on physicians to notify beneficiaries of coinsurance. Instead, CMS should eliminate any out-of-pocket costs associated with screening colonoscopies.

CMS proposes establishing a requirement that the physician who furnishes a colorectal cancer screening notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply. The AMA supports CMS' attention to this issue; however, we disagree that the solution is to place the burden of notifying beneficiaries of Medicare's colorectal screening coverage onto providers. As we have stated previously, the AMA strongly urges CMS and Congress to use their authority to eliminate out-of-pocket costs associated with screening colonoscopies to help increase access to this potentially life-saving service.

The AMA also encourage CMS to consider the impact its proposed policy could have on deterring patients from colorectal cancer screening. When faced with the potential that a "free" screening could cost hundreds of dollars out-of-pocket, some beneficiaries may forgo the screening, which will not only be detrimental to their health, but also may eventually add significant financial burden to our health care system with increase in diagnosis of advanced colorectal cancers.

CMS' proposal that physicians notify Medicare beneficiaries of its coverage policy is inconsistent with reducing administrative burden for physicians. If CMS mandates a conversation with the patient regarding coverage and documentation of that conversation in the medical record, it will add to the already heavy administrative load faced by physicians and their staff.

CMS should prioritize allowing physicians and other medical staff to focus on providing high quality health care rather than serving as the primary point of contact to explain Medicare's coverage policy to patients. It is also impractical logistically for the coding and billing staff to meet with each patient before the patient is seen by the physician, as many practices outsource coding and billing services to a centralized location. Therefore, we urge CMS not to finalize its proposal and instead to eliminate any out-of-pocket costs associated with screening colonoscopies.

K. Opportunities for Bundled Payments under the PFS

- **Recommendation:** CMS should immediately work with the CPT Editorial Panel on code concepts that arise from the comments to this Request for Information on bundled payments to ensure the established CPT process is followed.

CMS is requesting information on opportunities to expand the concept of bundling to improve payment for services under the RBRVS. Specifically, CMS seeks to explore options for establishing payment rates or adjustments for services that are furnished together. CMS notes options could include a per-beneficiary payment for multiple services or condition-specific episodes of care. CMS specifically notes that it believes the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing the service, allows considerable flexibility for developing payments under the RBRVS.

The AMA notes that the RUC has reviewed the valuation of numerous bundled services.⁸ Over ten years ago, the RUC, via the Relativity Assessment Workgroup, began identifying services that are inherently performed together by the same physician on the same day of service. The screen started with services reported on same date by same physician 95%+ with another service. The screen was then lowered for services reported together 75%+ of the time to capture more services to be bundled. After five iterations of this screen, the CPT Editorial Panel has created code bundling solutions and the RUC submitted recommendations for approximately 340 services. The most common bundled combination is to ensure that any imaging inherent to a procedure is bundled within the code and valuation.

The CPT Editorial Panel worked with several organizations to develop episode bundles for services performed by physical therapists and occupational therapists. After development of described bundles of care, CMS expressed concern. In the end, the codes were not implemented as CMS preferred to pay for services performed at a granular level.

The AMA highlights that the RUC has significant expertise in reviewing the resources required in the provision of bundled services. Specialty societies are best able to determine if opportunities exist for development of new CPT codes to describe an episode of care. CPT code applications should be submitted for these services and the CPT Editorial Panel will promptly review these proposals. Accordingly, CMS should immediately work with the CPT Editorial Panel on code concepts that arise from the comments to this proposed rule to ensure the established CPT process is followed.

⁸ Obviously, codes with assigned global periods of 010 or 090 days have multiple discrete services bundled into one payment amount. These services include: all pre-operative work performed within 24 hours of the surgery; the surgery itself; all post-operative work on the day of the procedure and for 010 or 090 days following the procedure, including hospital and office visits. In 2019, there are 465 010-day global codes and 3,777 090-day global codes. In addition, there are 17 maternity codes (MMM global) that describe the bundled services in obstetrical care codes. For example, CPT Code 59400 begins with the first visit of antenatal care and continues through labor and delivery and then all postpartum care. End Stage Renal Disease monthly codes and Radiation Treatment Management are two commonly performed services that are valued with a bundle of services. In summary, bundled services are common in the RBRVS payment system.

L. Payment for E/M Services

- **Recommendations:** The AMA greatly appreciates CMS' proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. We urge CMS to finalize the CPT codes, CPT guidelines, and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC. CMS should work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the justified increases to office visits.

The AMA appreciates CMS' proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. The policy changes for the E/M office visits would be effective for services starting January 1, 2021. The CPT coding changes will retain five levels of coding for established patients; reduce the number of levels to four for new patients (by deleting 99201); and revise the code definitions and guidelines. A new CPT code for extended office visit time will also be implemented. The changes also revise the times and medical decision-making definitions for the office visit codes. History and physical exams should continue to be performed as medically appropriate; however, these elements will no longer be a consideration for code level selection. Physicians can choose the E/M visit level based on either medical decision making or time. The AMA agrees that this new coding framework will lead to administrative burden relief and better describe office visits as they are performed today.

The AMA appreciates the confidence CMS displays in the RUC process in proposing to adopt the RUC recommended work values, physician times, and practice costs for the stand-alone E/M office visits. CMS states, "The RUC recommendations reflect a rigorous robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians." In fact, one of the most consistent findings of the survey was that all specialty data indicated an increased complexity and time spent in providing office visits. Our comments reflect that the new CPT framework, where code selection is dependent on time spent or the level of medical decision-making, inherently defines the work to be equivalent, regardless of the physician's specialty.

Based on the information provided in the proposed rule, the RUC recommendations for physician work, time, and direct practice expenses contribute to five to six percent redistribution between those physicians who routinely provide office visits and those physicians or other health care professionals who do not report office visits. This is a significant reduction to absorb into practices that are already practicing at maximum efficiency. We urge CMS to finalize the CPT codes, CPT guidelines, and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC. CMS should work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the justified increases to office visits.

1. Proposed Add-On Code GPCIX

In addition to the CPT and RUC recommended changes, CMS proposes to implement a Medicare-specific add-on code for E/M office visits 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. We agree with the Medicare Payment Advisory Commission that the add-on code is problematic because it does not clearly define the types of visits that require additional resources and may lead to complexity and additional documentation burden. If CMS wishes to pursue this add-on code, the AMA recommends that CMS postpone the implementation of this add-on code, allowing the CPT

Editorial Panel to better define the service to meet its intended purpose. We note that CMS has received comments from the RUC, American Academy of Family Physicians (AAFP), and others that coding solutions are best addressed through CPT.

CMS does not provide any specific assumptions regarding the projected utilization for this new add-on code. A comparison between CMS impact tables indicate that more than \$1.5 billion will be redistributed between specialties if this code is implemented. Although the codes descriptor implies that all physicians may report the code, only the following specialties are projected to receive payment for the service, per the comparison of impact tables 111 and 115: Allergy, Cardiology, Endocrinology, Family Medicine, General Practice, Geriatric Medicine, Hematology/Oncology, Internal Medicine, Interventional Pain Management, Neurology, Nurse Practitioner, Obstetrics/Gynecology, Otolaryngology, Pediatric Medicine, Physician Assistant, Psychiatry, Rheumatology, and Urology.

If CMS plans to proceed with the proposed add-on code policy, CMS must explain the projected use of this code in detail. We request that CMS articulate all of the underlying assumptions regarding the potential use of this code and develop a specific impact table in the final rule indicating the impact by specialty. It appears that CMS assumes that add-on code would be applied to nearly 50 percent of the claims for these 18 specialties combined. If this same assumption is applied across all specialties, the cost of this code to the Medicare program is \$2.2 billion.

We understand that CMS' intent is to ensure that physicians are adequately paid for those patients that are outliers to the typical patient described in the valuation of office visits. However, the vignettes utilized in the survey often describe a patient that would have ongoing primary care services and/or have a single, serious, or complex chronic condition. For example, the vignette 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. The AMA agrees that regardless of service performed, a surgical procedure or an office visit, physicians should have a way to identify outlier patients where additional payment is warranted. However, the proposed code 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 not well defined. For example, what is the definition of "serious" in this code descriptor? Accordingly, we believe the add-on code is problematic and urge CMS to postpone its implementation and work with the CPT to better define it.

2. Systematic Adjustments to Other Stand-Alone Codes

CMS also seeks comments on whether it is necessary to make systematic adjustments to other services to maintain relativity between these services and E/M office visits, and whether it is necessary to make corresponding adjustments to E/M codes describing visits in other settings. The AMA does not believe that CMS should make systematic adjustments to services without additional review by the CPT Editorial Panel and the RUC. Any decision making on valuation of other codes first requires a review of the coding structure to assure that it aligns with the same burden reduction modifications of the office visits. Once the office visit coding changes and valuations are finalized, the CPT/RUC Workgroup on E/M would reconvene to consider similar coding changes to other E/M services. We urge CMS to treat any comments requesting increases to other E/M services, or other services mentioned in this section of the proposed rule, as potentially misvalued services and subject to additional survey and review in 2020 and beyond. A

list of these identified services should be published in the final rule.

3. *RUC Surveyed Physician Time*

CMS requests comments on physician time. The AMA urges CMS to adopt the RUC recommended median total time for the office visits, as submitted. The RUC recommendations were thorough in explanation of these time data. The total median time for office visits should be placed within the “total time” field in the CMS time database.

4. *Practice Expense Direct Inputs*

The AMA appreciates CMS’ proposal to adopt nearly all the RUC recommendations for direct practice expense inputs for the office visit services. CMS has declined to accept the desktop computer, ED021, *computer, desktop, with monitor*, used in examination rooms as a direct medical expense. We disagree with this decision. The computer is dedicated solely to each patient throughout the visit to collect history, share and discuss lab and test results, and document the visit. It is an essential tool in conducting today’s office visits and CMS should recognize it as a direct medical equipment cost.

5. *Suggested Modifications to Coding Guidelines – Prolonged Services*

CMS clarifies its interpretation of reporting CPT prolonged service codes 99358 *Prolonged evaluation and management service before and/or after direct patient care; first hour* and 99359 *Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (List separately in addition to code for prolonged service)*, relatively uncommonly reported codes used for reporting prolonged evaluation and management service before and/or after direct patient care. CMS states that “CPT codes 99358, 99359 can be used to report practitioner time spent on any date (the date of the visit or any other day)” This is not correct. These codes are not reported for time spent on the date of an office or other outpatient encounter (99202-99205, 99211-99215).

CMS further states that it is unclear if 99358 and 99359 can be reported in addition to or instead of the new 99XXX add-on code to describe extended time. The descriptor and guidelines clearly state that 99XXX should be utilized for the extended time on the date of encounter and that 99358 and 99359 are NOT to be reported for this time: “(Do **not** report 99XXX in conjunction with 99354, 99355, **99358**, **99359**, 99415, 99416).”⁹

The AMA agrees that 99XXX describes the add-on code for extended time and that this CPT code is administratively simpler than the original CMS proposal.

⁹ 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 (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)

(Use 99XXX in conjunction with 99205, 99215)

(Do **not** report 99XXX in conjunction with 99354, 99355, **99358**, **99359**, 99415, 99416)

(Do not report 99XXX for any time unit less than 15 minutes)

CMS states that CPT codes 99358 and 99359 may need to be redefined, resurveyed, and revalued. The AMA recommends that the CPT/RUC Workgroup on E/M review the issues discussed in this proposed rule and ensure that the codes and guidelines are clarified, as needed, prior to any future RUC survey.

6. Alternative Values Based on Flawed Work/Time Change Ratios

Potentially considering alternative relative values for CPT codes 99212 and 99214 by merely applying a formula based on a change in time illustrates the flaw displayed throughout the review of RUC recommendations this year. The entire concept of the RBRVS is for one service to be paid relative to another service based on the resources typically utilized in providing the service. This is applied through magnitude estimation. In evaluating the office codes, the RUC carefully reviewed not only the survey data, that CMS acknowledges to be robust, but also the relationship of the codes to other services. In addition, the RUC made certain that the office visit codes were valued appropriately to each other. If CMS were to modify the values of 99212 or 99214, it would distort these important relationships. Importantly, 99212 and 99214 already have a modestly lower work per unit time than the other office visit codes. Any reduction would create a misvaluation of 99212 and 99214 compared to the other office visit codes. The AMA recommends that CMS finalize the proposal to accept the RUC recommendations for the E/M office visits as submitted.

| CPT Code | Descriptor | Work RVU | Total Time | Work Per Unit Time |
|-----------------|--|-----------------|-------------------|---------------------------|
| 99202 | New Pt, straightforward medical decision making, 15-29 min day of visit | 0.93 | 22 minutes | .042 |
| 99203 | New Pt, low level medical decision making, 30-44 min day of visit | 1.60 | 40 minutes | .040 |
| 99204 | New Pt, moderate level medical decision making, 45-59 min day of visit | 2.60 | 60 minutes | .043 |
| 99205 | New Pt, high level medical decision making, 60-74 min day of visit | 3.50 | 85 minutes | .041 |
| | | | | |
| 99211 | Est Pt, Supervision | 0.18 | 7 minutes | .026 |
| 99212 | Est Pt, straightforward medical decision making, 10-19 min day of visit | 0.70 | 18 minutes | .039 |
| 99213 | Est Pt, low level medical decision making, 20-29 min day of visit | 1.30 | 30 minutes | .043 |
| 99214 | Est Pt, moderate level medical decision making, 30-39 min day of visit | 1.92 | 49 minutes | .039 |
| 99215 | Est Pt, high level medical decision making, 40-54 min day of visit | 2.80 | 70 minutes | .040 |
| | | | | |
| 99XXX | Prolonged visit new/est pt, add'l 15 min | 0.61 | 15 minutes | .041 |

7. Office Visits Included in Surgical Global Payment/Maternity Care

Although the surgical specialties participated in the RUC survey and their data were the same, and often greater, than primary care and other specialties, CMS proposes not to apply the office visit increases to

the visits bundled into global surgery payment. The AMA strongly urges that CMS reconsider this position. CMS emphasized the robust survey utilized in the valuation of office visits and this survey demonstrates what the law requires, all physicians should receive the same payment for the same service.

The RUC votes on the valuation of office visits are posted [here](#). RUC members serve as experts in ensuring that relativity is fairly applied to all services described by individual CPT codes. This was particularly evident in the RUC votes for the valuation of office visits. As CMS reviews comments from individual specialty societies on the incorporation of office visit increases to the post-operative office visits, it is important to understand that some will be motivated by monetary impacts to their members. The 27-1 vote by the RUC, however, is motivated on ensuring fairness and appropriate relativity within the RBRVS.

CMS is still in the process of gathering information on global surgery codes and does not propose modifying the values of visits into the bundled payment until it is assured that the number and level of visits are accurate. Physicians who work in practices with 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island are required to report using CPT 99024 on post-operative visits furnished during the global period for select procedures furnished on or after July 1, 2017. CMS encourages stakeholders to comment on the three RAND reports it released with this proposed rule regarding global surgery. Detailed flaws in the RAND analyses are outlined below. We do not believe the reports should be used to reject the RUC recommendation of applying the increase to E/M office visits to post-operative visits in the global period.

The post-operative work of cataract surgery illustrates the flaw in conflating the valuation of the individual visits with the RAND reports on the ongoing claims reporting of 99024. The RUC's recent recommendations to include three office visits in the post-operative work for cataract surgery is supported by claims reporting of 99024 and other extant data and studies. The ophthalmology survey data for office visits reflect similar time and work as the primary care data and RUC submitted overall data. It is, therefore, not appropriate to distort the relativity of the post-operative visits for cataract or any other surgical procedure. If CMS believes that certain codes should be identified for further review of the number of post-operative visits, it should be a separate process under the misvalued code initiative.

CMS should implement the RUC recommendation to increase the post-operative office visits and maternity care bundled visits to retain relativity within the RBRVS. Increasing the visits bundled into the surgical global payment, would increase spending by approximately \$440 million, requiring an approximate 0.4 percent reduction to the Medicare conversion factor. This is a minor budget neutrality impact in comparison to the impacts proposed for the increases to the stand-alone office visits and other CMS proposals.

8. CMS History of Valuing Office Visits in the Post-Operative Period

The relativity of the RBRVS must retain integrity and ensure that office visits with patients are valued consistently, regardless of specialty. The new office visit framework requires physicians to report on either time or medical-decision making. The surveys of these new codes indicated a high level of consistency in the work required for office visits by each specialty. CMS has acknowledged this equivalent work for nearly 30 years. Each time stand-alone office visits increased since 1992, the visits bundled into the surgical global period also increased. The following are the three instances of these increases:

- 1997 First, Five-Year Review of the RBRVS
- 2007 Third, Five-Year Review of the RBRVS
- 2011 Elimination of consultation codes led to budget neutrality adjustments to office visits

9. Inconsistent Arguments Regarding Bundled Services in the Proposed Rule

In this proposed rule, CMS expresses its interest in increasing bundled payments under the Medicare Physician Fee Schedule. If CMS aims to increase bundled payments, it is counter-intuitive to attempt to deconstruct bundled payment for surgical procedures. These bundled procedures include all pre-operative work in the 24 hours before surgery, the surgery itself, and then post-operative work on the date of the surgery and in the 10 or 90 days following. These services include not only direct face-to-face interactions with the patient and family but also care management services.

M. Review of RAND Reports

- **Recommendation:** The AMA recommends that CMS indicate specific codes which it believes are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period. The AMA also provides specific comments on the methodology issues included in the three RAND reports.

The Medicare Access and CHIP Reauthorization Act (MACRA) required CMS to collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. The statute stipulated that CMS use these data and other available data, as appropriate, to improve the valuation of surgical global services. To comply with these requirements, CMS contracted with the RAND Corporation. As part of this ongoing effort, CMS included three new RAND reports with this proposed rule.

Previously, CMS has appropriately aligned the changes in valuation of the office visits in the surgical global period with the valuation of the stand-alone office visits. This time, responding to political pressure from certain stakeholders and the RAND analysis of incomplete claims data, CMS has proposed to pay surgeons at a different rate from other physicians and distort the relativity within the established RBRVS. The AMA recommends that CMS instead indicate specific codes which it believes are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period.

In addition, the RAND reports are already outdated. For example, the RUC has recently reviewed cataract surgery. The three office visits incorporated in the global period for 2020 align with the three office visits reported by ophthalmologists in the MACRA-mandated global code data collection project. The new office visit code framework requires at least 10 minutes be spent on the date of encounter to report a 99212 and 20 minutes to report a 99213. The global for cataract surgery now includes one 99213 and two 99212. The RAND survey and report on the time spent on post-operative visits for cataract surgery is consistent with these code levels. The RUC will review hip arthroplasty in October 2019. If there are other services that CMS is specifically concerned about, the services should be identified.

CMS has requested specific comments regarding three RAND reports, which are included below.

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

Since July 1, 2017, Medicare practitioners in nine states have been required to report on the postoperative visits they furnish during the global period of specified procedures using CPT code 99024 *Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*. The 299 010-day or 090-day surgical global procedures included in this initiative are those that are furnished by more than 100 practitioners and either are nationally furnished more than 10,000 times annually or have more than \$10 million in annual allowed charges.

The AMA does not believe that this dataset can reasonably be used to forecast any overall trends, given the limited and likely intermittent participation of eligible physicians as well as the current difficulty the CMS and RAND researchers have implied in matching up procedures to CPT code 99024. Only 46 percent of practitioners were expected to submit tracking code 99024 through June 2018. 54 percent of physicians eligible for this data collection project were either not aware of the requirement to participate or were unable to participate for another reason. In addition, only 17 percent of eligible physicians were classified as “robust reporters,” indicating that a majority of those that did participate did so intermittently or did not begin until partway through the reporting period. If most of the eligible providers did not participate, the median count of post-op visits would be zero irrespective of what study participants reported, and the mean number of visits would be greatly understated.

Participation also varied widely by both specialty and state. Primary care physicians only participated at a rate of 16 percent and NPs/PAs only at a rate of 23 percent; these providers collectively account for nearly 40 percent of the 40,000 eligible providers in the nine states and perform a large proportion of the 010-day global services included in the study. The participation rate by state varied widely, with the highest participating state, North Dakota, participating at a rate four times higher than that of the lowest participating state, Nevada (per figure 3.2 in report).

Furthermore, the dataset that includes only practices with 10 or more practitioners is potentially not representative as most physicians are in practices that have fewer than 10 providers. The AMA 2018 Physician Practice Benchmark Survey indicated that 54 percent of physicians are in practices with fewer than 10 physicians. In addition, for surgical specialties, 64 percent of physicians are in practices with fewer than 10 physicians.

| 2018 AMA Physician Practice Benchmark Survey¹⁰ | | | | | |
|--|---------------------|-------------------|--------------------------|----------------------|--------|
| Practice size by physician specialty | | | | | |
| Practice size: | Physician specialty | | | | Total |
| | Medical specialties | Other specialties | Primary care specialties | Surgical specialties | |
| Fewer than 10 physicians | 53.8% | 35.0% | 60.5% | 63.7% | 53.5% |
| 10 or more physicians or direct hospital employees | 46.2% | 65.0% | 39.5% | 36.3% | 46.5% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| N | 568 | 857 | 1152 | 762 | |

Note: Medical specialties mostly includes internal medicine subspecialties such as cardiology, neurology, allergy, etc. Primary care specialties include family medicine, internal medicine, pediatrics, etc. Surgical specialties include general surgery and the various surgical subspecialties. Physicians who work directly for a hospital are not asked about their practice size; for this table, these physicians are grouped in with the “10 or more physicians.”

We do not agree with the RAND conclusion that only 39 percent of 090-day global visits and 4 percent of 010-day global visits were performed. Many flaws exist in the computation to arrive at these figures. First, 54 percent of physicians in the nine states who were eligible to participate, did not do so. RAND inappropriately assumes that each of these physicians did not provide any office visits in any surgery’s global period. Second, RAND includes ½ day work proxies for 99238 in the denominator of expected visits. The ½ 99238 in the CMS time files are simply proxies for additional work preparing the patient for discharge from the outpatient setting. Physicians would never report a 99024 for this work. Third, the study used physician time files that are several years old. Modifications to cataract surgery and other procedures’ post-operative visits in 2019 and 2020 dramatically change the results of this computation. If RAND utilized the robust reporters only; eliminated the ½ 99238 from the expected visits; and utilized the 2020 CMS time files, we compute that 51 percent of the expected visits were captured in the reporting of 99024.

RAND used the following definition to categorize study participants as robust reporters, “ten or more 90-day global procedures performed and half of those procedures include at least one reported visit reported during the global period.” This definition is flawed as it excludes any providers that only perform 010-day global procedures. In addition, most providers that joined the reporting initiative after the first day of the survey period would still be counted as robust reporters, when they participated in at least roughly half the reporting period. If RAND improved the definition of robust reporters, the number of reported visits compared to expected visits would be greater than 51 percent.

The top three 010-day global codes, 17000, 17004 and 17110, make up 65 percent of the utilization for all 010-day global services in the study. These three codes are typically performed by the same specialty, dermatology, and are all from the same destruction of benign or premalignant lesions code family. As all RAND analyses that refer to 010-day global services overall are volume-weighted, the findings are

¹⁰ <https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf>

dominated by these three services and, therefore, are not representative. For 090-day global codes, cataract surgery (codes 66982, 66984) and hip/knee arthroplasty (codes 27130, 27447) collectively account for 28 percent of the volume. As stated, cataract surgery was reviewed recently and the post-operative visits now align with the 99024 claims data collected. The RUC is reviewing hip/knee arthroplasty in October 2019.

The RAND researchers indicated that they attempted to expand their analysis to differentiate between visits not performed at all versus visits that were performed, but under an expanded definition. For example, tracking code 99024 was reported 15,955 times for 010-day global services shortly after the end of the global period (days 11-15), which if added to the visits reported within the 010-day global period, would increase the total number of visits by 37 percent and the ratio of observed visits versus expected visits would have increased by approximately 50 percent. Furthermore, when examining visits reported by other providers using either 99024 or a separately reported E/M service, the total number of post-operative visits would increase by another 75 percent. If these numbers are applied to only eligible physicians who were robust reporters, the ratio for observed versus expected increases dramatically. If the top three codes (17000, 17004 and 17110), are excluded from the 010-day global analysis; and the more expanded definitions of a visit are included; and the analysis is limited to robust reporters, then the 010-day global codes do in fact appear to typically include a post-operative visit.

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

To comply with MACRA's requirements, CMS also contracted with RAND to conduct a survey to collect additional data on post-operative services, including the level of post-operative services. RAND launched a pilot of the survey in fall 2017 with a sample size of 557 practitioners, and received only a single complete response. Following this setback, CMS and RAND decided to greatly narrow the scope of their survey initiative to only three high-volume services, cataract surgery (only CPT code 66984), hip arthroplasty (only CPT code 27130) and complex wound repair (CPT codes 13100, 13101, 13120, 13121, 13131, 13132, 13151, and 13152).

RAND's main conclusion in the second report was that the average visits were somewhat shorter than anticipated for cataract surgery (16.4 minutes vs 19.4 minutes) and hip arthroplasty (22.9 minutes vs. 29.6 minutes) and longer for complex wound repair (21.8 minutes vs 16 minutes). However, RAND misinterpreted the findings of their survey data as they compared only the survey physician time "on the day of the visit" to the CMS physician time file, where the pre-service and post-service time of E/M services is not specific to the date of the encounter, and inappropriately excluded nurse practitioner (NP) and PA time from their visit time comparison analysis. Additionally, in 2019, time is not the only factor relevant in selecting a code level.

RAND categorized NP/PA survey data as "staff time" and incorrectly observed that "...such staff time would be considered as part of PE in the RUC process and not contribute to the physician time component nor to the level of the visit." While this is the case for work performed by clinical staff, this is never the case for qualified health care professionals who can separately report Medicare services. The researchers did not account for Medicare rules on "incident to" and split/shared E/M services. When a nurse practitioner or physician assistant assists with an office visit, both the work of the physician and the work of the NP/PA is used to select the level of the visit if the requirements for "incident to" are met and the patient is an established patient.

RAND's survey for hip arthroplasty showed that for 37.4 percent of the surveyed physician visits, part of the visit logged by the physician included work performed by an NP/PA. The survey data also showed that of those visits, the NP/PA spent an average of 16.9 minutes. This survey data only included NPs and PAs that "assisted in the visit"; the survey respondents were explicitly instructed to "not include NPs, PAs and other staff who are billing for this visit separately." Therefore, it was made clear to the survey respondents that they should only include time estimates for work that was solely reported under their claim. As an NP or PA assisted 37.4 percent of the reported physician visits and the NP/PA spent an average of 16.9 minutes helping to provide the visit, the average hip arthroplasty visit would include 6.3 minutes ($16.9 \text{ minutes} \times 0.374$) of NP/PA time. Adding the 6.3 minutes to the day of physician time of 22.9 minutes would equal 29.2 minutes, which is very similar to the average CMS time cited in the study of 29.6 minutes. Similarly, seven percent of complex wound repair visits included NP/PA assistance averaging 19.1 minutes. This time should have been included with the wound repair time comparison analysis.

The RAND survey also collected time data before and after the date of the encounter. The researchers observed that "If this time were to be added to the time spent on the day of the visit, it would increase time spent related to the visit by 30 percent to 40 percent depending on the procedure." As the current pre-service and post-service CMS times are not specific to the day of service, this survey time should have also been included in the analysis to have made a like to like comparison. Comparing day-of service time to the CMS time file was not accurate.

Certain aspects of the survey methodology were concerning. Survey respondents were provided with completed examples of the surveys. The researchers correctly observed "that providing sample surveys could potentially affect survey responses." yet the survey method still included this tool to help the survey respondents understand the survey burden. This same task could have been accomplished with blank copies of the survey without risking the integrity of the survey data. In addition, each survey respondent was requested to provide survey data on five of their visits, though based on the survey instructions, the respondents would have been reporting on five different patients. These five visits could have been disproportionately only one or two types of visits (i.e., the first hospital visit or the first office visit) and therefore, would not be representative.

Most importantly, the new E/M office visit framework allows for a physician to report a 99212 if 10 minutes is spent on the date of encounter. Most all surgical post-operative office visits are attributed as 99212 in the surgical global period in determining physician work, physician time and practice expense. The new coding structure renders this RAND report moot.

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

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

The analysis included in this study applied the four percent observed versus expected ratio from 111 010-day global services and the 39 percent observed versus expected ratio from 185 090-day global services to all surgical global services (over 4,200 codes). Applying an overall ratio from a pool of data where all non-participants were categorized as physicians who never perform post-operative services is not appropriate.

This study included a major error, where immediate post-service time was incorrectly included as a part of post-operative visit time for the analysis. The researchers stated that they “computed the total post-operative visit time by subtracting pre- and intra-service time from the total physician time.” However, this method would have included immediate post-service time, which does not coincide with any bundled visits, as part of the bundled post-operative visit time. 010-day global services typically include 10 to 20 minutes of immediate post-service time and 090-day global services typically include 25 to 45 minutes of immediate post-service time. This time reflects work after skin closure in the operating room and through discharge from recovery, which is distinctly different from E/M postoperative visits in the hospital or office.

The AMA does not agree with any suggested methodology that uses “reverse building block methodology” to systematically reduce a work RVUs for services. We believe that reverse building block methodology, or any other purely formulaic approach, should never be used as the primary methodology to value services. It is inappropriate as magnitude estimation was used to establish work RVUs for services since the publication of the first Medicare physician payment schedule in 1992. This methodology, for example, ignores the care coordination work that is performed during the surgical global period, with evidence from the RAND survey of hip arthroplasty.

Implementation of the methodology outlined in this RAND report would result in unreasonable reductions in total Medicare payment for many surgical specialties, putting at risk access to care for Medicare beneficiaries (e.g., payment reductions of -18.4 percent for cardiac surgery and -18.1 percent for surgical oncology).

In summary, the result from the RAND studies can not be used to justify distorting the relativity of office visits within the RBRVS. The RUC recommended submitting recommendations to CMS to apply the RUC office visit recommendations to both the stand-alone E/M office visit codes and the E/M office visit component of the codes with global periods (010, 090, and MMM). The AMA urges CMS to finalize a policy that adopts this recommendation.

N. Immunization Administration (CPT Code 90460)

- **Recommendation:** The AMA recommends that CMS utilize the RUC recommended direct practice inputs for CPT Code 90460 to ensure greater access to vaccines.

The AMA requests that CMS utilize the RUC recommended direct practice expense inputs to publish Practice Expense relative value units for CPT code 90460 regarding immunization administration. The recent measles crisis spotlights the importance of the service being appropriately valued. Since one-third of pediatric visits include immunizations, appropriate payment is essential to ensure access to vaccines provided in the medical home, where studies have shown immunization rates are higher.

The CMS crosswalk from CPT code 96372 to codes 90471/90460¹¹ has brought about a 60 percent reduction in PE RVUs, resulting in payment substantially lower than current Centers for Disease Control and Prevention (CDC) regional maximum charges. Since CPT code 90460 is reported more frequently in pediatrics than code 99213 (level 3, established patient office visit), the impact to the bottom line of a pediatric practice is tremendous and can cause some practices to stop offering vaccines.

Historically, CMS typically only uses a crosswalk for work values, not PE values. Additionally, when the RUC creates crosswalks, it disconnects the codes after the initial crosswalk—so that changes to the source code no longer affect the crosswalked code. Finally, it should be noted that CMS has already validated the RUC-recommended values for CPT code 90460. CMS used the RUC-recommended values for CPT code 90460 to value the fast-tracked H1N1 immunization administration code (90470) for 2010—as both codes were reviewed during the same RUC meeting (October 2009). Accordingly, CMS should use the RUC recommended direct practice inputs for CPT code 90460.

O. CMS.gov Physician Fee Schedule Search Tool

- **Recommendation:** AMA recommends publication of RVUs and other payment data for non-covered/bundled Medicare services in the CMS.gov Physician Fee Schedule Search Tool.

The AMA requests that CMS include the relative values and other payment information for non-covered/bundled Medicare services in the CMS.gov [Physician Fee Schedule Search Tool](#). CMS already includes this information in the CMS RVU file and the Medicare Physician Fee Schedule Addendum B and should include the same information in its online search tool.

There are 104 Medicare Status indicator “N” or “B” CPT/HCPCS codes with RVUs published in Addendum B in the Proposed Rule. When any of these services are queried in the online search tool, instead of providing the RVUs and other payment data, the tool instead states, “The current Physician Fee Schedule does not price the requested HCPCS Code(s).” CMS could still retain this disclaimer along with providing the RVUs and other payment information. Many payers utilize these RVU units and some

¹¹ Rather than accepting the RUC recommendations made in 2009, CMS cross-walked 90460 from CPT code 90471 Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid), which is crosswalked from CPT code 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular (formerly CPT code 90772 and then 90782).

payers, including Medicaid programs, also pay for certain services at 100 percent of the Medicare rate.¹² Unlike other CMS data files, this tool also provides locality specific payment data which is very useful to many stakeholders. The AMA recommends for CMS to include the RVUs for non-covered or bundled services in the CMS.gov Physician Fee Schedule Search Tool along with a non-covered/bundled disclaimer with search results.

P. Medicare Shared Savings Program (MSSP) Quality Measures

- **Recommendation:** The AMA does not support aligning the MSSP quality scoring methodology with the MIPS quality scoring approach and adopting the MIPS quality methodology. We also do not support eliminating pay for reporting from the MSSP program.

CMS proposes to align the MSSP methodology with the MIPS methodology and seeks comment on adopting the quality scoring approach used in MIPS for MSSP. The AMA does not support this change. The quality performance standard is the specific criteria that an Accountable Care Organizations (ACOs) must meet to be eligible to share in any savings earned and determines the magnitude of losses for which an ACO may be liable. Making a change to MSSP quality scoring methodology in the name of alignment introduces too much uncertainty into the MSSP program. The MIPS methodology is also flawed, does not incorporate pay-for-reporting and is undergoing extensive revisions as CMS proposes to transition the program toward MVPs. Therefore, making such a drastic change to the MSSP quality performance standard at the same time ACOs must decide if they will take downside risk presents too much instability and complexity into the program. If CMS finalizes the proposal we suspect more ACOs will choose to leave the program.

The AMA also has concerns with the administrative claims-based measures used for MIPS, and we do not feel these measures would be a better alternative to the current administrative claims' measures.¹³ ACOs currently utilize a very different cost evaluation approach from MIPS, which CMS acknowledges by not scoring ACOs on cost in MIPS. This demonstrates that it may not always be appropriate to align methodologies areas among all quality programs. ACOs are responsible for total cost of care for a specific patient population, and therefore CMS must use a different approach in evaluating ACOs as compared to individuals or groups reporting quality measures in MIPS, who are not participating in a total cost of care model.

Additionally, AMA has significant concerns with CMS' discussion of removing the pay-for-reporting year. Providing ACOs in their first contract year with 12 months to assess performance, study measure specifications, and implement workflow and IT changes necessary to capture data to document quality performance as specified by the measure steward is a huge undertaking. In addition, this time is crucial to educate clinicians and support staff on how to incorporate processes to implement the quality measures in practice. ACOs are responsible for 24 quality measures, and each quality measure has its own measure specifications, exemptions, and requirements. New ACOs need time to educate physicians and staff on measure specifications and begin tracking performance, which makes a pay-for-reporting year critical. This is also important to maintain when measures undergo significant changes, which demonstrates the

¹² For example, the AMA has heard from its members that some Medicaid programs are unable to apply the rate increase as provided by the state plan amendments because the CPT codes are in status "N" not active on the PFS Search Tool (e.g., well-child codes 99381-85 and 99391-94).

¹³ ACO-8, All Conditions Readmissions, ACO-38, Acute Admissions Rate for Patients with MCCs, and ACO-43, Ambulatory Sensitive Conditions Acute Composite.

acknowledgement that ACOs and their clinicians and support staff need at least one year of preparation prior to being held accountable for performance on the measure.

1. ACO Quality Measure Updates Proposed for 2020

We urge CMS to not finalize the proposal to add ACO-47 to the MSSP quality measure set for 2020. The measure has not undergone testing and endorsement to determine whether it is appropriate to measure at the ACO or physician level. CMS also lacks consistent payment coverage for many vaccinations included in this composite vaccination measure, such as only covering tetanus if there is an injury or only covering a vaccine under Part D. Instead, we urge CMS to maintain the current vaccination measure ACO-14, Preventive Care and Screening Influenza Immunization.

CMS should make ACO-17, Smoking Cessation, pay-for-reporting in both 2018 and 2019 and make changes to the measure specification requirements to better reflect clinical practice. We support making ACO-43-Ambulatory Sensitive Condition Acute Composite pay-for-reporting for 2020 and 2021 because the measure underwent significant changes.

The AMA has concerns with CMS' proposal to add ACO-47, Adult Immunization Status, to the ACO quality measure set. CMS lacks consistent payment coverage for many vaccinations included in this composite vaccination measure, such as only covering tetanus if there is an injury or only covering a vaccine under Part D. ACOs also have concerns with supply issues which could be out of the ACOs' control and affect performance on such a measure. In addition, the measure has not undergone testing and endorsement to determine whether appropriate to measure at the ACO or physician level. Therefore, holding ACOs accountable for the measure is inappropriate. We urge CMS to not finalize the proposal to add ACO-47 to the MSSP quality measure set for 2020. Instead, we urge CMS to maintain the current vaccination measure ACO-14, Preventive Care and Screening Influenza Immunization.

CMS also proposes to make substantive changes to the following web-interface measures in 2019: Smoking Cessation; Screening for Depression; Colorectal Cancer Screening; Breast Cancer Screening; Statin Therapy; Depression Remission at 12 months; Diabetes HbA1c Poor Control; and Hypertension. We reviewed the changes and as a result, we believe there are impacts to the benchmarks and a need to provide pay-for-reporting for 2019 and 2020 performance years. With the screening for depression and depression remission measures it is questionable whether the changes impact the benchmarks but urge CMS to explore and consider whether the two depression measures warrant pay-for-reporting along with the other web-interface measures.

Q. Open Payments

- **Recommendation:** The AMA recommends that CMS not consolidate the continuing education categories and exclude textbooks and medical journals from the Open Payment reporting requirements.

The AMA appreciates CMS' commitment to stakeholder engagement to limit burden in the Open Payments program reporting processes and improve clarity for the public. To further reduce burden and improve clarity, the AMA supports significant modifications to the Open Payments program, including substantially increasing the monetary threshold for reporting, protecting physician rights to challenge false and misleading reports, changing the dispute process so that successfully disputed charges are not

included publicly on the Open Payments database, and providing a meaningful, accurate picture of the physician-industry relationship.

CMS proposes to consolidate the accredited/certified continuing education category with the unaccredited/non-certified continuing education category. While this proposal may streamline reporting requirements, this consolidation detracts from the underlying context of the data. Continuing Medical Education (CME) is independent and manufacturers have no control or input into the content, the speakers, or the attendees. Certified CME is defined as (1) nonpromotional learning activities certified for credit prior to the activity by an organization authorized by the credit system owner, or (2) nonpromotional learning activities for which the credit system owner directly awards credit.¹⁴ Thus, by combining the existing categories, CMS is ignoring a key distinction of potential manufacturer influence on the CME by conflating certified and non-certified CME. Accordingly, CMS should not consolidate the continuing education categories.

Moreover, to limit burden and improve clarity, CMS should place textbooks and scientific peer-reviewed medical journals, reprints, supplements, and abstracts among items excluded from the reporting requirements.

The Sunshine Act was designed to promote transparency about payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined 12 specific exclusions from the reporting requirement, including educational materials that directly benefit patients or are intended for patient use. In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer-reviewed scientific clinical journal articles, and abstracts of these articles are not directly beneficial to patients, nor are they intended for patient use.

We believe that patients benefit directly from improved physician medical knowledge. The importance of up-to-date, peer-reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical text books have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer-reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients.

Moreover, Congress included a specific exclusion of items that directly benefit patients, such as reference materials that are often used side-by-side with a patient as a first resource when a patient brings an unfamiliar medical issue to a clinician. Many medical textbooks and scientific medical journal supplements and reprints are used in this way by physicians. The design of the reporting requirement presents a clear disincentive for clinicians to accept high-quality, independent educational materials; an outcome that was unintended when the provision was passed into law.

¹⁴ *Accreditation Council for Continuing Medical Education (ACCME) and AMA Glossary of Terms and Definitions* (2018), available at https://www.accme.org/sites/default/files/2018-04/011_20170421_Glossary_of_Terms.pdf. Certified CME encompasses all activities certified for AMA Physician Recognition Award (PRA) Category 1 Credit by Accreditation Council for Continuing Medical Education/state medical society accredited CME providers, activities certified through the American Academy of Family Physicians (AAFP) or American Osteopathic Association (AOA) credit systems, and activities certified directly by the AMA for AMA PRA Category 1 Credit or through one of the AMA's international agreements. AMA, *AMA PRA Frequently Asked Questions for CME Providers* (2014), available at <https://csms.org/wp-content/uploads/2014/03/provider-faq2.pdf>.

R. Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm

1. Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535

- **Recommendation:** The AMA recommends that CMS not finalize its new proposal to deny or revoke an enrollment for any action a state medical board takes or, alternatively, use a more targeted approach to focus on outliers.

The AMA strongly supports the efforts of CMS to protect its trust funds by ensuring that unqualified or potentially fraudulent individuals or entities are precluded from billing applicable programs. However, we have serious concerns with the proposal to allow CMS to deny or revoke an enrollment for any action a state medical board or equivalent entity takes that CMS determines led to patient harm (e.g., seeking treatment for a substance use disorder or mental health problem through a structured rehabilitation program in lieu of a disciplinary action). This proposal is a broad and unprecedented overreach, would significantly increase regulatory burden without efficiently targeting enforcement toward higher-risk providers and suppliers, and is duplicative, in part, of new revocation authority. Accordingly, the AMA recommends that CMS either (1) not finalize the new proposal or (2) limit application only to providers and suppliers that are identified as outliers using data analytics.

The CMS proposal is a broad overreach and the lack of deference to state medical boards and other oversight entities is troubling. CMS states that it, “rather than state boards, is ultimately responsible for the protection of its beneficiaries.” This statement is inaccurate. The role of state medical boards is to protect the health, safety, and welfare of the residents in the state—which include Medicare beneficiaries—through implementation and enforcement of laws involving the licensing and regulation of health care providers. Safeguarding public health and patient safety are also the primary purposes of the state statutes authorizing licensing boards to regulate health care professionals. It is crucial that licensing boards carry out the responsibilities assigned to them by state legislatures without being intimidated by federal overreach from CMS.

The AMA is also concerned that CMS buried such a major change to the denial and revocation authority in the annual physician fee schedule under the opioid treatment program section. Thus, the proposed rule gives the appearance of potentially only applying to “high risk” Medicare-enrolled opioid treatment programs; however, the proposed change impacts all clinicians. Moreover, CMS does not address the reality of a denial or revocation on a physician’s practice. Revocations lead to a mandated cross-termination of participation in Medicaid and most payers will also remove a clinician from their provider network when CMS takes this action. Thus, if a physician agreed to abstain from drugs or alcohol and be subject to random drug testing to simply provide evidence that no addiction exists, CMS now gives itself the authority to revoke that physician’s enrollment in Medicare, which includes a mandated cross-termination in Medicaid with most payers also following suit. In addition, adoption of this policy would be completely at odds with the nationwide effort to reduce the stigma associated with seeking treatment for substance use disorders.

CMS consistently touts its data analytics capabilities but does not propose to use these capabilities in the proposal. Instead, rather than take a targeted approach based off data analysis, CMS chooses a proposal that impacts all providers and suppliers. CMS’ program integrity efforts should be geared towards non-compliant providers and suppliers rather than burdening honest providers and suppliers. Compliance with this new requirement and other program integrity requirements increases regulatory burden without efficiently targeting enforcement toward higher-risk enrollees. Any program integrity proposal should be

more focused on identifying and weeding out potentially fraudulent parties. Moreover, this new proposal is confusing and overlaps with new revocation authority where CMS already has given itself the authority to revoke a physician or eligible professional with an abusive pattern or practice of ordering, certifying, referring, or prescribing that represents a threat to the health and safety of Medicare beneficiaries.

The AMA is working to protect patient safety by ensuring that the role of states and medical licensing boards to define appropriate medical standards at the state level is not undermined by federal overreach. CMS does not have the clinical expertise to make judgments regarding the competency of health care professionals to perform medical procedures. Moreover, CMS will not have been involved in the licensing board disciplinary process or its deliberations in evaluating the genesis of the complaint, the truth of the allegations, or the reasoning to settle. Denial or revocation based on an after-the-fact desk review is wholly inadequate, will punish rehabilitating physicians inappropriately, and lead to further provider shortages. Therefore, the AMA urges CMS to withdraw its proposal that impacts the complex medical issues involved in state medical licensure or, at a minimum, limit its application only to providers and suppliers that are identified as outliers using data analytics.

S. Deferring to State Scope of Practice Requirements

1. Ambulatory Surgical Centers

- **Recommendation:** The AMA opposes the proposed changes to the Conditions for Coverage that would allow nurse anesthetists to independently perform preoperative assessment of anesthetic risk and presurgical evaluation in the Ambulatory Surgical Centers (ASC) setting.

CMS proposes to allow Certified Registered Nurse Anesthetists to examine and evaluate the patient before surgery for anesthesia risk and the planned procedure risk. We oppose this proposal because a physician's education and clinical training provides the knowledge and skills that are necessary to assess the patient with respect to anesthetic risk and to also assess whether each patient's preoperative management has been optimized prior to undergoing a surgical procedure in the ambulatory surgery setting. The extensive training provided to physicians is essential to ensure that the clinical assessment takes into account underlying co-morbidities and to ensure that the ambulatory setting has the resources needed to manage the patient throughout the continuum of care.

To protect the health and safety of all individuals treated in an ASC, each patient requires a comprehensive assessment and perioperative plan to ensure safety throughout the surgical procedure and safe and timely discharge to home. Without such an assessment by a physician, patients may require transfer to a hospital setting or require hospital admission after discharge from the ASC to manage perioperative complications. Therefore, we are concerned that CMS' proposed changes will undermine our shared goal of protecting the health and safety of patients and recommend that CMS withdraw its proposal.

2. Hospice

In response to CMS' solicitation on the current and future role of non-physician practitioners, or advanced practice providers (APPs), the AMA defers to state law where practical, but in the absence of state law, we support APPs working in physician-led teams. Specifically, when there is no state law governing physician supervision of or collaboration with APPs, we do not support showing documentation of APPs' scope of practice and indicating their relationships with hospice medical directors to deal with issues outside of their scope of practice.

T. Advisory Opinions on the Application of the Physician Self-Referral Law

- **Recommendation:** The AMA appreciates CMS stating the importance of having an accessible process that produces meaningful physician self-referral law (Stark) advisory opinions. We support the overall intent of the proposed reforms and value CMS' thoughtful effort to streamline this arduous process.

The AMA supports the CMS proposals to move to a 60-day timeline, to create an expedited timeline, to preclude all parties subject to an advisory opinion from imposition of sanctions, and to not pursue sanctions against third parties whose arrangements are materially the same to existing advisory opinions. We are concerned; however, with whether CMS has the adequate resources to deliver timely and useful guidance to the provider community. Under the existing 90-day timeline, the advisory opinion process has historically taken significantly longer. This leaves physicians with uncertainty over whether existing or proposed arrangements may violate Stark.

CMS sought comments on expanding the scope of advisory opinion requests. The AMA believes that CMS should expand the scope to include hypothetical arrangements and general questions of interpretation. Stark is a payment statute. In Medicare, CMS and its contractors provide countless interpretive guidance for physicians regarding when an item or service is payable. Stark should be treated like any other Medicare payment statute. Accordingly, CMS should expand the scope of advisory opinions to account for the nature of the Stark law.

II. UPDATES TO THE QUALITY PAYMENT PROGRAM

A. MIPS Value Pathways (MVP) Request for Information (RFI)

- **Recommendations:** The AMA urges CMS to ensure that participation in the MVP is voluntary, focus on measures that are meaningful to physicians rather than administrative claims / population health measures, ensure that the MVP option provides a more holistic track for physicians, and ensure there are appropriate incentives for physicians to report on new quality measures and for multispecialty groups to engage in subgroup reporting by specialty.

The AMA appreciates CMS' efforts to further improve the MIPS program through MVPs, and agrees with CMS that the goal of MVPs should be to reduce the complexity of the MIPS program and physicians' reporting burden. The MVP approach responds to some of the recommendations made to CMS by the AMA after significant consultation with specialty and state medical societies, and we commend CMS for incorporating feedback from the physician community as it works to improve the MIPS program.

While we are appreciative of CMS' efforts to develop a high-level MVP framework and recognize it is a first step in the right direction, we are concerned with several aspects of CMS' MVP proposal, and recommend that numerous policies included in the MVP framework outlined in the proposed rule be changed or adopted. Specifically, CMS must:

- ensure that participation in the MVP is voluntary;
- ensure that the MVP option provides a more holistic track for physicians by allowing for attestation for PI and automatic full credit in IA;
- provide for a minimum point floor that is equal to the performance threshold for those who report via the MVP track receive;
- focus on measures that are meaningful to physicians rather than administrative claims/population health measures;
- allow MVPs to test innovative and flexible approaches to measuring costs involved in an episode or condition, as well as new risk adjustment and attribution models;
- allow for appropriate pilot testing and timeframes in implementing MVPs, and
- develop a subgroup reporting option for multispecialty practices and incentivize physicians to engage in subgroup reporting by specialty and report new quality measures.

1. Assignment to MVPs

In the MVP RFI, CMS asks how it should determine MVP assignment, and seeks feedback on the level of choice clinicians should have in MVP selection. CMS notes that it believes clinicians should be assigned to MVPs to simplify the program and reduce the physician administrative burdens that can be associated with having to choose from among the various measures and reporting options.

While the AMA appreciates CMS' intent, we strongly oppose mandatory assignment of MVPs to physicians, and recommend a different approach that would allow physicians to choose how they participate in MIPS. Specifically, the AMA urges CMS to adopt an opt-in process for MVP selection that would allow physicians to opt-in to CMS' suggested MVP, to choose an alternative MVP, or to continue to report measures through the traditional MIPS pathway.

An opt-in process would achieve CMS' goals of reducing the necessity for physicians to choose how they participate in MIPS, while still allowing physicians to retain the ability to freely choose measures and/or participation pathways in the program if they want. We believe physicians are in the best position to determine which clinical area will be most meaningful to their practice, and it may be many years before MVPs exist for the majority of physician subspecialties and practice arrangements.

First, the AMA suggests that CMS use past performance data to determine if an appropriate MVP exists for a particular physician. We urge CMS to provide its suggested MVP to each physician in several ways to ensure physicians receive adequate notice of CMS' recommendation. CMS should include its recommended MVP in the QPP Participation Status Tool, and it should be clear to physicians when they log in which MVP CMS is recommending for the upcoming performance year. In addition, CMS should include a physician's recommended MVP in the QPP submission portal when physicians submit their data following the end of a reporting period. Finally, CMS should include information on a suggested MVP in the performance feedback provided to the clinician on the previous years' reporting data.

The MVP track is new and will need to go through several iterations as it is developed and refined. In addition, the MVP track as envisioned by the AMA is not meant to replace traditional MIPS reporting, but rather to enhance it. The MVP track should exist to offer a hybrid MIPS/APM option for those physicians who are ready to move into a more focused, reporting methodology, while allowing physicians who have found MIPS meaningful, to continue reporting in the traditional MIPS program. Therefore, CMS should avoid mandating that physicians participate in a specific MVP, and instead should implement an opt-in process.

2. Holistic Program

Throughout the MVP RFI, CMS asks questions such as “how many improvement activities (IAs) should be required in an MVP?” Questions such as this illustrate the continued need for CMS to shift its focus to allow MVP to be a step toward a holistic, cohesive program rather than another option with four separate reporting categories. For example, we believe the question should instead be framed: How can CMS develop the MVP track in a way that eliminates or reduces the IA reporting burden?

One of the main complaints the AMA has heard from physicians about MIPS is that the program is complex and requires reporting in four separate performance categories. When the AMA first engaged in conversations with CMS about a possible MVP track, we were encouraged that an MVP track could be a way to allow physicians to receive credit for measures that spanned multiple performance categories and reduce their reporting burden.

Unfortunately, while CMS’ current MVP framework groups measures together into bundles in a specific clinical area, it still requires physicians to report in each performance category, and still maintains the status quo with PI and IA categories. Instead, CMS’ MVP proposal should eliminate the need for physicians to report in four separate performance categories.

a. IA

First, instead of a physician having to attest to IAs, the developer of each MVP should note to CMS which IAs are inherent in a particular MVP, and IA credit should be automatic. This is similar to how MIPS APMs and recognized patient centered medical homes are currently scored in the IA performance category. Those submitting proposals for an MVP would notify CMS of the IAs that are inherent in participation in the MVP, such as implementing a cost display for laboratory and radiographic orders.

b. PI

Physicians consistently report that the PI category is burdensome and not relevant to their clinical practice or improved patient outcomes. Physicians should receive credit for using health IT in ways that work for their specialty and patient population. Additionally, because MVPs are a potential glide path to Advanced APMs, the AMA recommends allowing physicians to become familiar with how Advanced APMs are scored on their use of health IT: attestation of use. A physician should be able to attest that they (or at least 75 percent of the eligible clinicians in their group) are using CEHRT or health IT that interacts with CEHRT rather than reporting individual PI measures. When a physician or group practice reports on quality measures through an EHR, qualified registry, or QCDR, they should receive automatic credit for the PI category, as they are inherently using CEHRT. This would allow each practice to use CEHRT or health IT in a way that worked toward its specific focus or goals. Alternatively, an MVP could be allowed

to utilize a QCDR to satisfy its PI requirement. This option has the added benefit of incentivizing use of QCDRs.

To truly drive change, the MVP track must allow physicians to report across categories, and receive credit automatically for the things they are already doing. In many ways, this is how APMs are structured. For example, MIPS APMs are scored on quality, while receiving automatic credit in the IA and PI categories. Allowing physicians an option that includes a reduced reporting burden, and familiarizes physicians with a model more similar to APMs should be the goal of the MVP track.

3. MVP Point Floor

Given that the MVP track will take a few years to develop and refine, the AMA suggests that all physicians who report via the MVP track receive a minimum point floor that is equal to the performance threshold. We recommend that CMS start with the large framework for the MVP track and then revisit issues such as the details of how to score multispecialty practices within the MVP track once the general framework has been established and tested.

Generally, the AMA believes that the MVP track will be beneficial to both CMS' program goals and physicians. First, it will help achieve CMS' goals by familiarizing a greater number of physicians with a model more similar to an APM. In addition, CMS and physicians will obtain more useful data by focusing on a public health priority or clinical area that is meaningful and relevant to a physician practice.

In addition, there are certain groups that could benefit from the MVP track, but may need to be incentivized to undergo yet another shift in their MIPS reporting. For example, the AMA believes it could be useful to multispecialty groups and CMS to have these groups report different MVPs for various specialties within the group. This would allow a multispecialty group to report on measures that are more relevant to each specialty within their practice. However, the time and resources required to revamp MIPS reporting within a large specialty group may not be worth moving to the MVP reporting option.

Therefore, the AMA urges CMS to provide an incentive to all physicians who choose to report MIPS via the MVP track. The AMA suggests that all physicians who report via the MVP track receive a minimum point floor that is equal to the performance threshold. This would incentivize physicians in multispecialty groups to report via subspecialty through MVPs. It would also incentivize small practices or solo practitioners to report using the MVP track and thus become more familiar with a model more analogous to an APM.

4. Include Measures Meaningful to Physicians Rather than Administrative Claims or Population Health Measures

- **Recommendation:** The AMA urges CMS to retain a robust list of QCDR and MIPS quality measures. The AMA does not support the use of global and population health administrative claims measures for use in MVPs and/or a requirement of MVP proposals. If CMS moves forward, administrative claims measures should only apply to group practices and cannot be a requirement of MVP. Alternatively, CMS could make them optional and allow practices the option to self-designate whether they wanted CMS to calculate the measures on their behalf.

The AMA is concerned whether organizations will develop MVPs if CMS moves forward with the proposal to require population health measures and administrative claims to be included in MVPs. The

population health administrative claims measures proposed were developed for use at the county or health-plan level, and CMS cannot automatically assume the measures will appropriately distinguish quality among individual physicians and group practices. The measures also move the program away from incorporating the patient's voice, measuring clinical conditions and outcomes, and generating real-time feedback. Measure developers moved away from administrative claims measures due to concerns over attribution, retrospective analysis, inability to measure individual physicians, and outcomes. Organizations shifted to develop electronic clinical quality measures (eCQM) and QCDRs due to the shortcoming with administrative claims measures. Absent CMS maintaining the existing suite of measures and removing population health measures as an MVP foundation, we do not believe organizations will devote the time and resources to develop, propose, and implement MVPs.

Specifically, CMS seeks feedback on the appropriateness of requiring administrative claims measures within each MVP proposal and/or having a sole MVP based on administrative claims measures. CMS is considering the following measures for use within MVP: Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicator (PQI) 91 and two risk adjusted utilization HEDIS measures, Acute Hospital Utilization (AHU) and HEDIS Emergency Department Utilization (EDU). In addition, CMS is proposing the inclusion of the administrative claims quality measure, All-Cause Unplanned Admission for Patients with Multiple Chronic Condition (MCC) beginning with the 2021 MIPS performance period.

Measure developers (and CMS) previously moved away from administrative claims measures in part due to concerns over attribution and the inability to move to clinically meaningful outcome measures. QCDRs and eCQMs electronic tools provide for a much richer data source. For example, it is very difficult to get to intermediate outcomes such as diabetes HbA1c levels or blood pressure level measures without requiring additional data collection. Therefore, CMS will be left to select measures that may be sufficient from the community or population perspective but are not appropriate to attribute to an individual physician or practices and are so far removed from clinical practice that the measure does not provide meaningful and actionable data at the point of care.

To date, we have yet to see a reliable attribution model developed for any existing administrative claims measures. CMS also relies on retrospective attribution which greatly decreases a physician or practice's ability to drive improvements in care as he or she will not be working with a pre-determined set of patients. If CMS insists on moving forward with administrative claims measures to provide more accurate assessment of physicians, we recommend that each measure demonstrate the following:

- **High level of reliability:** Physician performance on any administrative claims measure should not be used for payment or be publicly reported unless a minimum reliability of 0.80 can be demonstrated AND the risk adjustment model is developed, tested, and released for comment prior to implementation with social risk factors adequately addressed in the model. Testing should be completed at the individual and group level, including various sizes of groups. Statisticians and researchers generally believe coefficients at or above 0.80 are considered sufficiently reliable to make decisions about individuals based on their observed scores, although a higher value, perhaps 0.90, is preferred if the decisions have significant consequences.^{15,16}

¹⁵ Webb, Noreen, et al. *Reliability Coefficients and Generalizability Theory*. Handbook of Statistics, Vol. 26. 2006 Elsevier B.V. DOI: 10.1016/S0169-7161(06)26004-8.

http://web.stanford.edu/dept/SUSE/SEAL/Reports_Papers/ReliabCoefsGTheoryHdbk.pdf.

¹⁶ Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 06/13/2016. http://researchbasics.education.uconn.edu/instrument_reliability/.

- **Robust testing of the validity of the measure, including:** The attribution approach must be tested to demonstrate that the assignment of a measure to specific physicians, groups, and specialties is clinically appropriate and tied to the physician's or group's ability to meaningfully influence the outcome. Correlations between quality and cost measures to demonstrate the validity of the measure when applied to a specific physician, group, or specialty must be evaluated. CMS should demonstrate when measuring cost measures in conjunction with quality results in the intended outcome.
- **The ability to provide timely and relevant information:** For example, being notified in real time which patients will be attributed to a physician or group for any of these measures could enable them to actively seek to reduce costs and avoid unnecessary services such as a readmission.

In addition, while the AMA recognizes CMS believes that administrative claims measures reduce burden, we do not believe CMS took into consideration the following:

- Physicians do not treat a population, but treat patients as individuals tailored to their specific needs. Therefore, at a minimum CMS must develop robust risk-adjustment models that account for social risk factors. To date, CMS' risk-adjustment methodologies do not appropriately adjust for such disparities.
- The measures do not provide granular enough information for patients to make determinations on where to seek the best quality of care for specific conditions and procedures.
- If administrative claims measures are required, CMS should allow specialty societies to develop and propose their own administrative claims measures.
- The measures may incentivize providing poor care or lead to unintended consequences. For example, the literature is beginning to show that readmission measures, which are based on administrative claims, may be leading to increased mortality.
- Relying on claims-based measures may inaccurately penalize or incentivize physicians. For example, when it comes to staging a disease, coding does not accurately capture that information.
- Implementation of population health measures will further diminish the viability of small practices. Most of the promising strategies related to addressing population health, such as hiring nurse coordinators may be a violation of the Stark and Anti-Kickback statutes. Therefore, the only way to work around the statute is to become employed by a hospital. Individual and small practices also do not typically have a large enough patient sample size to calculate a reliable score.
- We have serious objections to CMS' proposal to move a problematic Value Based Modifier measure (PQI 91) into the MIPS quality category. Re-classifying the measure as "population health measure" under the quality category does not fix any of the inherent problems with the measure.
- MACRA does not require CMS to use global and population-based measures but states that CMS "may use" such measures.
- The measures disincentivize the private sector, such as specialty societies, to continue to invest in the development of quality measures and maintain existing measures.

As part of the RFI, CMS states they are considering several population health measures as a requirement to be incorporated into each MVP. The AMA does not support the expansion of the Population Health Quality Measure Set until CMS is able to align the attribution model, shared data elements and

definitions, and risk adjustment approach across the existing and proposed measures as well as any new measures that may be proposed in the future.¹⁷

In addition, we believe that commonly used definitions, such as admissions and readmissions, and the risk adjustment approach, must also be consistent across the various measures to reduce confusion and lack of comparability of information. Specifically, it is not clear that the HEDIS® AHU and EDU measures define planned admissions in the same way as the MCC admissions measure. All three measures utilize different risk adjustment approaches rather than what is currently included in the HWR measure, and none of the measures adequately address the need for social risk factors.

This scattershot approach of implementing measures with different attribution models, definitions, and risk adjustment approaches within one program is not sustainable and must be addressed to create a system that promotes and facilitates quality improvement in a way that is meaningful and actionable by physicians.

In addition, CMS must maintain a robust list of meaningful QCDR and MIPS quality measures. Acceleration and development of MVPs is contingent on CMS' acceptance and willingness to approve new and maintain existing QCDR measures, as well as maintain the existing suite of MIPS measures. Many measures that could apply to the development of initial MVPs, making them essentially "shovel ready" proposals, CMS proposes to eliminate in 2020. For example, CMS proposes to eliminate Measure 343, Screening Colonoscopy Adenoma Detection Rate, which is very well suited to be incorporated into a colonoscopy MVP given it is an outcome measure and there is a colonoscopy episode cost measure. CMS must send the signal that it will accept specialty proposed MVPs. CMS must maintain the existing portfolio of measures and willingness to work with specialty societies, including specialty-led QCDR stewards. Based on the assumption that CMS maintains the suite of measures, the first set of MVPs could be proposed for 2021 MIPS. The timeline will have to be extended several years if CMS finalizes its proposal to remove 55 measures and QCDR stewards continue to leave the program.

5. Allow Pilot Testing of Cost Measurement in MVPs

CMS should allow physicians to pilot test innovative and flexible approaches to measuring costs involved in an episode or condition, through MVPs. CMS should also allow for the development and testing of new risk adjustment and attribution methods. For instance, non-patient-facing clinicians may not be attributed episode-based cost measures but may wish to develop and test a cost measure around appropriate use criteria and clinical decision support, which can ensure that evidence-based screenings and treatments are provided while also preventing inappropriate costs.

¹⁷ Specifically, CMS must address the lack of alignment of the various attribution models used for the MIPS administrative claims-based outcome and cost measures such as the Hospital-wide Readmissions (HWR) measure and TPCC measure. Based on the possible changes to attribution in many of these measures to hold more than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits), physicians and practices will have different patients assigned to them for different measures. This lack of consistency across measures will further decrease a physician's ability to drive improvements in care as he or she will not be working with a pre-determined set of patients. Rather, patients will be assigned retrospectively and could be assigned to more than one clinician.

6. *Timeframe for Transition*

First, it will take many years for stakeholders to develop a sufficient number of MVPs to allow the majority of physicians the opportunity to participate in the MVP track.

Physicians will also need time to be educated on MVPs and scoring rules and methodologies, receive notification from CMS of applicable MVPs and make updates to electronic systems, such as QCDRs and EHRs. They also will need time to understand and decide whether they should participate as an individual or group in an MVP. The group practice decision may also require awareness of sub-group reporting and the process for informing CMS of their desire to participate as a sub-group.

If CMS moves forward with administrative claims measures, practices will also need to understand how the measures apply to them. We expect CMS to first provide administrative claims measures as informational only. With administrative claims measures, CMS is discounting the effort required to understand the measures and implement changes.

While the AMA strongly supports the MVP track, we also recognize that it is a new model that will take years to implement and refine. In addition to providing a point floor for the MVP track in the early years as mentioned above, the AMA encourages CMS to continue to review and improve the MVP track and understand that flexibility will be needed as this new model is implemented.

7. *Request for Feedback on Multispecialty Practices Participation in MVPs*

- **Recommendation:** Physicians and groups of all sizes and specialties should have the choice to voluntarily participate in MVP individually, as a virtual group, as a group at the taxpayer identification number (TIN) level, or as a sub-group. For MVP to be successful, CMS must incentivize MVP participation among multispecialty groups and operationalize sub-group reporting so specialists within a multispecialty group have the option to affiliate with physicians in the same or similar specialty within the group through a seamless registration process.

a. Need for Sub-Group Option for MVP

The AMA reiterates our support for operationalizing a sub-group reporting option that would facilitate participation in MVP by specialists who may be practicing within multispecialty groups. Currently, a clinician must choose to report MIPS data individually or through the group, which includes all MIPS eligible clinicians within a TIN. The AMA has heard from physicians who are part of a group practice that would like to report separately from the larger group and instead partner with their colleagues in the same or similar specialty. We support allowing an option for a portion of a group to report as a separate subgroup for purposes of MVP or traditional MIPS. This would allow a specialty in a multispecialty group to form a subgroup to report on MVPs that are more clinically relevant to that particular specialty.

We understand CMS faces challenges in implementing a sub-group level reporting option in MIPS. To ease the transition, CMS should consider offering this option in MVP before expanding to the traditional MIPS program. Because MVPs will be built around an episode of care or condition and most likely involve reporting via a registry or QCDR, multispecialty groups will find it challenging to engage in MVP unless members of the group are able to form sub-groups based on their combined interest in participation in an MVP track. Many MIPS-eligible physicians are part of a multispecialty group and, based on 2017 QPP Experience Report, 54 percent of eligible clinicians received their final score based

on participation in a group. For these reasons, we believe an option to report at the sub-group level will be key to the success of MVP.

We do not believe MVP should be considered a substitute for a sub-group reporting option. Physicians in the group who are not affiliated with the sub-group that is participating in an MVP should retain the option to participate as a group practice in traditional MIPS or select another MVP. We urge the agency to look to its “split-TIN” policy for certain Advanced APMs, where some of the clinicians billing under the group’s TIN participate in the model while others do not. In this case, the portion of the group that is not participating in the model has the option to participate in MIPS as a split-TIN and can register for the CMS Web Interface or report via another data submission mechanism. This will minimize the burden on multispecialty groups who have sub-group interested in an MVP.

b. Incentivize Sub-Group Option for MVP

While we have heard support for sub-group reporting from physicians and specialty societies, we acknowledge that large group practices would face trade-offs with this option. Depending on how MVP is structured, it could potentially mean reporting the same information multiple times, which will create additional administrative burden.

The AMA has made numerous suggestions to create a less burdensome, more streamlined option. We believe CMS must implement these suggestions to incentivize reporting at the sub-group level. Our recommendations include making MVP voluntary, establishing a point floor, requiring fewer quality measures, piloting testing, flexibility by allowing attestation for PI, and receiving automatic credit in the IA category.

CMS should also offer flexibility for single specialty groups with sub-specialists. For instance, if there were an MVP for cataract surgery, and all the cataract surgeons in the group worked together on it, the other physicians who do not perform cataract surgery, such as retina specialists, would likely have to start reporting on primary care measures because they do not have enough ophthalmic measures in MIPS.

c. Operationalizing a sub-TIN option for MVP

To allow physicians to form sub-groups, CMS should create an MVP registration process, similar to the CMS Web Interface or CAHPS for MIPS registration. We do not believe it is necessary to replicate a process as cumbersome as the virtual group agreement process for sub-groups interested in MVPs. Sub-groups would be members of the same TIN, unlike virtual groups which may be comprised of different groups coming together to form an agreement to jointly participate in MIPS. We believe this distinction, between sub-TIN versus multiple-TIN, is important and do not think CMS would need to establish a formal contractual process for members of the same TIN.

We also encourage the agency to explore the possibility of creating a sub-group identifier, such as the virtual group identifier, to facilitate sub-group reporting in MVP. The AMA would appreciate the opportunity to work with CMS to ensure that this option would not add complexity to the MIPS program and would offer a more meaningful reporting option to specialists that are part of multispecialty groups.

8. *Quality*

The AMA is glad to see the MVP proposal address our ongoing concern with the number of quality measures a physician must report to satisfy MIPS reporting requirements. The AMA believes the specific number of quality measures should be based on what is most appropriate for measuring a clinical condition or public health priority. We offer the following feedback on the Quality section of the MVP RFI.

a. Call for MVP

The AMA is concerned with constructing a “Call for MVP” process that aligns with policies developed for the call for Measures and Measure Selection Process, as the current process is extremely complex and requires a long lead time between the time a steward proposes a measure and the time a measure is implemented into the program. Initially, the process should not be too restrictive. Over time, CMS could move to make it more formal once there are numerous MVPs available. Therefore, the AMA prefers a process similar to the one CMS utilizes for developing specialty measure sets which will better ensure MVPs are driven by input from specialties and other stakeholders. The process also must allow stakeholders the opportunity to comment.

Eliminating review of MIPS measures by the MAP would significantly accelerate the timeline for measure implementation and help achieve CMS’ goal of moving to “Meaningful Measures.” For instance, the AMA initiated development of pre-diabetes measures (a MIPS measure gap area and public health priority) roughly two years ago and submitted them for the 2019 Measures under Consideration (MUC) list for implementation in 2021 MIPS. However, due to CMS’ testing requirements they were rejected and the earliest they may make it into MIPS is 2022 (5 years after initial development). Pre-diabetes and similar important preventive services could be good focus areas for MVPs as they are developed.

In addition, the lack of reliable MAP processes leads to inadequate review of the measures—especially in the context of considering appropriateness based on program requirements—and unpredictable MAP proceedings and reports issued with limited time to comment.

If CMS continues to insist that measures (and future MVPs) must undergo MAP review and requires testing at the time of submission for the MUC list, we recommend the following issues be addressed to improve the MAP process:

- The MAP treats measures undergoing maintenance/updates as if they are under development despite the fact that CMS has data about and experience with the measure, which, if shared, could lead to a more focused and meaningful discussion.
- Stakeholders often only have one week to 30 days to comment on MAP recommendations—depriving stakeholders and the programs of a thorough review and constructive feedback.
- Opportunity to re-review and consider measures after MAP-flagged issues have been addressed by the measure steward.
- Consider new measures (and future MVPs) in the context of the entire program, specifically the existing measures and whether new measures are warranted.
- The deliberations of the MAP coordinating committee and workgroups are highly dependent upon who has a seat at the table. If a measure within a particular specialty area is being reviewed,

and that specialty is not represented on the committee or workgroup, legitimate issues may be overlooked and measure review may be inadequate.

- Notices of opportunities for measure developers or stakeholders to publicly comment are sometimes inadequate. Agendas are all too often unavailable until on or close to the day of a MAP meeting. The order of review of items on the agenda frequently deviates from the published schedule, making it difficult for those not present, including clinicians and the public, to participate or provide comments.

b. Quality Measure Selection in MVPs

CMS asks whether MVPs should include only required measures and activities or a small list of quality measures and activities from which physicians could choose from. The number of measures within an MVP and whether to only include required measures or a small list is dependent on whether CMS allows for a robust number of MVPs and accepts sub-specialty MVPs. Therefore, we recommend CMS accept sub-specialty MVPs and if reporting on an MVP is required, physicians should not be required to report on the measures with the MVP. For example, the proposed surgery MVP is not applicable to all surgeons, so CMS would have to allow physicians to select the measures they report on within the MVP.

c. Criteria for MVP measures

CMS asks for feedback on the criteria that should be used to determine what measures and activities should be included in an MVP. The general rule for developing MVPs should be that the measures are all related to a particular clinical condition or specialty focus area. The number of quality measures should be dependent on what is most appropriate to measure for the clinical condition and evidenced based. There should be no requirement to prioritize based on outcome, high priority, or patient reported measures.

d. Collection Type

CMS asks whether physicians should be required to use a certain collection type in order to have a comparable data set in the MVPs. Ideally, all measures should be reportable via EHR at no cost, with no additional vendor support required, and seamlessly submitted to CMS. However, the current electronic infrastructure and portfolio of measures does not support that. In addition, MACRA calls on CMS to encourage the use of QCDRs and requiring eCQM reporting would be counter to statutory intent. Therefore, physicians should not be required to use a certain collection type to report MVPs.

MVPs should be compared against the same collection type. For example, under MIPS a quality measure may only be available through an eCQM or registry and not claims. For purposes of scoring, the measure is compared against the same collection type: Measure x eCQM, scored against Measure x eCQM; or Measure x Registry, scored against Measure x Registry. Collection type calculations should not be blended.

There will also be significant burden to require physicians to change and adopt a certain collection type. Moving to electronic clinical quality reporting is expensive. Small practices will especially be burdened due to the expense and the only available no additional cost reporting option is through claims reporting.

CMS also asks what methodology could be used to develop a single benchmark when multiple collection types are used. We do not support creating a single benchmark when multiple collection types are used. However, if CMS moved to improve the existing benchmarking methodology through a manual+data

driven approach it would allow for better benchmarking across each collection type. Please see Flat Percentage/ Benchmarking section for more details.

e. QCDRs in MVPs

CMS seeks feedback on whether QCDR measures should be integrated into MVPs along with MIPS measures or limited to specific MVPs consisting of only QCDR measures. The AMA believes QCDR measures should be allowed to be integrated into MVPs along with MIPS measures just like QCDR stewards can incorporate MIPS measures into their QCDR along QCDR measures. CMS should not change the requirement on the type of measures.

The AMA also strongly urges CMS to continue to encourage clinicians to use QCDRs under MVPs. CMS must continue to accept unique QCDR measures into the program and allow QCDRs to satisfy PI as long as they e-prescribe. Patients, physicians, and other care team members should be empowered to make decisions based on what works best for their need and not what regulatory boxes must be checked.

CMS' current handling of approval of QCDR measures is unsustainable, and the overly stringent and one-size-fits-all approach will lead to more physician-led QCDRs dropping out of the program. CMS must recognize that changes to QCDRs, registries or EHRs require significant financial resources and time to plan, incorporate and test. This time-lag limitation becomes very challenging when CMS makes annual changes to the Quality Measure Blueprint, quality requirements, measure specifications, or technology functionality. In addition, changing the QCDR process and expectations of QCDRs on a yearly basis creates the perception among specialty-led QCDRs that the changes are arbitrary, lack evidence or reason, and that CMS is more interested in making arbitrary distinctions about quality than making meaningful distinctions leading to actual improvements in patient care and outcomes. The annual changes are also administratively burdensome and do not allow sufficient time for implementation. Therefore, there must be consistency from year to year, including with the approved measures especially if there is evidence to support the measure and documented gap in care.

9. All-Cause Readmission Measure (ACR)

While the MVP RFI does not specifically ask for feedback on the ACR measure that is currently used in MIPS, it is considered a population health administrative claims measure, and we continue to have serious concerns and issues with the measure that warrant attention and consideration by CMS. The ACR measure lacks transparent evaluation on whether it is appropriate to use at the physician-level and the continued lack of adjustment for social risk factors in the risk-adjustment model continues to be a concern. There is also emerging evidence that these programs and measures may be leading to negative unintended patient consequences and no longer capturing the appropriate patient population due to the structure and timeframe of the measures. The AMA sent a letter to CMS in February 2018, reiterated in our 2019 Inpatient Prospective Payment System (IPPS) and PFS/QPP proposed rule comments which included a set of questions that should be investigated to assist CMS, physicians, providers and patients in better understanding the impact our actions have on readmissions and outcomes. Therefore, until appropriate evaluation and potential refinements to the measure can be made, physicians should not be held accountable for the ACR measure and the measure should be removed from the program.

10. Small and Rural Practices in MVPs

CMS requests feedback on how MVPs should be structured to provide flexibility for small and rural practices and mitigate challenges small or rural practices may have in MVP reporting. Generally, the AMA believes that the MVP track itself has the potential to even the playing field between large and small practices. One of the main disadvantages small practices face compared to large groups is the inability to hire or acquire additional resources to comply with the MIPS program. Therefore, if CMS develops the MVP track in a way that significantly reduces a physician's or practice's need to report measures to CMS, it will allow small practices to be judged on their actual performance rather than their ability to pay for additional resources.

The AMA has made numerous suggestions to create a less burdensome, more streamlined option. We believe CMS must implement these suggestions to incentivize small and rural practices. Our recommendations include making MVP voluntary, establishing a point floor, requiring fewer quality measures, piloting testing, flexibility by allowing attestation for PI, and receiving automatic credit in the IA category.

Furthermore, CMS asks what kind of technical assistance would be helpful for small and rural practices. While the AMA has and continues to strongly support technical assistance for small and rural practices, we believe the most useful assistance CMS could provide to small and rural practices is data. The AMA typically hears from these practices that they are at a disadvantage because, unlike large practices, they do not have the resources to pay for access to, or analysis of, data. The AMA believes that the lack of access to data is a key reason why small and rural practices often find it more difficult to take on risk and move into APMs. Therefore, the AMA encourages CMS to provide all practices with access to program data under the MVP to help all practices move into APMs. In addition to providing the data, CMS should also use its technical assistance funding to analyze the data for small practices and provide recommendations and assistance based on the results.

While we believe MVP may be helpful for small practices, the most important way to ensure small and rural practices remain viable is to maintain the low volume threshold. To eliminate or reduce the threshold and force physicians to participate in MIPS or MVPs would be extremely detrimental to small practices. Financially, it does not make sense for these practices with limited resources to invest in MACRA compliance when they have such a small Medicare patient population. These practices see fewer than 200 Medicare patients per year or fewer than four Medicare patients per week.

11. Scoring MVPs

- **Recommendation:** CMS should reduce program complexity and administrative burden for physicians by scoring MVPs similarly to how MIPS APMs are currently scored.

The AMA views the ability to simplify scoring within the MIPS program as one of the most valuable aspects of the MVP track. To create a simplified reporting option and reduce physician reporting burden, the AMA suggests that CMS score MVPs similarly to how MIPS APMs are currently scored.

a. Quality

First, physicians would report on quality measures related to a specific clinical area or public health topic. Depending on the number of quality measures included in an MVP, the quality score for a physician could be calculated by adding up the points for each quality measure and multiplying it times the

percentage weight of the quality performance category, similarly to how the quality category is currently scored. The AMA urges CMS not to require a fixed number of quality measures for MVPs but instead to allow each MVP to include as many quality measures as are relevant, up to a certain number.

If an MVP developer submits a proposal with an episode-based cost measure that aligns with the MVP, then CMS would score the cost measure the same way it currently scores the cost performance category. We also urge CMS to work with specialty societies and other stakeholders submitting MVP proposals to pilot test new and innovative cost measures to measure physicians' costs in treating patients for a certain clinical condition. For instance, non-patient-facing physicians may wish to develop and test a cost measure around clinical decision support, which can ensure that evidence-based screenings and treatments are provided while also preventing inappropriate costs.

b. IA

Each MVP developer should include in its proposal to CMS a list of the IAs that are inherent in the MVP. For example, an MVP on Percutaneous Coronary Intervention (PCI) could include quality measures aimed at PCI, such as Measure 323, which is a high-priority registry measure of whether cardiac stress imaging after PCI meets appropriate use criteria. Because physicians who choose to report this quality measure would report it using a QCDR, the IA that provides credit for reporting via a QCDR is inherent in the PCI MVP. Therefore, no need exists for a physician to attest that they have completed an IA, but instead the physician should automatically receive full credit for the IA performance category. Each stakeholder that submits an MVP should be required to also submit the related IAs that are inherent in the MVP.

c. PI

CMS should not require reporting on individual measures in the PI category for physicians who are reporting on the MVP track. The physician (or 75 percent of physicians in a group practice) would attest that they are using CEHRT to e-prescribe for at least one patient and exchange health information on at least one patient, unless an exception applies. This complies with MACRA's requirement that PI credit be granted based on subsection (o)(2) of Health Information Technology for Economic and Clinical Health (HITECH) Act to be considered a meaningful user while also utilizing the Secretary's discretion allowed under HITECH's subsection (o)(2)(c)(i)(I) to allow a professional to satisfy demonstration of meaningful use through attestation. (Note that neither the 2017 nor 2018 program year required the measurement of quality through CEHRT in the PI category). If an exception applies, the physician or group would describe how they plan to use CEHRT or health IT that interacts with CEHRT as part of their management of patient care for the MVP they have chosen to report. This would allow CMS to pilot attestation in the PI category among MVP reporters and help CMS understand how clinicians can use health IT that interacts with CEHRT to advance health outcomes.

In addition, the AMA urges CMS to allow physicians and practices that submit their quality data for MVP quality measures using a QCDR if they also have a certified EHR to enable e-prescribing to receive automatic full credit for the PI category as long as the physician or practice attested to e-prescribing for at least one patient (unless an exception applies).

The AMA recognizes CMS' emphasis on patient access and interoperability measures in the current PI program. These two priorities will continue to receive a large emphasis from physicians, even if they receive automatic credit in the PI category, as there will be multiple levers, with significant penalties to

ensure that patient access and health information exchange occur. These levers include MIPS information blocking requirements, Office of the National Coordinator for Health IT's (ONC's) information blocking rule, and the Health Insurance Portability and Accountability Act's (HIPAA's) patient right of access. Continuing to measure physicians and practices on the current prescriptive PI measures would detract from clinical relevance. In addition, PI measures are not flexible enough to shift into value-based care models, which is why CMS currently allows MIPS APM participants to receive full PI credit for using CEHRT. Even if CMS allows physicians to receive automatic credit for using CEHRT, the EHR will still capture which functionalities are used—and how frequently—which can provide valuable data back to CMS and ONC and serve as an audit trail to address program integrity concerns.

12. Request for Information on Clinician Data Feedback

- **Recommendation:** CMS should use the MVP track to test and refine ways to allow physicians to access and analyze Medicare claims data to identify opportunities to reduce spending, measure the impacts of care delivery changes, and quickly identify when services for patients need to be changed.

We recognize the challenge of balancing the goal of providing as much data as possible with the goal of simplicity and enhanced usability. We appreciate CMS' efforts to provide more detailed data in the 2018 MIPS feedback reports, which included demographic and clinical characteristics for attributed beneficiaries, costs related to services billed by the clinician, and utilization of hospital and post-acute care. However, this information is difficult to interpret because it does not include comparisons, definitions, or summaries to help identify trends across the data.

The AMA believes the MVP track creates a unique opportunity to test and refine the most effective methods to provide feedback data to physicians. For example, the AMA urges CMS to test presenting claims data in conjunction with more digestible elements, such as summaries, so physicians can easily understand what they are being measured on, how they are performing relative to other similar physicians, and what they are supposed to be doing with this data to improve overall value. With MVP, there will be opportunities to distill the data around an episode, condition, or specialty to help improve the actionability of the information.

a. Look to APM Feedback to Improve MVP Feedback

As CMS sees MVP as a pathway between MIPS and APMs, the agency should look to the types of claims data analysis it currently provides to physicians in APMs as a guide. Claims data analysis is an essential factor in successful APM participation and would help physicians to identify opportunities to improve care and reduce costs, while also enabling them to design effective APMs. To ensure that it is useful and actionable for physicians in MVPs who are working to reduce unnecessary costs and improve quality, CMS should go farther than simply providing total cost of care or total utilization metrics. Below we recommend a framework for CMS to use on the front-end to tailor claims data feedback for physicians, especially small practices, who have fewer resources to hire consultants to interpret claims data.

Rather than providing total utilization based on setting, such as inpatient or post-acute care settings, to be most useful data should be categorized based on the physician's level of influence over the expenditures or utilization. Five such categories are:

1. Services their patients receive that are both ordered and delivered directly by the physician.

2. Services delivered by other providers that are integrally related to services delivered by the physician. For example, anesthesia services are only delivered when a surgeon performs surgery.
3. Services delivered by other providers that resulted from orders or referrals from the physician. This could include imaging and lab tests ordered by the physician directly as well as tests ordered by a specialist that the patient saw following a referral by the physician.
4. Services delivered by other providers that were related to services delivered or ordered by the physician. For example, if the patient developed complications following a surgical procedure, the treatment of these complications would be related to the surgery performed by the surgeon, even if the surgeon did not directly treat the complications.
5. All other services the patient received that appear to be unrelated to services delivered or ordered by the physician.

Collectively, these five categories add up to the total spending on all services a patient received. The services included in each category will differ for different types of physicians, so each specialty will need to define the categories for the types of patients and conditions they treat.

The five spending categories help identify which services physicians can control or influence, but they give only limited indications as to which aspects of spending could be *reduced* without harming patients' care. Consequently, it is desirable to further disaggregate spending into four subcategories:

- a. Services required to meet quality standards.
- b. Services that are potentially avoidable (e.g., services such as a magnetic resonance imaging [MRI] for lower back pain may provide relatively little benefit to some patients).
- c. Services needed to address potentially preventable conditions (i.e., situations where the health condition itself could potentially have been prevented if other services were delivered earlier).
- d. All other services ("typical services"). Even if there is not enough evidence about appropriateness or preventability to classify them in the other three categories, variation among physicians in the number and types of "typical" services they use for similar patients could indicate opportunities for savings and areas where research to determine appropriate use criteria are needed.

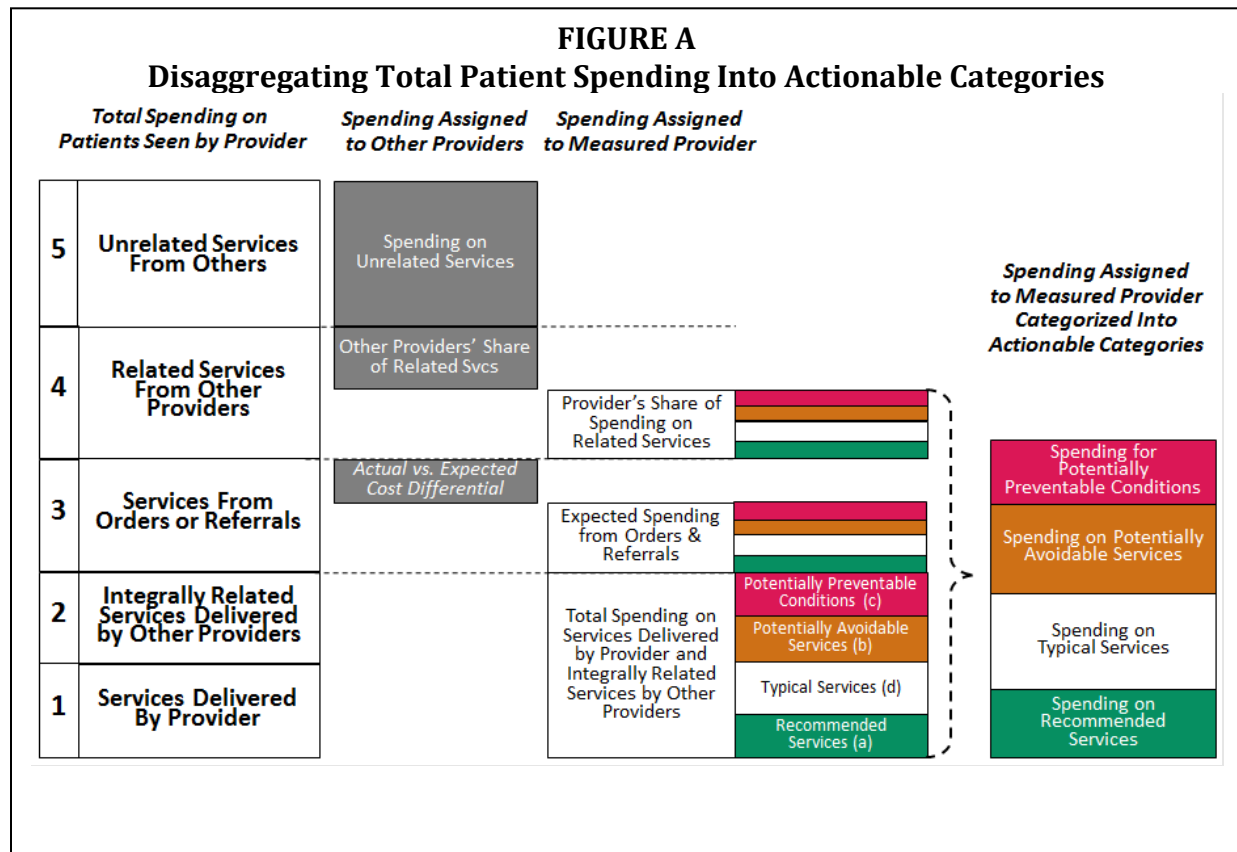
Figure A illustrates how the total spending on patients seen by a physician would be divided into the five spending categories based on the level of the physician's control and influence over the services delivered to the patient and then further divided into the four subcategories.

Even with these better categorizations of services and spending, comparisons among physicians will not be useful in identifying opportunities for improvement unless they distinguish differences in utilization or spending that were associated with differences in the needs of the patients for whom the providers were providing care. Current risk adjustment systems do not do this effectively; the following methods should be used instead:

- **Disaggregating Spending into Subgroups of Patients with Similar Health Conditions.** Instead of using a *single* risk score to *adjust* spending, a better approach is to *compare* spending separately for *different subgroups* of patients, with each subgroup defined such that patients in that subgroup would be expected to need similar levels of services.
- **Using Concurrent Risk Adjustment.** The patient categories should be based on complete information about the patients' health problems that occurred during the time period in which

spending is being measured, rather than only the kinds of historical information used in purely prospective risk adjustment systems.

- **Using Clinical Information from EHRs and Registries in Addition to Claims Data.**
- **Disaggregating by Non-Health Factors to Identify Impacts on Spending.** *Disaggregating* spending into different categories of patients is also preferable to *adjusting* overall spending based on patient characteristics because it enables disparities between different groups to be measured and acted upon, rather than hidden inside a risk adjustment formula.



b. Data feedback for specialty societies and MVP developers

- **Recommendation:** CMS should provide specialty-specific and condition-specific data from both QPP and claims data sources to help specialty societies develop and maintain MVPs.

In addition to providing clinicians with actionable data feedback, we urge CMS to provide specialty societies with detailed QPP and administrative claims data to help develop MVP proposals. While we appreciate CMS' focus on timely data analysis for clinicians who are busy taking care of patients, specialty societies are interested in delving deeper into the data and analytics to better understand opportunities for quality and efficiency improvements, to educate their members, and to advocate for program changes. More specialty-specific and condition-specific data from both the QPP and claims data

sources will help specialty societies understand and target opportunities for a more cohesive, clinically relevant MIPS participation experience via the MVP.

The most effective way to provide additional data is to build on the QPP Experience Report and Appendix. The AMA has worked closely with CMS since the inaugural report was released for the 2017 performance period to educate specialty societies and physicians about the reports and to share recommendations that would make the reports more robust.

Our recommendations to improve the QPP Experience Report and Appendix to assist with developing and maintaining MVPs include:

- The following data points would be helpful to see broken down by specialty. CMS has previously provided specialty-specific breakdowns in the PQRS Experience Reports and Quality and Resource Use Reports (QRURs), which are useful guideposts for the types of data that would be helpful to include in the QPP Experience Report and Appendix.
 - Average overall MIPS scores and payment adjustments.
 - Average scores for each year in each of the categories.
 - Percent of each specialty with negative versus positive payment adjustments.
 - Attribution and average scores for cost measures.
 - Reporting mechanism for quality, PI, and IA categories.
 - Exemptions from MIPS due to the low volume threshold or being newly enrolled in Medicare.
 - Special status categories (e.g., non-patient facing, hospital-based, facility-based, and ASC-based).
 - Participation in MIPS APMs.
 - Qualifying Participant (QP) and Partial QP status in Advanced APMs. Given the incentives to encourage APM participation, it would be helpful to understand which specialties are participating in which models.
- CMS should compare MIPS scores, payment adjustments, category performance, and APM participation rates by site of service.
- Provide a more holistic picture of what made a physician or group practice successful or other factors that may have contributed to the overall score. The report treats each category as a silo to some extent, rather than a comprehensive program. We would find utility in seeing how the components of MIPS and practice demographic information (e.g., hospital-based) contribute to final scores and payment adjustments.
- Provide information on hardship exemptions, including how many hardships are granted pursuant to an automatic exemption due to extreme and uncontrollable circumstances such as by zip code, as well as any data on applications for exemption from a specific category. For example, many physicians have MIPS submission problems due to certain EHR vendor issues, but the hardship exemption process has been a bit of a black box since meaningful use.
- Provide data around special scoring scenarios that may apply due to category re-weighting, bonuses due to small practice or complex patient status, and so forth. The program is more complex than just adding scores together across applicable categories and having this type of information would help tie everything together.

- Include information about the administrative claims measures, including all-cause readmission, total per capita cost, and MSPB. It would be helpful to see the average score by specialty, geographic location, and practice size.
- Provide quality measure performance broken down by reporting mechanism type.
- Include information on common errors when reporting on a measure and information on what prevented a physician from meeting the maximum category score. With PQRS, CMS used to provide information on errors and why considered unsuccessful with reporting on a measure and PQRS in general. The information CMS provided greatly assisted with education. For example, early in the program it was discovered that with certain measures practices were reporting on the wrong age range. A more universal one was when reporting measures through claims many carriers would reject measures if the line item was left blank so as a workaround practices were advised to document a \$0.01.
- Further segment the eligible clinician population. For example, we know that large groups are more than likely going to have an EHR, and many small groups do not. These trends could be more readily understood if CMS showed the data by (a) large group: EHR, Claims, Registry; (b) small group: EHR, Claims, Registry; (c) Individual: EHR, Claims, Registry; and the prevalent measures for each cohort.
- Provide cost performance distribution in a format like the charts in the QRURs that showed the midpoint and distribution. If CMS could break these down by measure and different demographics (specialty, practice size, etc.) that would be helpful. If not, even the aggregate performance range would be useful.
- Provide reporting rates on specific PI measures and PI performance data by specialty (ideally, per measure, but average PI category scores per specialty would be helpful, too). This would help us to better understand which PI measures are more challenging for certain specialties.
- CMS should include data on patient outcomes.
- A longitudinal trend report for the 2018 report and later would be helpful to show any shifts in participation level amongst different types of groups (*i.e., Did the mean score for small groups stay the same throughout the years as the requirement got harder to reach?*), where they go for reporting through the years (*i.e., was there a shift to registry reporting since many practices do not have EHRs still, and claims was more difficult through the years*), as well as any changes in the top measure selections (*i.e., how do topped out measures, and more specialty specific measures change this trend?*).
- Provide QCDR-specific reports that identify trends and measures in comparison to the national data, for example, the QCDR's participants.

13. Enhanced Information for Patients

a. Patient Experience and Satisfaction

The AMA recognizes the importance of incorporating a patient's voice and engaging in shared decision making with a patient. A positive aspect of MVP is that there is the potential for inclusion of measures that capture the patient experience and satisfaction data in a way that is more useful and relevant than the current approach under MIPS. We particularly see Patient Reported Outcome (PRO) measures playing a role. However, we very much caution CMS with moving forward with a single question or brief survey to measure the quality of patient experience and satisfaction due to the diversity among physician practice settings and specialties.

Patient experience encompasses the range of interactions that patients have with the health care system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other health care facilities. Patient satisfaction is related to whether a patient's expectations about a health encounter were met.¹⁸ When the Physician Quality Reporting Initiative (PQRI) started, the AMA through the PCPI[®] extensively explored to identify and develop universally applicable patient satisfaction measures. However, we found universal measures to be difficult to define in a way that clearly links to measuring an outcome. Therefore, CMS should invest time and money in expanding PRO types of measures rather than a one-size-fits-all-measure approach. We would not support mandatory MVP adoption of a single measure that was then aggregated and scored across all physicians. As we have highlighted, the measures associated with an MVP should be specifically tailored to what is most important to measure with the clinical condition.

Patient experience, while important, does not always correlate with better clinical outcomes and may even conflict with clinically indicated treatments. For example, a physician who recommends that a patient lose weight, stop smoking, or limit pain medications, is likely to receive a low "performance" score, even when these are clinically indicated. Therefore, tying a measure and score related to CAHPS to publicly reported ratings and accountability can be problematic, as CAHPS often depends more on patient perceptions than on good medicine. In addition, we believe CAHPS survey administration protocols are outdated and a need exists to allow for measures that use multiple modes of data collection. Allowing physicians to collect the information in the office through a tablet while the patient is in the waiting room, via smartphone app, for example, is needed. The broader patient population physicians can reach, the more likely they are to receive good response rates.

CMS needs to also look outside of CAHPS to measure patient experience, such as the CollaboRATE tool/measure. CollaboRATE is a patient-reported measure of shared decision making which contains three brief questions that patients, their parents, or their representatives complete following a clinical encounter. The CollaboRATE measure provides a performance score representing the percentage of adults 18 and older who experience a high level of shared decision making.

Generally, it appears that collecting open-ended questions may provide valuable feedback to physicians for quality improvement purposes, but we believe it is premature to move to publicly posting patient narratives in-conjunction with CAHPS for MIPS survey data or other surveys. Narratives can be helpful at times but context is needed to understand what happened during the patient encounter. We also believe additional research is needed to explain the potential reasons for variations among patients, especially more complex and sick patients.¹⁹ Therefore, due to the subjective nature of narratives and lack of testing, we do not see how CMS could score the information under MIPS or Physician Compare.²⁰

¹⁸ What is Patient Experience? Patient Experience Defined. About CAHPS. Agency for Healthcare Research and Quality. <https://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html>. Accessed 09-05-2019.

¹⁹ We are aware of AHRQ conducting analysis on patient narratives but it was performed on an extremely small sample, so it is premature to make a generalizable statement and for CMS to move to implement the patient narratives in a national program. It also remains unclear how the data will be used because posted protocol on the CAHPS database on AHRQ's website states that AHRQ has no plans at this time to accept submissions on patient narratives, nor is there an explanation offered by AHRQ on how narratives will be assessed/scored and by whom.

²⁰ See MIPS Final Score Methodology, Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure for additional comments on patient narratives.

When designing a potential pilot related to capturing patient experience, satisfaction or PROs, CMS must recognize and consider the amount of time and dollars it takes for practices to implement and report on such measures.²¹ Recognizing the potential burden on collecting the various types of measures and patient interest, we encourage CMS to conduct user testing to understand whether patients would prioritize experience over satisfaction or over outcomes. Otherwise, we are potentially designing an unsustainable program and adversely hurting small and individual practices that cannot afford to manage all the various tools and surveys and at the same time be expected to act on all the measures.

b. Physician Compare/Public Reporting

The AMA supports public reporting of physician data when it is valid, reliable, and meaningful to both consumers and physicians. Recognizing the MACRA statute requires increased public reporting on the Physician Compare website, we want to continue to work with CMS to ensure information is accurate, not misleading, and presented in a format consumers can understand and use appropriately. We are also appreciative of CMS taking a gradual approach to expansion and ensuring a high reliability when publicly reporting data. However, we are concerned with CMS' lack of consideration of MIPS program policies and methodologies, failure to consider how the Physician Compare data interacts with MIPS benchmarking methodologies, and the lack of solicitation for feedback and comment. CMS has been operating Physician Compare in a silo and majority of the time proposes and finalizes methodological changes through sub-regulatory comment and webinars.

Within the current environment of health care quality measurement and assessment, there are multiple programs that CMS is attempting to rank and compare. MIPS involves awarding points to physicians based on where they fall in decile-based categories calculated from historical quality measure data (when available). Notably, this methodology differs from CMS' Physician Compare star rating public reporting program. Physician Compare uses the Achievable Benchmarks of Care (ABC) methodology to place physicians into one of five categories (each with a corresponding "star rating") for purposes of helping patients compare physicians to make more informed decisions about where they seek care. In contrast, the MIPS methodology uses nine categories (and point system) to score physicians on quality measure reporting and cost measures to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive. As a result, through our examination, the two methodologies (MIPS and 5-star) results in inconsistent ratings and comparisons. See Appendix A. *MIPS Benchmark White Paper* for more details.

At a minimum, we urge CMS to immediately align and move to one consistent data calculation policy between the two programs on the following issues:

- Only incorporate data used to calculate a physician's quality and cost measure score;
- Have consistent reporting by individual or group;
- Create separate benchmarks for each reporting mechanism;
- Move to the same number of achievable points across programs; and
- Limit the PI performance category indicator to that of only "successful."

²¹ Barr PJ, Forcino RC, Thompson R, et al. Evaluating CollaboRATE in a clinical setting: analysis of mode effects on scores, response rates and costs of data collection. *BMJ Open*. 2017;7(3):e014681. Published 2017 Mar 24. doi:10.1136/bmjopen-2016-014681.

The inconsistencies highlighted and demonstrated in our analysis outlined in Appendix A. *MIPS Benchmark White Paper* could result in physician frustration and further dissatisfaction, and ultimately lead to a lack of confidence in the MIPS program. Furthermore, these inconsistencies also send mixed signals to patients who might make incorrect assumptions about physician quality when deciding to seek care and leads to additional administrative burden and complexity.

We also offer the following recommended Physician Compare policy changes:

- **Expand the Preview Period to 90-Days:** The current 30-day review period ignores the demands of patient care and competing priorities physicians face on a daily basis. Ultimately, the Physician Compare preview report and preview period should be combined with the MIPS Feedback Report and Targeted Review process. In addition, data under appeal should not be publicly reported. If at any time a physician files an appeal and flags information as problematic, CMS should postpone posting the information until all issues are resolved.
- **Allow Physicians Three Years to Report on Measures Prior to Public Reporting:** The AMA supports CMS' proposal to not publicly report on a first year quality measure for the first two years a measure is in use. However, the AMA continues to urge CMS to expand this exclusion to measures that have been in use for fewer than three years. Publicly posting information on measures after two years of reporting does not allow CMS to adequately evaluate meaningful trends over time or provide physicians with an adequate period to fix data collection issues. Allowing physicians three years to report on measures prior to posting measure data on Physician Compare will improve the chances that only robust and meaningful data is included on the website.

B. MIPS Quality Performance Category

The AMA is extremely concerned with the direction CMS is taking the MIPS program due to the number of proposed changes with the Quality Category in 2020. Yearly program changes increase administrative burden, adds to the complexity and cost of the program, and run counter to the Patients Over Paperwork initiative. Practices invest time and resources to incorporate quality measures into their practice workflows and systems. Proposing to once again increase the performance threshold and remove such a large number of quality measures in 2020 forces a practice to pick new measures to satisfy MIPS requirements and leaves a limited number of available measures to report on, which increases burden and the chance of not earning an incentive payment. While CMS may believe a limited set of parsimonious measures will lead to the ability of creating benchmarks, it will not lead to better quality care or allow patients to better identify high performing physicians. It will also hinder physicians' transition to MVP because many of the measures proposed for elimination could have been part of an MVP. Therefore, we recommend several modifications within the quality performance category to follow the spirit of Patients Over Paperwork and allow the program to begin to transition to MVP in 2021.

As detailed in the following sections, the AMA urges CMS to maintain the quality category weight, the existing MIPS quality measures; and the data completeness threshold at 60 percent.

1. Weigh the Quality Performance Category at 40 percent for the 2022 MIPS Payment Year

- **Recommendation:** We do not support CMS reducing the quality category to 40 percent of a physician or group's final score.

CMS was granted increased flexibility in the Bipartisan Budget Act of 2018 (BBA) to set the performance threshold and category weights, and the AMA urges CMS to follow congressional intent. Altering the category weights before the cost category has been sufficiently refined leads to less stability with the program, adds complexity, and is counter to the Patients Over Paperwork initiative. The measures under the cost category are new and many have questionable reliability. Physicians need time to review their cost data and opportunity to make improvements in practice. CMS is discrediting the effort, time, and money required to make changes into practice based on administrative claims measures.

2. *Removal of Measures*

- **Recommendations:** The AMA recommends maintaining the existing MIPS quality measures to ensure consistency with program requirements, reduce the creation of additional burden, and allow for more measures to form the basis of MVPs. We also recommend that CMS not finalize the new measure removal factor.

As part of the Meaningful Measures Initiative, CMS proposes to remove 55 quality measures in 2020, which results in a 21 percent decrease in the total number of available MIPS quality measures. Over the last two years, CMS has removed approximately 32 percent of MIPS traditional quality measures.²² CMS also proposes to add an additional removal factor: *remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods*. MACRA requires all physicians to participate, regardless of specialty, so there must be a sufficient number of meaningful and actionable measures that all physicians can report on to satisfy the quality category and not force physicians to report for the sake of reporting.

The proposals to remove a large number of measures also do not take into account whether the measures contribute to patient safety or improved patient care. Absent a reduction in the number of measures a physician must satisfactorily report, the AMA does not support immediate removal of the proposed measures or the new removal factor. However, we would support a phased approach as CMS previously finalized in 2018, as long as there is a better or equivalent measure to replace each measure being removed.

Many physicians, particularly specialists and sub-specialists will be left with an insufficient suite of measures to report and forced to report on measures simply to check a box. Accordingly, the AMA recommends maintaining existing MIPS quality measures. For specific examples, please see the following.

For example, CMS has proposed to immediately remove several radiology measures from the MIPS measure set:

- Measures 146, Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms
- Measures 225, Radiology: Reminder System for Screening Mammograms
- Measures 361, Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry

²² Does not include the number of QCDR measures CMS has removed from the program or proposes to remove as part of the 2020 QCDR deeming process.

- Measures 362, Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes
- Two were removed in 2019 (359, 360)

A number of the radiology measures are also sub-specialty specific (i.e., 146 and 225 – breast imaging) and many practices only have a case mix relative to these measures. Removal of the two breast imaging measures would leave many groups without any or perhaps only one measure to report.

Pathology Measures

- Measure 249: Barrett's Esophagus
- Measure 250: Radical Prostatectomy Pathology Reporting
- Measure 395: Lung Cancer Reporting (Biopsy/Cytology Specimens)
- Measure 396: Lung Cancer Reporting (Resection Specimens)

Based on the number of measures CMS proposes to remove from the pathology set and only propose to add the following two new measures, Measure 440: BCC/SCC Biopsy Reporting Time and Measure 397: Melanoma Reporting, only about 50 percent of practicing pathologists will be able to be scored on quality. CMS is also sending the signal that it is only interested in measuring pathologists on two skin care measures as opposed to the other important areas of focus related to improving patient care. Given that most pathologists are exempted from PI and unable to be scored on Cost, the rest will receive a neutral payment adjustment since they can only be scored in the IA category

CMS proposes to eliminate several outcome and inter-immediate outcome measures. For some specialties, such as gastroenterology, this proposal would eliminate the only outcome measure (Measure 343, Screening Colonoscopy Adenoma Detection Rate) available for the specialty. It is also well suited to be part of an MVP because there is a cost episode on colonoscopy. In addition, CMS proposes to eliminate Measure 192, Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures, but cataract surgeons frequently state it is the most meaningful measure they report on because it is a true indicator to patients whether the physician provides good quality care.

CMS also proposes to remove several eCQMs when there are already a very limited number of eCQMs, which conflicts with CMS' goal of moving practices to electronic reporting. For example, CMS proposes to remove Measures 375, Functional Status Assessment for Total Knee Replacement and 376, Functional Status Assessment for Total Hip Replacement, which if finalized, will leave orthopedic surgeons without a sufficient suite of eCQMs on which to report.

We are also concerned with CMS' proposal to remove Measure 147: Preventive Care & Screening: Influenza Immunization and replace it with Measure #TBD: Adult Immunization Status stewarded by National Committee for Quality Assurance as the measure has not yet been specified or tested. Available CMS benchmark data still shows a significant gap in care for all data collection types with Measure 147. While composite measures may be desirable for reporting purposes, they do not always foster quality improvement due to the lack of information provided regarding the individual measures included in the composite. CMS also provides no information on what rate they intend to score physicians on or clarified whether they plan to include individual rates for each immunization type as feedback to physicians. Moreover, CMS lacks consistent payment coverage for many vaccinations included in this composite vaccination measure, such as only covering tetanus if there is an injury or only covering a vaccine under

Part D. Changing to a complicated composite measure on short notice is burdensome to physicians who report on the measure and require practices to reprogram the systems they have in place to collect and report the new measure.

Therefore, the AMA believes that CMS did not take into consideration the following additional issues with the proposals:

- Practices invest time and resources to implement quality measures into practice and update their systems. Removing measures forces a practice to pick new measures to satisfy MIPS requirements which increases burden and the chance of not earning an incentive payment. For example, an orthopedic practice stated the following:

2018 is the first year that we will have benchmarks for both of the measures [375 and 376] that are applicable to our specialty and that we do a good job on and now they are removing one of them just when we just figured out how to report given the 2018 revision. It's just frustrating that there aren't that many EHR measures that we can report on and that are available to us for reporting. Registry reporting is just so costly to practices like ours.

- Removing measures creates a lack of consistency of available quality measures in the program. This inconsistency does not allow (1) CMS to measure practices on improvement and (2) practices to focus on incorporating improvement strategies.
- It reduces the number of measures available to form MVPs and delays transitioning MIPS into a more meaningful program.
- CMS' program policies perpetuate the problem of small sample sizes and do not allow for uptake of new measures because the MIPS quality scoring requirements discourage reporting on new measures. We are frequently told by practices that they do not want to report on new measures when there are no predefined benchmarks and they are at risk of only scoring three points on a measure. Therefore, if CMS determines that a measure is appropriate for MIPS, the program must be designed to allow for uptake of new measures and sufficient time for adoption.
- Some measures that are based on a clinical condition or specialty may have small sample sizes that are intrinsic to the patient population; yet, the measure addresses a critical process or outcome. Therefore, the proposed new factor could remove measures that are needed to demonstrate quality of care and limit the number of available measures to be paired with cost measures in the future.
- Many high-performing measures are still showing low adoption rates among physicians and the reason for the high performance score may be a result of a small pool of high-performing individuals choosing to report measures with a high score, skewing the average score to appear higher than it truly is.
- CMS places adoption and promotion of new measures solely on the developer. CMS does not actively promote new measures and must invest in better education materials.
- Eliminating a measure only after two years in the program will deter measure stewards from investing in and developing new measures, maintaining existing measures, and putting forward MVP proposals. The proposed rule presents the real potential of removing measures that developers have spent more than two years to develop and test to only have it in the program for a small number of years (even just two years).

- The selection of a two-year time frame appears arbitrary. We encourage CMS to perform analysis and work with measure stewards to learn the time it takes for measures to achieve acceptable numbers of adoption.
- If benchmarking is a concern, moving to a manual+data driven benchmark methodology would better allow CMS to create quality measure benchmarks. Please see Flat Percentage/ Benchmarking section for more details.
- Evaluating to determine whether there is an equivalent or better measure to replace it because the current factors are not sufficient to fully understand why a measure lacks uptake. For example, if CMS removes an outcome measure, there should be another outcome measure available for reporting. Otherwise, physicians lose out on the opportunity to meaningfully participate, meet the minimum requirements, and achieve the maximum number of points.

3. Removal of MIPS Quality Measure If Not Available to All Third-Party Intermediaries

- **Recommendation:** The AMA continues to believe licensing/sharing a measure with another QCDR or Third-Party Intermediary (qualified registry or EHR) should be at the discretion of the QCDR measure steward and not at the expense of jeopardizing data integrity. If the steward does not comply it should not be subject to CMS automatically removing the measure(s) from the program.

Without clarification in the regulatory text, QCDR measure stewards are concerned that they will be in violation of CMS' policy on sharing measures and could result in the loss of important measures within their own QCDR. The allowance of such requirements when sharing a measure with a third-party that does not steward the measure will better ensure the integrity of the measure(s) and that it is implemented as specified, as well as meet basic quality assurance and control systems and activities to prevent disorganized or biased data collection.

Precedent exists to require vendors to possess minimum business requirements. To become an approved survey vendor to administer CAHPS for MIPS or ACOs, vendors must meet certain criteria and follow the measure protocol.²³ In addition, AHRQ, the steward of CAHPS provides guidance on administration of the survey based on best practices in survey design and administration, which CMS adheres to.²⁴

For example, a QCDR steward may require as part of the licensing agreement the following of the QCDR or third-party using their measure:

- **Clinical and Quality Improvement Expertise:** Demonstrated clinical expertise in medicine, quality measure development and improvement by providing methods to ensure data quality, routine metric reporting, and quality improvement consultation.
- **Demonstrated Quality Control Procedures:** Provide detailed information on the data collection, analysis and validity processes as requested to ensure that the measure will be implemented as specified.

²³ [CAHPS® Survey for Accountable Care Organizations Participating in Medicare Initiatives](https://acocahps.cms.gov/en/vendor-tools/business-requirements/). Minimum Survey Vendor Business Requirements National Implementation of the CAHPS Survey for Accountable Care Organizations (ACOs) Participating in Medicare Initiatives. Center for Medicare and Medicaid Services. <https://acocahps.cms.gov/en/vendor-tools/business-requirements/> Accessed 08-27-2019.

²⁴ CAHPS Clinician and Group Survey. Agency for Healthcare Research and Quality. <https://www.ahrq.gov/cahps/surveys-guidance/cg/index.html>

- **Sharing of Testing Results:** Allow the measure steward to review the measure specifications and testing results to ensure that the measure is implemented as intended.
- **Sharing of Data:** Be willing to share the data with the measure steward so that they can use it for benchmarking and testing purposes.
- **Data Mapping Schema:** If pulling data from the EHR agree to utilize the data mapping schema developed by the measure steward.
- **Measure Implementation Training:** Adhere to all protocols and specifications, and agree to participate in training sessions.
- **Documentation Requirements:** Must provide documentation as requested for site visits and conference calls, including but not limited to: HIPAA compliance, mail material production, staff training records, telephone interviewer monitoring records, and file construction documentation.

CMS must keep in mind that the QCDR reporting mechanism allows QCDRs to develop their own quality measures for use in MIPS. QCDRs should not be required to license their measures in lieu of QCDR, Qualified Registry or EHR vendors developing their own measures.

4. Global and Population Based Quality Measures- Inclusion of All-Cause Unplanned Admission for Patients with MCCs

- **Recommendation:** The AMA does not support the inclusion of the All-Cause Unplanned Admission for Patients with MCCs beginning with the 2021 MIPS performance period. We also do not support CMS moving forward with additional Global and Population administrative claims measures into the MIPS program as they do not allow to clinically meaningfully measure outcomes and reliably attribute who is responsible for providing care.

We continue to have concerns with the MCC measure due to lack of evidence to support applying the measure to individual physicians or practices. The measure as constructed is also not actionable to ensure that improvements can be made by those that the measure attributes as the responsible entity. In addition, CMS has not yet provided testing to demonstrate that the measure is reliable and valid at all levels to which the measure is attributed.

The AMA strongly believes that attribution must be determined based on evidence that the accountable unit is actually able to meaningfully influence the outcome, which aligns with the most recent National Quality Forum (NQF) meeting, *Improving Attribution Models*.²⁵ While we agree that evidence exists to demonstrate that improved care coordination and programs focused on care management can lead to reductions in hospital admissions, the majority of the cited evidence involved multiple partners such as a health system and/or hospital. We also note that not all of the studies demonstrated a decrease in hospitalizations.

We do not believe that sufficient evidence was provided to support the theory that physicians or practices, in the absence of some coordinated program or payment offset (e.g., care management fee), can implement structures or processes that can lead to improved outcomes for these patients. Since the care coordination programs and initiatives are mostly led by health plans, integrated delivery systems, ACOs,

²⁵ National Quality Forum. *Improving Attribution Models*. Final Report. August 31, 2018. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88154>. Last accessed December 18, 2018.

or other large entities, assignment of responsibility of the reduction of admissions to individual physicians and practices in MIPS is inappropriate.

In addition, the anti-kickback statute, Stark, and the civil monetary penalty law are potential barriers to tailoring and delivering services to patients. The laws can have a negative impact on the ability of physicians to assist with coordination, especially for patients with social risk factors because they inhibit collaborative partnerships, care continuity, and the engagement of patients in their care. Continuity of care requires smooth transitions to prepare for patients' changing clinical and social needs. The Stark law may impede this continuity and these care transitions. Specifically, in certain circumstances, physicians are prohibited from employing promising care coordination strategies on behalf of their patients, e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care among a hospital, physician specialists, or a primary care physician may induce future referrals to their own office to avoid an unnecessary readmission to the hospital. Instead, patients, in addition to dealing with the physical and emotional aspects of a disease or condition, often find themselves having to coordinate their own care in a fragmented and siloed system. Placing the obligation on the patient to know how to properly manage follow-up care without the assistance of their physician or care coordinator may have a negative impact on patient care, the physician-patient relationship, and on a physician's ability to achieve high levels of performance for beneficiaries with social risk factors. However, this barrier can be overcome through creating an anti-kickback safe harbor and Stark exception to facilitate coordinated care.

The AMA is also concerned that a clinician or group's ability to drive improvements on this measure is limited because the developer is using retrospective attribution. The AMA understands that it remains difficult to implement measures that use prospective attribution. However, CMS must begin to explore approaches that more clearly assign patients to physicians and practices in advance of the reporting year to better enable them to drive improvements. The current approach toward attribution along with the use of administrative data that is not timely makes it difficult for physicians to drive toward reductions in admissions.

In addition, CMS must address the lack of alignment of the various attribution models used for the MIPS outcome and cost measures such as this measure, the HWR measure and TPCC measure. Based on the proposed changes to attribution in many of these measures to hold more than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits), physicians and practices will have different patients assigned to them for different measures. This lack of consistency across measures will further decrease a physician's ability to drive improvements in care as they will not be working with a pre-determined set of patients. Rather, patients will be assigned retrospectively and could be assigned to more than one clinician. Therefore, the AMA is extremely concerned that the multiple attribution approaches across measures defeats this purpose and it must be addressed immediately by CMS. Otherwise, this approach will only further increase physician frustration about MIPS and unnecessary increase administration burden.

The AMA supports and is encouraged to see that social risk factors were tested and will be included in the risk adjustment approach for the MCC measure and recommended that dual eligibility be included when the measure was released for comment earlier this year. This addition must be made prior to implementation of the measure since the testing demonstrated that dual eligibility was strongly predictive of an admission.

The AMA also encourages CMS to continue to ensure that measures meet minimum acceptable thresholds for testing such as 0.7 for reliability and demonstrate the validity when attributed to the

physician or practice. Both reliability and validity must be demonstrated prior to implementation in MIPS. The preliminary testing results provided during the public comment period in April of this year indicated that the reliability minimums would not meet a target of 0.7 or greater and no testing to demonstrate the validity of the measures when attributed to individual physicians or practices was provided.

CMS must balance the desire to apply this measure to the broadest number of physicians possible with the unintended consequences of inappropriately attributing measures to physicians for which they cannot meaningfully influence patient outcomes. The AMA believes that CMS must carefully consider the potential misinformation that could be provided to patients and caregivers if the measure does not have a clear evidence base to support attribution of the outcome to a specific physician and could potentially produce scores that are invalid and unreliable.

5. Increasing Data Completeness Threshold to 70 Percent

- **Recommendation:** The AMA recommends that CMS maintain the data completeness threshold at 60 percent for all reporting mechanisms. However, the AMA continues to believe 50 percent is a sufficient threshold.

The increased reporting requirement²⁶ is counter to the Administration's Patients Over Paperwork initiative. Physicians do not stop complying with quality protocol once they hit minimum threshold requirements. However, they may just stop submitting data to CMS due to the administrative burden of data collection and reporting, especially if reporting on patient reported outcome measures.

While the AMA recognizes that CMS highlights that the average data completeness for reporting on a quality measure is 70 percent of denominator eligible patients it does not take into consideration the following factors:

- Practices need stability to focus on improvement and reduced burden to transition to MVP in 2021. The increased threshold is also more difficult and burdensome for small and rural practices to meet.
- Some specialties provide services across multiple sites using the same National Provider Identifier (NPI)/TIN but not all sites (including across sites of service) may participate in MIPS, the registry, or EHR that the physician opts to use for MIPS reporting. Specialties such as anesthesiology, radiology, gastroenterology, geriatricians, emergency medicine, and primary care physicians have these challenges with site of service differing; yet, the NPI/TIN remains the same. Therefore, until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, it is premature to continue to increase data completeness and encourage reporting through a registry or EHR.²⁷

²⁶ With the 2020 MIPS program, CMS proposes to increase the data completeness threshold when reporting on a quality measure from 60 percent of denominator eligible patients to 70 percent of denominator eligible patients. This is the second time CMS is changing the data completeness threshold. In 2017, the data completeness was 50 percent of denominator eligible patients. In 2018, it was increased to 60 percent of denominator eligible patients.

²⁷ For instance, the ease of reporting is frequently based on the number of facilities for which the group provides services. For many measures, the radiology or pathology practice must rely on the hospital to assist in data extraction from hospital systems for the group to report measures. The more facilities that a group works with, the

- 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.
- We believe the average rate of reporting is actually less than 70 percent because the statistic does not include data on patients that are not captured in the registry or EHR.
- The time it takes to implement new measures or updates to measures into practice workflow or the registry or EHR and further discourages practices from reporting on new measures. EHR vendors often charge for any requested changes. CMS also does not release educational materials in a timely manner and often in the middle of the performance period.
- If vendors are cherry-picking cases on which to report, then CMS should implement corrective action plans with these vendors, rather than increase reporting burdens for all MIPS-eligible clinicians. Alternatively, CMS could institute requirements around randomized sampling of patients to guard against cherry picking. All physicians in MIPS should not be penalized and face unrealistic requirements for a bad actor.

6. Increasing Data Completeness Threshold for Extremely Topped Out Measures and Issue of Topped out Measures

- **Recommendation:** CMS should maintain topped out measures that have a linkage to cost measures or MVPs so the program begins to measure value. We also urge CMS to revise the existing quality measure benchmark methodology to incorporate more of a manual+data driven approach which will allow for less clustering of data. We do not support an increase to the data completeness threshold for extremely topped out measures.

The AMA continues to remain concerned with CMS' handling and evaluation of topped out measures. Topped out measures will become more paramount to maintain in the program as the program expands to measure episodes of care in the cost performance category. When defining value, the topped out measures assist in determining whether the reason physicians are succeeding in the cost performance category is because they are stinting on care. For instance, topped out process measures can aid in determining whether a break in process leads to increased or decreased cost and/or better outcomes. In addition, while current performance may reflect the top performers, it may not reflect true performance across all physicians. For example, when we examine the changes in rates on these measures over time, many measures demonstrate gaps in care and sufficient variation initially; however, physicians were able to improve performance across reporting periods. We are concerned that CMS' current approach to topped out measures may discourage physicians from reporting on important aspects of care that they may not be currently providing to all of their patients, especially as we begin to measure cost of care. Furthermore, a high performance rate on one specific measure should not be considered an automatic trigger for removal; moreover, there are measures for which every physician should be aiming for top performance. We once again offer the following recommendations to improve the process:

- **Process Measures:** Process measures, for which there is strong evidence that fulfillment of the measure intent, such as providing or not providing a specific treatment will improve patient outcomes or safety, should be retained. CMS should exercise caution in measure removal until possible unintended consequences of removing each measures have been explored. The

harder it becomes. A good working relationship with hospital staff, particularly IT, is also key in successful extraction of data.

unintended consequences of removing key topped out measures are unknown. If a topped out measure directly impacts outcomes and is no longer reported, its removal may cause negative effects on patient care.

- **Outcome Measures:** There are very few outcome measures in the program and difficult to measure through a quality measure. A specialty should not be penalized because they have good outcomes on a procedure. We should be incentivizing and encouraging good patient care.
- **Analysis:** Physician performance can vary by practice setting, patient population, geography, years in practice, volume of cases of a particular condition, or how long the physician has been reporting. We urge CMS to examine the breadth and depth of reporting based on the number of physicians who successfully report on a measure and the length of time a measure is reported on within a given performance year.
- **Benchmark Methodology:** We urge CMS to revise the existing quality measure benchmark methodology to incorporate more of a manual driven approach which will allow for less clustering of data.
- **Consultation with Measure Stewards and Specialties:** CMS should consult with measure stewards and specialties to determine whether a measure is in development that could replace the topped out measure. If a measure is almost ready for implementation but needs a little more time, then it should be kept in the MIPS program until it can be replaced.
- **Performance Results:** Performance results of a measure being considered for removal should be examined for any evidence of variation among subgroups defined by the above factors and other nonclinical factors. For example, are primary care physicians who treat patients in the nursing home showing different results on their diabetes patients because they care for sicker, frail, and elderly patients?
- **Reporting Options:** CMS should refrain from removing or classifying a measure as topped out until it is topped out across all reporting options. If the reporting mechanism produces substantially different results, it may indicate an issue with the measure itself (e.g., the ability to accurately capture quality, potential bias in inclusion/exclusion).
- **Data Sources:** We encourage CMS to compare the scores to other current data as a possible way to verify if the scores are reflecting true performance. For example, if a study or clinical registry shows a gap in care remains, then the performance scores in MIPS may not reflect performance across all physicians. The results of these subgroup analyses should also be shared with the relevant stakeholders.

a. Increasing Data Completeness Threshold for Extremely Topped Out Measures

- **Recommendation:** The AMA does not support increasing the data completeness threshold for extremely topped out measures that are retained in the program because it will increase burden and complexity, and set unrealistic targets for certain specialties.

As we mentioned above, specialties that practice at multiple sites but participate in MIPS under one TIN will be challenged with meeting a 70 percent threshold and moving to anything higher is unachievable. Also, creating a requirement that is not held across all quality measures will add to the complexity of the program because for some measures physicians will have one data completeness threshold and others a different one. Therefore, we continue to recommend revising the existing quality measure benchmark methodology to incorporate more of a manual+data driven approach for handling extremely topped out and topped out measures because it will allow for less clustering of data. See Benchmark Methodology and Flat Percentage Benchmark Methodology section for more details.

7. *MIPS Quality Measure Stewards to Link Their MIPS Quality Measures to Cost Measures and Improvement Activities*

- **Recommendation:** CMS should provide the option for MIPS quality measure stewards to link their measures to cost measures and improvement activity measures.

While the concept of having to link your quality measure to cost measures and IAs is ideal, we believe it is premature. The cost measure category is in flux due to CMS continuing to expand the number of available episode of care measures. There also might be valuable quality measures but no associated cost episode or IA. If no available IA or cost measures exist, quality measure stewards should have the option to propose a new IA or cost measure. Also, measure stewards may be mid-development cycle so they need lead time to build such an association into items they consider as they develop measures. Therefore, quality measure stewards should have the option to link their quality measure to cost and IAs. If CMS makes this requirement mandatory, it should not take effect until the 2023 performance year given the timeline to develop a measure and propose to CMS.

8. *Qualified Clinical Data Registries and Deeming Process*

a. Measure Testing

- **Recommendation:** While the AMA believes measure testing holds value, we do not support CMS' proposal to require measure testing as defined by the CMS Blueprint as part of the QCDR deeming process starting with the 2021 performance period.

Requiring testing as part of the deeming process will severely delay incorporating new measures into the program and encouraging organizations to put forward MVPs. Measure testing is extremely time and resource intensive. Even when practices are available to test measure, the practices are often only academic institutions because they have the bandwidth and expertise to test electronic and registry measures, which skews testing results. Moving forward with this requirement will further diminish the QCDR reporting option because many specialty societies will be unable to meet the additional demand and change by CMS. Therefore, CMS should maintain the current testing requirements and continue to allow provisional approval until testing is completed.

b. QCDR Licensing

We do not support requiring mandatory licensing for QCDRs to third parties, including other QCDRs. However, we would consider sharing of measures if the third party adhered to certain standards and terms set out by the QCDR measure owner. See Removal of Measures, Removal of MIPS Quality Measure If Not Available to All Third-Party Intermediaries for specific recommendations.

c. Definition of a QCDR

We recommend CMS further refine the QCDR definition to include that the entity must have quality improvement and clinical guideline development experience to ensure the registry is current on best practices and what is most important to measure and can assist practices with implementing care improvements. Therefore, we recommend the following QCDR definition: *The approved entity must have clinical expertise in medicine, quality measure development and improvement by providing methods to*

ensure data quality, routine metric reporting, and quality improvement consultation. In addition, the entity must have experience in clinical guideline development to ensure the registry is current on best practices and what is most important to measure.

This more refined definition will allow the profession to better prioritize measurement efforts and coordinate activities. Furthermore, MACRA requires the Measure Development Plan to take into account how clinical practice guidelines and best practices can be used in the development of quality measures. To follow the intent of the law, the AMA recommends that CMS only include QCDR entities with broad and deep experience authoring guidelines.

9. Request for Information on Potential Opioid Overuse Measure

- **Recommendation:** The AMA strongly opposes the adoption of the eCQM, Potential Opioid Overuse, and urges that it be withdrawn. Quality measurement should not focus on preventing and/or reducing opioid use but rather should address the larger clinical issue—how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of developing an opioid use disorder.

At 84 FR 40752, CMS poses five questions concerning an eCQM focused on Potential Opioid Overuse. The measure is intended to capture the proportion of patients who receive opioid therapy for 90 days or more with a daily morphine milligram equivalent (MME) dosage of 90 or higher. Significant issues with the usability and feasibility of the measure are described in the rule.

The singular focus on the dose and duration of opioid prescriptions flies in the face of important steps that the administration has taken to address the national epidemic of opioid-related overdose deaths which the AMA strongly supports. The [final report](#) of the Department of Health and Human Services (HHS) Interagency Pain Management Best Practices Task Force, for example, made a compelling case for the need to focus on patients experiencing pain *as individuals* and to develop treatment plans that meet their individual needs, not employ one-size-fits-all approaches that assume 90 MME for 90 days is an indication of overuse. Likewise, a CDC publication in the *New England Journal of Medicine*, “[No Shortcuts to Safer Opioid Prescribing](#),” expressed concern that its opioid prescribing guidelines have been misapplied and wrongly used to nonconsensually discontinue or reduce prescriptions for patients with pain, with some actions likely to result in harm to patients. The CDC has specifically called out the guideline’s discussion of 90 MME dosages as having been misapplied, noting that the guideline’s discussion of 90 MME dosages does not address or suggest discontinuation of opioids already prescribed at higher dosages, yet it has been used to justify abruptly stopping opioid prescriptions or coverage. Finally, the CMS Overutilization Monitoring System already employs a thoughtful patient-centered approach to potential opioid overuse, requiring that Medicare Part D plans consult with the individual patient’s prescribing physician(s) to understand and confirm the appropriateness of prescribed medications.

The AMA has submitted multiple comment letters to CMS opposing the adoption of this measure. The AMA believes that the current approach to address the opioid epidemic through quality measurement has been too narrowly focused on preventing and/or reducing opioid use in the absence of addressing the larger clinical issue—ensuring adequate pain control while minimizing the risk of opioid addiction. Quality measurement must focus on how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. The CDC has clarified that its guidelines do not apply to those patients receiving active cancer treatment, palliative care, and

end-of-life care as well as those with a diagnosis of sickle cell disease. The denominator for the proposed measure would need to be significantly refined to ensure that the right population of patients is captured consistent with the evidence. Otherwise, there is a significant risk for clinicians' performance to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences, including suicide. If pain can be well controlled and function improved without the need for opioid analgesics for more than 90 days, then that may be an indicator of good patient care, but the measure would need to precisely define the patients for which it is appropriate. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

C. MIPS Cost Performance Category

As detailed in the following sections, the AMA urges CMS to:

- Retain the cost category weight at 15 percent of the final MIPS score;
- Remove the TPCC and MSPB measures that hold physicians accountable for costs outside their control;
- Phase in new episode-based cost measures to reduce unintended consequences;
- Increase the reliability and actionability of cost measures; and
- Not move forward with the Psychoses/Related Conditions measure.

1. Cost Category Weight

- **Recommendation:** The AMA urges CMS to maintain the weight of the cost category at 15 percent of the final MIPS score for at least the 2020 performance period while CMS addresses concerns with the cost measures, provides physicians with feedback about their resource use, and develops the MVP framework to make the program more sustainable.

CMS proposes significant changes to the cost category in 2020, including adding 10 new episode-based cost measures and revising the existing TPCC and MSPB measures. While the AMA has been supportive of the episode-based measure development process established by CMS and Acumen we believe new measures should be introduced with guardrails to prevent any unintended consequences and to ensure physicians understand how they are being measured on their resource use for episodes of care.

Physicians continue to familiarize themselves with the cost measures but have received detailed feedback on their attributed patient population and cost measure performance for only one year—2018. We appreciate that the 2018 feedback reports include demographic and clinical characteristics for attributed beneficiaries, costs related to services billed by the clinician, and utilization of hospital and post-acute care. However, the feedback does not provide comparison information to help physicians determine the extent to which unwarranted variation in spending exists and to understand his or her own patterns of care. In addition, the feedback is based on measures that CMS is proposing to revise beyond recognition in 2020. Furthermore, physicians have received no information about any of the episode-based cost measures, the first wave of which went into effect in 2019.

Although CMS and Acumen made feedback reports available to physicians who were attributed episode measures during field testing, there was limited outreach and education, few physicians could access

them, and the reports are no longer available for physicians to retroactively review. We have heard from physicians who were able to access their reports that the information was complex and difficult to interpret. We recognize the challenge of balancing the goal of providing as much data as possible with the goal of simplicity and enhanced usability. We appreciate Acumen effort to provide more granular data, while also providing upfront summaries, appendices, and links to supplemental information. However, we continue to urge CMS to present cost measure data in more digestible terms so that clinicians can easily understand what they are being measured on, how they are performing relative to other similar clinicians, and what they are supposed to be doing with this data to improve overall value.

Finally, because 2020 is a transition period to the MVPs, we believe it is especially important for the program to be stable while specialty societies and physicians shift their time and focus toward developing or preparing to report on MVPs to make the MIPS program more sustainable in the long run. We urge CMS not to increase the cost category weight in 2020 during the transition period to the MVPs.

2. *Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) Measures*

- **Recommendation:** The AMA strongly urges CMS to remove TPCC and MSPB from MIPS. Measures should only cover costs that physicians can reasonably be considered to control. Neither the TPCC nor MSPB measure can meet that criterion because the measures hold physicians accountable for patients' medical conditions that are managed outside of their organization and for costs they cannot influence like drug prices. If CMS does not remove TPCC and MSPB, CMS must address the attribution, exclusions, double counting, and validity concerns raised in the following sections.

a. Revised TPCC Attribution Methodology

The revised TPCC would eliminate the problem of attributing costs that occurred before the physician ever saw the patient; the AMA agrees that physicians should not be held responsible for such services. However, we have concerns about other aspects of the new attribution approach. The new attribution methodology assumes that a primary care relationship exists if two things happen within three days or three months, and not otherwise. This will lead to new problems as identified in the following examples:

- If a patient is getting cataract surgery or knee surgery, the surgery center will generally require the patient to be cleared for surgery by a primary care physician. The patient will find a primary care physician to examine them, the physician will likely order an electrocardiogram (EKG), and under the new TPCC measure, it appears that the physician will be accountable for everything that happens to the patient over the next 12 months, including the cataract surgery or knee surgery that was the only reason they came to see the physician in the first place. The revised measure could cause primary care physicians to refuse to do pre-surgical clearance visits on new patients in order to avoid having the surgery patients appear on his or her attribution list.
- If a new patient comes to see a primary care physician, and the patient has multiple chronic conditions or health problems, the revised measure would give the physician an undesirable disincentive to schedule follow up visits within three months so the patient and their costs are not attributed to the physician.
- On the other hand, new patients who are healthy or whose health problems are appropriately managed and who do not need to come back to see the primary care physician for six months or one year would not be attributed to that physician. The low costs would not be reflected in the

primary care physician's TPCC average, making it appear higher than reality. In that case, the primary care physician would need to order an EKG or other test simply to trigger attribution.

Another significant problem with the revised methodology is that it does not identify the end of a clinician's primary care responsibility for a patient. TPCC assigns responsibility for all Medicare Part A and B costs for 12 months after attribution. Because, however, CMS is aware that Medicare beneficiaries switch physicians or move to new states, CMS proposes a workaround that would attribute the same patients and overlapping costs to multiple clinicians in different practices if they meet the attribution criteria. To illustrate the problems with this change, under the current measure, when a patient switches to a new primary care physician, the patient's new doctor may be held responsible for things that happened before he or she took over, but once the patient starts seeing a different doctor, the patient will be attributed to the new doctor. Under the revised measure, both physicians will be held responsible for services and procedures that happened after the patient switches to another physician. In another example, a beneficiary travels to a different city, experiences a health problem and visits a new primary care physician, who runs a laboratory test and determines the beneficiary is fine. The new physician is now responsible for all spending for this beneficiary for the next year, even though the beneficiary does not even live in the community.

The AMA does not believe physicians should be held responsible for costs that occurred long after they saw the patient and potentially after the patient has moved to another city or state. Also, we do not support attribution of the same costs to multiple physicians in different practices when there is no evidence that they are practicing as a team. We have concerns about the impact of spreading accountability so widely, which CMS believes will improve care coordination. Yet this assumes data regarding services provided by other physicians is readily available and therefore actionable by the attributed physician. CMS does not provide this information, and it would be next to impossible to track patients and make value-enhancing changes in their care because the revised attribution methodology relies on a lengthy list of services, including services provided by a separate physician practice. If CMS continues using a TPCC measure, the attribution methodology should be changed to eliminate retrospective accountability without creating new problems by adding 12 months of prospective accountability for multiple physicians.

b. Measure Exclusions

In addition, we have concerns about the equity of the revised TPCC measure. We question the decision to make exclusions at the specialty level and not at the service level. While certain specialties would be excluded from this measure, the services they provide would not be excluded. Therefore, a practice comprised of excluded specialists might still be subject to the measure if it also uses a physician assistant or nurse practitioner who provides an E/M visit and another primary care service. This will make it hard to determine which practices are likely to be subject to the TPCC measure. It also creates a fairness issue by excluding certain specialties regarded as not providing primary care, but it then holds primary care physicians responsible for the costs of these non-primary-care services that they do not provide and cannot control. If this revised measure is adopted, we urge CMS to develop exclusions based on service.

c. Double Counting of the Same Costs

We are also concerned that TPCC and MSPB double count costs when physicians are measured on episode-based cost measures. The use of total cost of care measures incorporates the same costs used to construct the MSPB measure and the episode cost measures. A patient's total cost could be attributed to

one physician, a subset of those costs could be included in the MSPB and attributed to another physician(s), and another subset of total costs could be attributed to multiple physicians for the episode cost measures.

One concern is that the various attribution methods could provide mixed signals to physicians as to who is actually in charge of delivering efficient care. This problem is exacerbated by the fact that many of these clinicians may be unaffiliated and thus there is no real way for physicians to actually coordinate. The delay in providing physicians with lists of attributed patients also stifles real-time coordination. We believe the extent of the problem is likely to vary with the number of measures in a physician's MIPS cost score. We urge CMS to include information about the extent of this overlap in its annual experience report.

CMS does not believe costs are double counted because each measure is compared to expected costs for its own beneficiaries or episodes. However, the observed costs are still being counted multiple times within different frameworks and with different benchmarks and comparison groups. Therefore, we request that CMS elaborate on how different comparison groups and benchmarks under different measures address the issue of double counting costs and demonstrate that CMS can analyze the overlap between the revised TPCC and MSPB measures and the episode measures.

d. Validity of the Measure

In the proposed rule, CMS discusses changes to increase utilization of care management services, such as transitional care management and CCM, which CMS believes are beneficial. "Early data show that, in general, CCM services are increasing patient and practitioner satisfaction, saving costs and enabling solo practitioners to remain in independent practice." Yet there is no discussion about whether physicians who are managing their patients' care and billing for more frequent services are at a disadvantage in the cost category. Nor is there any discussion about whether the savings generated by CCM are being captured and rewarded in MIPS. CMS should ensure the measure does not disadvantage physicians who may appear to have higher costs due to robust delivery of care management services and fully captures the savings generated by those physicians. We believe this should be demonstrated through validity testing of the measure and its attribution methodology.

e. Measuring as Many Physicians as Possible

CMS considered removing the TPCC measure from the program but proposed to retain it to measure more physicians and address the costs of primary care. We believe it is inappropriate to put measuring the largest number of physicians in the cost performance category above getting the measures and methodology right. We are pursuing legislative refinements to MACRA that would give CMS more flexibility to develop and use cost measures without an arbitrary target of Medicare Part A and Part B expenditures and to score cross-category measures. We hope the agency will work with the AMA and Congress to seek this authority so CMS can prioritize actionable measures with a demonstrated need for improvement and that measure cost within the context of quality.

f. Lack of Alignment with Attribution Models

CMS must address the lack of alignment of the attribution models utilized for the various administrative claims measures used for the MIPS population health quality measures and costs measures, such as HWR, MCC and TPCC. Based on the proposed changes to attribution in many of these measures to hold more

than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits), physicians and practices will have different patients assigned to them for different measures. This lack of consistency across measures will further decrease a physician's ability to drive improvements in care. The lack of a cohesive approach on attribution across one program is not sustainable and must be addressed to create a system that promotes and facilitates improvements to patients in a way that is also meaningful and actionable by physicians.

CMS must address the lack of alignment of the attribution models utilized for the various administrative claims measures used for the MIPS population health quality measures and costs measures, such as HWR and TPCC. Based on the proposed changes to attribution in many of these measures, they now hold more than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits),

3. Episode-Based Measures for the 2020 and Future Performance Periods

- **Recommendation:** CMS should adopt a more phased-in approach, including episode-based cost measures in the MIPS program, to increase the reliability and actionability of cost measures. We also urge CMS to establish a transparent and consistent measure maintenance policy so specialty societies and physicians can work with the agencies to make appropriate measure updates.

a. Phase in new measures

The AMA has been supportive of the process that CMS and Acumen established to develop new cost measures. We want this process to be a success but believe the pace and desire to apply cost measures to as many physicians as possible comes at the expense of ensuring physicians have adequate time to learn about the measures and of additional analysis to prevent unintended consequences. The process, timeline and methodological decisions should put more emphasis on getting it right than on rapid expansion of the number of clinicians that can be scored on cost measures.

We believe more time is needed to road test and evaluate the episode-based cost measures prior to implementing them and increasing the weight of the category. Our concerns are compounded by several of CMS' decisions that appear to favor increasing the number of captured clinicians over ensuring integrity of the measures. We are also hearing increased frustration from specialty societies with the timelines and opportunities for input in the measure development and evaluation process for the Wave 2 measures. Physicians, including those who participated on the measure workgroups, had challenges accessing their reports and interpreting the information.

We recommend several strategies to create a softer glide path for the new measures, including:

- Making them informational for the first year;
- Making them voluntary and giving bonus points to those who agree to have them included in their score; and
- Setting higher reliability and minimum episode thresholds for the first year and then reducing the threshold in later years as appropriate.

b. Reliability

The minimum case thresholds should be set at the level needed for reliability and CMS and Acumen should accept that this will lead to fewer clinicians being attributed the measure. We agree with CMS that mean reliability for the Lower Gastrointestinal Hemorrhage episode-based measure at the TIN/NPI level of 0.20 is far too low and support CMS' decision not to score this measure at the individual MIPS eligible clinician level. Regarding its proposal to score the measure at the TIN level, we request clarification about what size TIN is needed to reach a mean reliability of 0.51. Only 75 percent of TINs reached a reliability threshold of 0.51 as shown in Table 38. Without more detailed data about the spread of reliability scores, we cannot determine whether it is appropriate for CMS to score TINs consisting of only two MIPS eligible clinicians on this measure. We urge CMS to release additional data about the range of reliability scores by practice size and to consider an exclusion for small practices that have a reliability score lower than the mean of 0.51. Precedent exists in the MIPS program for limiting administrative claims measures to larger group practices as the agency does with the All-Cause Hospital Readmissions measure.

Reliability is also a concern for other episode-based cost measures. Three of the new measures demonstrate reliability below the 0.4 threshold set by CMS at the physician level. For the Inpatient COPD Exacerbation measure, 32 percent of TIN/NPIs had reliability rates below 0.4. For Hemodialysis Access Creation measure, 30 percent of TIN/NPIs had reliability rates below 0.4. Fifteen percent of TIN/NPIs had reliability rates below 0.4 for the Acute Kidney Injury Requiring New Patient Dialysis measure. We strongly urge CMS to increase the case minimums for these measures to improve reliability. At a minimum, CMS should increase reliability in the first few years that a measure is introduced into the program to ensure that it is reliably and consistently measuring resource use during an episode of care.

c. Actionability

The AMA shares CMS' belief that the MIPS cost measures must be actionable so physicians can make informed decisions about their cost effectiveness without being inappropriately penalized for care outside their control or for caring for medically and socially complex patients. To ensure the cost measures are actionable, CMS should:

- Perform and make publicly available predictive and constructive testing for validity of the measures;
- Demonstrate attribution is accurate and tied to the physician's ability to meaningfully influence the outcome;
- Make episode-based cost measure field testing reports available after the testing period concludes;
- Conduct additional field testing if significant changes are made to episode measure specifications after the initial field testing is complete;
- Provide detailed feedback and education to physicians and groups about their performance on cost measures, including patient-level information, such as the supplemental QRURs and drill-down tables previously available under the Value-Based Payment Modifier program; and
- Conduct outreach and education about how to access their applicable cost feedback via QPP website.

d. Measure Maintenance

We urge CMS to provide stakeholders with clear guidance about how it will make needed updates to the measure and how specialty societies should continue to engage with CMS as the measure developer once the measure is in the program. We appreciate the process CMS and its contractor, Acumen, have established for seeking and incorporating physician expertise into the measures as they are initially developed. CMS should continue to seek input from the impacted community after the measure is initially developed. We understand CMS has proposed to conduct routine measure maintenance through its annual review of service codes and diagnosis codes and to make those changes via the measure specifications documents. We believe, however, these measures could be subject to significant variation year-to-year based on broader changes to Medicare payment policies, such as expanded Medicare coverage of procedures in the outpatient and ambulatory settings, and the market entrance of new technologies and innovative drugs. Therefore, the AMA recommends that CMS address such changes in a transparent fashion and allow sufficient opportunity for stakeholder input.

As an example, we have heard concerns about the cataracts episode-based cost measure, which includes the costs for certain FDA-approved drugs with pass-through payment status. The concern is that this will skew the utilization data collected to determine an accurate Medicare payment rate due to physicians substituting other drugs and avoiding the ones included in the measure because it will negatively impact their MIPS scores. However, there is currently no pathway to discuss a policy change to the measures to address this concern, i.e., excluding drugs on pass-through status. We believe CMS should establish consistent and transparent process for working with specialty societies to make these types of updates to measures after they have been developed and more often than the three-year technical expert panel (TEP) process when appropriate.

4. Request for Comments on a Future Potential Episode-Based Measure for Mental Health

- **Recommendation:** The AMA urges CMS not to adopt the Psychoses/Related Conditions measure and to work with the key specialty societies to identify opportunities for development of episode-based cost measures focused on mental health care.

This measure received a “Do not support for rulemaking” recommendation from the NQF MAP Coordinating Committee earlier this year. We share concerns expressed by the MAP that there was a lack of validity testing and that the measure depends on community support, which varies based on where a person lives. In addition, the challenges to transition from inpatient to outpatient care are often accentuated for persons suffering chronic, psychotic disorders. Influential patient-level factors include lack of primary supports, absence of an ongoing relationship with an outpatient provider prior to admission, clinical comorbidities (i.e., co-occurring substance use disorders, atherosclerotic cardiovascular disease), and disproportionately high negative social determinants of health (i.e., poverty, unemployment, housing and food insecurity, stigma). At the system level, this vulnerable population faces greater barriers that have a well-established negative impact on the cost and availability of care, including inadequate insurance coverage, a fragmented system of care, and lack of access to specialty care.

D. MIPS Improvement Activities Category

1. Participating Clinician Threshold and Performance Period

- **Recommendation:** The AMA recommends maintaining the existing participating clinician threshold of requiring one clinician in a group to perform an IA for the TIN to receive IA credit to ensure consistency with program requirements and minimize burden. We support CMS' proposal for a 90-day performance period.

The AMA opposes CMS' proposal to increase the participating clinician threshold from one clinician to 50 percent of a TIN to receive credit in the IA category. CMS has previously defined an IA to mean an activity that MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care delivery and that when effectively executed is likely to result in improved outcomes. Nothing in the MACRA statute requires a certain number of clinicians in a TIN to perform the activity; rather, the emphasis is on activities that improve outcomes. Creating a separate threshold will add to the complexity and administrative burden of the program, and may deter reporting of certain IAs, all of which we believe CMS should avoid.

Furthermore, the 50 percent threshold would be a significant change and would create complexity for groups who would need to evaluate members of their TIN to determine which IAs would be appropriate to meet the 50 percent threshold. Certain IAs can clearly be performed by one clinician and still have the intended outcome. For example, if a clinic extends its hours, those hours have been extended for all of the clinic's patients, regardless of the percentage of clinicians who work the extended hours. If a practice with 20 clinicians extends its hours, are 10 clinicians expected now to stay late, every night for 90 days, for the practice to receive IA credit? This type of policy could actually discourage such changes. It should be enough for the practice to instead ensure that it has enough clinicians to staff the extended hours.

2. IA Inventory

- **Recommendations:** The AMA recommends that CMS be judicious in its removal of IAs, particularly if utilizing the proposed "duplicative" criteria. The AMA also strongly recommends that CMS provide stakeholders with more detailed guidance for submitting new IAs and thorough explanations of why activities are not adopted for inclusion in the IA inventory.

The AMA believes removing activities is contrary to the intent of the IA category and strongly urges CMS to be judicious in how it implements such a process. CMS' primary goal in the IA category should be to support the performance of any IA that improves patient care. Yet, a policy that removes activities from the IA inventory would stymie this goal, suggesting that practices should only implement temporary rather than long-term changes. In fact, removing activities could harm practices and patients, particularly those in small and rural practices, which often have limited financial and personnel resources. Furthermore, many practices have made financial investments to perform a particular IA (for example, paying to connect an EHR to a QCDR). CMS' removal of activities could jeopardize the practice's return on that investment while requiring new program costs. We are disappointed that once again, CMS has removed far more activities this year than it is adding (15 to two).

Additionally, the AMA has repeatedly raised with CMS that the agency's responses to IAs submitted by specialties and other stakeholders are vague and unhelpful (e.g., "your submission does not fit the IA

acceptance criteria” and “your submission is a duplicate of a concept already in the inventory”). Despite suggestions that responses were more numerous and detailed than the foregoing, the AMA only received one of the above responses for all 15 of the IAs we submitted in 2018 for the 2019 program year. These responses are extremely limited in explaining why CMS rejects proposals and whether (and how) they may be amended for inclusion in future MIPS performance years. Many specialties invest significant time and effort crafting IA proposals, including gathering sources of supporting validation documentation and the other elements requested on the submission form.

CMS this year conducted a webinar on the IA proposal process but unfortunately it did not contain much new information—highlighted points included that CMS does not want duplicate activities, that the proposed activity should be feasible to implement, and that CMS should be able to validate the activity. Even after reviewing the webinar and other CMS materials on the IA category, specialties and the AMA do not understand why submitted activities fall short.

Importantly, CMS does not explain how it defines “duplicate.” For example, the AMA submitted an activity titled “Outbreak Control” in 2018 and received a response stating that the activity was a duplicate. The activity was aimed at practice preparation for public health emergencies through activities such as vaccinations, community education, staff training on patient screening for disease, emergency preparedness plans, and emergency response drills. Upon review of the IA inventory to find a duplicate activity, the closest activity was IA_ERP_1, which is described as a minimum 6-month volunteer commitment for disaster or community emergency responder teams. This is not duplicative—the activity we proposed was aimed at preparing the community and practice for an emergency as part of the practice’s internal efforts (i.e., we did not intend for our proposal to require the physician to volunteer outside of the clinic for 6 months). Again, without additional guidance, it is difficult for stakeholders to know how CMS evaluates IA proposals. The AMA still is unclear of how it should modify its “Outbreak Control” proposal such that CMS does not classify it as duplicative. Given this lack of clarity, we are concerned that CMS will remove IAs that it—but not others—view as duplicative. As noted above, practices often invest significant time and resources adjusting workflows to ensure that they can report on a particular IA. CMS’ subjective determinations about duplicity could thwart practice efforts to be successful in the IA category.

We also question how CMS is evaluating proposals in light of CMS’ criteria for new IAs. The CMS webinar on IAs in early 2019 included discussion about CMS’ need for activities that “focus on meaningful action from the [patient] and family’s point of view,” noting that the agency would “like to receive activities that would support the patient’s family or personal caregiver, and activities that are representative of activities that the multiple individual MIPS eligible clinicians or groups could perform”, are “feasible to implement” and have a high probability of improving beneficiary outcomes. It is very difficult to understand activities meeting the above criteria are not accepted. For example, one of the AMA’s proposals from 2018 would provide credit to physicians who engaged with their health IT vendors to learn about and discuss the availability and usage of patient-facing apps to facilitate beneficiary engagement. We believe that this should have been accepted for a number of reasons: (a) it met one or more of the criteria on the submission form; (b) CMS has placed a large emphasis on the importance of patient and caregiver access to medical information; (c) in its proposed rules, CMS has solicited ways to incentivize the use of health IT in IAs, including in 2019 since it removed the PI bonus, and this activity would utilize functionality that is new to 2015 Edition CEHRT; and (d) open Application Programming Interfaces (APIs) are one of CMS’ two chosen methods of providing information to patients (which will only increase with the new health information technology rules). We are again left wondering what we should change in that submission to ensure it is accepted in the future.

If CMS will not provide more detail about what it wants from a proposal and will not accept proposals that meet the enumerated criteria, we suggest the agency provide more information about the types of IAs it does not want so that stakeholders do not spend time cultivating proposals in those areas. We also urge CMS to issue additional guidance so that stakeholders can refine (or resubmit) their IA submissions in 2020. This is particularly critical given that there is now a 2-year lag between proposed and approved activities.

E. MIPS PI Category

The AMA supports many of CMS' proposed changes to the PI category. However, we urge CMS to continue to limit regulatory requirements in the PI program as long as physicians can share data among themselves and with their patients. Additional comments on specific proposals, as well as policy recommendations to move past CMS' continued "all-or-nothing" scoring structure, are included below.

1. 90-day Reporting Period in 2021

The AMA recommends that CMS adopt its proposal for a 90-day reporting period in 2021. The AMA has previously noted that practices, especially small practices with limited resources, often require a significant amount of time to upgrade their EHR technology, conduct tests and training, and change workflows after the EHR has passed certification. We value CMS' recognition that a 90-day reporting period will provide flexibility in reporting PI measures.

2. Query of Prescription Drug Monitoring Program (PDMP) Measure

- **Recommendation:** The AMA recommends that CMS finalize its proposal that the Query PDMP measure remain optional and eligible for 5-bonus points for 2020, as well as requiring only a "yes/no" response to satisfy the measure in 2019.

The AMA is committed to addressing the country's opioid epidemic. In last year's QPP rule, we supported CMS' proposal to provide a bonus PI score in 2019 to physicians who choose to utilize a PDMP when clinically appropriate and in accordance with state law and urged the agency to continue rewarding the activity with bonus points in 2020. We appreciate CMS' recognition that the operationalization of this measure is complex and can be burdensome. Furthermore, we appreciate that by continuing to score this measure as a bonus for an additional year, CMS can keep the Provide Patients Electronic Access measure's value at 40 points in 2020, underscoring the agency's commitment to patient access while incentivizing clinicians to utilize the PDMP when clinically appropriate.

We also support CMS' proposal to remove the numerator and denominator for this measure and applaud the change to an attestation ("yes/no") response. We agree with CMS that a "yes/no" attestation, rather than a numerator and denominator response, significantly reduces burden on physicians, which we know is a CMS priority. We strongly urge CMS to apply this "yes/no" attestation reporting model to all PI program measures, as discussed more fully below. We appreciate CMS' ultimate goal of reaching a state in which PDMP data is accessible and integrated into the clinical workflow so that physicians do not need to access multiple systems to find and reconcile PDMP information. However, we urge against further regulating the use of technology; rather, CMS should continue to promote the use of PDMPs through positive incentives and examine how to achieve such integration at no cost to health care providers.

3. Removal of the Verify Opioid Treatment Agreement Measure

The AMA recommends that CMS finalize its proposal to remove the Verify Opioid Treatment Agreement measure. We agree that this measure was complicated, burdensome, and did not promote interoperability.

4. Clarified Exclusion Language

- **Recommendation:** The AMA does not support CMS' proposed clarification of the description of the "Support Electronic Referral Loops by Receiving and Incorporating Health Information" (Referral Loop) measure exclusion and urges it to maintain the current exclusion language.

CMS is proposing to modify the exclusion for the Referral Loop measure to read, "Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period." The agency explains in its proposal that the current exclusion language "could be construed in a way that would make the exclusion more difficult for a MIPS eligible clinician to meet" by potentially being read to create two different sets of exclusion criteria. We disagree. As CMS notes, clinicians who receive 50 transitions of care, 50 referrals, and 50 patient encounters in which they have never before encountered a patient will have 150 "eligible encounters" and thus will not be able to utilize the exclusion. The same clinician would, however, be eligible for exclusion under the current exclusion language ("Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period"). While the current exclusion may not have been CMS' intended policy, it is disingenuous for CMS to frame its revision as a way to make the exclusion criteria easier for clinicians to meet.

5. Definition of Hospital-Based and Non-patient Facing Groups

The AMA recommends that CMS finalize the proposed revision to its definition of hospital-based groups to be those in which 75 percent of the NPIs billing under the group's or virtual group's TIN meet the definition of hospital-based individual MIPS eligible clinician. Similarly, the AMA supports CMS' proposal to define a non-patient facing group as one in which at least 75 percent of the group's members qualify as non-patient facing and eligible for PI category reweighting.

The AMA appreciates CMS' recognition that the definitions of hospital-based and non-patient facing groups have been confusing and difficult for clinicians to meet. We support CMS' proposed revision and thank it for its responsiveness to stakeholder concerns.

6. Leverage EHR Vendor-Generated Information to Reduce Physician Burden

CMS and ONC should leverage EHR data generated as a byproduct of PI participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS' "Support Electronic Referral Loops by Receiving and Incorporating Health Information," PI measure groups summary of care records received and the reconciliation of clinical information into one process. Physicians are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks physicians with juggling the technical aspect of interoperability, i.e., digital document capture and incorporation, and the laborious process of reconciliation. In fact, our members view information reconciliation in an EHR as "overwhelming" and adding "a lot of non-meaningful noise" to their patients' charts.

Instead of focusing on EHRs as a tool for measuring physician actions, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the physician, whether the EHR was able to provide the physician with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. Essentially, more needs to be done to understand how EHRs actually function and should function in the real world. This type and level of information is far more meaningful and valuable to physicians, CMS, and ONC, and should be what federal EHR reporting programs promote. Analyzing this information would expose the usefulness of the EHR, if the EHR could accommodate the needs of the physician, whether the EHR contributed to or detracted from patient care, and whether the EHR supported the goal of health information exchange. Knowing this will also help EHR vendors build better products. Opportunely, because EHRs already track what functionalities are used to perform tasks, EHR vendors should directly provide such information to CMS and ONC. This data capture mechanism also conveniently provides an audit trail for CMS.

ONC and CMS should work together to implement a “record once, reuse multiple times” approach, leveraging EHR-captured data for multiple needs—including CMS’ PI programs and to inform EHR development going forward. To be clear, the intent is to reduce the reporting requirements on physicians by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for physician reporting in programs like Promoting Interoperability. Ideally, EHR vendors would report on how a measure was achieved and physicians would attest (as discussed in the previous section) to their experience in meeting that measure. This not only reduces physician reporting burden, but also creates a feedback loop to EHR vendors—allowing them to improve EHR use based on physician need. The AMA strongly suggests ONC and CMS identify a plan to operationalize this concept. We offer our assistance in further reducing physician burden through this and other novel approaches.

F. Future Direction of the PI Performance Category Request for Information

1. Potential Opioid Measures

Recommendations:

- The AMA believes that quality measurement should not focus on simply preventing and/or reducing opioid use but rather should address the larger clinical issue—how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of addiction and developing an opioid use disorder. Therefore, we offer the following feedback on the NQF and CDC measures.
- The AMA has provided specific recommendations to the Drug Enforcement Agency (DEA) for modifying its Electronic Prescribing of Controlled Substances (EPCS) regulations under §1311.116 Additional requirements for biometrics. Until the DEA complies with the mandate from SUPPORT that the EPCS requirements for the biometric component of multifactor authentication be updated, the AMA strongly urges CMS not to issue any regulations requiring EPCS.

a. Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)

As described earlier in this comment letter in the AMA’s response to the Request for Information on Potential Opioid Overuse Measure, the singular focus of this proposed measure on the dose and duration

of opioid prescriptions flies in the face of important steps that the administration has taken to address the national epidemic of opioid-related overdose deaths which the AMA strongly supports. For a detailed rationale for the AMA's opposition to this measure, please refer to our comments on the RFI on Potential Opioid Overuse Measure.

b. Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950)

The AMA has significant concerns with the proposed inclusion of this measure in the Promoting Interoperability Program because it was developed with the intention of determining the quality of care provided by prescription drug health plans, and not for physicians. The measure as currently specified requires access to health plan medical and pharmacy claims and member enrollment information; physicians are less likely to have access to these data sources and we do not believe that re-specifying this measure for electronic health record reporting is appropriate nor would it produce valid results. Comprehensive assessment of the feasibility of collecting and reporting these data at the physician practice level must be determined. For example, it is unclear whether physicians can access data to confirm that prescriptions were not received. Ensuring that physicians can collect the data needed to satisfy the measure requirements is necessary to inform and allow thorough evaluations of the reliability and the validity of the performance scores.

In addition, like similar proposed measures focused on potential overuse of opioid analgesics, this measure as currently defined lacks the precision needed to ensure that only those patients as defined by the clinical recommendations are included in the denominator. For a more detailed discussion of the AMA's rationale for not adopting this measure, please refer to the AMA's response to the RFI on Potential Opioid Overuse Measure.

c. Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951)

As the AMA outlined in our comments on the individual NQF measures (2940 and 2950), this rolled-up measure lacks consistency with the CDC guideline recommendations and we question the validity of the results when derived from electronic health record data. In addition, after reviewing the performance scores provided during the NQF endorsement of the health plan version of the measure, we question whether this measure has adequate variation in scores to enable meaningful comparisons in performance. The testing results demonstrated that less than a 2.5 percent difference existed between the minimum and maximum rates for the Medicare population and less than 5.5 percent difference existed for the Medicaid population. If similar rates were to be found when applied to physicians, we believe that it will be difficult to distinguish better versus worse care. In addition, this measure must be adequately specified and tested across inpatient facilities prior to its implementation. Given the ongoing concerns with this measure, the AMA does not support its inclusion in the PI Program.

d. CDC Quality Improvement (QI) Opioid Measures

As the AMA highlighted in our comments on the RFI on Potential Opioid Overuse Measure (pages 75-76) and the above NQF measures, the AMA believes that the current approach to address the epidemic of opioid-related overdose deaths through quality measurement has been too narrowly focused on the dose and duration of opioid prescriptions, which is completely contrary to other important steps that the administration has taken to address this national epidemic which the AMA strongly supports. Quality measurement should focus on the larger clinical issue—how well patients' pain is controlled, whether

functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of addiction.

e. EPCS

Section 2003 of SUPPORT requires, with certain exceptions, that covered drugs in Schedules II, III, IV, and V prescribed to patients with Medicare Part D prescription drug coverage must be transmitted electronically in accordance with the DEA regulations for EPCS effective January 1, 2021. Section 2003 also requires that, not later than one year from the act's enactment (which would be October 24, 2019), the DEA must update the requirements for the biometric component of multifactor authentication with respect to EPCS.

The rules governing the biometric component of multifactor authentication for EPCS are a serious problem. In 2010, the DEA issued an interim final rule setting forth the requirements that EPCS systems must meet in order to be utilized by DEA registrants. Even though the final rule was "interim," no subsequent rulemaking has ever been issued. The AMA agrees that requiring multifactor authentication increases EPCS security, but the rigid and burdensome requirements for biometrics included in the 2010 regulations preclude physicians from deploying user-friendly devices already found in their practices to satisfy these requirements. Instead of using laptop computers and smartphones with fingerprint scanners, they must utilize separate biometric technology that has been reviewed by the DEA or a DEA-approved certifying organization for specific compliance with EPCS requirements. These requirements state, for example, that the "biometric subsystem must operate at a false match rate of 0.001 or lower." Yet even though Apple products, for example, have a biometric error rate of less than one in 50,000 and are validated for compliance with Federal Information Processing Standards (FIPS) [140-2 Level 1](#), Apple products have not been certified to meet DEA requirements and cannot be used for EPCS.

The biometric fingerprint scanners found on consumer devices commonly found in medical practices are used for secure access to other sensitive information, like banking and medical records, but typically do not comport with rigid rules for EPCS. The regulations further require that the biometric device either be co-located with or built into the computer that is being used for EPCS. This rule has led to development of a niche market for EPCS products, such as Imprivata's Confirm ID, which have been certified to comply with DEA regulations for EPCS. The fingerprint reader on a smartphone could not be used by a physician for EPCS because, even if it had been reviewed by the DEA, the smartphone would be separate from and work independently of the e-prescribing software and hardware being used in the practice. The existence of this niche market allows health information technology vendors to charge high prices to physician practices to add the technology they need for EPCS, and even after assuming these costs, EPCS technology is still likely to disrupt workflows because it is not integrated with physicians' other systems. The AMA stresses that it is the cost and impact to physicians' workflows that has led to the low uptake of EPCS, not physicians' lack of desire to adopt these tools.

The volume of controlled substance prescriptions for a subset of physician practices makes compliance with the biometric component of two-factor authentication, particularly as a distinct process from e-prescribing of non-controlled substances, onerous and a significant strain on practice workflows. On top of the fact that few health information technology vendors support EPCS, and the cost of add-on modules and separate monthly service fees, the methods and processes that vendors utilize for EPCS are often not well-aligned with normal e-prescribing workflows. These problems with EPCS systems and DEA requirements were also noted in the strategy for reducing administrative and regulatory burden issued by the National Coordinator for Health Information Technology.

2. Improving the Efficiency of Providers within EHRs

Recommendations:

- Reduce the burden of health IT measurement in the PI category by focusing on relevance of measure to clinical practice and patient improvement and eliminating any additional electronic data collection that does not align with a physician’s clinical workflow.
- CMS should move away from prescriptive measures tied directly to certified EHR use. All new measures should be based on an “yes/no” attestation.

The AMA supports CMS’ goal of thinking creatively to reduce burden while promoting health IT and interoperability. Put simply: non-traditional outcomes require non-traditional approaches.

The AMA is particularly interested in the concept of leveraging vendor-provided health IT utilization data to facilitate physician reporting. We explored this idea in our [OPP CY 2019 comments](#) and in [our response to ONC’s EHR Reporting Program Request for Information](#). EHRs track and record the process to meet measure requirements—making physicians feel they are just “going through the motions to check a box.” The incentive is to use the EHR, and therefore EHR usage has become the focus. This is a major contributor to physician reporting burden. Rather than measuring a physician’s ability to juggle the technical process of data access or interoperability, CMS’ interest should be in which EHR functions best serve patients and physicians.

For instance, a physician could attest yes/no to a health information exchange (HIE) measure in PI. Their EHR vendor could provide the actual functionality the physician used to accomplish the HIE measure. Was Direct used (identifying the usefulness of that EHR function)? Did the physician’s query find unique patient records (identifying patient matching/record completeness issues)? How many “places” did the system need to search (providing focus for HIE frameworks such as the Trusted Exchange Framework and Common Agreement [TEFCA])? Was any information discoverable but “blocked”? EHR vendor-reported data could eventually expose health IT system efficiency, whether the EHR accommodated the needs of the physician, whether the EHR contributed to or detracted from patient care, areas where federal policy could address gaps, and whether the EHR supported the goal of health information exchange—all of which is missing right now. We recognize reaching this level of analysis may take time to achieve. CMS should first leverage vendor-provided data to level set its understanding of current use and provide a metric for measurement.

a. Reduce Burden and Burnout Through an Attestation Approach

The AMA appreciates CMS’ engagement with physicians in burden reduction efforts. We will continue to interface with CMS by responding to its call for measures. HHS should strive to reduce physician reporting burden by transitioning away from EHR measurement. Information generated as a byproduct of physician-patient engagement and clinical care is far more insightful. Furthermore, all future physician measures should be “yes/no” attestation. Granular data on EHR use should be provided by the health IT vendor.

Weaving physician attestation with vendor reporting would be a powerful combination as it would reduce physician burden, facilitate return on investment (ROI) discussions, and more accurately represent the real-world use of technology. HITECH permits a professional to satisfy the demonstration of meaningful

use of CEHRT and information exchange through attestation. We also believe that HITECH would permit third party-supported physician attestation via “other means specified by the Secretary.” Again, the AMA worked with medical specialty associations to generate support for this strategy.

Interoperability measures should be specifically linked to or targeting improving patient outcomes. New measure attributes should center on improving patient care, yet physicians continue to shoulder most of the responsibility of implementing measures—which is no longer appropriate. This is traditionally very taxing on physician resources and provides inconsistent value in terms of care. As an analog, some structure and process quality measures are being retired since many were unable to demonstrate any linkages to driving improvements in patient outcomes. This linkage should be a core element of EHR measure development, established early in the process, and included in all newly proposed measures. CMS should recommend a process to develop an evidence base to demonstrate the linkages (and whether they are successful) and seek feedback from medical specialties. This process is consistent with the ONC Roadmap on Interoperability as well.

Removing the burden of PI compliance and reporting will also help alleviate physician burnout related to EHR use. Continuing to require prescriptive PI measurement will detract from clinical relevance, add burden, and focus PI participation on documentation, reporting and compliance rather than improved patient outcomes.

Furthermore, technology continues to evolve, and current PI measures are likely to become quickly outdated or fail to promote innovative uses digital health tools. Said another way, even the proposed 2020 MIPS PI measures are tied to the legacy of Meaningful Use. Given the Administration’s focus on Patients over Paperwork and emphasis on reducing physician burden, measures that track and monitor physicians’ use of EHRs should be abandoned.

CMS should create broad categories of PI objectives allowing physicians to attest “yes/no” to the use of CEHRT to achieve those categories. This will provide flexibility for patients and physicians to efficiently test new uses of technology—identifying what does and does not work while encouraging the use of EHRs. For example, CMS could create an objective called “Chronic disease management enabled by digital medicine.” Measures could be developed that support physicians using not only emerging CEHRT functionalities, like APIs and patient-generated health data, but also could also promote the use of digital health tools, such as remote patient monitoring services. We stress, however, that absent an attestation approach, any new objectives and associated measures should be optional to provide additional opportunities for physicians to be successful in the PI program. Compliance with MIPS information blocking requirements, ONC’s information blocking regulation, TEFCA, and HIPAA’s patient right of access are themselves far better mechanisms to drive interoperability and promote patient access while reducing federal regulatory burden.

In sum, an attestation-based approach would give physicians freedom to choose the technology they want to use, and how they want to use it, as long as it helps them support patient care and long-term wellness. CMS should prioritize this attestation-based approach to reduce provider burden and get physicians back to practicing medicine.

b. Potential New Measures (Trusted Exchange Networks)

The AMA has previously submitted two proposals for new PI measures that: (1) Participate in a trusted exchange network (TEN) and (2) Search for or Directly Request Patient information from a TEN. Each of

these measures would contribute significantly to the PI program's goals of interoperability and greater health information exchange.

By their very nature, participation in and query of a TEN advance CMS' goal of decreasing information blocking. They also can reduce the burden on both the clinician and the patient of relying on paper exchange and use of the fax machine. Furthermore, they have the potential to exponentially improve program efficiency as clinicians would not need to duplicate documentation or order unnecessary tests. They also help improve patient safety and outcomes by offering clinicians a more complete picture of the patient's health. While participation in public health registries and clinical data registries are current measures, this measure would encourage exchange of a broad swath of clinical information as opposed to specific quality measures. Again, because an EHR can automatically track when a TEN is used and queried, CMS should permit "yes/no" attestation of the measures.

Coupled with an attestation-based approach to reporting, these new measures would encourage greater TEN participation by clinicians, both by adopting a TEN and using it to search for or request patient records. Physicians may also become more familiar with TENs—whether regional, EHR-based, or—perhaps—through the TEFCA. However, we note that some of the potential use cases outlined in ONC's draft TEFCA raised questions as to physicians' ability to willingly participate (or not participate) in TENs. Due to the sensitive nature of protected health information and the potential disruption to physician practices involved in implementing the technology required to participate in a TEN, the AMA underscores the importance of ensuring that physicians understand and can willingly elect to participate in information sharing via TENs. We urge CMS to address issues of physician choice and voluntary participation when evaluating the use of TENs as a PI measure, and stress that absent an attestation approach, these new measures should be optional.

3. Provider to Patient Exchange Objective

Recommendations:

- CMS should refrain from creating additional provider to patient exchange measures given the multiple and more robust regulatory levers in effect that promote interoperability.
- CMS must contemplate the utility of ONC's proposed Electronic Health Information (EHI) export function and be cautious in too quickly attaching PI measures to untested EHR functionality.
- CMS should coordinate with ONC to advance more standardized data elements for patient matching by leveraging the U.S. Core Data for Interoperability (USCDI). Additionally, CMS and ONC should work together to establish guidance surrounding common issues that could be resolved by standardization.

We appreciate CMS' emphasis on patient access and interoperability measures in the current PI programs. However, we note that these two priorities will continue to receive a large emphasis from physicians due to multiple levers—with significant penalties—ensuring that patient access and health information exchange occur: (1) MIPS information blocking requirements; (2) ONC's information blocking regulation and TEFCA; and (3) HIPAA's right of patient access (the Office for Civil Rights' Director Severino has already noted publicly that patient access enforcement will increase this year). These levers provide significant motivation for physicians to use health IT, greatly empower patients to access their records, and advance interoperability.

a. Immediate Access to Health Information

In light of the proposal in its Patient Access and Interoperability proposed rule requiring certain health plans and payers (Payers) to make patient health information available through APIs no later than one day after receipt by the Payer, CMS seeks comment on whether physicians should make patient health information available to Payers “immediately.” The AMA strongly opposes this problematic potential policy, which would have numerous downstream consequences, including whether such tactics will narrow a Payer’s provider network. Narrow network plans have become increasingly common in private health insurance markets, including Medicare Advantage, and both the AMA and other physician groups have raised concerns that narrow physician networks create challenges for patients seeking care and pose potential patient protection issues.

Moreover, physician practices have limited resources, including administrative staff, and have developed procedures and workflows to turn claims around quickly. The faster physicians submit claims, the faster they are paid, so there is already a built-in incentive to submit claims quickly. Furthermore, payers have much more leverage in a physician-payer relationship than a physician—particularly a small physician practice—and they will point to comments like these to strong-arm physicians. Requiring physicians to adjust their workflows to ensure that Payers “immediately” receive information—particularly given that Payers must only provide the information to their enrollees as soon as they receive it (i.e., not within a certain amount of time from the date of service)—would be an intrusion upon a practice’s long-standing business operations, would require renegotiation of numerous contracts, and should not be permitted by an administration seeking to eliminate regulatory burden.

b. Bonus for Early Adoption of Standards-Based APIs

CMS seeks comment on whether the PI program should offer a bonus to participants who adopt certified Fast Healthcare Interoperability Resources (FHIR)-based APIs before ONC’s final rule compliance date. We note that ONC’s proposed changes to 2015 Edition CEHRT will be significant and it will be difficult for health IT developers to finalize the technology within the proposed timeframe. Obviously, a physician’s EHR adoption timeframe is, in large part, dependent on its health IT vendor’s development timeline. As such, the AMA commented that physicians should be given additional implementation time following the development timeline for the new certified FHIR-based APIs. We believe that few, if any, physicians would be able to take advantage of this potential early adoption bonus. That said, we do not believe there is harm in CMS offering a bonus to physicians who are able to adopt the technology before CMS’ required deadline and would support such a proposal.

c. EHI Export Measure

CMS seeks comment on an alternative measure under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR (EHI Export for Patient Access). The AMA strongly supports patients’ right to have access to complete copies of their entire medical record in a computable format. We see the spirit of this new certification criterion as aligned with this right; however, there are several layers of ambiguity that will inhibit uniform implementation and widespread use of this functionality. For example, we note that patients requesting an EHI export will likely obtain vastly different payloads based on three factors: (1) the health IT developers certified to deliver the export; (2) the implementation decisions and customizations at each implementation; and (3) the

institution's interpretation of what constitutes EHI.²⁸ The result of these factors may add more confusion than benefit to patients. We also note that widespread use of this functionality will be inhibited because the task of making sense of the data falls largely on patients and families, not the developers or clinicians delivering the export. We therefore caution that the EHI Export for Patient Access needs refinement. Until this refinement occurs, it would be premature for CMS to consider adding an EHI Export measure, unless it is optional, attestation-based, and scored as a bonus.

In addition, we flag the following additional points for CMS' consideration:

- Export difference across developers: Given that ONC does not propose specific transport, content, or syntax standards for EHI export (either Patient Access or Database Export), it is difficult to understand how ONC will judge conformance to this criterion. As we have seen in numerous other certification criteria, it is likely that developers are much more uniform in their conformance testing than in the real world, and it is very likely that this lack of specificity will deliver different exports for similar patients.
- Export differences based on implementation decisions and customizations: ONC expects that EHI exports will encompass "all the EHI that the health IT system produces and electronically manages for a patient or group of patients." Holding aside the ambiguity of "produces and electronically manages," there is the simple fact that health care facilities have made implementation decisions and customizations that likely differ across sites, even when using the same developer, which will enable some systems to deliver data that other systems cannot.
- Export differences based on interpretation of EHI definition: ONC defines EHI broadly. Generally, physicians have struggled to define the Designated Record Set (DRS) consistently, which by comparison is a more constrained concept. Given that the definition of EHI does not dictate which data must be delivered via Patient Access and Database Export, there is a high probability that institutional interpretations will create difference in what similar patients receive as part of this criterion.
- EHI export security considerations: The EHI Export for Patient Access should be tied to "HIPAA compliant uses," which would be physician access for treatment, payment, or operations for the purposes of continuity of care, and patient data access for whatever purpose they deem appropriate. We stress that until such time EHR vendors utilize an API orchestration to provide patients direct EHI export capabilities, the ability to request an EHI export be medical practice-facing. We have concerns with the potential of hundreds or thousands of users' "requests" coming into an EHR for an export. This would severely bog down an EHR's performance, putting patients at risk. Furthermore, externally-facing EHI export capabilities (i.e., download or export functions provided via patient portals), would expose an EHR to denial-of-service attacks (DoS). To be clear, patients could still request their electronic Protected Health Information from the medical practice, but the act of querying the EHR should be reserved for authorized users, administrators, and medical office staff. Until such time that EHR vendors have proven capable

²⁸ For a full technical discussion of our concerns, please see the AMA's response to ONC's 2015 Edition certification criterion proposal, available at <https://search.usan.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2019-5-31-Letter-to-Dr-Rucker-re-ONC-NPRM-Comments.pdf>, pp. 45-46.

of supporting patient-facing EHI requests while also mitigating privacy and security issues, EHI Export should be protected from potential abuse or exploitation.

4. *Patient Matching*

CMS seeks comment on ways for ONC and CMS to continue to facilitate private sector efforts on a patient matching strategy. The absence of a consistent approach to accurately identifying patients has resulted in significant costs to the health care system. Patient identification errors often begin during the registration process and can initiate a cascade of errors, including wrong site surgery, delayed or lost diagnoses, and wrong patient orders. As data exchange increases beyond traditional medicine, patient identification and data matching errors will become exponentially more problematic and dangerous. Precision medicine and disease research will continue to be hindered if records are incomplete or duplicative. Accurately identifying patients and matching them to their data is essential to coordination of care and is a requirement for health system transformation and the continuation of our substantial progress towards nationwide interoperability. The AMA shares the goals of CMS and ONC in increasing patient matching to improve patient safety, better coordinate care, and advance interoperability.

- Patient matching algorithms and software: Before discussing the requirement of patient matching algorithms or software, the AMA believes that indicators surrounding proper validation should be first established as guidance and provide flexibility in allowing patient-matching technologies to mature. Indicators that are necessary for assessment and reporting include database duplicate rate, duplicate creation rate, and true match rate. The current lack of consensus, adoption, and transparency of such indicators makes communication, reporting, and cross-provider or cross-organizational comparisons impossible, impedes a full and accurate assessment of the extent of the problem, prohibits informed decision making, limits research on complementary matching methods, and inhibits progress and innovation in this area. Moreover, CMS needs to account for the fact that specific algorithms and software solutions are system, vendor, data, and organization dependent. Thus, any guidance or requirements should be algorithm agnostic.
- CMS identifier: The AMA has concerns about requiring a CMS-wide identifier as being a step towards a government-issued unique patient identifier. CMS and ONC should be offering technical assistance to private-sector led initiatives that support a coordinated national strategy to promote patient safety by accurately identifying patients and matching them to their health information. A CMS identifier would go beyond such technical assistance and raises privacy concerns and risk that the identifier becomes a de facto ID for other potentially questionable purposes. Moreover, implementation and operation of a required identifier could be expensive and administratively burdensome. Furthermore, the presence of an identifier does not equate to a high assurance identity proofing process or a high assurance authentication process.
- Use of USCDI: The AMA believes that CMS should coordinate with ONC to advance more standardized data elements for patient matching by leveraging the USCDI. Additionally, CMS and ONC should work together to establish guidance surrounding common issues that could be resolved by standardization, such as the following:
 - Recording names with spaces, hyphens, or apostrophes;
 - Listing addresses in single or separate fields (e.g., separately street names from the city and state);

- Including special characters in phone numbers; and
 - Handling missing data for fields (e.g., SSN, email address).
-
- Verifying data sources for identity proofing: The AMA believes that use of any potential data source for identity proofing and patient matching should only be used for those specific purposes. CMS should not support the use of identifying proofing data sources for discriminatory reasons, eligibility determinations, or to limit medically necessary care.

5. *Patient-Generated Health Data (PGHD)*

- **Recommendation:** CMS must address several outstanding questions related to the inclusion of PGHD in the PI program. Apps are posturing to be regarded by patients as trusted intermediaries for data collection and exchange. However, this is often not the case. The AMA has provided [detailed comments and a set of recommendations](#) that must be addressed prior to widescale promotion by the federal government of consumer-facing apps.

CMS seeks comment on a number of concepts related to PGHD, including how the PI program should be leveraged to reward physicians for obtaining, reviewing, and analyzing PGHD. We begin by noting that though the prospect of patient-generated data is evolving, there are still questions of whether patient-generated information is relevant, accurate, and meaningful, to say nothing of the issues related to information collection, usage, storage, privacy, and security.

Today's app landscape offers more opportunity than ever before for patients to generate and collect health data. Yet the information yielded through health-related smartphone applications can be of uncertain reliability (for example, one study showed a 30 percent error rate in assessing melanoma risk that could result in delayed diagnosis and associated patient harm).²⁹ Moreover, patients may not be aware that the HIPAA Rules are inapplicable to apps, networks, and service providers that are neither covered entities nor business associates, thereby affording a significantly lower degree of regulatory protection to information collected, generated, or transmitted in this fashion. The AMA highlighted these concerns in its comments on CMS' Patient Access and Interoperability proposal and ONC's Information Blocking proposals, noting that a recent study published in the *Journal of the American Medical Association (JAMA)* found that many health apps created to track a user's progress in battling depression or quitting smoking are sharing the personal details they collect about an individual with third parties—like Google and Facebook—without the individual's knowledge or informed consent:

Transmission of data to third-party entities was prevalent, occurring in 33 of 36 top-ranked apps (92 percent) for depression and smoking cessation, but most apps failed to provide transparent disclosure of such practices. Commonly observed issues included the lack of a written privacy policy, the omission of policy text describing third-party transmission (or for such transmissions to be declared in a nonspecific manner), or a failure to describe the legal jurisdictions that would

²⁹ Joel A. Wolf *et al.*, *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, *JAMA Dermatology*, 149 no. 4 (2013): 422-426.

handle data. In a smaller number of cases, data transmissions were observed that were contrary to the stated privacy policies.³⁰

Not only do these practices jeopardize patient privacy and commoditize an individual's most sensitive information, but they also threaten patient willingness to utilize technology to manage their health—a goal frequently expressed by the administration. Until such concerns are addressed, physicians should not be required to encourage their patients to utilize apps to generate and collect PGHD or be penalized for failing to collect PGHD.

We are also concerned that a PGHD measure would lead to mounds of information without proper context or data segregation. It is not clear how data would be tagged so that it is obvious to the physician where external data originated. Tagging is also an important feature to ensure information is not inadvertently mixed in with clinically generated data. There is a lack of educational resources that help patients, clinicians, and researchers understand the benefits of PGHD use. More guidance and best practices are needed to aid the incorporation of PGHD into clinical and research workflows and cultures.³¹ Without data integration standards, vendors are likely to vary in the form PGHD are presented to the physician. While this variation could be seen as flexibility in system design, the simple fact is physicians will be challenged to ensure usability. We are concerned patient information could be entered simply as a “data dump” that is not actionable for physicians.

Lastly, we worry about security issues associated with PGHD and seek clarification on how CMS intends to mitigate these issues. For instance, PGHD could be incorporated into an EHR in a variety of ways. It could be hand keyed into a portal by a patient, sent through secure email, or uploaded into the EHR as a file attachment. Each method could open an EHR up to external threats or cyber-attacks. In one of many scenarios, a physician's EHR allows patients to upload patient-generated data into the EHR through a portal. In this instance, if a patient felt it was necessary to share their data collected through a wearable or remote monitoring device, more than likely the data would be encapsulated into a file for ease of transfer. By selecting and uploading the file from their local computer, the patient may inadvertently introduce a virus or other malicious software into the physician's EHR. We are very aware of the well-documented threats large medical centers and payers are facing when it comes to cyber-attacks. An infected file uploaded from a patient's computer could devastate a health system or medical practice's medical information. Worse still, a compromised EHR could expose the personal medical history of tens of thousands of individuals to the outside world. This level of data breach is drastically different from someone's credit card number being stolen given the sensitive nature of health care information. As with other industries, it will take time for best practices to develop and evolve to protect EHRs. Based on these numerous concerns we recommend that CMS refrain from adopting PGHD-related measures at this time. Alternatively, CMS should consider taking the following enabling actions:

- Prompt collaboration with industry to strengthen model practices, consumer education, and outreach that support the private and secure capture, use, and sharing of PGHD.

³⁰ Kit Huckvale et al., JAMA Netw Open. 2019;2(4):e192542, *Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation* (April 19, 2019), available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730782?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=041919.

³¹ Office of the National Coordinator for Health Information Technology. *Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024*. (2018). Available at: https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf.

- Increase funding for programs that aim to understand the outcomes of PGHD use as part of advanced health care models.
- Provide guidance that assists physicians in understanding the intersection of medical malpractice and liability laws with legal issues related to the use of PGHD.

6. *SAFER Guides*

CMS should offer points towards a physician's PI program score who attest to performance of an assessment based on ONC's SAFER Guides. The AMA proposed this concept as an Improvement Activity in the Merit-based Incentive Payment System with a recognition that it would help physicians identify recommended practices to optimize the safety and safe use of EHRs. We continue to believe that the SAFER Guides offer value to practices, and we appreciate CMS' suggestion that points would be rewarded based on an attestation approach.

G. MIPS Final Score Methodology

1. Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment

- **Recommendations:** CMS should institute a manual+data driven approach as we have previously highlighted, which could set the top decile based on a specific percentage such as 90 percent and allow the remaining deciles to be driven by the actual reported performance rather than flat percentages across the benchmark. While we recognize that some physicians may appear to perform better under the flat percentage methodology, moving to our recommended approach will allow CMS to appropriately score physicians; ensure benchmarks align with evidence; and maintain many of the outcome, intermediate and inverse measures that are proposed for removal in 2020 due the inability to score under the current methodology.

In the 2020 PFS proposed rule, CMS proposes to establish flat percentage benchmarks in limited cases where CMS determines that the measure's otherwise applicable benchmark could potentially incentivize treatment that could be inappropriate for particular patients. The modified benchmarks would be applied to all collection types where the top decile for a historical benchmark is higher than 90 percent. In sum, MIPS thresholds for a select set of measures would be set at "flat percentage benchmarks" (90 percent, 80 percent, 70 percent, etc.), regardless of evidence or recommended targets. Within the rule, CMS proposes to only apply the methodology in 2020 to the following two measures:

- MIPS #1 ((NQF 0059): Diabetes: HemoglobinA1c (HbA1c) Poor Control (>9%)
- MIPS #236 (NQF 0018): Controlling High Blood Pressure

While we understand the issues that arise when a large proportion of the evaluated group is already performing at a high level (e.g., above 90 percent), we believe that the thresholds should always be determined—at least in part—by peer performance (that is, it should always contain some "data-driven" aspects).

If "fixed" thresholds are to be used in circumstances where data-driven thresholds are highly influenced by skewed distributions, we recommend that these fixed thresholds incorporate clinical and practical considerations, and be individually determined for each measure to allow for the specific nature of the measure itself (e.g., in the case of blood pressure control NHANES data shows targets are around 69

percent³² and Adenoma Detection rate where 75 percent is the goal, as opposed to a goal of 100 percent for other measures) and the underlying distribution of physician performances (e.g., you may set a manual benchmark differently depending on “how skewed” the distribution is: if 40 percent of physicians are operating at 100 percent you may set a manual benchmark higher than if only 20 percent of physicians were operating at 100 percent). Therefore, benchmarks should first be set based on clinical evidence and potentially data from other relevant programs before applying the flat percentage capped at 90 percent. As we have previously detailed, we believe some combination of efforts (a “Manual + Data-Driven” method) would be the most prudent approach. For more detail, please refer to Appendix A for our analyses and our 2019 QPP proposed rule comments.

Based on our review and analysis of the flat percentage proposed methodology (see Appendix B), we have the following additional concerns that we do not believe CMS considered when putting forward the proposal:

- The use of two different benchmark methodologies to construct thresholds will produce inconsistencies regarding how physicians are evaluated, and increase administrative burden. Specifically, the methodology as proposed will result in physicians being compared to their peers on some measures (through data-driven thresholds based on the performance of their peers) and static thresholds on other measures that are unrelated to peer performance (through the “flat” deciles).
- The methodology still does not consider whether the proposed thresholds are appropriate for a given measure. We previously have noted that the goal should likely be set lower than 90 percent such as near 75 percent for the Adenoma Detection rate to reduce the chance for false positives. Establishing “flat” deciles for any and all measures where the top decile is at least 90 percent ignores clinical and practical considerations to which we previously called attention. We believe that this important aspect is still not addressed by the proposed cut-offs.

2. *Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure*

- **Recommendation:** The AMA believes that it is too early to support the expansion of the CAHPS for MIPS measure to incorporate patient narratives without more testing and explicit information on how the information will be used and the purpose of collecting and publicly posting the information. We also do not support expanding CAHPS for MIPS to the individual clinician as CAHPS for MIPS was designed to assess the group as a whole, not individual clinicians. CMS should consider and look beyond the traditional CAHPS survey for measuring patient experience.

AHRQ, the entity responsible for administering CAHPS, started initial testing work to determine the feasibility of data collection but has not publicly posted information on the project since 2018 and the numbers of those surveyed remains small. To date, AHRQ has only tested the open-ended questions or patient narratives using an existing Internet Panel and tested in Massachusetts and California.

³² Wozniak, Greg. Et al., Hypertension Control Cascade: A Framework to Improve Hypertension Awareness, Treatment, and Control. *Journal of Clinical Hypertension*. 2016 Mar;18(3):232-9. doi: 10.1111/jch.12654.

Due to numerous challenges,³³ additional research is needed to explain the reasons³⁴ for variations among patients, especially more complex and sick patients. The analysis performed was also on an extremely small sample, so it is premature to make a generalizable statement and for CMS to move to implement the patient narratives in a national program. It also remains unclear how the data will be used because posted protocol on the CAHPS database on AHRQ's website states that AHRQ has no plans at this time to accept submissions on patient narratives, nor is there an explanation offered by CMS or AHRQ on how narratives will be assessed/scored and by whom. Patient narratives are extremely subjective, and we do not see how CMS could score the information under MIPS or Physician Compare.

We suspect collecting this additional information will be costly, creating an added expense practices will have to consider if they would like to continue to report the CAHPS for MIPS measure. Therefore, it is too early to support the expansion of the CAHPS for MIPS measure without more testing and explicit information on how the information will be used and the purpose of collecting and publicly posting the information. The only way we could see CMS scoring free texts narratives is by providing general credit or bonus points for engaging in the collection of obtaining patient narratives. Otherwise, we cannot think of a way to assign points that would not introduce bias into the scoring. Therefore, CMS should not move forward with collecting individual patient narratives until testing has been completed, results released and vetted by experts.

In addition, CAHPS for MIPS was designed to assess the group as most of the questions ask about the group as a whole so it is not appropriate to evaluate individual clinicians based on CAHPS for MIPS. The goals of data collection must be that it is easy to request feedback from patients and families and minimizes the data collection burden, costs of practices and increase response rates. Therefore, until CMS can achieve the goals and ensure capturing patient experience does not increase burden and results are reliable and valid, we urge CMS to not move forward with assessing individual clinicians.

To better capture the patient experience, we offer the following suggestions and items of consideration:

- CMS must move beyond measures that do not provide real-time feedback to physicians. Even with the addition of narratives, the information is not provided in a timely way.
- Narratives may be more useful for quality improvement than aggregating ratings from a scale.
- CMS must allow for broader methods for data collection outside of mailed paper surveyed, including allowing for web or email surveys and potentially use of apps on smartphones. All of these additional survey collection modes could provide more timely results to practices. We assume practices could more easily receive raw reports of results periodically.

³³ The pilot, particularly in Massachusetts, identified the following challenges.³³

- The need to collect this information electronically, which requires a process to store and maintain up-to-date email addresses while also protecting patient information.
- A systematic process to analyze the narrative feedback is required.
- How to report this information to providers in a user-friendly way.
- The need to determine how to integrate this information into quality improvement efforts effectively.

³⁴ Based on the pilot, AHRQ determined the following:

- Commentary that was more positive was associated with higher scores on the doctor communication composite, access composite, care coordination composite, global ratings of the provider and a greater willingness to recommend the provider.
- Race/ethnicity, gender and education background were not associated with the overall variance of patient narratives; older patients and those with better self-rated health were more positive in their narratives.

- CMS should consider and look beyond the traditional CAHPS survey, such as the CollaboRATE measure.

If CMS decides to move forward with a pilot, CMS must evaluate and consider the implications and costs associated with any change for capturing patient experience, including expansion of questions, collection of narratives, and attribution to individual clinicians. Therefore, before moving forward CMS must assess the feasibility of each of these surveys and then determine if the results can be used to provide reliable and valid comparisons.

3. Scoring Measures When Measure Undergoes Significant Updates and Impacts Benchmarks

- **Recommendations:** Benchmarks should not be changed after the start of the performance period unless there are methodological concerns or other factors that would lead CMS to believe that the results are compromised. Any changes must be done with broad messaging and in coordination of the measure steward.

One solution to assist with communication and better track and inform CMS on the status and impact a change may have is to update the measure submission and maintenance forms to include question(s) around whether the change(s) to the measure and/or measure specifications will impact the benchmarks and scoring. We also recommend that CMS define what is considered a material or substantive change in a measure that warrants a subsequent change to a benchmark and suggest the following:

A material or substantive change to a measure (e.g., change in numerator requirements, expansion of the denominator) is one in which the effect of the change may impact the current reliability and/or validity testing results and/or the resulting changes in performance scores are more likely to reflect changes in specifications and not actual changes in the quality of care provided to patients.

In addition, benchmarks to any measure that is changed should not unfairly disadvantage participants; rather, MIPS eligible clinicians should earn the maximum number of points or at least seven points should be awarded. Alternatively, if substantive changes to a measure are made CMS should create new benchmarks and not base performance period data and scoring on the old/original benchmark.

While we recognize CMS is not currently seeking comment on how it scores a measure when measure specifications undergo refinements or the definition of what is considered a significant change, we continue to remain concerned with CMS' vague definition and current policy for scoring measures. In the proposed rule, CMS proposes to make substantive changes to 79 measures for the 2019 MIPS performance period/ 2022 MIPS payment year. The changes will also make the historic benchmarks less reliable and inappropriate to score a physician against. It remains unclear whether physicians truly understand how benchmarks are set for the Quality Category and whether they are aware when revisions are made (e.g., different stratum are used, exclusions added, benchmarks are removed).

Creating benchmarks that are stable, reliable, and valid remains an important component of MIPS and will better ensure that physicians are able to engage in a meaningful and useful way. In 2019, the benchmarks for three MIPS measures were removed well after the 2018 reporting period closed. In addition, the basis for one of those measures (MIPS #226) was changed and a different stratum was

selected with minimal information or communications to those who participate in MIPS. As we expressed previously, we are very concerned with the:

- Sudden change to established benchmarks in the middle of a reporting period;
- Inability of physicians to potentially achieve more than three points unless a benchmark can be calculated from 2018 data; and
- Lack of communication to specialties, physicians or measure stewards.

However, the AMA would like to work with CMS and others to determine how we can create greater stability in the benchmarks, improve the reliability of the data used, and ensure that the benchmarks are viewed as valid assessments of the quality of care delivered. Specifically, we would like to:

- Further discuss our proposed refinements to the benchmarking approach (see modifying benchmark comments above) and better understand the potential challenges and barriers that may be encountered if implemented.
- Identify how the AMA, specialty societies, and others can assist in ensuring that the benchmarks are viewed as stable, reliable, and valid when used by physicians and others to assess the quality of care delivered to patients.
- Determine how the AMA, specialty societies, and others can assist in communicating any changes to the benchmarking approach and adjustments made to benchmarks as quickly and broadly as possible.
- Improve the policy for scoring benchmarks when changes to measure specifications result in the need to create new benchmarks and no longer appropriate to utilize the existing historic benchmarks. We urge CMS to award maximum MIPS points when the scenario occurs to allow physicians the opportunity to adopt the changes into practice; otherwise, physicians are at jeopardy of only earning three points per quality measure.

4. Requirement to Report on All-Payer Data

- **Recommendation:** CMS should eliminate the all-payer data requirement and make it optional.

As part of the MIPS reporting, physicians are required to report on all-payer data (except if reporting through claims). While we recognize CMS' intent is to increase the sample size of eligible patients a physician has to report on a measure, this requirement is extremely burdensome and outweighs the potential perceived benefits by CMS. We urge CMS to eliminate the all-payer data requirement and make it optional.

We frequently hear from physicians that the all-payer data requirement is extremely time-consuming due to the amount of data entry required. It also ignores the fact that physicians are still contractually obligated to meet various other private payer quality initiatives using different data. If their MIPS quality data could be potentially used to satisfy their private payer program requirements and obligations then physicians might see the value in reporting on all-patients, regardless of payer.

In addition, as physicians are measured on more outcome and intermediate outcome measures, their payer mix and associated patient population will affect scoring. The AMA performed a query of 2016 National Ambulatory Medical Care Survey (NAMCS) data, looking at blood pressure control rates and on a national level the rates are different by insurance types.

| Insurance | Visits |
|---|---------------|
| All sources of payment are blank | 85.5% |
| Unknown | 67.0% |
| Private insurance | 66.9% |
| Medicare | 75.8% |
| Medicaid, CHIP or other state-based program | 70.2% |
| Worker's compensation | 49.8% |
| Self-pay | 65.7% |
| No charge/Charity | N/A |
| Other | 80.1% |
| OVERALL | 71.8% |

Therefore, we urge CMS to eliminate the all-payer data requirement and make it optional. At a minimum, CMS must improve risk-adjustment methodologies and risk-adjust at the measure-level. Alternatively, we encourage CMS to consider and reinstate the PQRS requirement that physicians report on a majority of Medicare Part B patients.

H. MIPS Final Score Calculation

As detailed in the following sections, the AMA urges CMS to:

- Maintain the complex patient bonus;
- Hold physicians harmless from data errors outside their control and provide an opportunity to submit data to earn a MIPS bonus; and
- Not move forward with its proposal to reweight the cost performance category to 85 percent of the final MIPS score in any circumstance.

1. Complex Patient Bonus for the 2022 MIPS Payment Year

- **Recommendation:** The AMA continues to support the complex patient bonus at the composite score level as the initial approach to addressing this issue at this time and encourages CMS to identify better methods for identifying patients' social and clinical risk factors.

Although CMS presents the 2017 performance and risk scores as informational, we urge caution against making any changes to this policy based on 2017 MIPS performance scores, which did not include cost measures and so do not fully capture scoring variation based on the clinical and social risk factors of a physician's patient population. Also, since the 2017 performance period, CMS has changed and created new MIPS policies, including expanded eligibility to include new clinicians, increased low-volume threshold with an opt-in option, and a cap for topped-out quality measures. We do not yet know how these policies will impact clinicians who care for the most vulnerable patients.

We also strongly encourage CMS to continue to identify new data sets and strategies to better represent the clinical and social complexity of the patients seen by physicians or practices participating in MIPS.

Adjustment based on the Hierarchical Condition Category (HCC) and the number of dual eligible patients serves as an acceptable proxy to capture the clinical complexity of the patient panels for a physician or practice. However, this approach does not sufficiently identify those patients with social risk factors that can also positively or negatively impact a patient's access to medications, treatments and other services and a physician's ability to deliver the needed services and treatments.

2. *Reweighting Performance Categories Due to Data that are Inaccurate, Unusable, or Otherwise Compromised*

- **Recommendation:** The AMA agrees physicians should be held harmless when their data is inaccurate, unusable, or otherwise compromised through no fault of their own. We also urge CMS to work with affected physicians who wish to submit data to earn a MIPS incentive payment.

Beginning with the 2018 MIPS performance period, CMS proposes to reweight the performance categories for a MIPS eligible clinician who the agency determines has data for a performance category that are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician or its agents if CMS learns the relevant information prior to the beginning of the associated MIPS payment year. This would be effective starting with the 2018 MIPS performance period.

The AMA agrees physicians should be held harmless when their data is inaccurate, unusable, or otherwise compromised through no fault of their own. We also urge CMS to recognize that collecting and reporting data is not free, and physicians and practices spend substantial resources, including physician time, staff time, vendor fees, and consultant fees, to meet the MIPS requirements. When CMS learns that a vendor is collecting and submitting flawed data, the agency should work swiftly to notify physicians and practices so they can take corrective action to remain eligible for an incentive payment for their high performance. Also, when a physician or practice identifies data issues, CMS should work with the physician if they wish to submit new or additional data to earn an incentive payment. Such options should include an opportunity to report data for the remaining parts of the performance period even if that data would not meet the otherwise-applicable data completeness requirements.

We also urge CMS to ensure that the process for identifying and notifying the agency about data issues is not unduly burdensome. For instance, if the issue stems from a pattern of noncompliance or incompetence by vendor, CMS should not require each individual eligible clinician to submit evidence that they were not at fault. Instead, CMS should automatically reweight the necessary categories due to the faulty data. In addition, we urge CMS to offer individual eligible clinicians and small practices support if they are affected by data issues.

3. *Redistributing Performance Category Weights*

- **Recommendation:** Rather than increase the cost category weight to nearly the full MIPS score, CMS should continue to increase the weight of the Improvement Activities category to reflect physicians' quality improvement efforts and consider holding physicians harmless for a category they cannot report.

The AMA does not support CMS' proposal to reweight the cost category to 85 percent and keep improvement activities at 15 percent in situations where the weights of both the quality and PI

performance categories are redistributed. We also urge CMS not to redistribute more weight to the cost performance category in additional situations beginning in 2021.

As we have discussed in greater detail in the Cost Performance Category section, we believe there are problems with the cost measures themselves as well as attribution, reliability, and actionability of this category. We urge CMS to work with the AMA and the specialty societies to improve the cost category before increasing the weight of the cost category.

CMS includes two examples where reweighting the cost category to 85 percent of the MIPS score may happen: (1) when an eligible clinician chooses not to report quality measures and (2) when an eligible professional is exempt from reporting quality measures based on extreme and uncontrollable circumstances. In both circumstances, we believe it is inappropriate to weight cost as most of a physician's performance and score in MIPS. The AMA believes that quality and resource use must be considered together. Penalizing physicians for higher spending but not rewarding them for better quality and vice versa is not the intent of MACRA, nor does it further the transition to value-based care. Additionally, as outlined above, we have concerns about the current state of the MIPS cost category that should be addressed before the cost category weight increases in any circumstances.

We suggest CMS hold physicians harmless or score them as "average" in the category they cannot report on. CMS could also increase the weight of the IA category to make up for the lack of quality or other measures. CMS should leverage the breadth of the IA category when it needs to re-weight the MIPS components.

Finally, we believe it would be counter to the language in the BBA that created a more gradual glidepath to full implementation of the MIPS cost category. Specifically, the cost category can be weighted between 10 and 30 percent over the first five years of the program. To ratchet up to 85 percent of the MIPS score would be at odds with a gradual implementation of the MIPS cost category as intended in the BBA.

I. MIPS Payment Adjustment

1. Establishing the Performance Threshold

- **Recommendation:** CMS should gradually increase the performance threshold in 2020 to 35 points to ensure continued high participation in the program, to support small practices, and to be consistent with the size of the proposed increase in the exceptional performance threshold increase.

We do not support CMS' proposals to increase the performance threshold from 30 points in 2019 to 45 points in 2020 and to 60 points in 2021. Although we support a gradual increase of reporting requirements in MIPS, we believe a jump from 30 points to 45 points is inappropriate. CMS should prioritize participation and reducing reporting costs so the value of a high score is more than the cost to achieve it. The MIPS program requires time-intensive study of complex, evolving rules to participate successfully and substantial resources to comply. Each year, the agency introduces new and revised measures and removes others. The agency tinkers with the reporting requirements and scoring approach on an annual basis. CMS has increased the performance threshold from 3 points to 30 points over the course of three years alone.

We are also concerned a 45-point threshold will disproportionately harm small practices. Although we were encouraged by results showing most eligible clinicians were successful in the first two years of the program, we remain concerned that the same results show small practices, rural practices, and eligible clinicians who report as individuals remain at a disadvantage compared to larger groups. In 2017, the national mean and median scores for all MIPS eligible clinicians were 74.01 and 88.97 points. However, the mean and median scores for small practices were 43.46 and 37.67. According to this MIPS data, more than half of small practices would face a penalty in 2020 based on the proposed performance threshold of 45 points.

As detailed in our comments, we have concerns about the underlying scoring and measurement methods in MIPS and do not believe the agency should put physician practices, particularly small practices, at risk of a penalty while the program evolves into something more sustainable. We urge CMS to maintain stability and prioritize continued levels of high participation that will provide the agency with more data and evidence to make the program more clinically meaningful and less burdensome. CMS should consider raising the performance threshold to 35 points to be consistent with the size of the proposed increase in the exceptional performance threshold increase.

We also urge the agency not to finalize an increase in the performance threshold to 60 points in 2021. While the agency points to a hypothetical jump to approximately 75 points in 2022 when the statute requires CMS to set the performance threshold at the mean or median, we urge the agency to prioritize stability and participation in the earlier years of the program. There is reason to doubt whether the mean or median will remain as high as 75 points in 2022, particularly as the cost category is expanded to include new measures and new clinician types become eligible for MIPS. Because we only have one full year of data and do not yet understand how the new program variables will impact MIPS performance scores, we believe CMS should refrain from rushing to a mean or median that may not be reflective of the program in several years. Particularly while CMS is seeking feedback about ways to make the program simpler and more clinically relevant, the performance threshold should remain at a level that ensures that most physicians can successfully participate in MIPS.

J. Physician Compare

We appreciate CMS taking a slow and methodical approach to expanding the available data and ensuring any publicly reported information meets high reliability standards to better ensure Physician Compare does not lead to inaccurate distinctions about quality. As CMS expands the website to include year two of data, we recommend the following:

- Align and move to one consistent data calculation between MIPS benchmark methodology and Physician Compare star ratings
- Only incorporate data used to calculate a physician's score: Regardless, if data is for star ratings, performance indicator or aggregate, CMS should only publicly release data that was used to assess physician performance under MIPS scoring.
- Create Separate Benchmarks for each reporting mechanism: CMS is mixing various reporting mechanisms when developing the benchmarks for Physician Compare, which CMS does not do when setting MIPS benchmarks. Therefore, CMS should create separate benchmarks for each reporting method instead of aggregating data from all reporting mechanisms.
- Move to the same number of achievable points across programs: Physician Compare places physicians into one of five categories to calculate star ratings, while the MIPS methodology uses

nine categories (and point system) to score physicians on quality measures reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive.

Retain only the “successful” performance indicator for PI: CMS should limit the PI performance category indicator to that of only successful. CMS should refrain from including EHR utilization performance information on Physician Compare. EHR utilization performance is largely dependent on an EHR’s functionality—or lack thereof. Information exchange is a complex interweaving of factors largely outside physician control, including: the availability of other providers to exchange information with; the number of data intermediaries; Health Information Exchange availability and costs; patient matching issues; vendor-initiated information blocking practices; and the unique ways EHR vendors send and receive data. It is inappropriate to list performance or compare physicians based on measures outside of their control.

K. MIPS APM Scoring

- **Recommendation:** CMS should encourage physicians to continue to participate in MIPS APMs, not impose more burdensome quality reporting requirements on them.

Currently under MIPS APM scoring, CMS requires MIPS APMs to submit data on APM quality measures for the purposes of MIPS reporting. When an APM has no measures available to score for the quality performance category, CMS reweights the quality performance category to zero for that MIPS APM. This might occur when none of an APM’s measures would be available for calculating a quality performance category score by the close of the MIPS submission period because measures were removed from the APM measure set due to changes in clinical practice guidelines. CMS notes that it was regularly reweighting the quality performance category for certain MIPS APMs that run on episodic or yearly timelines that do not always align with the MIPS performance periods and deadlines for data submission and scoring.

Therefore, in the CY 2020 proposed rule, CMS considers new approaches to the quality performance category scoring for MIPS APMs. One option CMS proposes is to require MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures. The AMA strongly opposes this approach. The MIPS APM track was developed to help move physicians into streamlined, simplified models that focus on reducing cost and improving quality. Forcing MIPS APM participants to report MIPS quality measures would be a step backwards toward four separate siloed performance categories.

In addition, requiring MIPS APM participants to report APM quality measures through their APM entity and also report MIPS quality measures is duplicative and unnecessary. In order to become an APM, the model has to prove that it does not reduce the quality of care it provides to patients. Participants are also required to report quality measures relevant to the APM through the APM entity. Therefore, MIPS APMs are already reporting quality measures and held accountable for providing quality care to patients. CMS should not add a requirement for MIPS APM participants to report arbitrary MIPS quality measures in addition to the reporting already required through each APM.

CMS also requests comment on a proposal to apply a minimum score of 50 percent or an “APM Quality Reporting Credit” under the MIPS quality reporting category for certain APM entities participating in MIPS where APM data cannot be used for MIPS purposes. As CMS notes in the proposed rule, APM participation requires a significant investment in improving clinical practice. The AMA agrees that MIPS APMs need to invest in quality performance to a degree that is equal to or greater than that required to report MIPS quality measures outside of an APM framework. Therefore, rather than giving MIPS APM

participants a minimum score of 50 percent, CMS should provide full credit in the quality performance category, given the time and resources needed to participate in APMs.

CMS notes in the proposed rule that one reason it developed separate scoring for MIPS APMs was to ensure that physicians were not forced to engage in duplicative reporting. The two new approaches CMS introduces that would require physicians to report MIPS quality measures as well as APM quality measures in order to receive full credit in the quality performance category would work against that goal. They are also counter to the CMS Patients Over Paperwork efforts to reduce physicians' administrative burdens, including MIPS-related administrative burdens. The AMA believes that CMS should be encouraging physicians to participate in MIPS through engagement in MIPS APMs, especially as this is one of most promising pathways for physicians to move into Advanced APMs. Requiring more burdensome reporting quality reporting requirements for physicians and practices participating in MIPS APMs would send the wrong signal to physicians and disincentivize innovation and participation in new payment arrangements.

L. APM Proposals

- **Recommendation:** The AMA urges CMS to issue the lump-sum incentive payments to 2017 QPs immediately. The AMA opposes the proposed changes in APM financial risk standards and recommends that CMS exercise greater flexibility in allowing Advanced APMs and Other Payer APMs, including medical home models and capitation arrangements, to count for purposes of achieving QP status. We also recommend that CMS help physicians who are Partial QPs to achieve the best possible outcome if they are involved in multiple avenues of participation or reporting.

1. 2019 APM Incentive Payments for 2017 APM Participants

The AMA is very concerned that CMS has not yet paid the five percent lump-sum incentive payments for physicians who achieved QP status for the 2017 reporting period. The announced plan for this aspect of the QPP was to pay the incentive payments in mid-2019. Many physicians invest significant financial and other resources in APMs, and the QP incentive payments are supposed to help physicians with the cost of transitioning into these new models of care delivery. The AMA urges CMS to make the payments as soon as possible.

2. Advanced APM Nominal Financial Risk

The AMA strongly opposes the proposal to the financial risk standards for Medicare Advanced APMs and Other Payer Advanced APMs. CMS proposes to amend financial risk standards to require that the "expected expenditures" for which an APM Entity is responsible under an APM be no higher than the "expenditures that an APM Entity would be expected to incur in the absence of the APM," and to exclude the "excess expenditures" when considering whether the APM meets the financial risk standards for Advanced APM status.

CMS clearly anticipates that "expected expenditures" and "expenditures expected" will differ, but it does not explain how "expenditures expected" will be calculated or when the calculation will be performed. Although the language in the proposed rule is very confusing, it appears that an APM Entity could be penalized even if it is managing patient care in a way that holds expenditures below the target price specified in the APM. If CMS or someone else estimates that expenditures would have been even lower in the absence of the APM, CMS could financially penalize the APM Entity or it could determine that the

APM Entity is not part of an Advanced APM.

In some APMs, it may be appropriate and desirable for one APM Entity to spend more than would have been expected in the absence of the APM as long as other APM Entities are spending less. Although there are many situations in which spending can be reduced without harming patients' care, there are other situations in which spending should increase in order to provide adequate care for a group of patients, and an APM Entity that focuses on the latter group of patients should not be penalized for doing so. In a properly designed APM, the benchmarks and target prices can be set in a way that requires lower spending where current spending is too high and permits higher spending where it is currently too low, with a net reduction in overall spending, but the proposed regulation appears to preclude that. The statute does not require that each APM Entity spend less than would otherwise have been expected, only that overall Medicare spending be lower than would otherwise have been expected.³⁵ In the preamble, CMS states that CMS "would not consider risk adjustments to be excess costs." We recommend that CMS codify this language in the proposed regulations. Current risk adjustment methods used by CMS do not capture all of the factors that could appropriately require higher spending for some patients.

In addition, participants in APMs need to know in advance what level of spending they need to achieve to avoid risk-based penalties and need to be assured that spending targets will be adequate to meet their patients' needs. If CMS believes that the benchmarks or target prices in its APMs are too high, it should revise them, rather than create what would appear to be a second set of lower benchmarks or target prices using an unspecified methodology. Similarly, if CMS believes that the spending targets in an Other Payer APM are too high, it should address that directly, rather than requiring an unspecified calculation of what spending would be in the absence of the APM.

3. Capitation Payments

CMS also seeks information about services that may typically be excluded from capitation payment arrangements, as its existing regulations only focus on full capitation arrangements that do not have any exclusions. Based on our understanding of the structure of private sector capitation arrangements, such arrangements always include some type of Division of Financial Responsibility (DOFR), and the DOFR excludes multiple specific aspects of costs or utilization that the capitated entity cannot successfully control or manage. The AMA encourages CMS to allow not only for exclusions from full capitation arrangements, but also partial capitation arrangements to meet the Advanced APM risk criterion. We recommend that services and aspects of costs that physicians cannot reasonably be expected to control, such as drug prices, should be excluded from such arrangements.

4. Marginal Risk

CMS also proposes to change the requirements for marginal risk for Other Payer APMs. The AMA urges CMS to simplify the requirements for Other Payer APMs to help physicians achieve QP status. The evaluation criteria not based on arbitrary requirements for how financial risk is structured. Instead, such criteria should be based on the ability of Other Payer APMs to improve the quality of care for patients, reduce spending for payers and patients, and maintain the financial viability of physician practices and other APM participants. CMS should be adopting successful private sector APMs to the Medicare program, not excluding them from the QPP with ever-changing regulations.

³⁵ Section 1115A(b)(3)(i) of the Social Security Act states that an APM must "improve the quality of care without increasing spending under the applicable title."

5. Partial QP Status

The AMA opposes the CMS proposal regarding partial QP status. CMS is considering a change in the way it applies Partial QP status because it believes some Partial QPs would like to be able to earn positive MIPS incentive payments. Under the current system, decisions about Partial QPs being excluded from MIPS are likely made at an APM Entity level and the physician may not have an opportunity to influence the Entity's decision. The change CMS is proposing would only apply the Partial QP status to the TIN/NPI combination through which Partial QP status is attained so that physicians can report through the MIPS program through other TINs in which they are involved.

The AMA opposes this proposal because it adds a new layer of complexity to what is already a complex program and set of decisions for physicians to navigate. A better course would be to give individual physicians the option to choose whichever designation is more favorable to them. In either case, the physician will need to take appropriate steps to improve the quality of care and control spending, so financially penalizing physicians by placing them in a less favorable category is inappropriate. This flexibility would be similar to what CMS currently does for physicians who could either qualify as facility-based or report through the normal MIPS measures. CMS should evaluate the possible ways that Partial QPs could achieve the best incentive payment for the subsequent year (or if the best they can do is avoid a penalty), and then inform the physicians of the available choices.

CMS expects the number of Partial QPs to increase over time as the thresholds for attaining QP status increase and fewer physicians are able to qualify for QP status. The AMA agrees that this is a serious concern and is supporting technical corrections to the MACRA statute that would give CMS the authority to modify the QP payment thresholds to correspond better to the actual structure of Advanced APMs and the expected percentages of physician revenues likely to be coming through them.

6. APM Termination

CMS proposes that if an APM Entity terminates from an Advanced APM at a date on which it would not bear financial risk for the QP performance period, then eligible clinicians could not achieve QP or Partial QP status for that year unless they can do so through participation in other APM Entities. The AMA opposes this change and believes it could have a chilling effect on APM participation. Advanced APMs are payment innovations and physicians who choose to participate in them simply cannot be assured that the APM Entities will be able to succeed. With a quality reporting period of a full calendar year, physicians participating in APMs that fail midway through the year may have little recourse to avoid a MIPS penalty if they cannot be QPs or even Partial QPs. Data reported to the APM Entity could be lost in many cases, giving clinicians no resource for reporting data to MIPS since they could already be well into or have already completed the performance year. Many physicians who participate in APMs invest significant financial and in-kind resources in the development and operation of the APM, which will likely be lost if the APM fails, whether or not it is required to make payments to CMS. The AMA urges CMS not to finalize this proposal.

7. Medical Home Models

CMS proposes a new category of Other Payer APM which would be an Aligned Medical Home Model. This would allow physicians participating in a CMS multi-payer medical home model that qualifies as an Advanced APM, but who do not reach the levels of participation to be QPs solely based on their Medicare payments or patients, to reach QP status through their other payer payments or patients involved in the

medical home model. The AMA agrees with the need to include Medical Home Models for commercial payers as well as in Medicaid and believes it should be expanded beyond commercial payers that are formally partnering in a CMS Multi-Payer Medical Home Model. CMS has only implemented such models in a subset of states and with a subset of practices in those states; there are many other primary care practices participating in well-designed Medical Home Models with private payers, and they should be able to count these models as Other Payer Advanced APMs. The regulations do not require Medicaid Medical Home Models to be part of CMS Multi-Payer Models, and they should not require Medical Home Models for commercial payers to meet a different standard. CMS should create a definition of “Other Payer Medical Home Model” that parallels the definitions of “Medical Home Model” and “Medicaid Medical Home Model” in the current regulations.

The AMA continues to oppose the limitation on the application of the medical home financial risk standard to APM Entities that have no more than 50 eligible clinicians. This limit should be eliminated and should not apply to Medicare medical homes, Medicaid medical homes, or Other Payer medical homes.

M. Accountable Care Organizations (ACOs)

- **Recommendation:** The AMA recommends that MIPS payment adjustments be excluded from calculations of ACO expenditures relative to benchmarks.

Most Medicare ACOs are in the upside-only Track 1 model, which CMS qualifies as a MIPS APM, not an Advanced APM. The AMA urges CMS to exclude MIPS payment adjustments from ACO expenditure calculations. The current CMS approach of including the current MIPS bonuses and penalties in ACO expenditures in the performance year, but failing to adjust the ACO’s benchmark based on those payments, can have the perverse effect of penalizing ACOs whose physicians have improved quality and rewarding ACOs whose quality has decreased. This problem is particularly severe if the ACO’s physicians have qualified for exceptional performance payment adjustments under MIPS. CMS should change this policy so that the MSSP gives the highest rewards to physicians and ACOs that have both delivered higher quality care and achieved savings.

Appendix A.

MPFS MIPS Benchmark White Paper: MIPS Benchmark Methodology Analysis and Recommendations

Executive Summary

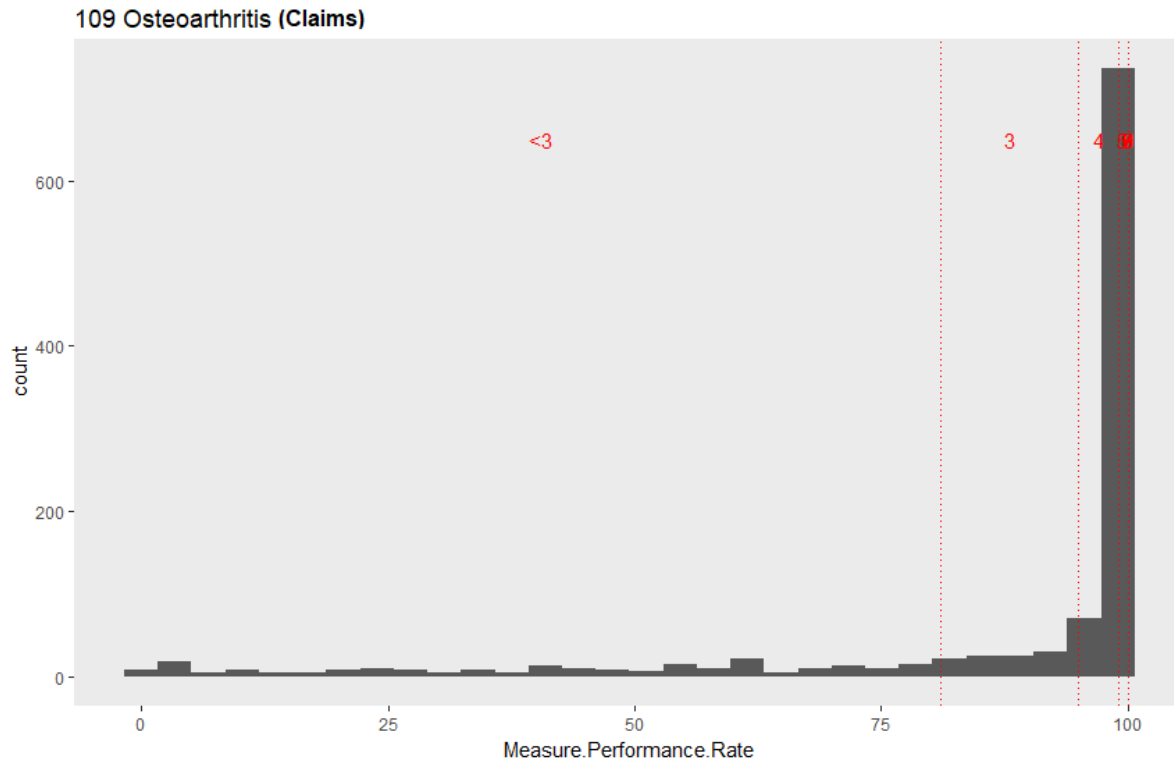
The Merit-based Incentive Payment System (MIPS) within the Quality Payment Program (QPP) awards points to physicians based on their performance relative to decile-based categories calculated from historical data (when available). In this document we highlight several concerns regarding the current MIPS benchmark methodology and offer illustrative examples using the 2015 Individual Physician Compare data downloaded from the CMS website. Our main concerns with the MIPS benchmark methodology are:

1. For topped-out or highly-skewed data, thresholds are clustered close together (meaning that similar performance may not result in similar points awarded) and even relatively high performance can place a physician in one of the lower deciles. For example, a physician could score 88% and be in the 4th decile while another physician scores 92% and is in the 8th percentile. Therefore, on the same measure two physicians can perform very similarly on the measure but be awarded very different points;
2. There is a lack of consideration of the role played by random fluctuation, especially for small denominators;
3. Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality;
4. There may be significant changes to the population of physicians and groups between the time that the historical data represents (2 years prior) to the time period to which the resulting thresholds are applied; and
5. Under certain circumstances, physician performance score under MIPS may differ significantly from their performance under the Physician Compare methodology, *even for the same measure*.

We urge CMS to revise the benchmark methodologies to allow measure thresholds to **incorporate clinical knowledge and evidence**, consider the **impact of random fluctuation**, and be adjusted for **practical considerations of comparison and relative performance**. To address the shortcomings of the existing benchmark methodologies, we suggest that CMS implement a methodology that allows for manual manipulation of thresholds. As we explore below, this would allow for enough flexibility to address the above issues when they arose. We acknowledge that this would add process to an already complex method, but we believe that what is most important is ensuring the fairness and clinical relevance of the measure benchmarks. We further acknowledge that there may be modifications to the methodology other than what we suggest which may also address our concerns, and welcome the opportunity to discuss further with CMS. *A note about our methods: We acknowledge that limitations in the data do not allow us to replicate exactly the MIPS benchmarks, but attributes of the methodology remain, allowing us to adequately illustrate the underlying issues.*

1. **For topped-out or highly-skewed data, thresholds are clustered close together (meaning that similar performance may not result in similar ranking) and even relatively high performance can place someone in one of the lower deciles.**

Although there are many examples of topped-out measures, we used the quality measure 109 for Osteoarthritis to calculate the MIPS cut-offs below (in red). The close clustering near 100% demonstrates that very small differences in performance may result in very different decile assignments. Additionally, relatively high performance (above 90%) can still result in performance of only the 3rd decile.



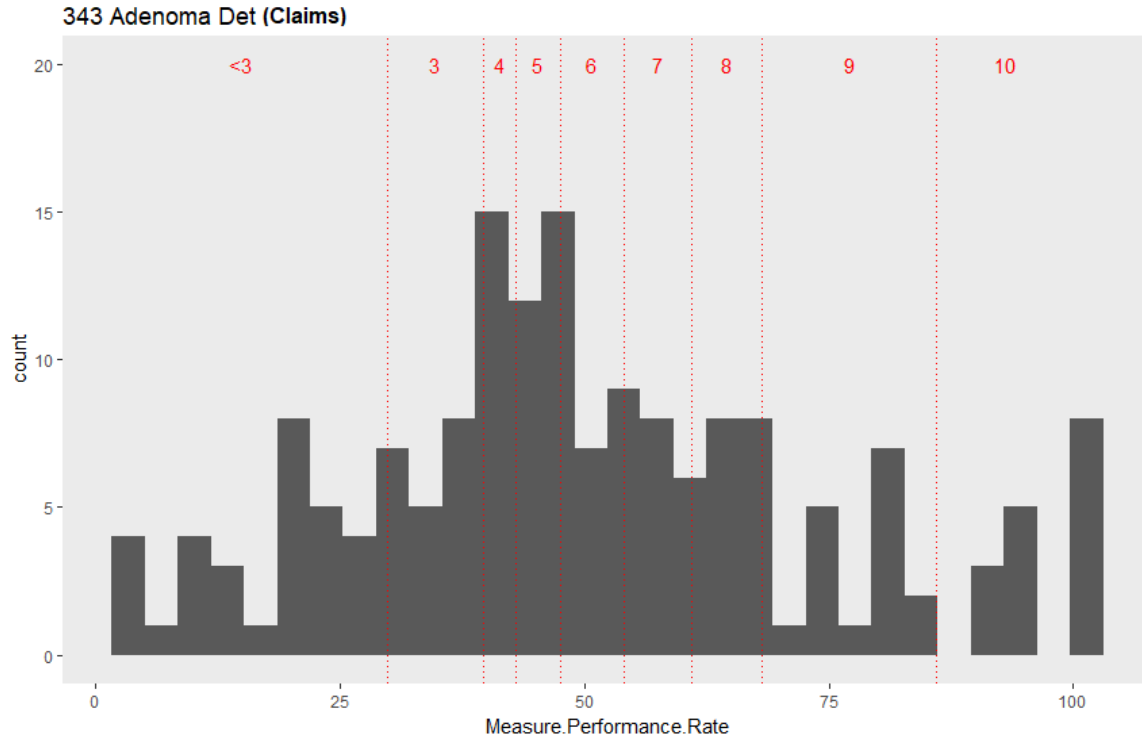
This is a concern because based on points awarded using these benchmarks, it suggests that physicians who score in the low 90s (3rd decile) are closer in quality to those who score 1% (lowest decile) than they are to those who score 100% (highest decile). Or, from the standpoint of encouraging performance improvement: improving from 1% to 90% results in only 1 additional point.

2. There is a lack of consideration of the role played by random fluctuation, especially for small denominators.

When denominators are small (e.g., 20 patients), there are limited possibilities for what the calculated performance can be (e.g., 100% [20 out of 20], 95% [19 out of 20], 90%, 85%). If the physician’s “true” (but unknown) underlying quality is, for example, 97%, statistical randomness says that sometimes he/she will perform at 100%, sometimes 95%, and sometimes even 90%. Depending on where the MIPS-calculated benchmarks are, it is possible for the physician to be punished for changes in performance that are entirely due to random variation, rather than his/her true quality. In the above example, if historical data places the highest benchmark at 96%, theoretically the physician’s true quality is above that level, and he/she should be identified as such under a valid and reliable method. However, the probability that the physician will score 20 out of 20 (the only outcome that places them in the decile that reflects their true quality) is 0.544 (binomial probability where $n=20$, $x=20$, and $p=.97$). That is, *just slightly more than half of the time* that a physician will accurately be classified as being in the highest decile. The rest of the time they will score 95% or worse, placing them in a lower decile than what their true quality should indicate.

3. Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality.

For certain measures, such as screening measures, goals for physicians should be less than 100% to reduce the potential for false-positives. Using cut-offs that are strictly data-driven ignore these types of clinical considerations. We calculated deciles for the adenoma detection rate measure as follows:



The benchmark for the top (10th) decile is 86%, and there are a number of physicians who perform at 100%. As physicians seek to achieve the highest possible performance, it is possible that they will target 90% or even 100%, even though clinically this is not ideal because of the increase in false-positives that would result. Additionally, recommendations indicate that the detection rate for a mixed gender population should be at least 25%, suggesting that levels below 25% represent lower levels of quality. While the current cut-off (above) for this measure is 29% (which is close to 25%), changes in provider performance could shift this cut-off farther away from the clinically relevant level of 25%.

4. There may be significant changes to the population of physicians and groups between the time that the historical data represents (2 years prior) to the time period to which the resulting thresholds are applied.

A comparison of the 2015 and 2016 Physician Compare downloadable data produces the following results:

| Year | Unique MDs in Individual data | Unique Group PAC IDs in Group data |
|------|-------------------------------|------------------------------------|
| 2015 | 180,723 | 2,371 |
| 2016 | 126,054 | 9,837 |

The number of unique physicians included in the individual data dropped by over 50,000 individuals, or more than 30% from 2015 to 2016. At the same time, the number of unique group ID number in the group data more than *quadrupled*. And, this is over just a single year. One can imagine that over a two-year period the change might be even more significant. Further, overall performance of some measures changed drastically from the 2015 to 2016 downloadable data. Below are some examples from the individual physician data:

| Measure | 2015 Data | | | 2016 Data | | |
|---------|--------------------|--------------------|------------------|--------------------|--------------------|------------------|
| | Median Denominator | Median Performance | Mean Performance | Median Denominator | Median Performance | Mean Performance |
| 116 | 40 | 100.0 | 93.5 | 32 | 15.0 | 32.4 |
| 181 | 98.5 | 0.0 | 26.8 | 50 | 100.0 | 87.3 |
| 337 | 39 | 39.5 | 49.1 | 32 | 92.0 | 73.7 |

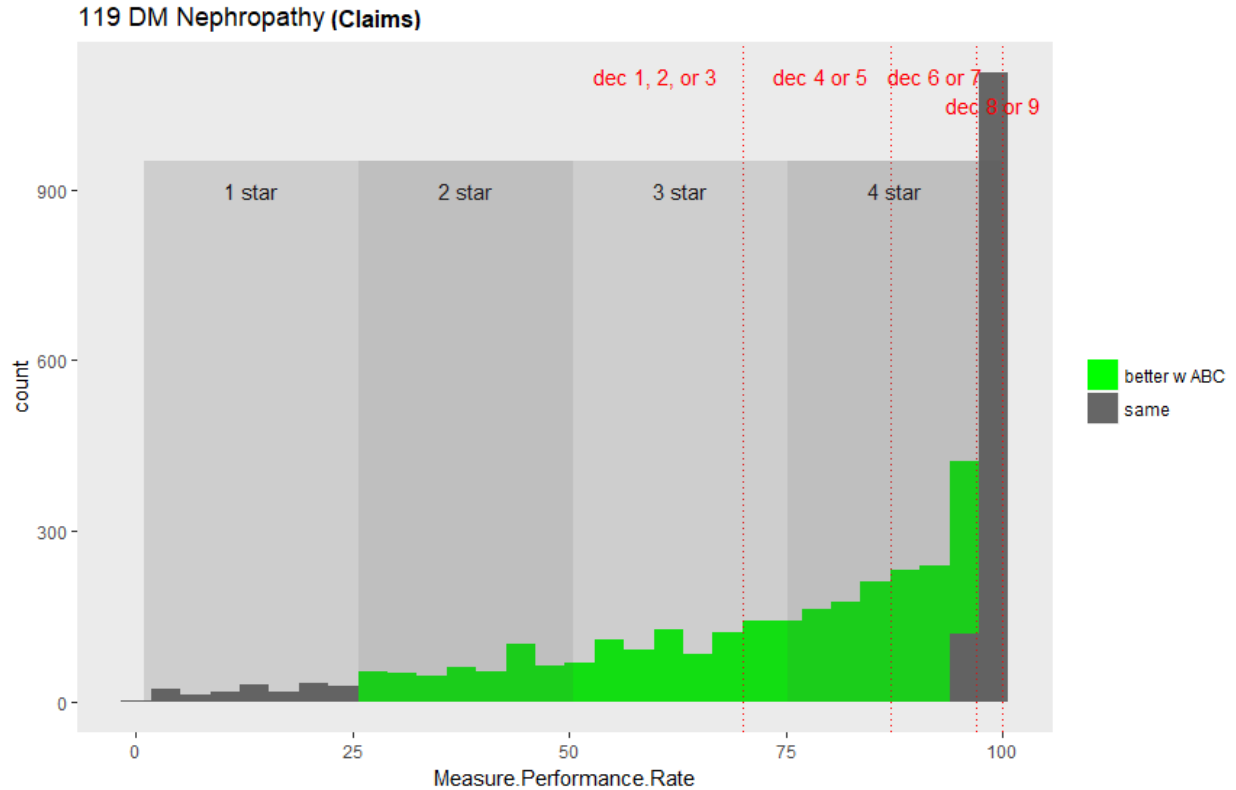
116 = Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

181 = Elder Maltreatment Screen and Follow-up Plan

337 = Tuberculosis Prevention for Psoriasis and Psoriatic Arthritis Patients on a Biological Immun

Even before examining the full performance distributions, one wonders whether historical data could provide reasonable benchmarks given how dramatically performance has shifted.

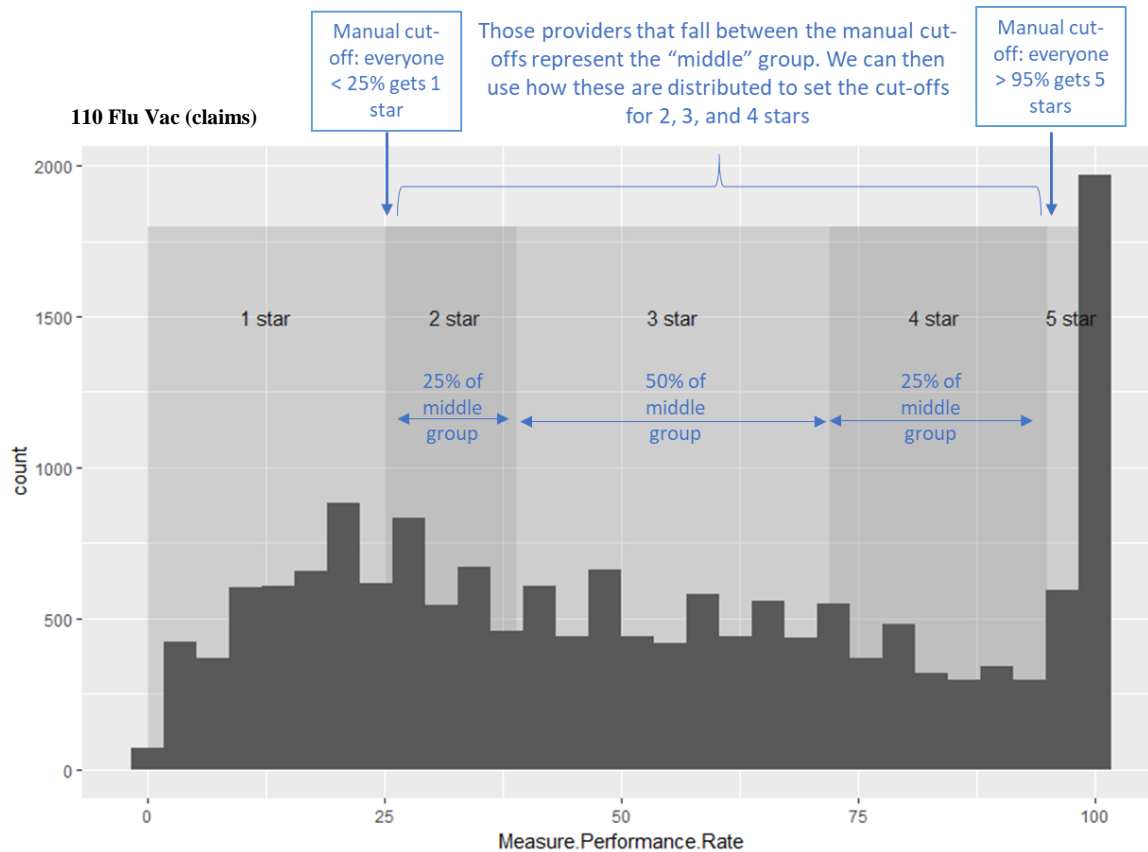
5. Under certain circumstances, physician performance score under MIPS may be significantly different from their performance under the Physician Compare methodology, *even for the same measure*. In the graph below, in addition to MIPS-based deciles, we calculated 5-star categories using the Physician Compare 5-star, equal-ranges methodology (in the shaded areas; 5-star = 100%).



Under certain assumptions regarding the equivalence (or non-equivalence) of certain 5-star categories to certain deciles (e.g., the lowest decile category and lowest 5-star rating category are roughly equivalent), one can see that physicians can perform very differently on the *same* measure when different (and incongruent) methodologies are applied. Additionally, under MIPS, benchmarks are created based on submission/reporting type and CMS combines individual and group reporters to create the benchmark for the reporting mechanism (eCQM, claims, qualified registry or QCDR). However, under Physician Compare, ratings are broken out by group reporting or individual by submission type. This is another inconsistency between methods.

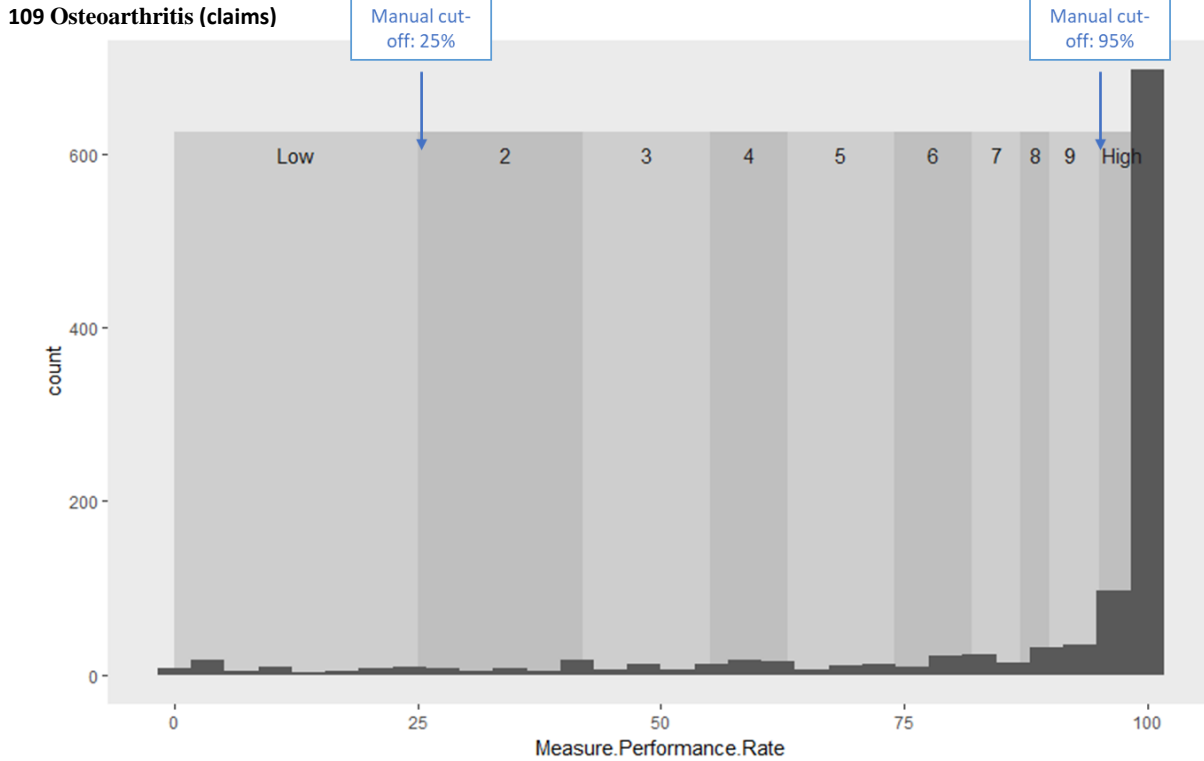
A Revised Methodology:

It is clear that certain types of performance distributions, combined with potential changes to the pool of eligible individuals and groups, can lead to performance thresholds which may be unfair, inappropriate, or inconsistent with clinical and practical considerations under the current methodology. We believe that allowing for **manual manipulation of thresholds** would alleviate many of these issues and **reduce the over-clustering of performance categories**, mitigate the likelihood of **penalties due solely to random fluctuation**, and increase the **congruence between MIPS thresholds and clinical knowledge**. Below is an example of a “Manual plus Data-Driven” (M+DD) methodology where the highest and lowest cut-offs are manually set, while the cut-offs between are data-driven. We illustrate the concept using 5 categories as used in Physician Compare before examining its effect when applied to the 10 categories used in MIPS.

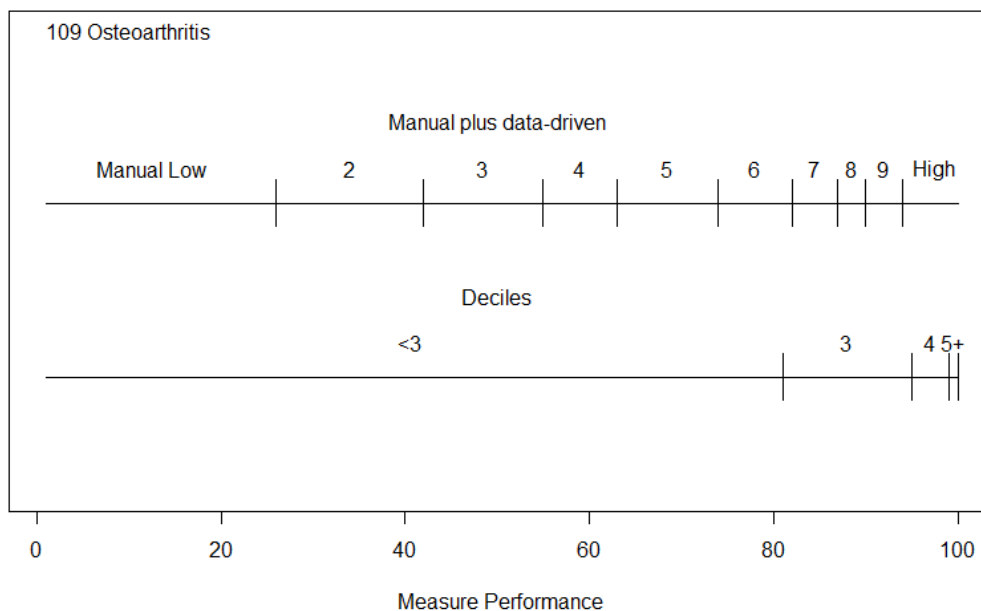


Obviously, this is not the only way to combine manual and data-driven thresholds, but it is easy to see how it could quickly alleviate many of the challenges imposed by the current methodology.

Applying the M+DD methodology for the 109 Osteoarthritis measure produces the following:



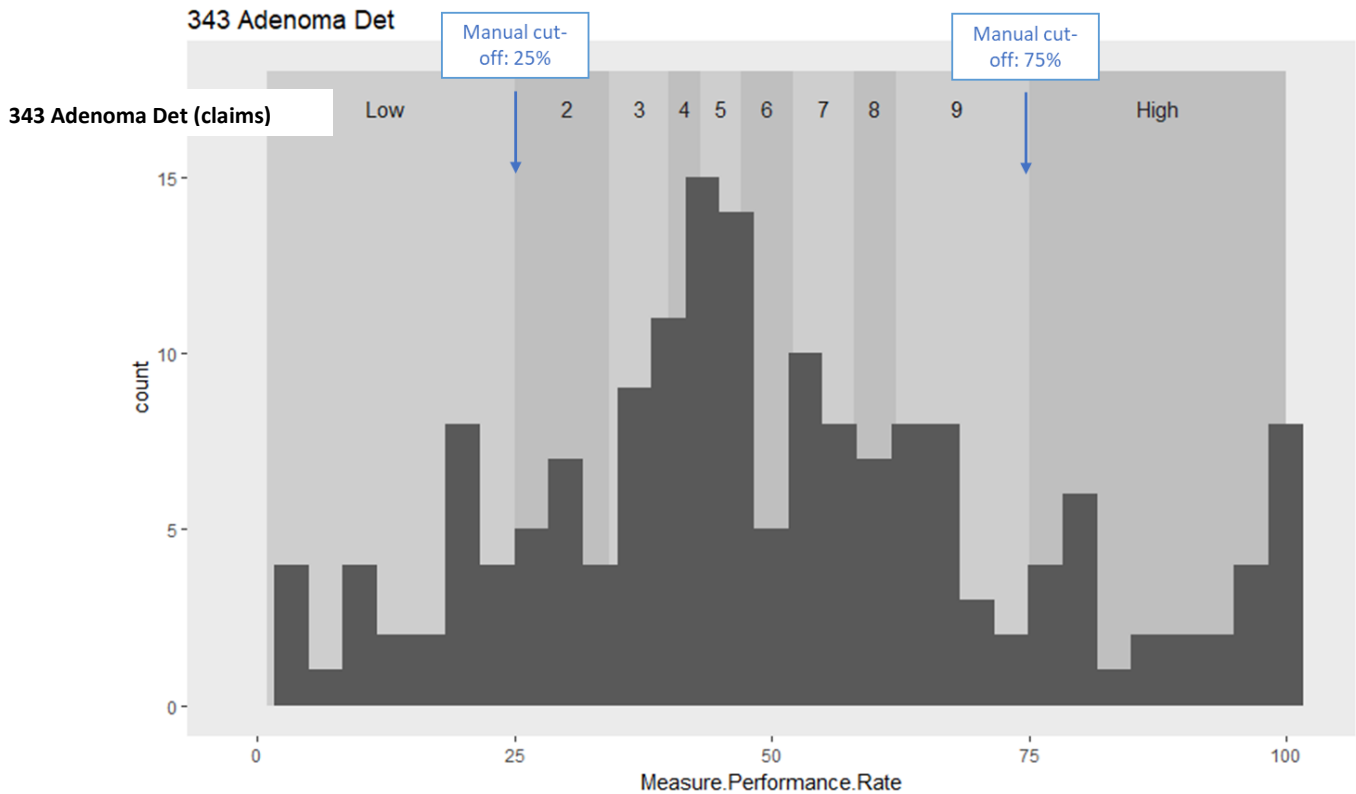
Compared with the current decile method, the M+DD method allows for greater spread across all categories and eliminates the need for physicians to score 100% to be in the highest category. A comparison of the cut-offs to those created by the current MIPS decile method is as follows:



You can see that by manually setting the top and bottom cut-offs (but still allowing the data to drive the distribution of the cut-offs using the data in-between), high performance is still required to achieve one of the top categories, but it is no longer the case that still relatively high performance (92%) results in a classification of the second-lowest performance category.

As an additional consideration, physicians scoring at 100% under the current methodology may feel the need to continue to devote significant resources to remain at 100%, given the large (relative) penalty of dropping even a single percentage point. This indirectly dis-incentivizes the same physician to improve in other areas where they may only be performing at a mediocre level, but where the return on the investment for improvement in that area is less than the return involved in remaining at 100% of the current measure. Under the thresholds in the M+DD methodology, in contrast, physicians may realize that they have some “breathing room” at the top of the performance scale for this measure and can devote resources to other areas where improvement is truly needed.

As another example, the M+DD methodology for 343 Adenoma Detection rate might look like this:



These cut-offs reflect clinical and practical considerations while allowing for the middle categories to be data driven. Therefore, the target for the highest category is 75% and those below the minimum level specified by guidelines will be in the lowest quality category. Knowing that the highest threshold will remain at 75% regardless of provider performance, physicians can target levels at or just above 75%, thereby reducing the likelihood of frequent false-positives that would occur if physicians consistently screened 90% to 100% of patients.

As needed, manual cut-offs could be adjusted to more closely reflect categories produced from other programs' methodologies (e.g., 5-star), to allow for random fluctuation in small facilities by spacing them out a reasonable amount, and to reflect changes to the underlying sample when using historical data that is two years old. In short, manual adjustments allow for more flexibility to address clinical and practical considerations of performance measurement and quality assessment.

Appendix B

Flat Percentage Proposal Analysis

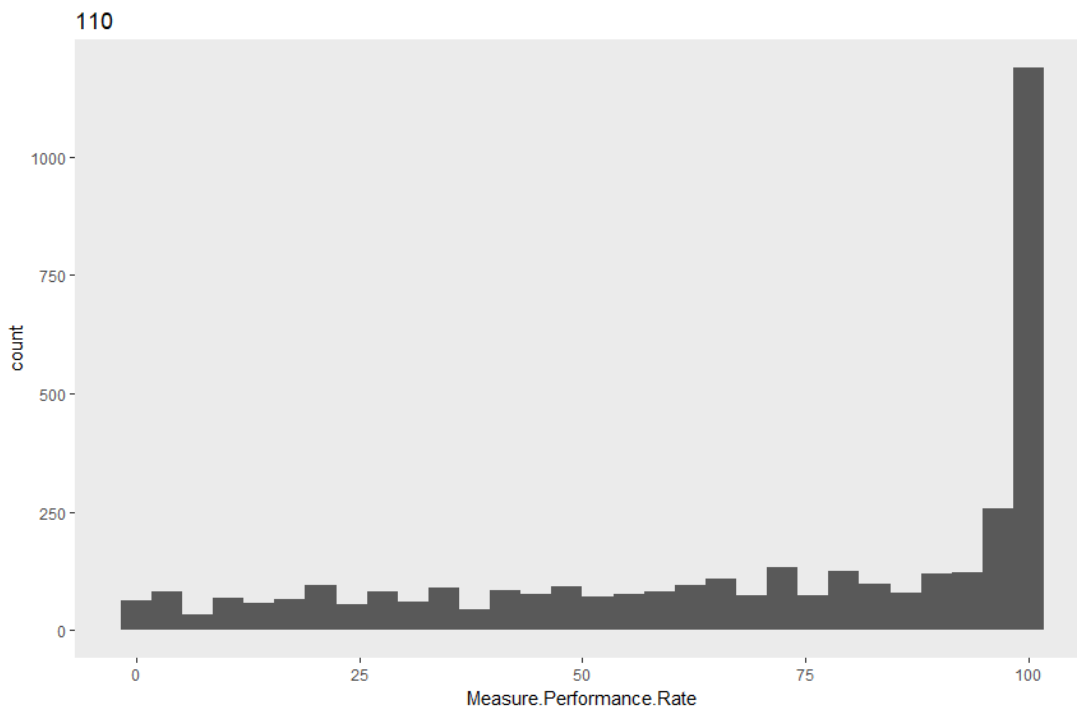
Analysis

In the analysis below, we attempt to explore the implications for moving to a flat percentage methodology using several measures available from the 2017 downloadable MIPS database. The example measures were chosen in part because of the shape of their performance distribution, since this will affect the placement of the thresholds under the current MIPS methodology (i.e., data-driven deciles). The conclusions here can be extended to other measures with similar distributions.¹ In each example we calculate these data-driven deciles using the current methodology, and then apply the proposed “flat” thresholds in the 2020 Proposed Rule to see how the thresholds change and what affect that would have on physician evaluated performance.

Specific Examples

To begin, we walk through an example using Measure 110: Preventive Care and Screening: Influenza Immunization. This measure is relatively uniform, except for a large proportion of physicians who perform at 100%. So, while this measure is highly skewed to the right, it is not technically “topped out.”

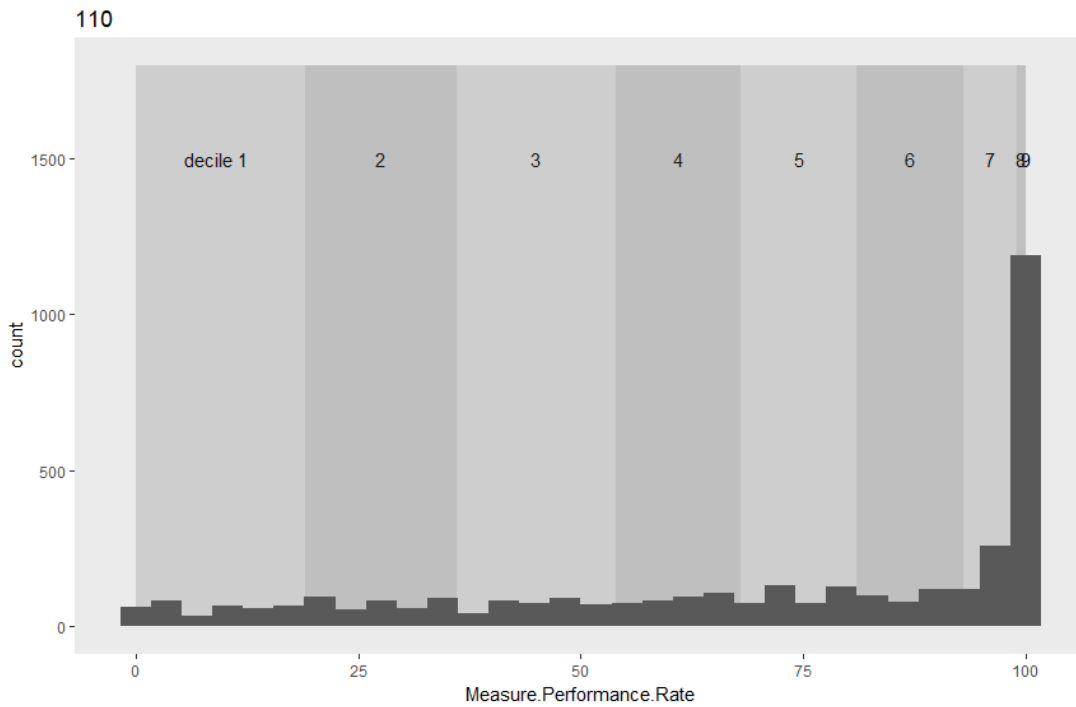
Distribution of Measure 110 from 2017 MIPS data



Under the current methodology, MIPS thresholds would be established by calculating deciles for these data. This is illustrated as follows:

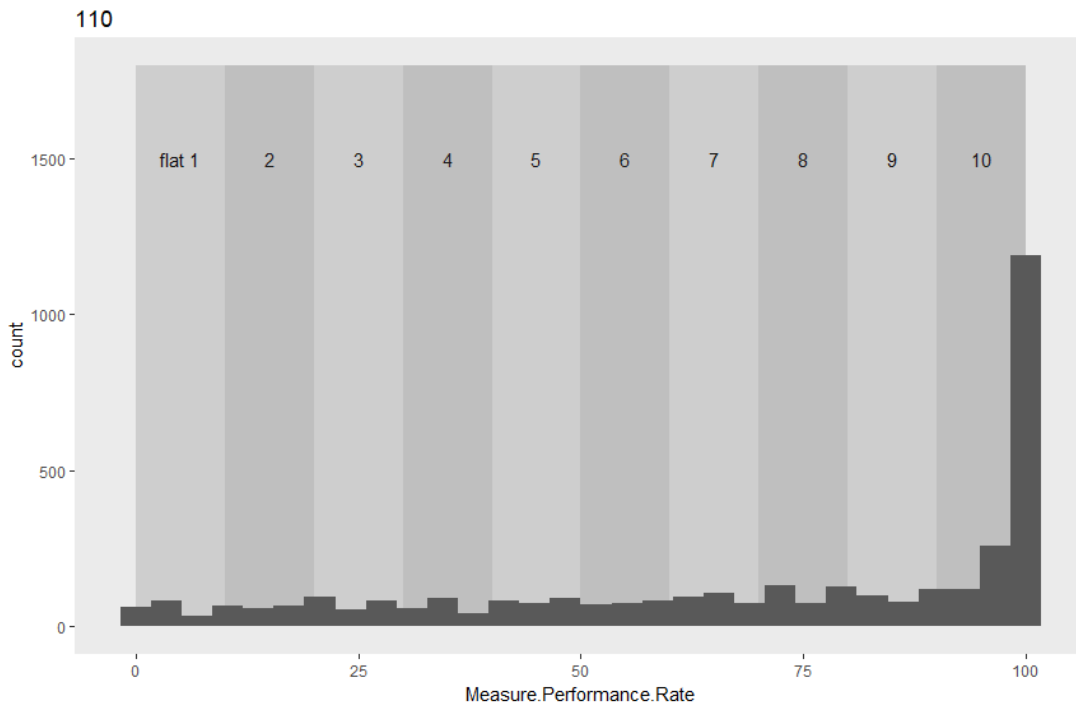
¹ We could not perform analysis on MIPS measures 1 or 236 because the data on the measures are not publicly available.

Thresholds when applying the current MIPS methodology:



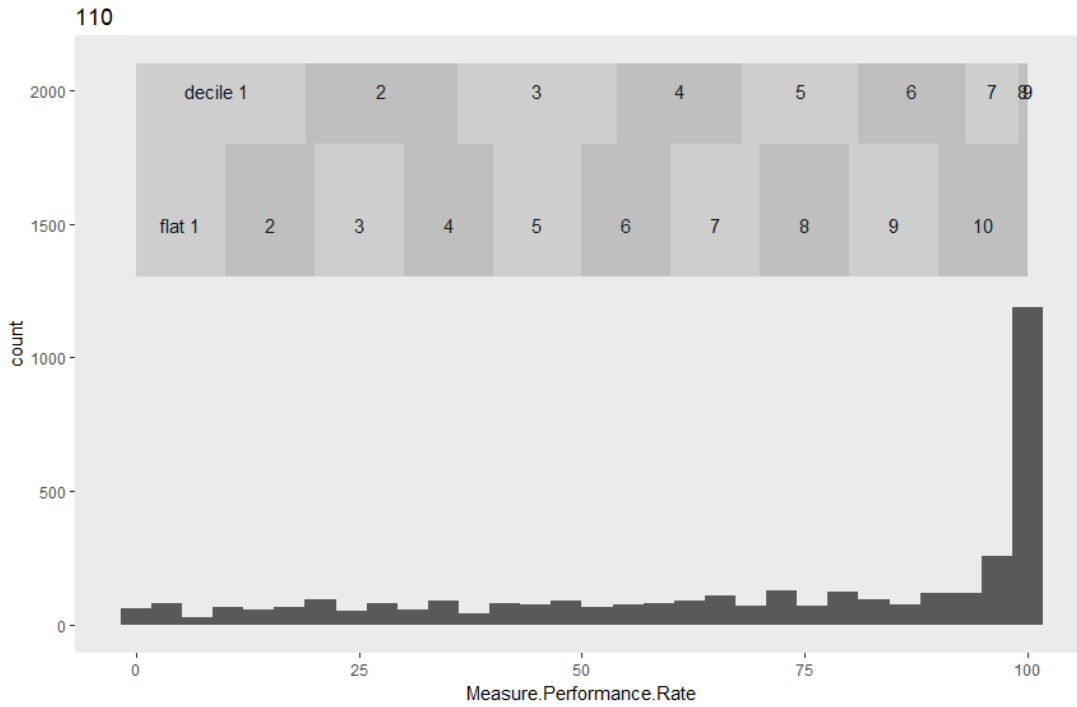
Clearly, the top decile is greater than 90% (it is 100%), so that this measure would qualify for the new “flat” deciles under the proposed rule. When we apply that methodology, we get thresholds that fall at each 10% increment of performance:

Thresholds when applying the “new” MIPS methodology (“flat” deciles):

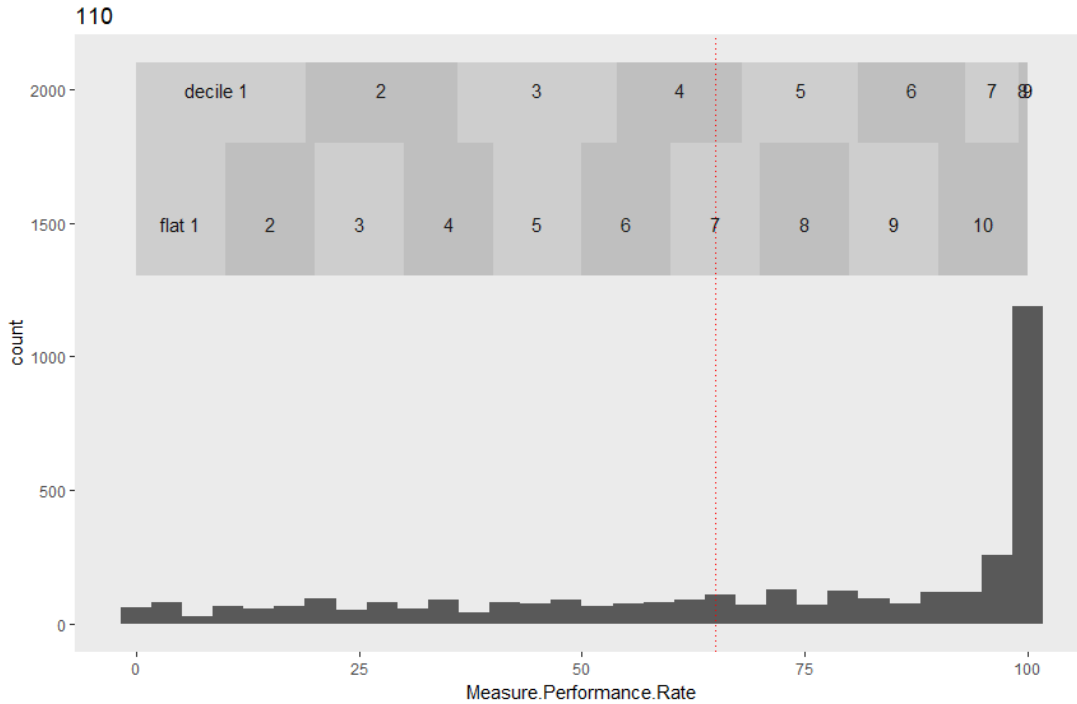


Comparing the top figure to this figure, we can see that in general thresholds are shifted “left” or towards lower performance levels in the new “flat” decile methodology. This means that, in general, a given level of performance would fall in a higher category under the new methodology than under the current methodology. In order to see this more directly, we can overlay the thresholds as follows.

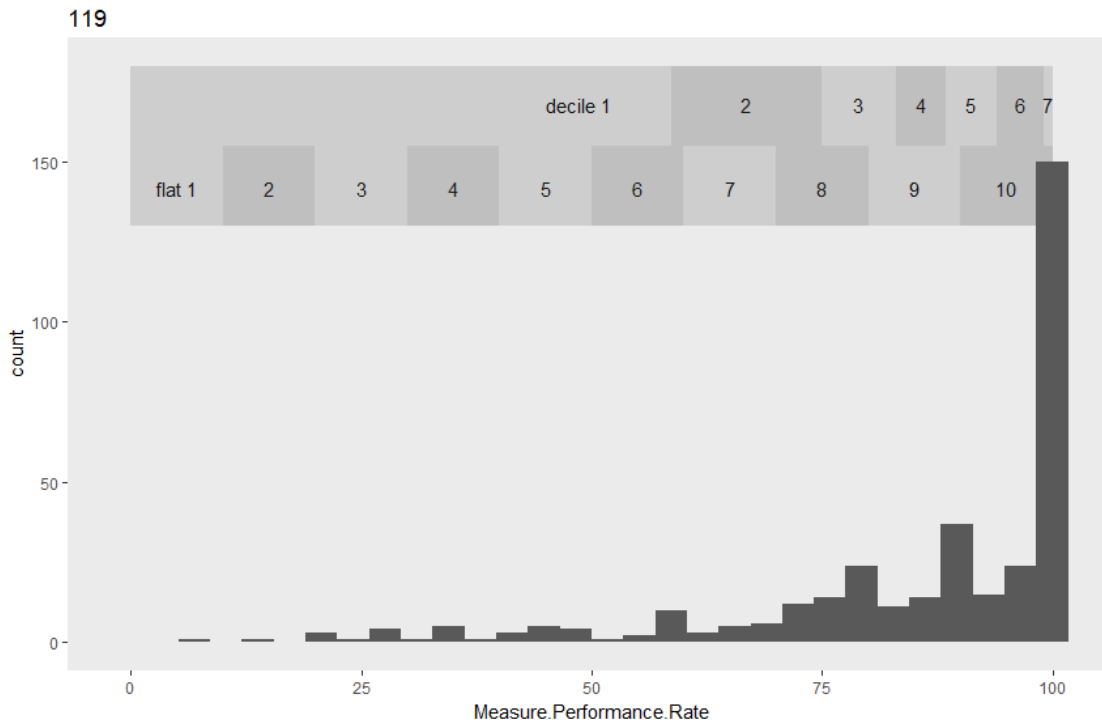
Overlaying the thresholds for comparison:



Interpretation: the new “flat” deciles would shift all the thresholds left, so that almost any performance level would be in a higher category under the new methodology vs the current methodology. To provide a more concrete illustration, one can select an arbitrary level of performance (say, 65%, as reflected by the red line in the graph below). One can see that level of performance would fall into the 4th decile under the current methodology but falls into the 7th (higher or “better”) under the new methodology. In this example, this will be true for almost any performance level selected.



A more severely skewed performance distribution will experience a more noticeable difference in the thresholds established by the current versus the new methodology. To illustrate, let's consider measure 119: Medical Attention for Nephropathy. This measure is highly skewed to the right, and when we overlay thresholds calculated under the current and new methodologies, we see the following:

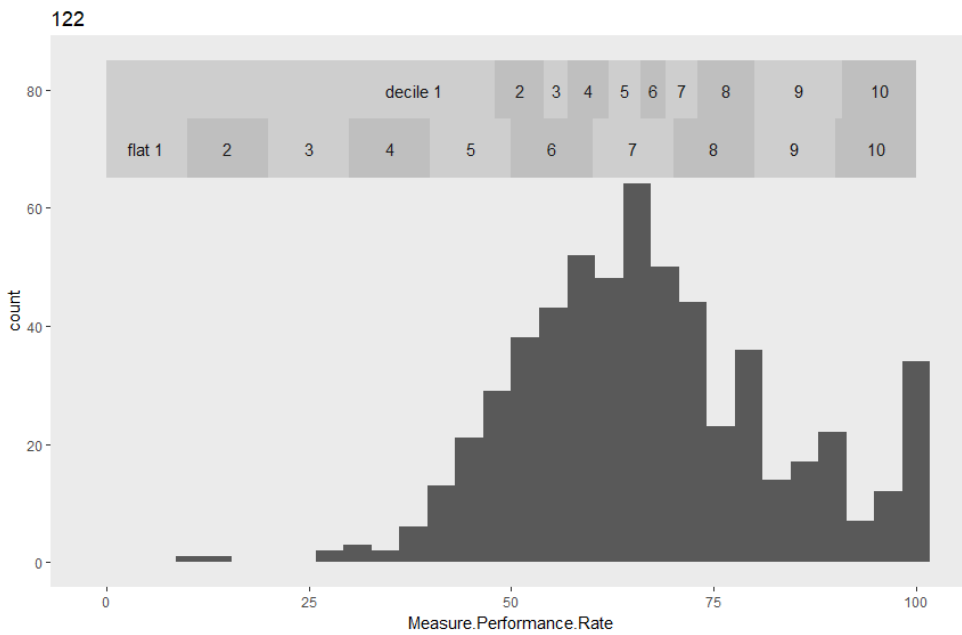


In this case, the potential change in performance category for a given performance level is dramatic. Individual performance which would be evaluated to be in the lowest 1 to 2 deciles under the current methodology could wind up being as high as an “8” under the new methodology (e.g., a performance of around 73% looks to be in decile 2 under the current method but decile 8 under the new methodology).

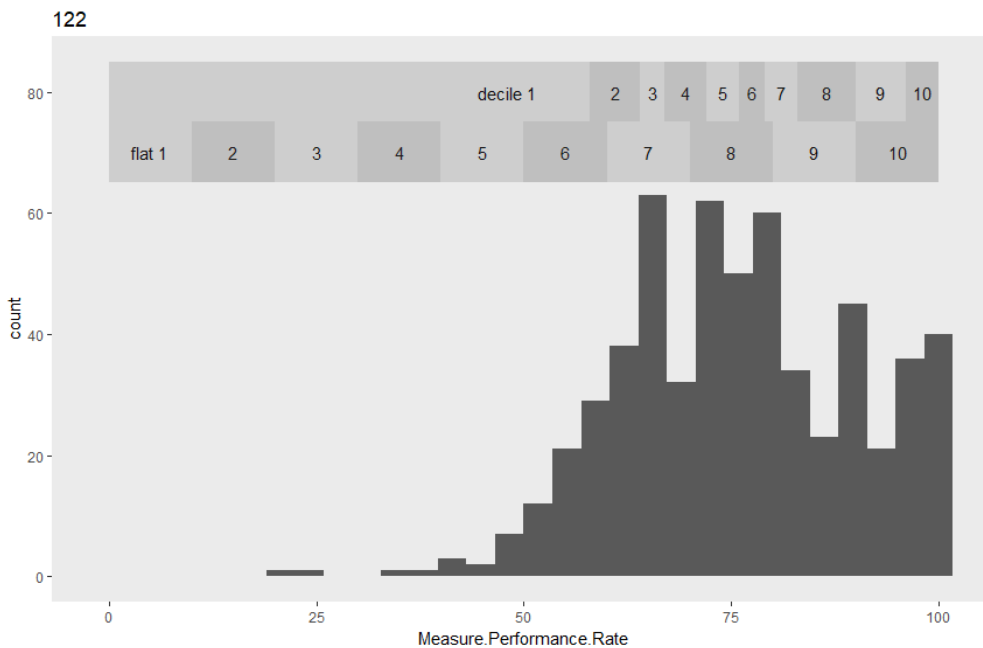
Note that when we compare calculated thresholds for Measure 110 versus those calculated for Measure 119, we see that the data-driven deciles under the current method produce very different thresholds, which reflect the different shapes of performance distribution between the two measures. However, the “flat” deciles will always produce the same thresholds, regardless of the distribution of performance (as long as the top decile is above 90%). Therefore, the “flat” thresholds basically ignore the underlying performance distribution, so that performance evaluation is completely devoid of any consideration of the performance of one’s peers, as long as the original criterion (the top decile is at least 90%) is met. This critique is similar to our critique of the “ABC equal ranges” methodology used in the 5-star evaluations: namely that the cut-offs are established by only a small portion of the data.

This phenomenon (i.e., the “dynamic” current methodology that will shift thresholds as performance changes versus the “static” new methodology that sets thresholds at the same places regardless of changes in performance) also has consequences for tracking change over time. Consider the following situation from the 2015 MIPS data for Measure 122 (chosen because of its roughly bell-shaped distribution) shown below. If, hypothetically, we observed a general improvement across all providers, that would shift the entire bell-shaped part of the distribution to the right, where everyone is performing at a higher rate than previously. Under the current methodology, such a shift would also shift the data-driven decile thresholds equally, so that even though the majority of individual performances increased, there would very little *relative* improvement in terms of which decile they fell into (if you’re in the 5th decile and *everyone* improves by the same amount, you’ll still be in the 5th decile). Under the current methodology, however, a shift of the entire distribution to the right would correspond to an overall improvement relative to the “flat” decile thresholds.

Actual Distribution of 2015 MIPS measure 122:

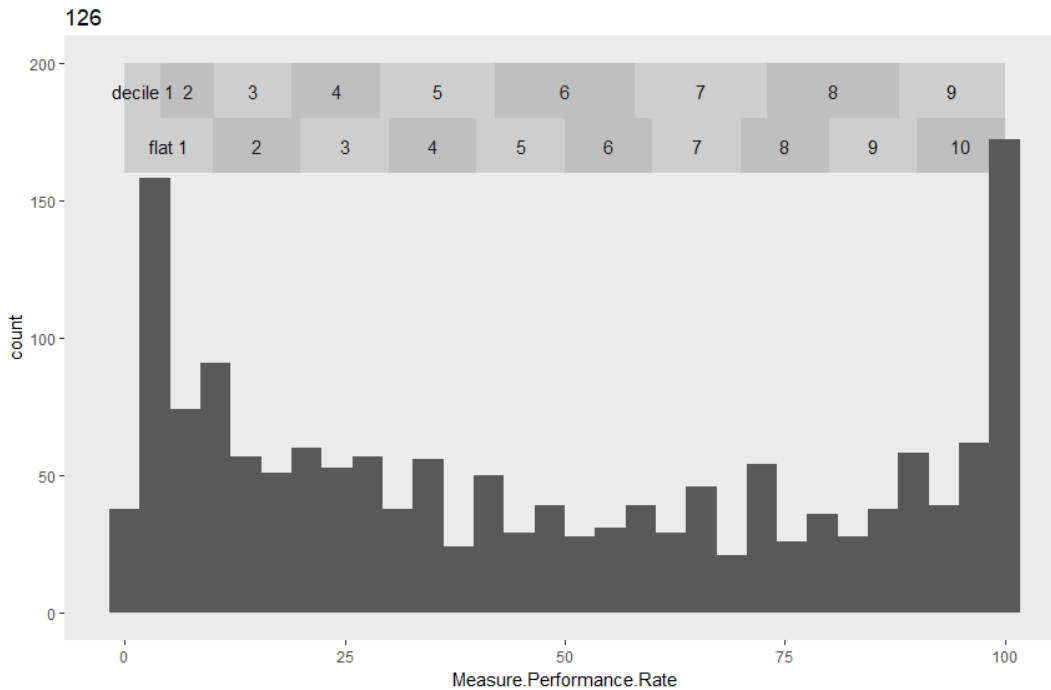


Hypothetical change if everyone experienced a similar improvement in performance to shift the entire distribution to the right:



It's perhaps not as clear as it could be, but the bell-shaped portion of the bottom graph has shifted to the right slightly compared with the original distribution above. Under the current methodology, the decile thresholds shifted to the right about the same amount that the distribution of performance did, so that while everyone improved, no one improved their relative standing (someone in decile 5 before is still in decile 5, even though they got better). Under the proposed new methodology, performance is compared to "static" thresholds of the "flat" deciles, so that those who improve their performance enough to reach the next category will be rewarded, regardless of what peers do. We should consider whether this is within the spirit of what this program aims to do: is it intending to measure and track *absolute* improvement or *relative* improvement? Keep in mind that the "flat" deciles are only applied in certain situations, meaning that while in those situations the thresholds would track *absolute* improvement, other measures using the current decile methodology would track *relative* improvement, which might be seen as inconsistent.

Another type of performance distribution that is sometimes seen is that of a “U-shaped” distribution. Consider the following situation from the 2015 MIPS measure 126. Here there are a lot of providers who either perform very well or very poorly, and few in-between. However, the top decile is still above 90%, so that it would qualify for the “flat” decile thresholds.



Notice that for performance levels near the top, providers would perform as well or better under the new methodology: those in decile 9 under the old methodology would either be in “flat” decile 9 or 10 under the new methodology. However, the opposite is true for those who perform poorly: those who fall in decile 3 in the old methodology would be in “flat” decile 2; those who fall in decile 4 in the old methodology would be in “flat” decile 3 in the new methodology. So, applying the proposed new methodology would improve the standing of those already doing well and worsen the standing of those already doing poorly. That, too, seems inconsistent.

Finally, the proposed methodology still does not consider whether the proposed thresholds are appropriate for a given measure. We previously have noted that the goal for the Adenoma Detection rate should likely be set near 75% to reduce the chance for false-positives. Establishing “flat” deciles for any and all measures where the top decile is at least 90% ignores clinical and practical considerations we previously called attention to. We feel that this important aspect is still not addressed by the proposed cut-offs.