

September 10, 2018

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-1693-P; Medicare Program: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

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 2019 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, published in the *Federal Register* on July 27, 2018 (83 Fed. Reg. 35704).

At the outset, we wish to express our sincere appreciation for your efforts to reduce paperwork and allow physicians to spend more time with their patients. The AMA strongly supports and urges finalization in 2019 for a number of this rule's proposals to reduce documentation of office visits. However, we have serious concerns and questions about the accompanying proposal to restructure payment and coding for these services, including its potential to harm complex patients and its failure to comply with existing statutes that govern Medicare payment to physicians. The proposed restructuring has generated a groundswell of opposition from individual physicians and nearly every physician and health professional organization in the country, including those whose members are projected to see increases in their Medicare payments. We ask that this part of the CMS proposal be set aside while an expert physician work group, with input from a broad spectrum of physicians and other health professionals, develops an alternative that could be implemented in 2020.

Our questions and concerns about this proposal are discussed in detail beginning on pages 7 to 15 of the comments that follow this letter. A separately submitted [letter](#), signed by 50 state medical societies and 120 national organizations of physicians and other health professionals, demonstrates the widespread support for moving forward with documentation changes while putting off any restructuring as the expert panel and stakeholders work to find a better solution. Legal issues are detailed in Appendix B, entitled, *MPFS Legal Concerns*.

The following outlines our other principal recommendations on the 2019 proposed rule:

PFS:

- The AMA strongly supports a number of proposals to reduce documentation of office visits; in particular, we urge immediate adoption of the proposals that would change the required documentation of the patient's history to focus only on the interval history since the previous visit, eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient, and remove the need to justify providing a home visit instead of an office visit.
- Given the groundswell of opposition from individual physicians and nearly every physician and health professional organization in the country, including the AMA, we ask that CMS set aside its proposal to restructure payment and coding for E/M office and other outpatient visits while an expert physician work group, with input from a broad spectrum of physicians and other health professionals, develops an alternative that could be implemented in 2020.
- The AMA does not support the expansion of the number of physician office laboratories required to report payment data as part of the calculation of the average weighted median payment amount for each test on the clinical laboratory fee schedule since the Office of the Inspector General has already concluded that this will not alter materially the payment amounts, and it will impose a substantial regulatory burden on physician practices.
- The AMA opposes reducing Medicare reimbursement for new drugs from Wholesale Acquisition Cost (WAC) + 6% to WAC + 3%. This proposal would limit use of these drugs in physician offices and hinder Medicare patients' access to new and innovative therapies that are more effective and/or less debilitating than existing drugs.
- The AMA supports proposed revisions to teaching physician documentation requirements related to the presence of the teaching physician during procedures and E/M services as well as the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary; however, we urge CMS to incorporate in the final rule its recently updated policy regarding E/M documentation provided by students.
- The AMA fully supports and endorses the recommendations and comments of the RVS Update Committee (RUC) regarding work, practice expense, and professional liability insurance relative values.
- The AMA applauds the Agency's proposal to advance coverage of digital medicine modalities in the proposed rule. We are particularly pleased with the proposed coverage of interprofessional internet consultations and the chronic care remote physiologic monitoring and management codes, but we urge CMS to adopt the recommended RUC work RVU and practice expense recommendations.
- CMS should seek statutory authority to exempt physicians from participation in the appropriate use criteria consultations mandated under the Protecting Access to Medicare Act if the physicians participate in the QPP because physicians participating in either Alternative Payment Models

(APM) or the Merit-based Incentive Payment System (MIPS) are already being held accountable for costs and outcomes.

QPP:

- The AMA supports CMS' proposals to add a third criterion for physicians to qualify for the low-volume threshold in 2019 and to allow practices to opt-in to participate in the MIPS program or create virtual groups if they meet or exceed one or two but not all of the low-volume threshold elements.
- Given the small number of virtual groups that we believe chose to participate in the MIPS program in 2018, the AMA highly recommends that CMS implement additional changes to turn this into a viable option for physicians in small practices.
- One of the AMA's goals has been to make improvements to the MIPS program that will reduce complexity and allow physicians to spend less time on reporting and more time with patients. We are disappointed that CMS did not move toward a more simplified scoring methodology in this proposed rule. One area where we think the program could be significantly simplified is the scoring of each performance category to calculate a physician's final score. We urge CMS to move forward immediately to implement the AMA's scoring proposal.
- CMS should avoid making policy changes, such as increasing the performance threshold, changing the category weights and removing quality measures, when there is no MIPS data to analyze. Decisions are being based on hypothetical assumptions from the legacy programs (PQRS, MU and Value Modifier). MIPS is a separate program with its own set of rules and requirements.
- To immediately reduce red tape and administrative burden, we continue to strongly advocate that CMS reduce the number of quality measures a physician must report under the Quality category. Without this reduction, the AMA does not support immediate removal of the proposed measures but would support a modified phased approach to the topped out measure process.
- The AMA strongly urges CMS to retain a 10 percent weight for the cost category and remain flexible on weights for the next four years while the eight new episode-based cost measures are evaluated and more are developed and piloted. We also object to several other provisions in the proposed rule, discussed in the attached detailed comments, because we believe that in its desire to "capture more physicians in the cost category," CMS is undermining the reliability of and confidence in the measures.
- The AMA applauds CMS' overhaul of the Advancing Care Information (ACI) category and supports many of the proposals within the Promoting Interoperability (PI) program. We urge CMS to continue to limit regulatory requirements, including aligning the PI programs so that hospitals and physicians achieve the same score to receive full PI Program credit; simplifying and reducing burden through Yes/No measure attestation, and scoring PI on the objective-level.

The Honorable Seema Verma

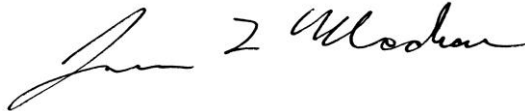
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- The AMA appreciates and urges CMS to finalize several of the proposed policies for alternative payment models, such as the proposal to maintain the revenue-based financial risk requirement at no more than eight percent for an additional four years. The AMA also urges CMS to increase the availability of well-designed alternative payment models under the Quality Payment Program.

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 "Jim L Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD

Enclosure

**2019 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 2019 PHYSICIAN FEE SCHEDULE

A. Evaluation & Management (E/M) Visits

The AMA greatly appreciates CMS' ongoing commitment to regulatory burden relief and enthusiastically supports most of the proposed rule's changes to E/M services' documentation requirements. The AMA, however, has very serious concerns about the simultaneously proposed coding and payment changes that CMS views to be "intrinsically related to" and essentially inseparable from the otherwise much welcomed documentation relief. In our view, several documentation changes proposed by CMS could in fact be readily separated from the coding and payment provisions of the rule and finalized for CY 2019 implementation. These changes have been long-sought and widely-supported by the AMA and other physician organizations, and could be immediately adopted without disrupting appropriate care of Medicare patients by collapsing the number of Medicare **new and established patient office** E/M payment levels to two **per code family**. Conversely, the AMA unequivocally believes that the remaining proposals by CMS for E/M coding and payment changes would lead to several unintended and undesirable consequences and are thereby far from ready for implementation. **The AMA, without reservation, recommends to CMS that the proposed changes to coding and payment for office E/M services be set aside to allow time for a Workgroup of coding and valuation experts, with input from across the medical community, to develop an alternative to the CMS proposal.**

i. E/M Visits: Background

As noted by CMS, physicians of nearly all specialties furnish E/M services to Medicare beneficiaries, and E/M services comprise approximately 40 percent of all allowed charges under the PFS each year. During the past five years, CMS has used the PFS rule-making process to adopt recommendations made by the CPT Editorial Panel and the AMA/Specialty Society RVS Update Committee (RUC) to address the lack of recognition of care coordination and non face-to-face E/M services (e.g., transitional care management, chronic care management, advanced care planning). For CY 2019, CMS proposes an extensive and complex package of documentation, coding, and payment changes for selected E/M services, intended to address repeated criticisms from physicians about the burden imposed by documentation requirements and the relevance of those requirements to modern medical practice. Given the large contribution of E/M services to Medicare's allowed charges, the proposed changes if finalized would have profound and wide-ranging effects on the PFS, physicians, and—ultimately—patients. CMS focuses its proposals on the office/outpatient visit subset of E/M services, acknowledging that any E/M revisions should be approached with caution before expansion to other categories of E/M services. Office visits comprise approximately 20 percent of all PFS allowed charges.

An E/M visit establishes or builds upon a preexisting professional physician-patient relationship, and that relationship includes an obligation for the physician to describe the visit. The content and extent of an appropriate medical record entry should reflect the professional judgment of the physician to document all clinically relevant information. The AMA has previously commented that medical records are intended to capture physicians' medical decision-making (MDM) for future reference or for relaying information to other providers during transfers of care. We, therefore, strongly agree with CMS' goal for the proposed E/M documentation changes as stated in the rule: "to allow practitioners more flexibility to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient."

However, as medical practice has evolved, the medical record has taken on multiple other functions, prominent among which is serving as the interface through which physicians are required to justify their payment requests for services rendered to a payer's beneficiary. The use of the medical record as a payment interface has led to the situation in which payer expectations about record content and extent have assumed equal or even greater importance than the professional judgment of the physician about sufficient documentation. Much information included in the medical record is to justify payment and is not clinically relevant to the patient's care. The Medicare program, the nation's largest single health care payer, has a fiduciary responsibility to ensure that taxpayer dollars are distributed only for professional medical services that are medically necessary and appropriate to the patient's condition. CMS has chosen to carry out that responsibility in part through mandating standards for documenting care provided to Medicare beneficiaries and through conducting program integrity activities that include documentation audits. The documentation standards that CMS applies to most professional E/M service claims are known as the "Documentation Guidelines" (DGs); currently there are two versions available for use by clinicians (known as the 1995 and 1997 DGs).

ii. **Documentation Changes**

• **Suitable for Immediate Implementation**

CMS has proposed several changes to the documentation requirements for the E/M categories of home and office visits. First, CMS proposes to eliminate the Medicare Claims Processing Manual provision that specifies justification in the medical record whenever a home visit is performed as to why the physician furnished the E/M visit in the home rather than office setting. The AMA strongly supports this proposal, agreeing with stakeholders who have long advocated that the decision about site of service is best left to the discretion of the **physician** and should not be subject to additional rules. Second, CMS proposes that documentation of the history and/or physical examination for an established outpatient visit may be limited to recording changes from the prior visit along with notation of pertinent absences of change. Third, CMS proposes for both new and established E/M office visits that a Chief Complaint or other historical information already entered into the record by ancillary staff or the patient may simply be reviewed and verified rather than re-entered by the physician. The AMA also strongly supports both of these proposals. We believe that they would reduce unnecessary redundancy in the medical record without sacrificing the clinical purposes of the record and free up additional time for physician-patient rather than physician-chart interaction. **The AMA believes that these three proposals do not require coding changes or have payment implications and we urge CMS to finalize them for implementation for CY 2019.**

• **Request for Comment on Eliminating Same-Day Visit Prohibition**

CMS has heard from some stakeholders that the current prohibition on same-day office visits by practitioners of the same specialty and from the same group practice may not reflect current medical practice. Specifically, while the Medicare enrollment specialty may be the same for two physicians from the same group practice, one or both physicians may also practice in other specialties or subspecialties that are not captured by their enrollment profiles. CMS, therefore, is requesting comment as to whether the longstanding prohibition continues to be appropriate. **The AMA conceptually supports eliminating the prohibition, as doing so could facilitate convenient and appropriate access for patients to multiple physicians on a single day.** We

agree with CMS in seeking input that could add clarity to the definition of the clinical circumstances in which such same-day visits would be appropriate and would help determine what, if any, limits should be placed on same-day visits.

- **Choices for Documenting Visit Level Selection**

CMS notes that there are five visit levels within each of the New Patient and Established Patient E/M code families and lays out a series of concerns it has heard from physicians about these codes. They include: problems in differentiating between levels, burdensome documentation requirements that detract from clinical care, voluminous medical records that make it difficult to locate and focus on the pertinent information, and failure to reflect modern day practice. While some groups express support for the current DG framework, others have suggested changes, such as: clarifying current requirements (especially for MDM) and/or basing visit levels simply upon total visit time, solely on MDM complexity, or some combination of the two. CMS proposes to address the questions of DG relevance and burden by expanding options upon which to base visit level selection to include total visit time (i.e., unrelated to counseling or care coordination time), MDM only, or the existing DG framework. Regardless of selection option chosen, CMS would expect the visit record to support the medical necessity for the service furnished. **Although we recognize and appreciate its intended burden reduction, the AMA cannot support this proposed flexibility in visit level selection and documentation criteria if it is tied to coding and payment structure changes that are unacceptable to the vast majority of physicians.**

- iii. **Payment-Linked Coding and Documentation Changes**

- **Office Visit Reporting under the Proposed Payment Collapse**

Under the banner of burden reduction and modernizing documentation requirements, CMS proposes to collapse payment for Levels 2 through 5 of both the New Patient and Established Patient Office Visit code families (i.e., 99202-99205 and 99212-99215), linking all of the services described by those codes to a single payment within each family. The collapsed single payment would be made regardless of the CPT visit level submitted by a clinician to CMS for payment. As a corollary, CMS additionally proposes to reduce the documentation required for payment of the collapsed code to that of a Level 2, which as described above, could be met through multiple options.

- **Burden Reduction**

CMS asserts that documentation burden would be substantially reduced and time available for patient interaction increased by the streamlined visit level selection and minimal medical record entry incorporated into the proposed office visit reporting process. **The AMA strongly disagrees. While we acknowledge and appreciate the burden reduction that would accompany the proposals suitable for immediate implementation, we disagree that the added documentation reduction from the code collapse-single payment proposal as envisioned by CMS will be realized** for reasons including:

- Appropriate medical care of Medicare beneficiaries frequently requires more than the care described by a Level 2 office visit; the most commonly billed office visits are those for Level 4 (99204 and 99214).
- The professional obligation to enter sufficient information into the medical record to support continuity of care for a typical Medicare patient will often result in more extensive documentation than is contained in the record of a Level 2 visit.
- The complexity of an office visit is often unpredictable, so that physicians usually cannot pre-select the appropriate visit level, limiting the potential time and documentation efficiencies that might be achieved by the proposed changes.
- Even with rapid access to multiple medical record templates designed to facilitate visit level documentation regardless of the basis for visit selection, time will be required to choose the proper template and this choice will not be possible until late in the visit.
- Maximizing burden reduction and time gained would require that every office visit be provided, documented, and billed at Level 2, at least for Medicare patients. Accurate determination as to whether Medicare will be a patient's payer would be necessary prior to the beginning of the visit.
- It is highly unlikely that commercial payors would be able to implement this proposal for 2019 and it is unknown if the plans would ever support these changes in documentation. Separate clinical workflows would now be required for patients depending upon whether or not they are Medicare beneficiaries. The inefficiencies for physicians and their staffs to continuously run parallel processes likely would be far more substantial than any efficiency gained through burden reduction flowing from the proposed payment collapse.
- A physician who follows a patient across sites of service (e.g., from office to hospital to skilled nursing facility) now would also have to contend with markedly divergent rules for documenting and reporting office visits versus other E/M services, further disrupting the practice's clinical workflow and billing processes. This challenge may be particularly acute for rural primary care physicians who tend to have smaller practices and to cover multiple clinical settings more often than their urban counterparts.

Furthermore, CMS notes that it expects that for record keeping, compliance with private payor requirements, and for clinical legal or other purposes, many physicians would "continue to choose and report the level of E/M visit they believe to be appropriate" and "would continue generally to seek to document medical record information that is consistent with the level of care furnished." **The AMA concurs. There are many reasons for medical record documentation and CMS' proposed payment collapse will not make them all go away. We anticipate that very few physicians will actually realize the 51 hours of average annual time savings estimated for each physician in the proposed rule.**

- **Delinking Physician Work from Payment**

In the rule, CMS notes that current payment rates for E/M visits increase as E/M visit levels increase. CMS goes on to say that "As for all services under the PFS, the rates are based on the resources in terms of work (time and intensity), PE and malpractice expense required to furnish the typical case of the service." However, implicit in the payment collapse proposal for office visits is the delinking of work from payment, since an identical payment would be made for

Levels 2 through 5 visits within each code family. Delinking payment from physician work and documentation also results in delinking payment from patient complexity. For example, the physician treating an established patient with an uncomplicated upper respiratory viral illness (most likely a Level 2 visit that currently pays \$45) would receive the same \$92 Medicare payment as for treating an established patient with a new cancer diagnosis (most likely a Level 5 visit which currently pays \$148). In other words, payment rates would more than double for the level 2 visit and decline by nearly a third for the most complex visits. For a new patient, the payments would rise from \$76 to \$134 (104 percent) for a level 2 visit and fall from \$211 to \$134 (nearly 38 percent) for a level 5 visit. The AMA finds absolutely no clinical or economic logic for these results and we believe that patients and their families will feel similarly.

- **Unintended Consequences of Delinking**

While CMS undertook the task of reducing physician burden with good intentions, the AMA is worried that implementing the payment collapse proposal with its implicit delinking of payment from physician work and patient complexity is highly likely to be accompanied by multiple unintended negative consequences for Medicare beneficiaries including:

- Avoidance of Medicare patients especially those with complex diseases and multiple chronic conditions-as they are likely to have more extensive health issues than beneficiaries of other payers;
- Shortening of office visits for Medicare patients and/or spreading their comprehensive care over multiple visits as physicians struggle to balance work and practice resources required with fixed payments regardless of visit level; and
- Truncated medical record documentation for complex patients that will impair continuity of their care, reflecting both the minimal documentation standard proposed by CMS and the reduced payment for higher level office visits.

Finally, the AMA views the delinking implicit in the payment collapse as highly disruptive to the PFS, a violation of the law that created the physician fee schedule's foundational Resource-Based Relative Value System (RBRVS) and a threat to Medicare patients' continued access to high quality and appropriate medical care.

- **Additional E/M Payment Policy Proposals**

After determining potential payment rates for office visits under the collapsed payment proposal, CMS looked at the impact on individual specialties and apparently concluded that its proposal resulted in too much redistribution of Medicare expenditures among specialties. This led to a series of "corrections" aimed at reducing projected wins and losses and smoothing out the specialty level impact of the payment collapse. To improve payments for certain types of care that it believed would be undervalued under its intended payment collapse, CMS created several new G codes for visits that involve prolonged care, primary care, or are typically provided by 10 specific specialties. These would be accompanied by two other new policies that will fund the add-on codes through the creation of two new codes for podiatrists and application of a Multiple Procedure Payment Reduction (MPPR) when separately billable procedures or other services are furnished on the same day as an office visit.

- *Add-on Code for Primary Care Services*

On grounds that current codes and therefore the collapsed payment do not fully capture the resource costs of a primary care face-to-face office visit CMS proposes to create an add-on G-code (GPC1X) to reflect “visit complexity inherent to evaluation and management associated with primary medical care services” for **established patients**. The code, which will pay about \$5, could also be billed with unspecified codes involving face-to-face care management and counseling but would not be billable for visits with **new** patients. It could be used in combination with the proposed prolonged E/M services (described below), but would not be billable with office visits subject to the proposed expanded MPPR policy. CMS expects that GPC1X would be billed with every primary care-focused established patient visit and would not be limited to primary care specialties.

Additional information critical to the use and evaluation of the proposed add-on is missing. CMS asserts that “the definition of primary care is widely agreed upon by the medical community,” yet simultaneously requests comment on how best to identify whether or not a primary care visit was furnished. CMS further proposes a work RVU of 0.07 and physician time of 1.75 minutes for GPC1X but then provides no information about the basis for these numbers other than that the proposed value is intended to maintain work budget neutrality across the office/outpatient E/M code set and help to mitigate potential payment instability that could result from their collapsed payment proposal.

The AMA believes that the proposed add-on code GPC1X is not clearly defined and is not resource-based. As indicated on our previously-submitted list of questions, we do not think that CMS clearly delineated which specialties could always use the codes and the circumstances under which others could bill for it. We doubt that Medicare patients will view 1.75 minutes of physician time added to an office visit as significantly enhancing the value of that visit. **The absence of even a rudimentary rationale for its proposed work RVUs and assigned time along with the references to preserving work neutrality and mitigating the impact of CMS’ proposed payment collapse illustrates the profound flaws of payment collapse rather than arguing convincingly for new code creation.**

- *Specialty Add-on Code for Inherently Complex E/M Visit*

CMS proposes a second new HCPCS add-on G-code (GCG0X) that would provide an additional \$14 above the proposed collapsed payment rate for “specialty professionals” whose practices consist primarily of E/M visits rather than procedural services and whose visit patterns are dominated by Levels 4 and 5 visits. Like GPC1X, GCG0X could be added to any office visit code but could not be reported with a procedure subject to the proposed expanded MPPR policy. Ten specialties are identified as routinely meeting the conditions for use of the code: endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. CMS implies that these specialties were selected through analysis of their current billing patterns for E/M and

procedural services. However, no details are provided on what criteria were employed and there are questions as to why this “nonprocedural” group includes two surgical specialties and does not include several other specialties that also predominantly bill the two highest level visit codes and/or have met the criteria for a MIPS complexity bonus. CMS proposes assigning a work RVU of 0.25 and physician time of 8.25 minutes, derived from crosswalking GCG0X to 75 percent of the values for 90785, the code used to indicate interactive complexity during a psychotherapy service. How this crosswalk was chosen and alternatives considered, if any, are not shared by CMS. Although CMS does not explicitly restrict use of GCG0X to the specialties identified above, the Agency also does not articulate criteria to permit use of GCG0X by other practitioners. **The AMA believes that the proposed add-on code GCG0X also is not clearly defined and is not based upon actual resource data, offering further evidence of the irreparable flaws in the underlying payment collapse.**

- *Add-on Code for Prolonged E/M Service*

CMS asserts that existing codes (CPT codes 99354 and 99355) available to report situations in which the face-to-face time of an office visit is prolonged substantially beyond that typical for the visit are inadequate. CMS bases this conclusion on stakeholder input that the prolonged time increment described by 99354 (i.e., one hour) is difficult for providers to meet and an impediment to billing. CMS proposes to address stakeholder concerns by creating an add-on G-code (GPRO1) to recognize those office visit scenarios when the typical visit time has been exceeded by 30 minutes. CMS acknowledges elsewhere in the rule that there is potential ambiguity in the proper usage of GPRO1 since the typical times for the collapsed office visit codes (one each for the new and established patient code families) to which GPRO1 would be applied have not yet been finalized. **The AMA believes there may be merit in an additional prolonged visit code and recommends that decisions regarding this code be deferred until the expert work group has developed the basic structure of an alternative to CMS’ proposed payment collapse.**

- *Proposed Changes to Podiatry E/M Services*

CMS proposes the creation of two separate codes for reporting of new and established patient podiatry office visits. Currently, Medicare does not distinguish E/M visits furnished by podiatrists from the analogous visits when furnished by other physicians of other specialties, as podiatrists are included in the definition of physician at Section 1861(r) of the Social Security Act. CMS proposes work RVUs (1.35/0.85) and physician times (28.11/21.60 minutes) for the new codes based on average payment rates for Levels 2 and 3 office visit codes, weighted by podiatric volume. Payment rates would be \$102 and \$67 for new and established patient visits, respectively; compared to \$134 and \$92 for the collapsed 99202-99205 and 99212-99215. As a rationale for this proposal, CMS notes that currently billing for office visits by podiatrists is heavily skewed towards Levels 2 and 3 and CMS and that a negative add-on adjustment to the single collapsed-code payments to podiatrists would have been necessary if podiatric office visits were retained in the office visit pools of the collapsed existing codes. The AMA views this proposal as yet another effort to mend the unsalvageable payment collapse proposal and

an additional example of CMS' failure to adhere to the RBRVS' legal boundaries. **The AMA has serious reservations about this payment change that is driven by the code collapse-single payment proposal, and we believe that there are legal ramifications as discussed in Appendix B, MPFS Legal Concerns.**

iv. **Multiple Procedure Payment Reductions (MPPR)**

Under the guise of eliminating duplicative payments for overlapping resources when an office visit is furnished on the same day as a procedure, CMS is also attaching a faulty and redundant MPPR policy to its proposed payment collapse. As we understand it, this proposal would add the current office visit codes and the two proposed podiatry codes to the 2019 surgical MPPR list. This would result in a 50 percent reduction in the service with the lowest total RVUs when a separately identifiable office visit is reported on the same day as any procedure on the list.

More than 5000 codes would be subject to the proposal and only 200 are valued lower than an office visit so the proposal will have a very broad reach and in most cases the 50 percent reduction will be applied to the visit rather than the procedure.

This proposal is based on a fallacious premise that is disputed by CMS' own observations elsewhere in the rule. The RUC has worked diligently along with national medical specialty societies and other health care professionals to ensure that there are no duplicate resource costs imbedded in procedure codes typically performed with E/M services. CMS is well aware of the RUC's ongoing efforts, as indicated in sections of the proposed rule that precede the E/M proposals and detailed in a separate comment letter submitted by the RUC. As shown in a previously-shared AMA analysis, virtually all specialties would face payment reductions from this proposal. Moreover, in another perverse effect of this proposal, the RVUs proposed for reallocation would be gained in large part from superimposing the MPPR reductions on top of the substantial reductions to payments for higher level office visits caused by the proposed payment collapse. For example, the combined effect of the two proposals on a Level 5 office visit is a reduction of nearly 70 percent from current values. **The AMA strenuously opposes CMS' proposal to expand the MPPR policy to include office visits performed on the same day as a separately billable procedures.**

v. **Practice Expense Impact of Code Collapse-Single Payment Proposal**

CMS states that another consequence of the code collapse-single payment proposal is a need to compensate for a large and unintended effect of the proposal on indirect practice expense (PE) allocation for office visits. As part of establishing the office visit single payment rates, CMS created a new Indirect Practice Cost Index (IPCI) solely for office visits and then transferred the indirect practice costs for office visits into the office visit IPCI and out of the IPCIs for all other specialties. As a result, many specialties experienced very large IPCI changes with corresponding changes in payments to other services they provide. For example, IPCI changes would range from -39 percent for Rheumatology to + 24 percent for Addiction Medicine and according to an analysis by AMA staff, 1100 CPT codes would experience a non-facility practice expense payment reduction that cannot be explained by any factor other than the IPCI change. Three specialties would experience a reduction of at least \$50 million in their indirect practice expense allowed charges for all services excluding office visits (Dermatology, Ophthalmology and

Otolaryngology). Ten chemotherapy codes with \$400 million in allowed charges last year all face total Medicare payment cuts of more than 10 percent despite being slated for slight increases in direct practice expenses due to a separate proposal to reprice equipment and supplies. **The AMA believes that the development of an E/M Practice Expense/Hour and resulting IPCI distorts the relativity of the RBRVS and has massive unintended and unexplained payment effects across the physician fee schedule. We regard this as a highly undesirable consequence of the code collapse-single payment proposal and we reiterate our strong opposition to that proposal.**

vi. E/M Payment Collapse Proposal Disregards Statutory Requirements

In addition to unintended consequences that could follow from adoption of the proposal to flatten payments for four levels of office visits down to one rate each in both the new and established categories, the proposal violates several statutory requirements. A detailed analysis of three legal shortcomings of the CMS proposal is included in an appendix to these comments, which is summarized as follows:

- From its initial establishment in the 1989 budget act, the Medicare physician fee schedule has required that rates be based on physician time and intensity as well as practice expense resources. The proposed rule disregards this requirement and would implement the same payment rate for four services requiring widely varying resources, with the 2018 work RVU for a new patient level 5 visit (3.17), for example, being 340 percent of the work RVU for a level 2 visit (0.93).
- Effective in 2016, the statute has prohibited one-year reductions in the total RVUs for a service that are equal to or greater than 20 percent compared to the previous year. The proposed RVU reductions for the levels 4 and 5 new patient visits and the level 5 established patient visit range from 20 to 38 percent, in violation of this statutory limit.
- The statute prohibits varying the RVUs for a service based on whether a physician is a specialist or on the type of specialty. The proposed add-on codes for some primary care office visits and some specialist office visits violate this prohibition, as do the proposed separate codes for office visits provided by podiatrists.

vii. E/M Visits: Conclusion

In summary, the AMA appreciates the attempt to reduce practitioner burden represented by CMS' proposals for change to E/M office visits; however, we find the centerpiece payment collapse proposal to be inconsistent with delivery of high-quality, up-to-date care of today's often complex Medicare beneficiary. We sincerely hope that CMS will agree to set the payment collapse proposal aside and work with the medical profession and the AMA-convened panel of experts to develop an alternative proposal that could be implemented in 2020.

B. Determination of Relative Value Units (RVUs)

The AMA appreciates the Agency’s acceptance of 71 percent of the RUC’s work relative value recommendations submitted for 2019. However, the AMA remains concerned about the RUC recommendations rejected by CMS. As a result, the AMA encourages CMS to carefully review the detailed RUC comment letter for information related to the valuation of specific codes. The AMA also fully supports and endorses the recommendations and comments of the RUC regarding work, practice expense, and professional liability insurance RVUs for particular services, the process and methodology for valuing services, potentially misvalued services, and pricing of equipment and supplies. The AMA also supports the RUC’s additional comments on other relevant issues. For the RUC’s detailed comments on these issues, the AMA refers CMS to its separate comment letter on this proposal rule of August 30, 2018.

CMS proposes to re-price supplies and equipment using a variety of methods in 2019, including 1) invoices provided by national medical specialty societies and others; 2) data from the General Services Administration (GSA); and 3) data from a subscription based benchmark database. The CMS proposal results in 357 medical supply items (27% of all medical supplies) and 105 medical equipment items (14% of all medical equipment) priced below the GSA pricing. In the Strategy Gen report to CMS, the contractor acknowledges that “...the GSA system by design provides the lowest available prices to government purchasers...”. Physicians cannot be expected to obtain medical supplies and equipment at rates lower than made available to the government. **The AMA requests that CMS reexamine this proposal and allow time for additional comment prior to full implementation.**

C. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

CMS has taken an important strategic step to expand coverage of clinically validated, technologically enabled, innovative virtual care services that should be available to patients, physicians, and the health care team. Such services better equip patients and clinicians with tools to ensure that the right medical care is provided at the right time and in a patient-centered manner. In our prior comments, the AMA has strongly urged CMS to prepare the Medicare program for the looming demands on the health care system precipitated by the unprecedented demographic shifts that, left unaddressed, will outstrip availability of public funding, health care professionals, and family caregivers within the next 15 to 20 years. The AMA applauds overall the forward-looking proposals in this proposed rule that will increase Medicare’s capacity while also implementing measures that promote prevention and medical care delivered in lower cost sites of care and in a more clinically efficacious manner. Even more laudable, these services are patient-centered and if developed and implemented consistent with user-centered design principles have the potential to reduce cognitive burdens, improve the quality of actionable clinical data, and reduce administrative burdens.

In 2016, the AMA commissioned a survey of physicians in order to examine their motivations, current usage, and expectations for integrating digital health tools into their practice ([Digital Health Study](#)). The Digital Health Study includes specific questions concerning telehealth as well as others related to mobile health, remote patient monitoring and management, and other mobile health applications. The overarching findings: physicians are optimistic that digital medicine tools will improve medical practice and patient care. In addition to ensuring that the tools and delivery models were clinically effective,

surveyed physicians ranked in order of importance the key issues that must be addressed to support their adoption of digital health tools including:

- standard liability insurance coverage;
- data privacy/security is assured by experts;
- workflow integration with electronic health record (EHR) systems; and
- coverage and payment.

While commercial insurers and other federal health care programs like the Veterans Health Administration and Department of Defense have moved forward to expand coverage of telehealth services and other virtual modalities such as remote monitoring and management of chronic conditions, the Medicare program has lagged behind. CMS has been confined by statutory limitations imposed on telehealth specifically, but had not, until last year, begun exercising existing authorities to expand coverage to non-telehealth virtual modalities validated by other health insurers.¹ Given the outsized role of the Medicare program in the health care system, this has chilled efforts by physicians to undertake the resource intensive process of altering their practices and training to provide virtual services integrated into in-person care. This proposed rule would provide the rational and necessary incentives to re-design care delivery.

Medicare Part B Program – Telehealth Statutory Definition and Limitations

The AMA agrees with CMS that Medicare telehealth services are limited by statute and regulation to two-way audio-visual, real time communication between a patient and a physician or other qualified health professional. CMS noted in the proposed rule that section 1834(m) of the Social Security Act (SSA) applies only to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional.² Unfortunately, section 1834(m) provides that telehealth coverage is subject to originating site and geographic restrictions (with limited exceptions). As a result, a large number of Medicare beneficiaries do not qualify to receive telehealth services since they do not receive their medical services in a qualifying rural location. Furthermore, even those who do live in a qualifying rural location are restricted by this statutory provision from receiving telehealth services in their home (with limited exception) due to the originating site restrictions.

The AMA strongly agrees with CMS that there are a number of virtual services that do not meet the statutory definition of telehealth services and, as a result, CMS has the discretion to provide coverage without the section 1834(m) geographic and originating site restrictions for such services. In particular, the AMA agrees with CMS that a number of virtual services that CMS currently covers and proposes to cover in this proposed rule are not considered telehealth such as, but not limited to, chronic care remote physiologic monitoring and interprofessional internet consultation.

¹ The AMA continues to vigorously advocate for federal legislation that will lift the restrictions on telehealth services in the Medicare program.

² There is not a consistent statutory definition of telehealth among various federal agencies. The telehealth definition is even varied within the Social Security Act. However, it is clear that for the Medicare Part B program, the statutory definition remains unchanged and encompasses a limited modality.

Telehealth – Demonstrations and Waivers

While CMS has the authority and discretion to expand coverage for non-telehealth virtual services to a Medicare beneficiary's home without regard to where they live, the section 1834(m) statutory restrictions on telehealth services represent a significant barrier to the adoption of clinically efficacious and cost-effective services for a broad array of services. The AMA agrees that CMS is barred by statute from expanding coverage using this important modality for delivering services, yet the Agency has the authority to undertake telehealth demonstrations that waive these restrictions for a select number of services to evaluate whether expansion is warranted under Center for Medicare & Medicaid Innovation (CMMI) authority. **The AMA strongly urges CMS to issue a request for proposal(s) for demonstrations to evaluate the telehealth services Medicare currently covers (albeit with restrictions) by waiving those statutory geographic and originating site restrictions.³ Furthermore, the demonstrations should be sufficiently large (e.g., several regions or multiple states) to provide sufficient claims data to evaluate whether telehealth is cost saving or cost neutral without the restrictions.** At a minimum, CMS should undertake a demonstration to waive the originating site restrictions for Medicare beneficiaries who live in an eligible geographic location to assess cost savings or neutrality of delivering such services while beneficiaries are at home. CMS would not only be able to expand coverage where such services are cost neutral or cost savings while maintaining or improving clinical care, but this would also generate essential claims data needed by Congress and the Congressional Budget Office to develop more accurate cost estimates based on the Medicare patient population that will be informative for other services.

Telehealth (Originating / Geographic Restrictions Apply) – Prolonged Preventive Services

The AMA supports coverage of the HCPCS codes G0513 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) **and G0514** (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service). The AMA agrees that these codes are similar to office visits currently on the telehealth list and supports the conclusion that these services can be furnished via interactive telecommunications technology.

Telehealth (Originating / Geographic Restrictions Do Not Apply) – Bipartisan Budget Act of 2018

The AMA strongly advocated for the inclusion of the Bipartisan Budget Act of 2018 (BBA) provisions that remove or modify the Medicare statutory geographic and originating site restrictions, respectively, for certain telehealth services, including for certain home dialysis end-stage renal disease-related services (ESRD), services furnished by practitioners in certain accountable care organizations, and acute stroke-related services. The AMA anticipates that coverage of these telehealth services without the geographic restriction and with expanded originating sites of service will unlock clinical benefits and savings that have not been realized due to the limited population eligible for these services prior to the BBA. In general, the AMA strongly supports implementation of applicable BBA telehealth provisions through this rulemaking.

³ The AMA's suggestion references the [list](#) of telehealth services Medicare currently covers subject to the originating and geographic restrictions.

The AMA supports CMS' revisions to the existing regulations with regard to the monthly ESRD-related clinical assessments via telehealth. In particular, the AMA supports the expansion of permissible originating sites to include additional facilities as well as a patient's home. Furthermore, the AMA supports the implementation of the BBA provisions that lift the geographic limitations of section 1834(m) for ESRD-related clinical evaluations.

The AMA is also very pleased that CMS is implementing BBA provisions that lift the geographic restrictions for diagnosis, evaluation, or treatment of symptoms of an acute stroke delivered via telehealth (acute stroke telehealth services). Clinical literature establishes that patients with ischemic and hemorrhagic stroke who receive telehealth services benefit from earlier recognition, more accurate triage, improved management of blood pressure and other critical physiological variables, and eventually earlier implementation of effective therapies.^{4,5} Acute stroke telehealth services are an important modality to facilitate treatment of patients with acute ischemic stroke with tissue plasminogen activator (tPA) within 4.5 hours.⁶ In addition, multiple peer-reviewed publications support the use of endovascular revascularization for large vessel occlusion ischemic stroke—an entity that is easily recognizable via telehealth with resultant triage and appropriate use of stroke (health) system resources.

Furthermore, the AMA supports the modification of existing regulations to add mobile stroke units as permissible originating sites for acute stroke telehealth services. However, the AMA urges CMS to specify that a mobile stroke unit should be defined as a unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke, and must include a computed tomographic (CT) scanner and a telehealth (audio and video) connection or an in-person physician who is able to interpret the CT scan and prescribe an intravenous thrombolysis.⁷ The unit must also have a qualified health professional who is able to administer an intravenous thrombolysis if the physician interpreting the CT scan and prescribing the treatment does so via telehealth. **The AMA also urges CMS to include as an originating site Emergency Medical Service (EMS) transports equipped with telehealth connection to stroke specialists in order to provide faster national access to patients who require an accurate stroke diagnosis and decision about eligibility for intravenous or endovascular therapy, and to determine where to take them (such as a primary stroke or comprehensive stroke center).** These decisions can be facilitated by telestroke communication in the ambulance with stroke experts. CMS is urged to establish a different modifier based on whether the service is delivered via mobile stroke unit or an EMS transport vehicle equipped with telehealth. CMS has the discretion to establish both as originating sites consistent with the proposed rule and the BBA authorizing language in the final rule. Both approaches have an evidence base supporting coverage and constitute improvements on current options available to Medicare beneficiaries. Also, establishing both as originating site options will generate important comparative clinical efficacy and cost data.

Chronic Care Remote Physiologic Monitoring

The AMA strongly supports coverage of the CPT Editorial Panel adopted chronic care remote physiologic monitoring and management codes (CPT codes 990X0, 990X1, 994X9) and the

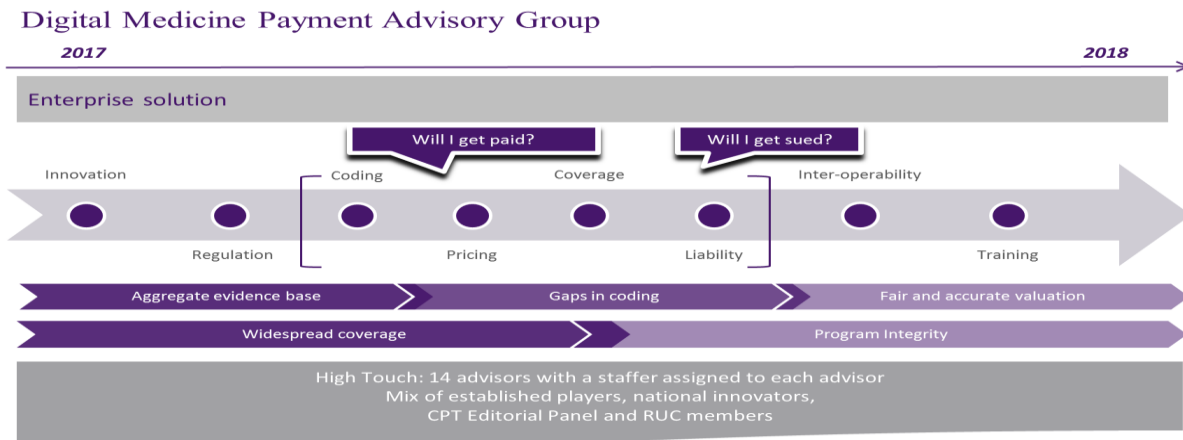
⁴ E Substudy, Ebinger, Martin MD, et al., Effects of Golden Hour Thrombolysis: A Prehospital Acute Neurological Treatment and Optimization of Medical Care in Stroke (PHANTOM-S) *AMA Neurol.* 2015;72(1):25-30. doi:10.1001/jamaneurol.2014.3188

⁵ Weschler, L., Advantages and Limitations of Teleneurology, *AMA Neurol.* 2015;72(3):349-354. doi:10.1001/jamaneurol.2014.3844

⁶ Id.

⁷ Rajan, Suga, PhD, et al., Effects of Golden Hour, Id.; Implementing a Mobile Stroke Unit Program in the United States: Why, How, and How Much? *AMA Neurol.* 2015;72(2):229-234. doi:10.1001/jamaneurol.2014.3618; Itrat, A MD et al., Telemedicine in Prehospital Stroke Evaluation and Thrombolysis: Taking Stroke Treatment to the Doorstep, *JAMA Neurol.* 2016;73(2):162-168. doi:10.1001/jamaneurol.2015.3849

proposed valuation for 990X0 and 994X9. The AMA strongly urges CMS to include the licensing and cellular fees attributable to each patient as part of the PE valuation for 990X1. The clinical evidence base in support of chronic care remote physiologic monitoring services is substantial. The AMA established a [Digital Medicine Payment Advisory Group](#) (DMPAG) in 2017 comprised of national experts (primarily practicing physicians) in the area of virtual health services and others with expertise in coding, valuation, and coverage in order to identify which virtual services and modalities have a sufficient clinical evidence base to support payment.⁸



The initial appointment of the DMPAG advisors was for calendar year 2017, and the work of DMPAG was extended for calendar year 2018. The DMPAG focused on chronic care remote physiologic monitoring and interprofessional internet consultation services, the latter discussed in the next section.

The DMPAG considered literature establishing that early deployments of remote monitoring and management services took place in the early 1990s, but since 2009 the incidence of such services has been increasing.⁹ The DMPAG advisors evaluated the meta-analyses related to remote monitoring and management services contained in the [Technical Brief Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews](#) (2016) conducted by the Agency for Healthcare Research & Quality. In addition, the DMPAG considered the summary of the meta-analysis conducted by the National Quality Forum summarized in NQF's draft report [Creating a Framework to Support Measure Development for Telehealth](#) (July 2017), which included a review of remote monitoring and management services. The DMPAG advisors also submitted and considered peer reviewed literature in support of such services for a number of conditions. There is extensive evidence that validates clinical efficacy of remote patient monitoring/management for chronic conditions (asthma, COPD, obesity, hypertension, diabetes, and congestive heart failure) and other follow-up care (post-surgical, cancer).

In addition, as summarized in comments and an attachment submitted by the AMA as part of last year's proposed PFS, a number of DMPAG advisors provided detailed information on the remote monitoring and management services that their affiliated systems provide to patients and are scaling, including Cleveland Clinic, University of Mississippi Medical Center, University of Pittsburgh Medical Center, and

⁸ For a complete listing of the current DMPAG Members please visit <https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group#Digital%20Medicine%20Payment%20Advisory%20Group%20Members>.

⁹ Source: http://www.nahc.org/assets/1/7/10hc_stats.pdf

University of Virginia Health System. Based on the literature review and case studies provided by experts, the DMPAG concluded that a number of health systems and providers around the nation have established a significant body of evidence demonstrating both the clinical efficacy and value of remote monitoring and management for patients with chronic conditions, including chronic kidney disease and heart failure. For example, the Cleveland Clinic system provides outpatient remote monitoring and management for patients with chronic medical conditions and those who need management for anticoagulation, chronic kidney disease, congestive heart failure, anemia, and osteoporosis. A published study involving services delivered by Cleveland Clinic describes benefits of remote monitoring and management services based on a multicenter, randomized clinical trial that evaluated home- with clinic-based multidisciplinary management for post-acute heart failure patients.¹⁰ Additional literature considered by the DMPAG demonstrating the clinical efficacy of these services include:

- Study participants were given a device that uploaded blood glucose and blood pressure readings daily to a central server. The authors concluded that technology-assisted case management by a nurse with medication titration under physician supervision is efficacious in improving glycemic control in low-income rural adults with poorly controlled type 2 diabetes.¹¹
- A study evaluating remote patient monitoring using paired glucose testing and asynchronous data analysis in adults with type 2 diabetes. The authors concluded that an eHealth model incorporating a complete feedback loop with remote patient monitoring and paired glucose testing with asynchronous data analysis significantly improved A1c levels compared to usual care. The study concluded that remote patient monitoring may improve clinical outcomes, care coordination, engagement, and satisfaction.¹²
- A study assessing the feasibility, acceptability, and preliminary outcomes of a prototype medication and blood pressure self-management system for kidney transplant patients with uncontrolled hypertension. The finding included that the remote patient monitoring intervention group exhibited significant improvements in medication adherence and significant reductions in clinic-measured systolic blood pressures.¹³
- A systemic review of English-language studies published in MEDLINE, The Cochrane Library, and the INAHTA databases that presented results on the clinical effects of home remote patient monitoring on patients with diabetes, asthma, heart failure, or hypertension. The paper assessed the research in those four chronic conditions, and identified critical success factors for home RPM programs. It demonstrates the broad use of home remote patient monitoring devices.¹⁴

Based on the foregoing and expert deliberations, the DMPAG submitted a code change application to the CPT Editorial Panel to establish the following three new codes to support chronic care physiologic monitoring:

¹⁰Gorodeski, EZ et al., Home-base care for heart failure: Cleveland Clinic's "Heart Care at Home" transitional care program, *Cleveland Clinic Journal of Medicine* 2013 January; 80(e-suppl 1):e-S20–e-S26

¹¹Egede, LE et al. Randomized Controlled Trial of Technology-Assisted Case Management in Low Income Adults with Type 2 Diabetes, *Diabetes Technology & Therapeutics* 2017 June 5

¹²Greenwood DA et al., Overcoming Clinical Inertia: A Randomized Clinical Trial of a Telehealth Remote Monitoring Intervention Using Paired Glucose Testing in Adults With Type 2 Diabetes, *J Med Internet Res* 2-015 Jul; 17(7): e178.

¹³McGillicuddy JW et al., Mobile Health Medication Adherence and Blood Pressure Control in Renal Transplant Recipients: A Proof-of-Concept Randomized Controlled Trial, *JMIR Res Protoc* 2013 Jul-Dec 2(2): e32

¹⁴Pare, G, Clinical Effects of Home Telemonitoring in the Context of Diabetes, Asthma, Heart Failure, and Hypertension: A Systematic Review, *J Med Internet Res*. 2010 Apr-Jun 12(2): e21

- CPT code 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).
- CPT code 990X1 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).
- CPT code 994X9 (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).

The above codes were approved by the CPT Editorial Panel in the fall of 2017. To ensure appropriate use of the codes and to enhance program integrity, the CPT Editorial Panel has provided instructions in the form of parentheticals that identify restrictions regarding reporting for 990X0, 990X1, including:

- Do not report 990X0 more than once per episode of care (see parenthetical following 990X0).
- Do not report 990X0 for monitoring of less than 16 days (see parenthetical following 990X0).
- Do not report 990X1 for monitoring of less than 16 days (see parenthetical following 990X1).
- Do not report 990X0 and 990X1 when these services are included in other CPT codes for the duration of time of the physiologic monitoring service (eg, 95250 for continuous glucose requires a minimum of 72 hours of monitoring (found in guideline language for the code subsection)).
- Do not report 990X0, 990X1 in conjunction with codes for more specific physiologic parameters (eg, 93296, 94760) (see parenthetical following 990X1).

Also, the CPT Editorial Panel has provided guidelines regarding use of these codes including:

- Codes 990X0 and 990X1 are used to report remote physiologic monitoring services (eg weight, blood pressure, pulse oximetry) during a 30 day period (see guideline language for subsection).
- To report 990X0 and 990X1, the device used must be a medical device as defined by the Food and Drug Administration, and the service must be ordered by a physician or other qualified health care professional.

In addition to the newly adopted codes for 2019, the AMA also urges CMS to carefully consider the CPT Editorial Panel's approved revisions to the guidance for CPT code 99091 (Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days). To ensure accurate reporting of these new services with the currently active CPT code 99091, the CPT Editorial Panel updated the parentheticals immediately following the code descriptor to note the following:

- Do not report 99091 in conjunction with 994X9.
- Do not report 99091 if it occurs within 30 days of 99339, 99340, 99374, 99375, 99377, 99378, 99379, 99380, 994X9.

Adoption and dissemination of this information is critical to providers, a number of whom have reported that they were not able to utilize CPT code 99091, which was unbundled and activated by CMS for CY 2018 because there was insufficient information on parameters for use. The AMA urges CMS to include the above parentheticals and guidelines to assist providers with the appropriate adoption and use of these new codes.

The AMA also strongly urges CMS to specify that where services are rendered “incident to” that such services are subject to general supervision. If CMS requires direct supervision for services rendered “incident to” it will substantially limit the benefit and value of these codes.

In addition to activating the above codes, CMS has proposed in the CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements (HH proposed rule) to establish a new CMS HCPCS Level II code for remote patient monitoring technical components for inclusion as allowable costs in a home health agency’s cost report. However, the AMA strongly urges, for purposes of consistency and to avoid duplicate billing and confusion over appropriate reporting, that CMS ensure that when home health agencies are providing the technical component, they report these allowable costs utilizing CPT codes 990X0 and 990X1 where appropriate as opposed to a new HCPCS Level II code defining remote patient monitoring as proposed by CMS in the HH proposed rule. The AMA also strongly urges CMS to issue subregulatory guidance so that reporting by home health agencies is consistent and not duplicative of those billing on the Medicare PFS for the same patient receiving chronic care remote physiologic monitoring and management services.

Finally, while the AMA supports CMS’ proposed valuation and payment for 990X0 and 990X4, CMS is strongly urged to reconsider its proposed valuation and payment for 990X1. Specifically, the AMA strongly urges CMS to consider that the disallowance of the monthly cellular and licensing service fee does not account for the documentation submitted by the RUC that establishes that these costs are directly and discretely allocable to the use of an individual patient for an individual use. As a result, these costs do not constitute indirect practice expense. The cellular capability is specific to the U.S. Food and Drug Administration (FDA) device provided to the patient to ensure continuous connectivity. (If the patient lacks assured cellular connectivity, it places the patient at risk of harm and undermines the efficacy of the modality.) Similarly, the licensing service fee is not a general cost, but specific and allocable to individual patients. As a result, the AMA strongly urges CMS to reconsider documentation and invoices provided to CMS for consideration of these direct practice expenses.

Interprofessional Internet Consultation

The AMA strongly supports the proposed activation and coverage of Interprofessional Internet Consultation codes (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449). Enhancing the quality and coordination of care while overcoming the persistent shortages of medical specialists are all advanced by the Agency’s proposal to cover these services. As outlined below, there is a significant body of literature that provides clinical validation for use of these services that continues to grow. In 2017, the AMA’s DMPAG submitted an application for the two codes detailed below which the CPT Editorial Panel approved in the fall of 2017:

- 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient’s

treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time).

- 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a physician or qualified health care professional, 30 minutes).

The clinical evidence aggregated and considered by the DMPAG demonstrated the efficacy of these services. The DMPAG also considered that multiple health care systems are implementing e-consults to resolve large patient backlogs where the patients require medical specialty care. For example, the Los Angeles County Healthcare System (LACHS), the second largest public health care system in the United States, is responsible for 670,000 patients. LACHS launched an eConsult system in 2012, and in four years the implementation of this system across thousands of physicians and dozens of specialty services resulted in reduction of the median response time to less than one day, with a quarter of the requests resolved without a specialist visit.¹⁵ By 2015 the system was in use by over 3,000 primary care providers, and 12,082 consultations were taking place per month, compared to 86 in the third quarter of 2012.¹⁶ The DMPAG also considered the deployment of e-consults at the Cleveland Clinic and the University of Virginia Health System as well as the implications for medical genetics where shortages are prevalent across the U.S.¹⁷ and are unlikely to be resolved without deployment of virtual modalities.

It is important to note that shortages of medical specialists and access challenges are not only faced by patients in public health systems. There are shortages of many adult and pediatric specialists and subspecialties. In addition, certain subspecialties/specialties are often concentrated in urban academic centers, and geographically separated from the patients in need of the services by large geographic distances. As a result, patients must travel long distances for the initial appointment as well as routine follow-up care or the management of their condition(s). For medical home providers of these patients the virtual modalities (telephone/Internet/electronic medical record) provide the most accessible and reliable method of obtaining the consultative expertise they and their patients require, while limiting the number of needed distant visits to specialty/subspecialty offices. It also enhances team-based care, adherence, and seamless care coordination. The AMA urges CMS to consider the following literature in support of coverage:

- A randomized controlled trial of e-consultations by 36 primary care clinicians to test the efficacy and effectiveness in reducing wait times and improving access to specialty care of e-consultations. The authors concluded that e-consultation referrals improved access to and timeliness of care for an underserved population, reduced overall specialty utilization, and streamlined specialty referrals without any increase in adverse cardiovascular outcomes. They further concluded that e-consultations are a potential solution for improving access to specialty care.¹⁸
- A case study focused on interprofessional communication (specifically poor communication between primary care and specialists) that tested eReferral, a HIPAA-compliant web-based referral and consultation system that replaces hardcopy, telephone, and fax referral requests. The

¹⁵Barnett, ML et al. Los Angeles Safety-Net Program eConsult System Was Rapidly Adopted and Decreased Wait Times to See Specialists, *Health Affairs* 36, no. 3 (2017) 492-499

¹⁶Id.

¹⁷Johansen Taber, KA, et al., The Promise and Challenge of Next Generation Genome Sequencing for Clinical Care, *JAMA Intern Med.* 2014;174(2):275-280. doi:10.1001/jamainternmed.2013.12048

¹⁸Olayiwola JN, Electronic Consultations to Improve the Primary Care-Specialty Care Interface for Cardiology in the Medically Underserved: A Cluster-Randomized Controlled Trial. *Ann Fam Med.* 2016 Mar;14(2):133-40

study provides documentation of the outcomes from a successful electronic referral program, and it suggests a range of design features and implementation factors that accounted for the program's success. Users perceived that eReferral largely prevented the occurrence of low-value specialty visits due to unclear consult questions, incomplete workups, and referrals for problems that could be managed in primary care. The system was also perceived as having markedly reduced wait times for specialty services, which had previously been up to a year for some specialties in a historically under-resourced setting.¹⁹

- A study focused on communication between primary care clinicians in 26 clinics in San Francisco and the specialist clinicians at San Francisco General Hospital and the use of eReferral, a Web-based electronic referral system. The eReferral system was designed to foster an electronic dialogue between primary care clinicians and specialist reviewers.²⁰

The AMA supports the proposed valuation and payment for CPT codes 994X0, 99446, 99447, 99448, and 99449. However, the AMA strongly urges CMS to reconsider the valuation and payment proposed for 994X6 which describes the services of the consulting physician/qualified health professional. While the treating physician/qualified health professional must prepare a referral, the RUC documentation and survey establishes that there is a differential in the work RVU between the treating/requesting and consulting physician/qualified health professional. The AMA asks that CMS re-assess the documentation submitted by the RUC in support of the RUC recommended work RVU for 994X6 (0.70) and adopt that recommendation in lieu of CMS' proposed work RVU (0.50).

Also, the AMA strongly urges CMS to consider the CPT Editorial Panel instructions in the form of parentheticals and guidelines that identify appropriate use and restrictions regarding reporting of these codes. These parentheticals and guidelines enhance program integrity. Furthermore, the instructions and guidelines establish unambiguously that these services are attributable to a single beneficiary. And, these codes describe services that differ from clinician interactions for the benefit primarily of the treating practitioner. The AMA agrees that general information shared as professional courtesy or continuing education would not constitute a service directly attributable to a single Medicare beneficiary, and therefore neither the Medicare program nor the beneficiary should be responsible for those costs. As demonstrated by the clinical literature and deployment in various health systems, these consultation codes describe services that are separately identifiable services attributable to a single patient, and can be distinguished from interactions between physicians and other qualified health professionals that are primarily for the benefit of the treating practitioner. Finally, the ability of CMS to evaluate whether an Interprofessional Internet Consultation is reasonable and medically necessary is optimized as information concerning the consultation will either be automatically integrated into the electronic medical record or incorporated by the treating physician/qualified health professional into the patient's 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, similar to the conditions of payment associated with the care management services under the PFS. 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. For example, exigent circumstances should encompass when laboratory or other data results are returned to the treating/referring clinician

¹⁹Straus SG et al., Implementation of an Electronic Referral System for Outpatient Specialty Care, MIA Annual Symposium Proceedings, Oct 2011; 1337-1346

²⁰Chen, AH et al., A Safety-Net System Gain Efficiencies Through "eReferrals" to Specialists, Health Affairs May 2010 vol. 29, no 5 (969-971)

after the patient visit has concluded and the clinician seeks to address clinically relevant matters through an Interprofessional Internet Consultation process. Where notice and advance consent are not possible due to emergent or exigent circumstances, practitioners should document reasonable efforts to provide notice subsequently.

Additional Virtual Services (Proposed HCPCS Level II Codes)

CMS has proposed descriptors for two new HCPCS Level II codes for a virtual check-in (GVCII) and for remote evaluation of pre-recorded patient information (GRAS 1) and corresponding proposed valuation, payment, and coverage guidelines.²¹ The AMA generally appreciates CMS' efforts to identify virtual services that would not be limited by the telehealth geographic and originating site restrictions. However, because the CMS proposed descriptors for both codes do not involve a two-way audio, video real-time interaction between a patient and a physician/qualified health professional and these are patient initiated services, CMS should only cover these services where a valid patient-physician relationship already exists or can be established as described below. The AMA's House of Delegates (HOD) carefully considered a broad array of factors to ensure that virtual services are efficacious and do not compromise care while also addressing program integrity concerns.²² Based on the HOD's extensive, evidence-based deliberations, the AMA urges that, if CMS covers the GVCII and GRAS 1 services in the final rule, the Agency should only permit these services for established patients. Specifically, at some point prior to the rendering of these virtual services a face-to-face examination (either in-person or through a real-time, two-way audio, video interaction) should be conducted by the physician providing the subsequent GVCII/GRAS1 service or the rendering physician is on-call for or has a cross coverage agreement in place with a physician who already has an established patient-physician relationship. The caveat to the foregoing: the AMA urges adherence to specific standards for the establishment of a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine (broadly defined to include a range of modalities beyond telehealth) developed by major medical specialty societies, such as radiology, dermatology, and pathology. The existence of a valid patient-physician relationship not only ensures that the treating physician/qualified health professional meets a threshold standard of care, but will minimize the potential for program integrity abuses including inappropriate utilization, enhance care coordination/continuity of care, and ensure that patients are afforded advance notice when the relationship is being established that such patient-initiated services may result in out-of-pocket expenses including deductible and co-pays/co-insurance.

The AMA also urges CMS to consider that the GRAS 1 description does not specify that the device

²¹CMS has also proposed that starting January 1, 2019, rural health clinics (RHCs) and federally qualified health centers (FQHCs) receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC all-inclusive rate or the FQHC prospective payment system when the requirements for these services are met. The AMA urges that CMS adopt include a coverage requirement that a valid patient-physician relationship must exist or an exception apply as outlined for the GVCII or GRAS1 codes.

²²In 2010, AMA physician leaders, comprised of representatives from every national medical specialty society and state medical association, adopted the first AMA policy statement concerning telemedicine (considered broadly to include an array of virtual modalities and not limited by the Social Security Act definition of telehealth) and remote patient monitoring and management. In quick succession since that time, a range of AMA policies have been developed, debated, and adopted by these same physician representatives addressing a range of topics including research and clinical validation resources, regulatory oversight and accountability, coverage and payment, ethical practice, virtual supervision, medical education, and integration of mobile health applications and devices into practice. *Telemedicine and Medical Licensure* (Council on Medical Education (CME) Report 06-A-10); *Professionalism in Telemedicine & Telehealth* (Board of Trustees (BOT) Report 22-A-13); *Coverage and Payment for Telemedicine* (Council on Medical Service (CMS) Report 7-A-14); *Facilitating State Licensure for Telemedicine Services* (BOT Report 3-I-14); *Ethical Practice in Telemedicine* (Council on Ethical and Judicial Affairs (CEJA) Report 1-A-16); *Virtual Supervision of "Incident to" Services* (CMS Report 5-A-16); *Telemedicine in Medical Education* (CME 06-A-16); and, *Integration of Mobile Health Applications and Devices into Practice* (CMS Report 06-I-16).

(which includes hardware, software, and system) used to take and transmit the video or images should be a FDA medical device. Unlike telehealth which involves a real-time interaction where additional time would be available to collect information and more images/visuals of the patient, the lack of specificity in the GRAS 1 descriptor might raise patient safety questions and CMS is urged to consider the extent to which the clinical literature validates the use of store and forward images and discrete video clips for an open ended number of conditions using any technology or modality where an established patient-physician relationship is lacking.

Finally, CMS has sought specific comment on whether the remote evaluation of pre-recorded patient information (GRAS 1) should be available to new patients for dermatological or ophthalmologic services. The AMA urges CMS to consider the national medical specialty society clinical practice guidelines for the conditions and requirements for the provisions of such services. National medical specialty societies have developed such guidelines to ensure quality virtual services are provided given the variability that can exist. For example, the results of a recent study evaluating patient initiated teledermatology produced sobering results and conclusions. The authors concluded that virtual services offer significant promise to increase access and high-value health care. However, the authors expressed concern with the quality of skin disease diagnosis and treatment provided by many direct-to-consumer telemedicine websites.²³ The authors noted further that improvements were needed so patients would not risk using health care services that lack transparency, choice, thoroughness, diagnostic and therapeutic quality, and care coordination. Addressing such concerns and ensuring quality care is delivered, the American Academy of Dermatology Association (AADA) has a [Position Statement on Teledermatology](#) and offers [teledermatology resources](#) to promote appropriate patient care. CMS should utilize these guidelines from AADA when finalizing coverage requirements for GRAS 1 dermatologic services. Similarly, CMS is urged to consider other national medical specialty society guidelines when crafting coverage requirements for specialty specific services where the store-and-forward modality of patient generated images is addressed.

In sum, the AMA appreciates efforts to expand coverage for virtual modalities. To the extent that CMS finalizes the code descriptors, valuation, and coverage for the virtual check-in and the remote evaluation of pre-recorded patient information, there are a number of important patient protections and program integrity benefits to ensuring these services are provided to established patients or consistent with exceptions outlined above.

D. Creating a Bundled Episode of Care for Management and Counseling for Treatment of Substance Use Disorders

The AMA commends CMS for seeking better ways to pay for Medication Assisted Treatment (MAT) for substance use disorders and for soliciting comments on how to do so. As the primary intent of this policy is to help address the epidemic of opioid overdose deaths, we encourage CMS to limit its payment policy proposals to management of MAT for opioid use disorder (OUD), not the broader category of substance use disorders.

Payment Barriers

The current Medicare Physician Fee Schedule creates multiple significant barriers for physician practices that want to deliver MAT to patients:

²³Resneck, JS et al., Choice, Transparency, Coordination, and Quality Among Direct-to-Consumer Telemedicine Websites and Apps Treating Skin Disease, JAMA Dermatol. 2016;152(7):768-775. doi:10.1001/jamadermatol.2016.1774

- E/M service payments are insufficient to support the time required to identify and diagnose OUD and develop a treatment plan that the patient is willing to pursue.²⁴
- Most E/M service payments require face-to-face visits with patients. Although new codes added to the Medicare payment schedule in recent years pay for certain types of non-face-to-face services, payments are limited to specific types of patients and specific methods of service delivery that may not support delivery of MAT in ways that best match the needs of patients with OUD and are feasible for most physician practices, particularly small practices.
- There are no payments to enable primary care physicians and addiction specialists other than psychiatrists to communicate by phone or email to help the primary care physicians to diagnose and develop effective treatment plans for OUD and adjust treatment plans over time to ensure treatment is successful.
- There is no mechanism to pay for the costs of technology-based treatment and recovery support tools, remote monitoring, and similar services that could help to improve outcomes for patients. The study of web-based counseling cited in the proposed rule is an example of how technology can be used to improve patient outcomes, but the cost of obtaining and using such technologies will remain a barrier even if CMS pays physicians for the time they spend when the technologies are used.

How New Medicare Payments for MAT Should Be Designed

The AMA strongly supports changes in the way Medicare pays physician practices that would remove these barriers and provide the support physicians need to successfully and sustainably deliver MAT for patients with OUD. It is important, however, that new payment policies solve the current problems with payments without creating new problems in the process. The only way to ensure that payments are structured properly is to involve physicians with direct experience and demonstrated success in using MAT to treat these patients.

The AMA has been working with the American Society of Addiction Medicine (ASAM) over the past two years to develop a physician-focused payment model (called P-COAT) that would correct the barriers described above and enable more physicians to deliver MAT in a patient-centered way. We urge that any payment changes developed by CMS be based on the payment approach developed by ASAM and the AMA and include the following five elements:

1. **Payment for Initiation of Medication-Assisted Treatment (IMAT)**
Physicians should be able to receive a one-time payment to support (1) evaluation, diagnosis, and treatment planning for a patient with OUD and (2) the initial month of outpatient medication-assisted treatment for the patient. The amount of payment should be adequate to cover the costs of these services in small physician practices.
2. **Payment for Maintenance of Medication-Assisted Treatment (MMAT)**
Physicians should be able to receive a monthly payment to provide MAT and to provide or

²⁴Knudsen HK, Abraham AJ, Oser CB. Barriers to the implementation of medication-assisted treatment for substance use disorders: The importance of funding policies and medical infrastructure. *Evaluation and Program Planning* 34(4): 375–381. <http://doi.org/10.1016/j.evalprogplan.2011.02.004> (2011).

coordinate the provision of psychological treatment and social services for a patient who has successfully initiated treatment for OUD. Monthly payments should be able to continue indefinitely if the patient is determined to be appropriate for continued therapy. Payment amounts should be adequate to cover the costs of these services in small physician practices.

3. **Higher Payments for Patients with More Complex Needs**

In both the initiation and maintenance phases of care, higher amounts should be paid for patients with more complex needs who require more intensive supervision and services.

4. **Flexibility to Support Services of Primary Care Physicians and Addiction Specialists**

Some patients will obtain MAT directly from physicians who specialize in addiction medicine, but many patients, particularly in rural areas, will obtain MAT from a primary care physician who has a waiver to prescribe buprenorphine and who will need consultative assistance from an addiction specialist. In the latter case, payments will be needed to support the time and work of both the primary care physician and addiction specialist.

5. **Add-On Payments to Support Integration of Technology-Based Treatment and Recovery Support Tools**

In each phase of care, add-on payments should be available for physicians who use technology-based tools in order to improve treatment outcomes.

Physician practices should be able to bill for the IMAT and MMAT payments in addition to E&M payments for face-to-face visits with the physician, but a physician practice would not bill for other non-face-to-face services (such as care management or collaborative care codes) during the months in which the IMAT or MMAT payments were paid. Additional information about the elements of potential new codes for these services is contained in the [P-COAT concept paper](#) developed by the AMA and ASAM.

Problems with “Bundled Episodes of Care” for MAT

“Bundling” of payments for MAT would be desirable only to the extent that:

- (1) the bundles support services that are typically delivered by a single physician or physician practice, and
- (2) the bundling is designed to provide flexibility for the physician practice to use different combinations of services based on patient needs.

For example, the monthly MMAT payments recommended above would give physicians the flexibility to deliver MAT services differently to different patients, e.g., using both office visits and virtual visits, based on what will achieve the best outcomes for the patient. We would have concerns about creating bundled payments that:

- (1) combine payments for physician services with services delivered by other providers, and/or
- (2) combine payments for physician services with payments for medications or medical devices.

Physician practices that are willing to provide MAT to patients with OUD should not be expected to create claims payments systems in order to accept multi-provider bundles or to take financial risk for the prices of drugs, devices, or other supplies as part of bundled payments. Patients will benefit and Medicare

spending will decrease if adequate, flexible payments are made for MAT without forcing physicians to accept high levels of financial risk or administrative burdens.

Payments for MAT should not be restricted to a single “episode of care” with a fixed, maximum duration, similar to the fixed-length episodes used in the Bundled Payments for Care Improvement Initiative or the Comprehensive Care for Joint Replacement Program. For many patients, MAT will need to continue indefinitely in order to ensure they can remain opioid-free. Research on long-term outcomes of MAT has shown that many patients only continue to avoid illicit opioid use through continued long-term opioid agonist therapy as part of MAT.²⁵ As described above, we recommend the use of monthly payments to support MAT in two separate phases: a one-time payment to support initiation of MAT; and then monthly payments to support continuation of MAT, with no fixed limit on the number of such monthly maintenance payments.

Improving Payment for MAT through APMs vs. Medicare PFS

There would be significant advantages to initially implementing these improved payments through an Alternative Payment Model (APM) rather than the PFS. This would provide a more flexible mechanism for adjusting payment amounts and requirements than is possible through notice and comment rulemaking, and it would better enable development and use of new quality and utilization measures to ensure high quality care, good outcomes for patients, and savings for Medicare through reductions in OUD-related emergency visits and hospital admissions.

As described in the APM section of this comment letter, however, none of the stakeholder models recommended to the Secretary by the Physician-Focused Payment Model Technical Advisory is being tested and most physicians do not have the opportunity to participate in an APM for their Medicare patients today. Many Medicare patients are receiving lower-quality, more expensive care than necessary because so few APMs are available. There is an urgent need to address America’s opioid crisis, and there is an urgent need to remove the barriers in the current payment system that prevent the delivery of effective treatment to patients with OUD. The current process for developing and implementing APMs would be unacceptably slow for addressing this problem. Consequently, if CMS will be able to improve payment for MAT more quickly through changes to the fee schedule, that may be preferable than waiting for development and implementation of an APM.

E. Methods for Identifying Non-Opioid Alternatives for Pain Treatment and Management

CMS invites comments on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage. A [study published June 22, 2018, in JAMA](#), conducted by researchers at the Johns Hopkins School of Public Health and funded by the HHS Assistant Secretary for Policy and Evaluation, examined coverage policies for 62 pharmacologic treatments for low back pain. The study included a diverse group of insurers including Medicaid, Medicare Advantage, and commercial plans in a number of states, and was augmented with interviews with medical and pharmacy directors.

²⁵Weiss RD et al. Long-term outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study. *Drug Alcohol Depend* 150:112-119 (2015).

The study found that plans were universally working to limit opioid prescriptions, such as by morphine milligram equivalent limits and other quantity and duration limits, but it also found that plans had a lot of limits on non-opioid pharmacologic treatments. In particular, whereas the study found that utilization management (UM) appeared more frequently or at similar rates for opioids than non-opioids across all plans and all utilization management methods, the exception was the use of prior authorization by Medicare Advantage plans, which was more frequent for non-opioids than for opioid pharmacologic treatments. **CMS should modify its policies on use of prior authorization by Medicare Advantage plans to eliminate this barrier.**

Interviews conducted as part of the study reinforced that insurers have largely focused on efforts to constrain opioids rather than to promote comprehensive strategies to improve pain treatment. The report concluded: “Requiring patients and health care professionals to navigate burdensome and diverse utilization management policies for opioid alternatives likely results in slower adoption and implementation of these treatments.”

A recent [survey](#) by the American Board of Pain Medicine found that “93 percent of pain medicine specialists report that they have been required to submit a prior authorization for non-opioid pain care.” This has caused nearly 70 percent of those specialists having to hire additional staff. The ABPM reported that prior authorization was for a wide variety of non-opioid pain care, including:

- Physical therapy limits, psychiatric services, occupational therapy.
- Pain creams and patches (e.g. lidocaine, Lidoderm, Voltaren, topical NSAIDs).
- Non-opioid prescription medications (e.g. Cymbalta, Lyrica, Celebrex).
- Non-opioid pain treatments (e.g., TENS, facet blocks, spinal cord stimulators, epidural injections).

The physical therapy limits are exacerbated by high co-pays or the challenges patients face in accessing such care during normal work hours. The psychiatric and occupational therapy barriers often are the result of limited networks of specialists—a problem that could be addressed through enhanced incentives. Regarding pain creams and patches and other non-opioid treatments, the problems are two-fold. First, in addition to prior authorization, these treatments may not even be available on an insurance products’ formulary. And second, if it is on the formulary, it may be placed on a high-cost specialty tier, thereby making the non-opioid option economically impossible for most patients.

Considering that physicians and other health care professionals have decreased opioid prescribing by more than 22 percent since 2013, but patient access to alternative forms of pain care is hindered by these administrative burdens, we urge CMS support to remove these burdens.

F. Teaching Physician Documentation Requirements for E/M Services

Medicare Part B currently makes payment under the PFS for teaching physician services when certain conditions are met, including that medical record documentation must reflect the teaching physicians’ participation in the review and direction of services performed by residents in teaching settings. For E/M visits, the teaching physician is required to personally document their participation in the medical record. CMS proposes to simplify these documentation requirements by allowing, with a few exceptions, the medical records to show that the teaching physician was present at the time the service was furnished, and

such documentation may be made by a physician, resident or nurse. In addition, the extent of the teaching physicians' participation in each patients' care may be documented by a physician, resident or nurse, and no longer needs to be documented personally by the teaching physician.

While the AMA supports the proposed changes by CMS in this area, we request that CMS modify this rule to align with CMS guidance dated May 31, 2018, regarding [E/M Documentation Provided by Students](#). The May 2018 CMS guidance document (also detailed in Change Request 10412) allows the teaching physician to verify in the medical record any student documentation of components of E/M services, rather than re-documenting the work. Therefore, **we encourage CMS to modify this proposed rule to incorporate CMS' updated policy regarding E/M Documentation Provided by Students outlined in CMS' May 2018 guidance document and Change Request 10412.**

G. Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition Under the Medicare Clinical Laboratory Fee Schedule (CLFS)

The AMA has been closely following the implementation of the clinical laboratory provisions Protecting Access to Medicare Act of 2014 (PAMA). As you know, the first rates set under the new PAMA payment system went in to effect this year, resulting in 10 percent cuts to payment rates for almost all in-office rapid clinical testing services performed by physicians. The physician community continues to have serious concerns about the impact of the new payment system and resulting payment rates on patient access to these critical testing services. According to CMS' payment schedule for the current three-year data reporting period, payment rates for most rapid testing services performed in physician offices are slated to receive cuts of over 30 percent in total. Given the significance of these cuts, the AMA anticipates that physician offices will start reducing the number of testing services offered at the point-of-care, or will eliminate those services all together. We also anticipate that once physicians stop offering these services in the office, it is unlikely that they will return, even with positive changes to the reimbursement for those services.

In addition to serious concerns regarding the payment rates for these testing services, the AMA has significant concern regarding the impact of the PAMA reporting requirements on physician office-based laboratories. We expressed these concerns to the agency initially in 2016 and at many points during the initial reporting exercise in 2017. These concerns continue and extend to the proposals and discussion included in the CY 2019 physician fee schedule proposed rule that contemplate extending reporting requirements to additional physician office-based laboratories.

With regard to the initial reporting exercise under PAMA, physician offices were woefully unprepared to participate through no fault of their own. Given that CMS' implementation of the PAMA requirements required applicable laboratories to report data retrospectively, physician offices were forced to scramble to pull together information not easily accessible to them in a short amount of time. Many had difficulties identifying if they were even required to report at all, something which CMS stated the Agency would not assist with. Those that did participate in the initial reporting exercise reported significant burden in collecting and compiling information, including difficulties compiling information when it involved numerous different sources of payment (such as primary insurance, secondary insurance, co-pays, etc.), difficulty dealing with compiling information from paper claims, and a complete lack of any software available to provide assistance. Practices reported having to pull staff from regular duties to work full

time on preparing to report. Practices reported having staff spend over 40 hours working full time on reporting preparation and still not be able to fully and accurately pull together the required data.

While we anticipate that some physician-office based laboratories may be marginally more prepared to report in subsequent data reporting periods, we anticipate that physician practices are still going to be relatively overwhelmed by the process and report with varying degrees of success. Physician offices will still face significant difficulties in determining whether they are an applicable laboratory. They will also still be encountering difficulties in compiling data, as most practices do not have practice management software or systems that are capable of assisting in the compilation of all of the components necessary to determine the private payor payment rates for each test and the associated volume of those tests. This means that most practices are given no choice but to compile payment data manually and will likely continue to pull staff from other duties to prepare submissions. Applicable physician office-based laboratories would have an easier time reporting if practice management software vendors provided additional capabilities that would assist in compiling the requirement payment information. However, the AMA has reached out to several such vendors to discuss the possibilities, and most showed very little interest in expanding their offerings to physician practices in this space.

The initial PAMA reporting period proved to be unduly resource intensive for the practices that participated, with the data reported likely having significant inaccuracies due to the difficulty of the process. **According to the HHS Office of the Inspector General and CMS' own data, expanding the reporting requirements to additional physician office-based labs is unlikely to make any meaningful difference in the payment rates. Expanding reporting will, however, add a tremendous layer of unnecessary burden on those practices required to participate.** At a time when the agency's "Patients Over Paperwork" Initiative has set goals of reducing burdens on the physician-patient relationship, expanding physician reporting requirements seems misguided at best. We strongly urge CMS to explore alternative methods for validating and enhancing clinical laboratory payment data instead of overburdening physician practices with requests for data that will not meaningfully impact the bottom line.

H. GPCI Comment Solicitation

A long-standing concern of the AMA regarding the geographic adjustment of payments under the Medicare physician payment schedule has been the use of residential rents as a proxy for physician office rents. These markets may be related, but local conditions can result in residential rents that either over- or understate the rental costs that physician practices actually face relative to the national average. CMS is required to update the Medicare Geographic Practice Cost Indexes (GPCIs) at least every three years, with the next update to be implemented in CY 2020. In the proposed rule, CMS stated their intent to continue their search for a nationally representative source of commercial rent data that could be used in calculating the practice expense GPCI. The AMA supports CMS' efforts to acquire commercial rent data for use in updating the GPCIs. The data should be reasonably current and representative of actual physician rents within each Medicare physician payment schedule locality, and should have adequate sample size to allow precise measurement of rents in all localities. **We continue to urge CMS to explore both the collection of new data, along with the use of existing commercial rent data, as the basis for measuring geographic differences in physician office rents.**

I. Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Today, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers plus a percentage of the ASP. Currently the percentage add-on is 6 percent, which is then reduced to 4.3 percent under the budget sequester enacted in 2011. Discounts and rebates negotiated by very large purchasers but not typically available to physician practices are included in the calculations. Wholesale fees and state taxes that often are paid by many physicians also are not included. As a result, the ASP is often lower than the physician's price and even with the 4.3 percent add-on, Medicare reimbursement may not cover physicians' costs. Consequently, care for patients who require Part B drugs has been shifting out of physician offices and into hospital outpatient departments. Costs to Medicare and patients rise as a result because when drugs are delivered in an HOPD, there is a payment to the facility as well as a payment to the physician.

When a new drug comes to market and there is no data on discounts, rebates and actual prices, payments are based on the Wholesale Acquisition Cost (WAC) plus 6 percent (or 4.3 percent after sequester cut). Data is collected during the first full quarter the drug is available and then incorporated into an ASP two quarters later. The Medicare Payment Advisory Commission (MedPAC) argues that this means that Medicare reimbursement typically exceeds the ASP for the first nine months a drug is on the market. Based on a comparison of WAC to ASP prices for eight drugs, the Commission recommended that reimbursement for new drugs be reduced to WAC + 3 percent which becomes 1.4 percent after sequester and represents a drop of three percentage points before the sequester is applied and 4.6 percentage points after the sequester.

The AMA is opposed to this provision because as laid out above, the ASP's structure leads to prices that are inadequate for smaller purchasers such as physician offices, and any policies that use the ASP as the basis for other drug payment policy will only exacerbate the problem. Moreover, even if driving payments for new drugs down to the ASP level were an appropriate policy, we do not believe that the data MedPAC analyzed justifies a change of the magnitude recommended by the Commission and incorporated in the NPRM. Specifically, of the eight drugs in the analysis, only two (where the ASP reimbursement rate was 2.7 percent lower than the WAC rate) showed price differences that came close to 3 percent. For the other six, ASP rates were 0 to 2.1 percent lower than WAC rates.

Enactment of the proposal thus would trigger reimbursement cuts for new drugs that will preclude their use in most physician offices and hinder Medicare patients' access to new and innovative therapies that are more effective and/or less debilitating than existing drugs. The AMA strongly believes that this proposal should not be finalized.

II. OTHER PROVISIONS OF THE PROPOSED RULE

A. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The AMA appreciates CMS' decision to delay implementation of the Appropriate Use Criteria (AUC) program mandated in PAMA. We strongly agree that delay is necessary to allow ordering providers to choose a clinical decision support mechanisms (CDSM) and maximize the opportunity for public and stakeholder input. However, we are concerned that given the scale and complexity of the PAMA mandate

along with the implementation of other complex programs like the QPP, CMS' proposed start date may not provide sufficient time for proper education and preparation.

With AUC, both CMS and physician practices will have to work out significant technical and workflow challenges prior to full-scale implementation including the use of G-codes with modifiers. Additional time may also allow CMS to determine whether incentives in the QPP offer a less burdensome means of achieving the AUC objectives. **CMS should also consider exempting physicians from the AUC requirements when the physician is participating in the QPP.** This means that additional delay may be necessary. Then, having gained additional information, CMS can evaluate the program via analysis of claims data and determine whether the AUC program is ready for full implementation.

Significant Hardship Exceptions

CMS proposes to create three significant hardship exceptions from the AUC requirements that are specific to the AUC program and independent of other Medicare programs. AMA supports the three proposed significant hardship exceptions relating to insufficient internet access, EHR or CDSM vendor issues, and extreme and uncontrollable circumstances.

In order to promote administrative simplification, CMS also needs to align the hardship exceptions in the QPP with the AUC program including the exemptions for new physicians for one year and for low volume of Medicare patients. AMA does not understand why CMS is proposing different exemptions for closely related and similarly burdensome programs. Allowing for new physicians or low volume physicians to be exempted from participating in MIPS but not from the AUC program with its highly complex and potentially expensive requirements is inconsistent, confusing, and burdensome. Moreover, to reduce burden, CMS should also consider allowing for physicians to attest once as to the existence of certain hardship exemption rather than having a physician individually attesting on every claim especially in extreme and uncontrollable circumstances like a natural disaster.

Coding Methods

CMS proposes to establish the coding methods to include G-codes and modifiers to report the required AUC information on Medicare claims. While the AMA believes that any new reporting information introduces significant burden to physicians in multiple respects, the new G-code and modifier approach likely represents the best option that is available at this time. The claim fields already exist to report the data and individuals generally know how to report G-codes and modifiers. Furthermore, CMS should intend that the G-code/modifier be a long-term solution. Implementing a temporary solution and then a different permanent solution will be burdensome to providers from both a technology and education standpoint. The following depicts how the G-codes and modifiers would be reported in the claim.

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINTER	F. \$ CHARGES		G. DAYS OR UNITS	H. EPST Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
From MM	DD	YY	To MM	DD	YY			CPT/HCPCS	MODIFIER									
01	13	20	01	13	20	21		70544				A	1000	00	1		NPI	9876543210
01	13	20	01	13	20	21		GXXXX	XX			A	0	01			NPI	9876543210

The AMA realizes the law requires that each claim identify the specific G-code representing the consulted CDSM for a particular imaging service; however, given the burden, CMS may need to consider discussing potential legislative fixes with Congress or limiting the number of priority areas. We also have

concerns regarding the burdens of tracking when G-codes are available for newly approved CDSMs. CMS should tie the time when a specific G-code becomes available to the availability of newly-approved CDSMs. This approach provides more certainty than when the specific G-code “becomes available.”

For the modifiers, CMS will need to create one for each potential situation, including: 1) adheres to AUC; 2) does not adhere to AUC; 3) no applicable AUC; 4) emergency exception; 5) inpatient exception; 6) insufficient internet access; 7) EHR or CDSM vendor issues; and 8) extreme and uncontrollable circumstances.

In using the G-code and modifiers, CMS needs to address the issue of reporting multiple services in the same claim and how to address situations in which the service lines are unintentionally re-ordered during processing. Reporting additional data in the claim to link the procedure and AUC service lines should not be required, as this adds more burden on the physician to report the data. Instead, CMS should develop a process to identify these claims and a solution for how to maintain the original pairing of the procedure and AUC service lines.

For more technical discussion into the use of G-code and modifiers, the AMA refers CMS to the detailed and in-depth comments provided by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC).

More broadly, we have significant concerns about numerous workflow challenges and questions that will result from the AUC program requirements. Ordering physicians must be able to easily identify the diagnoses and specific advanced diagnostic imaging services to which the AUC requirements apply so that they can consult the CDSM at the time of ordering. Ideally, they would be prompted to consult the CDSM upon ordering a service to which the requirements apply. Information regarding the CDSM consultation will then somehow need to be communicated between ordering and furnishing providers, as the physician ordering the imaging service in most cases will be different than the physician performing the imaging. Thus, not only must the claim change but also all methods used to send an order (electronically or otherwise).

While a standard and technological solution for transferring this information from ordering to furnishing providers (Integrating the Healthcare Enterprise Radiology Technical Framework Supplement Clinical Decision Support Order Appropriateness Tracking) is [in development](#), it is in an immature, pilot stage, meaning that providers will most likely need to rely on manual workflows to exchange these data during the implementation of the AUC program. Additionally, providers will need to determine optimal procedures for these communications. For example, will ordering providers send the applicable G-codes and modifiers to the furnishing physician, or will they simply send the information in text format that the furnishing provider will need to translate into the code and modifier? These communications and reporting burdens will be further compounded when different providers are responsible for the technical and professional components of the imaging service, as the ordering physician will need to send the CDSM consultation information to two separate providers to be reported on the technical and professional claims.

Outliers and Prior Authorization

AMA has numerous concerns regarding outlier identification and prior authorization. Since the AUC program is in the early stages of development, we strongly urge CMS to take what will be learned from

voluntary and testing periods and allow for proper evaluation of that experience prior to implementing any type of outlier approach. We also strongly urge CMS to be cautious and judicious in identifying outliers to subject to prior authorization, due to the patient care delays and potential for negative impact on clinical outcomes associated with prior authorization. In the [2017 AMA Prior Authorization Physician Survey](#), 92 percent of respondent physicians indicated that prior authorization can delay access to necessary care, and 92 percent also reported that prior authorization can have a negative impact on patient clinical outcomes. These concerning data reinforce the need for restraint in implementing new prior authorization requirements via the AUC program to avoid harm to Medicare patients.

Outliers can occur for a variety of reasons. While some may reflect a pattern of inappropriate ordering, outliers may also arise because a physician is aware of new information or changes in clinical practice, the AUC is outdated, or a patient's specific clinical condition warrants a particular service. CMS should not mislabel physicians as outliers for being innovators and delivering cutting edge care. Therefore, CMS needs to use pattern analysis to determine whether the issue is with the criteria or the physician. It is also not clear that physicians will have enough cases in all of the priority areas to accurately judge their performance when outlier identification starts.

CMS should focus its outlier identification on areas where there is an underutilization of services that are always appropriate and overutilization of services that are almost always inappropriate. It will also be important to select only those conditions where there is significant variation in utilization among physicians and where there are generally agreed upon treatment guidelines. Physicians should only be compared against the criteria in the particular CDSM that they chose and not to all physicians who also ordered the service but used a different CDSM. AMA recommends that CMS focus outlier identification on a few of the clinical priority areas. Finally, as with any program that profiles clinician performance, CMS should furnish any physician deemed as an outlier, well in advance of the implementation of any prior authorization requirements, with a patient-level data report detailing the information used to make this determination and allow the physician the opportunity to request reconsideration based on unique clinical circumstances and/or changes in evidence-based guidelines not yet reflected in the CDSM.

With the CMS proposed delay of the AUC program, AMA believes there should be at least a similar delay as to when prior authorization begins. For example, the statute has the AUC program starting in 2017 with prior authorization starting in 2020. Thus, if AUC is fully operational in 2020, prior authorization should not start until at least 2023. Furthermore, any calculation used in determining prior authorization must be based on at least two full years of data to match the statutory requirement that two years of data must be used to identify any outliers. Finally, data collected during the educational and operational testing period should not be used to determine a physician's outlier status.

Quality Payment Program

CMS should exempt physicians from AUC requirements when the physician is participating in the QPP. Physicians participating in Alternative Payment Models (APM) and MIPS APMs should be exempted because those physicians are already being held accountable for costs and outcomes, and are assuming risk. It is inherently in the practice's best interest to avoid inappropriate over- or under-utilization if they are participating in an APM. Furthermore, physicians participating in MIPS should also be exempt from AUC requirements because physicians are held accountable for cost and quality measures in the MIPS program. Additionally, there are at least 12 MIPS clinical quality measures that address imaging appropriate use and there are likely more when considering Qualified Clinical Data Registry measures are

not part of traditional rulemaking. We realize that this recommendation may require amending existing statute and thus recommend that CMS seek legislative authority to exempt physicians participating in the QPP from the AUC requirements.

AMA appreciates CMS' belief that the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for advance notice of all involved parties. As a part of this stepwise approach, CMS needs to adequately address technical and workflow challenges with its implementation. Adding an additional year to the testing period may provide CMS adequate data to demonstrate whether the AUC program should be fully implemented or require further delay.

B. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

We support CMS' proposal to extend the Medicare PI program performance-based scoring methodology to not only Medicare-only eligible hospitals and critical access hospitals (CAHs), but also dual-eligible hospitals. We further support CMS' proposal to give states the option to adopt the performance-based scoring methodology, along with the corresponding measure proposals, for their Medicaid PI programs through their state Medicaid health IT plans. Physicians should not have to keep track of which measures they must report if they practice across care settings and payers.

C. Medicare Shared Savings Program Quality Measures

CMS proposes to reduce the total number of measures in the Medicare Shared Savings Program (MSSP) quality measure set by lowering the number of measures accountable care organizations (ACO) and their participating providers are required to report through the CMS Web Interface and to enhance the Patient/Caregiver Experience domain through proposed changes to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure set. **In general, the AMA supports efforts to reduce administrative burden and lowering the number of measures an ACO must report and providers are assessed on.**

Several of the measures CMS proposes to remove from the MSSP are maintained in the Medicare Advantage Star Ratings and Health Exchange Quality Ratings System programs, and thus private payers will continue to require and retain the measures in future physician private payer contracts. As a result, ACO providers will continue to be required to report on measures outside of the MSSP and it is our understanding that CMS did not consider the use of the measures for removal and their impact in other Medicare programs.

The AMA offers the following measure specific comments:

- *ACO-7: CAHPS: Health Status/Functional Status*

Tracking a patient's health and functional status and progress over time is important, but we do not believe ACO-7 is suited for pay-for-performance because it is not actually measuring, patient's functional status. The questions associated with the measure are an assessment of the underlying health of the population, i.e. how people feel about their health. The CAHPS survey methodology also does not account for differences in patient mix or incorporate baseline assessment or understandings on the

population's baseline functional and health status. Without incorporation of the information, performance scores will not accurately reflect the quality of care provided by the ACO nor could valid comparisons across participants be made. PROMIS or some other survey would most likely be a better tool with which health/functional status is assessed, but we caution CMS on using generic patient reported outcomes (PRO) tools in the absence of sufficient evidence to demonstrate that general assessments of a patient's health status can lead to improvements in clinical outcomes and reductions in cost (see v. *Quality Performance Category, Patient Reported Outcomes Measures* section for more details).

To improve collection and reporting on functional status, CMS also seeks comment on data collection procedures from assigned ACO beneficiaries over time. To appropriately implement tracking patients health and functional status over time, CMS would need to begin to risk adjust and take into consideration the differences in patient mix and incorporate baseline assessments as highlighted with ACO-7, as well as ensure adequate sample size and consideration of patient churn.

- *ACO-13, Falls: Screening for Future Falls Risk*
- *ACO-47, Falls: Screening, Risk Assessment and Plan of Care to Prevent Future Falls*

We support removal of ACO-13, but are concerned with CMS substituting the measure with ACO-47. We are concerned with the potential large administrative burden associated with collecting risk assessments and plans of care and the requirements that will be attached to ACO-47 in order to implement.

- *ACO-36, All-Cause Unplanned Admissions for Patients with Diabetes*
- *ACO-37 All-Cause Unplanned Admission for Patients with Heart Failure*

The AMA supports removal of the two admission measures and recommends CMS also remove ACO-38 measures (All-Cause Unplanned Admissions for Patients with Diabetes Mellitus, Heart Failure, and Multiple Chronic Conditions) because the admission measures are all based on hospitalizations that would be included in the overall spending assigned to the ACO. An ACO will be penalized through a reduction in shared savings if it has a high rate of any of these admissions, so it is unnecessary to include these as quality measures. The measures might be appropriate if there were reason to believe that ACOs would avoid addressing these clinical areas. But these all represent large patient populations for ACOs, and there are known ways to reduce high rates of admissions and readmissions for these patient populations. Thus, ACOs are unlikely to ignore these areas if there are opportunities to reduce them. Including them as quality measures could also force the ACO to focus on areas that do not represent the best opportunity to improve patient care and reduce spending.

The risk adjustment model for these measures also does not adequately address the ongoing concerns around socioeconomic factors (SES). As noted by the NQF All-Cause Admission and Readmission Committee and the developer (Yale/CMS), the analyses demonstrated that ACOs with higher numbers of low-SES patients performed worse than the national rate. These shifts in performance scores based on SES adjustment indicate that there may be other variables influencing admission rates that are outside of the ACO's control.

- *ACO-35, SNF-30 day All Cause Readmission Measure (SNFRM)*

We support removing ACO-35 which measures hospitalizations that would be included in the overall spending assigned to the ACO. An ACO will be penalized through a reduction in shared savings if it has a high rate of readmissions, so it is duplicative and unnecessary to include this as a quality measure. Moreover, ACOs that focus the use of skilled nursing facilities (SNFs) more on higher-acuity patients could see an increase in SNF readmission rates, even though the total number of readmissions from SNFs actually decreased. This would inappropriately penalize the ACO for doing something CMS is encouraging.

We believe it is premature for CMS to consider adding the Skilled Nursing Facility Quality Reporting Program (SNFQRP) measure, “Potentially Preventable 30-Day Post-Discharge Readmission for Skilled Nursing Facilities” without releasing more specific information on the measure and updating the measure specifications to include ICD-10 coding. The available specifications we could find are coded in ICD-9. We believe there is some overlap with ACO-8, Risk-Standardized All Condition Readmission, but hard to outline how much overlap without seeing the measure specifications that will be utilized for the MSSP program.

We also believe the risk-adjustment model and testing data is insufficient. The measure has only been tested to show how each of the conditions and procedures perform in the Skilled Nursing Facility (SNF) setting. The risk-adjustment model and testing data associated with the measure does not include functional status or any information on the risk model performance or data on the reliability of the measure score.

- *ACO-44, Use of Imaging for Low Back Pain*

We support removal of the measure. The measure was removed from the MIPS program several years ago. It is also an overuse measure and ACOs are already accountable for costs. They have an inherent incentive to appropriately manage patients with low back pain and determine when imaging is necessary, but are penalized by the measure when ordering necessary tests.

- *ACO-15, Pneumonia Vaccination Status for Older Adults*

We support removal of the measure but believe it is an important preventative clinical intervention and encourage CMS to develop a new measure with improved data collection methodologies. The current measure is a challenge to track because patients can receive the vaccine in multiple settings so it is hard to confirm whether the patient received the vaccine within the recommended measurement timeframe.

D. CY 2019 Updates to the Quality Payment Program

i. Low-Volume Threshold

The AMA supports CMS’ proposal to add a third criterion for physicians to qualify for the low-volume threshold in 2019. Currently, physicians qualify for the low-volume threshold if they have less than or equal to \$90,000 in Part B allowed charges for covered professional services or provide care to 200 or fewer Medicare Part B beneficiaries. Under CMS’ proposal, a third criterion would be added to the low

volume threshold for physicians who provide 200 or fewer covered professional services under the Physician Fee Schedule. The AMA also supports CMS' proposed new opt-in policy that will allow practices to opt-in to participate in the MIPS program or create virtual groups if they meet or exceed one or two but not all of the low-volume threshold elements.

While the AMA agrees with CMS' analysis that the third low-volume threshold criterion is unlikely to exclude any additional physicians from the program (given that most physicians who provide fewer than 200 Medicare Part B services also treat fewer than 200 beneficiaries), we support this third criterion as it will allow a greater number of physicians to opt-into the MIPS program. There will be physicians who treat fewer than 200 beneficiaries, yet provide more than 200 covered professional services under the PFS, and will therefore be able to opt-into the program. We encourage the opt-in policy which will allow those physicians that are ready to report or wish to gain experience with the program to learn the MIPS requirements and have an opportunity to earn an incentive payment.

The AMA continues to encourage CMS to maintain the existing low-volume threshold. The AMA's goal continues to be to help CMS develop a MIPS program that will allow physicians to succeed, not cause them to fail. We believe the low-volume threshold has been one tool CMS has used to ensure practices that treat very few Medicare patients, including many solo practitioners and small practices with limited resources, do not face a significant disadvantage in the program. The low-volume threshold was required by Congress in the MACRA statute, and Congress clearly envisioned excluding physicians who treated very few Medicare patients.

ii. Virtual Groups

The AMA has consistently supported the ability for small groups and solo practitioners to form virtual groups, and has encouraged CMS to maintain maximum flexibility in the formation of virtual groups. Despite CMS' previous proposals that have allowed for flexibility in the formation of virtual groups, the AMA remains concerned that a greater number of physicians are not choosing this reporting option. Given the small number of virtual groups that we believe chose to participate in the MIPS program in 2018, the AMA believes CMS must continue to make changes to make this a viable option for physicians in small practices.

Increased Transparency

In the AMA's conversations with CMS regarding virtual groups, CMS has noted that it is not releasing the number of virtual groups that were in formation during performance year 2018. CMS has also declined the AMA's requests to contact existing virtual groups to see if they would be willing to provide 'lessons learned' advice to other physicians interested in joining virtual groups. CMS' refusal to provide transparency around virtual group formation to date is harming physicians interested in forming virtual groups in the future. We strongly urge CMS to share information on existing virtual groups and their success or failure in the MIPS program, including difficulties these practices may have faced that could be unique to virtual group reporting.

Leveraging Clinically Integrated Networks (CINs) and Independent Practice Associations (IPAs)

The AMA has also heard from some physicians that the easiest way to form a virtual group would be to leverage existing CINs and IPAs of small group practices and solo practitioners. Therefore, CMS should

amend 42 CFR §414.1315(c)(3) to permit CINs and IPAs to facilitate these arrangements. CMS already permits quality and cost management by a central entity in ACOs and group practices, so using CINs and IPAs to ease the transition for small practices and solo practitioners into virtual groups should also be permitted.

Protection from Stark and Anti-Kickback Violations

Many solo practitioners and groups of 10 or fewer MIPS eligible clinicians have limited resources and technical capabilities. Virtual groups will involve preparation of health IT systems and training staff to be ready for implementation, sharing and aggregating data, and coordinating workflows. While these are necessary steps to ensure the success of virtual groups, these steps could raise concerns involving fraud and abuse. For example, the Stark law (physician self-referral statute) does not allow a physician to refer patients to an entity that the physician has a financial relationship with and the anti-kickback statute prohibits the exchange of anything of value in an effort to induce the referral of Medicare patients. By pooling resources together to participate in MIPS, individual physicians may receive an ownership interest in the virtual group or other compensation arrangement from the virtual group (e.g., disbursement of any incentive payments). Moreover, physicians may prefer to refer patients within their own virtual group to control unnecessary costs and provide higher quality care because both physicians' performance is tied to the same virtual group's MIPS score. Any of these referrals within the virtual group between physicians could violate Stark and potentially implicate anti-kickback. This outcome is different from a normal "group practice" where these referrals are protected from Stark and Anti-Kickback violations through exceptions and safe harbors.

Virtual groups, by definition, are not "group practices" as that term is specifically defined under the Stark regulations at 42 CFR §411.352 because virtual groups do not constitute a "single legal entity." Virtual groups consist of at least two legal entities. Thus, because virtual groups do not meet this definition, the Stark in-office ancillary services exception and the physician services exception does not apply. Furthermore, the anti-kickback safe harbor for investments in group practices also does not apply. Accordingly, physicians in a virtual group with a financial relationship with such virtual group may not be eligible to make referrals for designated health services payable by Medicare to the virtual group. A potential solution is to amend 42 CFR §411.352 (Group Practice) by adding an additional subsection (j) stating something like "notwithstanding the above, a virtual group (as defined by 42 CFR §414.1305) is considered a group practice for the purposes of this subpart."

While this solution will allow virtual groups to operate in the same manner as group practices, the AMA is also encouraging changes under the Stark law and Anti-kickback statute to allow both virtual groups and group practices to be successful as the health care system transitions to more value-based care models.

iii. Considerations for Social Risk

The AMA strongly believes that Medicare's current risk adjustment methodologies still do not adequately address treatment and outcome differences related to patient characteristics, including complexity of their illness and social risk factors that are outside of the control of physicians. 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.

CMS must begin to identify the degree of social risk factors and availability of services for specific patient populations. Strategies such as applying the American Community Survey or a similar data set to determine whether patients for a specific physician or practices live in an area where there are less resources available should be explored. We readily acknowledge that there are challenges to this type of approach since it requires linkages of patient panels to communities, which may not be the same area where the physician provides care. Nevertheless, these strategies would provide a more comprehensive assessment of the current state and would allow CMS to adjust the performance and/or final scores based on both issues—clinical complexity and social risk. **While adjustment based on the clinical complexity of the patients served through the complex patient bonus is a good first step toward addressing these disparities, we strongly encourage CMS to continue to explore and incorporate additional risk factors and strategies.**

iv. Complex Patient Bonus for the 2021 MIPS Payment Year

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. We 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. In addition, while we appreciate the continued work to ensure that the data used for the determination period is based on the actual reporting period, we ask that CMS attempt to use the full 12-month reporting period. This approach would provide the most accurate representation of the patients for whom the physician or practice provided care.

v. Quality Performance Category

The AMA supports many of CMS' proposals that will create stability and assist small practices within the quality performance category for physicians. First, we support CMS' proposal not to increase the number of quality measures a physician is required to report in 2019, but continue to recommend CMS reduce the number to ease administrative burden and better align with the Meaningful Measures Initiative. The AMA also supports CMS' proposal to not increase the data completeness threshold higher than 60 percent in 2019. In addition, we strongly support CMS maintaining the claims based reporting option and expanding the options to group practices of 15 fewer who report as a group practice (GPRO), but do not support limiting the claims option to only individual practices of 15 or fewer.

The AMA also appreciates CMS' proposal to maintain a minimum point floor for physicians reporting on a quality measure that meets the data completeness threshold, regardless of performance on the measure or measure type and removal of cross-cutting measures from specialty sets, and strongly encourages CMS to maintain the policy for future program years. This rewards participation in the MIPS program, maintains stability and encourages physicians to continue to participate in MIPS in the future. Furthermore, we support CMS removing high priority bonus points from web-interface participation because the MIPS program is budget neutral and by removing the bonus points it better balances the ability of non-web-interface participants to score well under MIPS, given there are a limited number of high priority measures and the web interface is not subject to topped-out measure point caps. Finally, the AMA supports maintaining reporting on CAHPS for MIPS as a voluntary measure. While patient experience data collected in the CAHPS survey is important, it does not always correlate with better

outcomes. Allowing CAHPS for MIPS to be voluntary acknowledges the diversity of practices participating in the MIPS program, as CAHPS for MIPS may only be applicable to internal medicine in a traditional office setting.

We do not support CMS reducing the quality category to 45 percent of a physician or group's final score. CMS was granted increased flexibility in the BBA with setting the performance threshold and category weights and the AMA urges CMS to follow congressional intent. Altering the category weights prematurely leads to less stability with the program and adds complexity.

There are also a number of modifications needed within the quality performance category. These changes include the elimination of the outcome/high priority measure requirement and moving to bonus points, the removal of the requirement to report on all-payer data, reducing the quality reporting period timeline, not limiting the claims reporting to small group practices, and revising the quality measure benchmark methodology. We also urge CMS to maintain the small practice bonus at the overall category score and not restrict it to only the quality category. In addition, align the quality category and Physician Compare policies, including the benchmark methodologies. The suggested changes the AMA provides below will simplify the program and reduce administrative burden for physicians. CMS' own analysis estimates the impact of participating in *only* the MIPS quality category costs between \$712.08 per physician to a maximum of \$1,340.80 per physician for a total maximum annual cost of \$368,320,442. The estimates do not include the cost or time to analyze feedback data and implement care improvements, which means physicians are spending way too much time and money reporting and not enough time on patient care. We urge CMS to consider our modifications as a way to help reduce administrative burden for physicians and move to a more cohesive, holistic and simplified program.

Meaningful Measures Initiative

We appreciate CMS' efforts to streamline regulations with the goal to reduce unnecessary cost and burden on physicians, as well as the initial efforts to identify the highest priority areas for quality measurement and improvement to improve patient outcomes through the Meaningful Measures Initiative. We also recognize the need to move to more measures focused on outcomes; however, absent true reforms to the quality category, benchmark methodology and overall MIPS program we find the Meaningful Measure Initiative short sighted and not a true reduction of administrative burden. At a minimum, **if CMS would like to see immediate reduction and return on "patients over paperwork" we strongly urge CMS to reduce the number of quality measures a physician must report.**

MACRA requires all physicians to participate, regardless of specialty so there must be a sufficient number of meaningful measures that all physicians can report on to satisfy the quality category and not force physicians to report for the sake of reporting because of the high bar CMS has set for achieving the performance threshold and fulfilling the quality category requirements. Under the current MIPS quality structure, CMS utilizes specialty measure sets and requires reporting on a minimum set number of measures (six), which still forces physicians to pick random individual measures and lumps a specialty together, regardless of sub-specialization. When you tie this to cost/an episode it does not ensure that the specialty set matches up with the episode and can appropriately evaluate potential for stinting on care to appear low cost.

To move to a more unified MIPS program, specifically, a more meaningful quality category we recommend the following reforms:

- **Propose quality reporting measurement through clinical continuums of care that tracks an episode and potentially spans across MIPS categories.** This allows for shaping measurement around improving or managing a disease or condition—similar to the concept of measure groups that CMS eliminated in 2017. For example, there were measures groups that revolved around cataract or colonoscopy procedures. Under the measure group option, the groups became problematic once CMS started incorporating unrelated measures into the individual measure groups outside of the original developer construction. The concept also allows measure stewards to focus on developing composites, which CMS has repeatedly highlighted through the years that it would like to move to when measuring quality.
- **Reduce the number of measures that must be reported to allow physicians to truly select and report the most meaningful measures to their patients and practice.**
- **Encourage CMS to identify an alternative to the current minimum reporting threshold/data completeness requirements.** For example, move to a set minimum number of patients rather than a percentage of patients that meet the denominator could reduce administrative burden and simplify reporting. Currently, participants must estimate whether they have submitted at least 60 percent of their entire patient population, which is difficult to predict at the start of the reporting period. A practice does not necessarily know the exact number of patients and the point in time during a calendar year when they will treat patients.
- **Any refinements to the quality category as with others must continue to allow physicians flexibility to report across multiple mechanisms.** There must also be an openness to accept and implement emerging measures that would demonstrate quality based on new evidence and data, regardless if submitted through claims, QCDR, qualified registry or EHR.

We believe allowing physicians to focus on activities that fit within their workflow and address their patient population needs—and providing them with credit for those activities that span across MIPS categories—will encourage increased participation and relevancy of MIPS and drive participation and continued improvement across categories. It would also facilitate the development of new measures and activities that addresses key gap areas such as patient-reported outcomes (PROs), leverage health information technology in a more meaningful way, and target key cost drivers such as through the use of clinical decision support and appropriate use criteria. Many QCDRs also operate through clinical continuums of care and, with the right signal, specialty QCDRs could further move in this direction. Our proposal also makes the transition to APMs easier since many of the APM proposals are focused on episodes. It also assists with re-designing PI because continuums of care can be used as use cases. Even with this more comprehensive approach, we recognize initial coordinated measure sets will not be relevant for every physician, but at least it moves MIPS in a direction that is more thoughtful and patient centered. A patient can more easily use the continuums of care to evaluate a physician in relation to how well they treat a particular disease or condition.

Delay Removal of Measures

As part of the Meaningful Measures Initiative, CMS proposes to remove 34 quality measures while maintaining the same quality reporting requirements and without consideration to 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 but would support a phased approach as CMS finalized in 2018 (see topped out discussion below). Many physicians, particularly sub-specialists, will be left with an insufficient suite of measures to report and forced to report on measures simply to check a box. For example, CMS has proposed to immediately remove three ophthalmology measures from the MIPS measure set:

- Measure 12, Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation;
- Measure 18, Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy; and
- Measure 140, Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement.

According to CMS' 2018 benchmarking data, none of these measures are topped out for all reporting options, and measure 18, which is only available for EHR reporting, is not topped out at all. Removing these measures leaves claims reporters with fewer than six ophthalmology specific measures available. While we recognize ophthalmology has a large suite of measures compared to other specialties, including the option to report through a QCDR, there are a limited number of measures for retina specialists. If CMS finalizes the proposal retina specialists will be challenged to find six relevant measures to their patient population and scope of practice, along with many other specialties such as cataract specialists, dermatology, otolaryngology, pathology, and sleep medicine.

In addition, process measures continue to serve an important purpose, especially when coupled with cost because it is often the breakdown in a process that contributes to poor outcomes and increased resource use. As we have previously highlighted, under the current MIPS structure it may appear that quality process measures do not hold much value because the quality category forces physicians to pick random measures that may or may not align with a clinical end goal. However, if the MIPS program was structured to allow physicians to focus on a targeted clinical or disease area, such as preventing diabetes and the measures correlated with the clinical episode, process measures would be seen as more valuable.

Furthermore, a large percentage of the measures targeted for removal and deemed "low value" in the proposed rule continue to be maintained by CMS in the Medicare Advantage Star Ratings and Health Exchange Quality Ratings System programs, and thus private payers will continue to require and retain the measures in future physician private payer contracts. As a result, physicians will continue to be required to report on measures outside of the MIPS program and it is our understanding that CMS did not consider the use of the measures and their impact in other Medicare programs.

Topped Out Measures and Remove Point Cap

The AMA supports a phased-out approach for removing "topped out" measures from MIPS. However, **the AMA does not support the following in CMS' proposal: the immediate removal of non-high priority measures when they reach the 98th to 100th percentile range in a year; the current timeline for classifying measures as topped out; and the elimination of QCDR measures from a topped out process or to cap achievement points for such measures at seven points.** 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. CMS' current strategy bases

performance scores and benchmarks on data that may or may not have sufficient sample sizes and utilizes PQRS reporting rates as a trigger. PQRS had low participation rates, and it is questionable whether the numbers represent a true indication of quality. For example, the 2015 PQRS Experience Report included measures that are identified as topped out in the QPP benchmarks; yet, less than five percent of eligible physicians reported on some of those measures.

We believe that, 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. These measures were deemed important to include in PQRS and now MIPS and by setting benchmarks that do not allow physicians to achieve the highest number of points, new participants will be less likely to select and report on these important measures which can drive improvements in patient outcomes. **MIPS benchmarks should be developed and based on MIPS reporting, not a program that sunset in 2016.**

We believe that CMS' proposal to begin the phased removal of topped out measures with only one- or two-years of MIPS data is also problematic due to the 2017 and 2018 transition years. Because of the pick-your-pace approach used in 2017, year one data is not a representative sample of how physicians are actually performing on quality measures and neither is year two due to the continued phased transition on implementing the MIPS program, including changes to the low-volume threshold definition. CMS has already removed or altered a fair amount of measures under MIPS, particularly measures under the claims, EHR and QCDR reporting methods, and the AMA remains concerned that removing and capping measures too quickly, absent a reduction in the quality requirements, may lead to a large gap in the measure portfolio.

If CMS is truly interested in measuring improvement, we believe that it is critical to consider consistency in the MIPS program. Consistency with measurement is the primary reason the web-interface has had such high performance and participation rates. The majority of the measures have remained the same since the inception of the option over five years ago.

We also encourage CMS to consider whether a measure is in development that could replace the topped out measure given that it typically takes about three years to develop a measure and propose a measure for adoption within the MIPS program.

The AMA supports the removal of measures when clinical evidence has changed or there is a patient safety issue, but we are concerned with the potential future gap that will be created by solely relying on faulty benchmark data, without consideration of clinical factors, scientific evidence, and the importance of a measure.

While we understand CMS may consider retaining a measure once it reaches extremely topped out status if there is compelling reason, such as removal impacting the number of measures available to a specialist or if the measures addressed an area of importance to the agency, we urge CMS to consider the unintended consequences of this proposal. We 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 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.
- **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.
- **Consultation with Measure Stewards and Specialties:** CMS should consult with measure stewards and specialties to determine whether there is a measure 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.
- **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 (i.e., the ability to accurately capture quality, potential bias in inclusion/exclusion, etc.).
- **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.
- **Small Sample Size:** We urge CMS to consider the impact on certain specialties before the agency begins removing measures that have low reporting rates. Some measures may only be reported by a small number of clinicians, such as pediatric specialists, and yet that small number represents a significant percentage of those caring for the patients to which the measure applies.
- **Public Health:** We recommend keeping measures that track performance on major public health issues such as tobacco use and counseling, screening for alcohol use, prediabetes, hypertension, opioid use, immunizations, and hepatitis C.
- **Measures Used in Other Programs:** There are many health plan-level measures that are part of the Medicare Advantage Star Ratings or Health Exchange Quality Rating systems that are reliant on clinical action. To ensure compliance, the private plans incorporate them into physician contracts. For purposes of alignment, CMS should consider alignment across other programs when deciding whether to remove or retain certain measures. Therefore, the removal of the measure(s) will not reduce burden because physicians will still be required to report and track them for Medicare Advantage and private payer plans.

- 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.

Point Cap: In addition, CMS should not penalize physicians for reporting on topped out measures by capping the number of achievement points at seven points. **Physicians should be eligible to earn maximum achievement points for reporting such measures until a measure is removed. Capping achievement points adds to the complexity of scoring and disregards the fact that there are multiple factors that go into the decisions for reporting on specific measures, such as a limited number of available measures by specialty or reporting mechanism, especially if the topped out measure is an outcome or high-priority measure.** Physicians are also hesitant to report on new measures as a substitute due to the lack of benchmark data and the unknown number of points they may earn for reporting on a measure. The cap also ignores that CMS is making classifications on measures based on extremely faulty data with low reporting rates. For instance, five of the measures from the neurosurgery specialty set are at risk of being subject to the seven point cap in 2019 and/or nearing highly topped out status. The remainder of the measures in the set have no benchmark.

2018 Neurosurgery Specialty Set				
#	Measure Title	Claims	Registry	EHR
21	Perioperative Care: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin	X	X	
23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis	X	X	
130	Documentation of Current Medications in the Medical Record	X	X	X
187	Stroke and Stroke Rehabilitation: Thrombolytic Therapy		X	
226	Tobacco Use: Screening and Cessation Intervention	X	X	X
345	Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive		X	
346	Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive		X	
409	Clinical Outcome Post Endovascular Stroke Treatment		X	
413	Door to Puncture Time for Endovascular Stroke Treatment		X	
459	Average Change in Back Pain following Lumbar Discectomy / Laminotomy		X	
460	Average Change in Back Pain following Lumbar Fusion		X	
461	Average Change in Leg Pain following Lumbar Discectomy and/or Laminotomy		X	

*BOLD: Outcome/high priority *Red: Topped out, at risk for 7-point cap in 2019 *Green: No benchmark, 3 point cap

New MIPS Quality Measures for 2019				
#	Measure Title	Claims	Registry	EHR
TBD	Average Change in Functional Status Following Lumbar Spine Fusion Surgery (ODI)		X	
TBD	Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery (ODI)		X	
TBD	Average Change in Leg Pain Following Lumbar Spine Fusion Surgery (VAS)		X	

*BOLD: Outcome/high priority *Red: Topped out, at risk for 7-point cap in 2019 *Green: No benchmark, 3 point cap

CMS is also putting in place more favorable scoring rules for web-interface participants because web-interface measures are not subject to a point cap. If CMS determines that it does not want to alter the point cap then we urge CMS to require web-interface participants to also be subject to the topped out cap.

Additionally, we urge CMS to institute a phased removal process on QCDR measures similar to the topped out process. Without such a process, it is extremely hard for specialty QCDR stewards to plan and fails to consider the length of time it takes to develop a measure. Throughout the proposed rule, CMS states that the agency wants to encourage the use of reporting through electronic means and use of QCDRs; however, physicians are disincentivized to report through a QCDR when there is no stability with the reporting mechanism. Furthermore, it is extremely difficult for physicians to create historic benchmarks if CMS changes or removes measures on an annual basis. It is the AMA's belief that the only way to truly measure improvement and track data over time is to have a process in place that allows for longitudinal data collection and tracking.

Future Tiered Scoring System - Categorizing Measures by Value

We do not support CMS' overall proposal to categorize measures by value (gold, silver, or bronze). First, we find that the proposal will increase MIPS complexity because physicians will be forced to find measures within each tier and there is no guarantee that all specialties or sub-specialties will be able to find a sufficient number of relevant and meaningful measures by gold, silver, or bronze. There is also no evidence that by reporting on tiered measures that it will improve health outcomes. The proposal still forces physicians to pick random individual measures and lumps a specialty together, regardless of sub-specialization. At a minimum there are more simplified ways CMS can encourage physicians to report on more "impactful" measures, such as:

- Provide maximum number of points for reporting on new measures or measures where there is no benchmark.
- Revise the MIPS benchmark methodology to allow for unique measure characteristics (ratios, shared decision making, etc.), fluctuation in performance and clinical evidence that are not based on arbitrary cut-offs as we discuss in more details in v. Quality, Quality Reporting, Requirements and Submission Criteria—*Benchmark Methodology* section.
- Continue to provide bonus points for reporting on high priority measures as a way to incentive and recognize the additional work that goes into reporting on high-priority measures.
- Reduce the number of quality measures a physician must report and provide the option to satisfy quality requirements by reporting on clinical continuums of care that tracks an episode and potentially spans across MIPS categories.
- Require EHR vendors, if requested by the physician at no cost to incorporate all available electronic clinical quality measures (eCQMs) in the MIPS measure set since CEHRT only requires a minimum number.

We also find the proposal flawed as CMS proposes to remove 34 measures from MIPS and phase-out 94 percent of measures due to topped out status, which makes implementing the proposal an extreme hardship on specialists. Furthermore, the proposal disenfranchises small practices because the majority of small practices report through claims and many high priority measures cannot be captured through the claims reporting mechanism. If finalized, the tiering proposal would force small practices to adopt electronic or registry reporting, which is often cost prohibitive.

However, we are intrigued by one aspect of the tiering and alternative proposal, specifically removing the requirements to have to report on a minimum number of measures and allowing physicians to achieve

points based on reporting. But, we would not support tiering the available amount of reporting points based on the measure tier. Instead, we would support the following:

- Automatically provide a set number of points for reporting on a measure or measure set, such as five points and additional points if the measure spans across MIPS categories;
- Plus, additional points based on performance against the quality measure benchmark.

We also support moving to sets of measures, as long as it is an option because we envision initially not all clinical areas will have a relevant set. However, overall we find the two proposals problematic because they involve tiering, which does not reduce complexity or ensure an equitable program.

Patient Reported Outcomes Measures

As part of the Meaningful Measures Initiative and ensuring the MIPS program has the right measures, CMS seeks comment on what patient reported outcomes (PRO) measures produce better outcomes and requests accompanying evidence that the measure do, in fact, improve outcomes. The AMA supports advancements in measurement that identifies and tracks improvements in outcomes, including those that are reported by patients. To date, research has demonstrated that assessment and treatment modification using PROs surveys can impact key outcomes such as quality of life or medication adherence but the majority of available evidence is targeted to specific clinical conditions. For example, overall survival improves in patients with cancer if PROs are assessed and addressed and implementation of a spine health survey at the Dartmouth-Hitchcock Spine Center resulted in improved health outcomes, patient satisfaction and reduced costs.²⁶

However, we caution CMS on using generic PRO tools in the absence of sufficient evidence to demonstrate that general assessments of a patient's health status can lead to improvements in clinical outcomes and reductions in cost. A monograph produced by Cella and colleagues recommends that approaches should use both generic and condition-specific tools that are tailored to the population of interest and determined to be meaningful both to physicians and patients.²⁷ We are not aware of any recent research that would warrant reconsidering this approach and believe that while surveys such as PROMIS® may have domains that apply to all patients, patients may prioritize what is most relevant to them based on their disease progression, symptomatology, and current experiences, which increases the heterogeneity in the population of interest. Therefore, we do not believe that using PROMIS or other tools as a one-size-fits-all solution will be responsive to patients needs and accurately represent the quality of care provided by all physicians.

Measures should be evaluated individually on whether the measurement of PROs drives improvement in clinical or patient-prioritized outcomes. There also must be evidence that these assessments can positively improve outcomes and we believe that the link between PRO measurement and improved outcomes must serve as the primary principle on developing and selecting these measures.

²⁶Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, Schrag D. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA*. 2017;318:197-198.

²⁷Cella D., Hahn EA, Jensen SE, Zeeshan B, Nowinski CJ, Rothrock N, Lohr K. Patient-reported outcomes in performance measurement. 2015. Available at: https://www.rti.org/sites/default/files/resources/patient-reported_outcomes_in_performance_measurement.pdf. Accessed on August 15, 2018.

High Priority Definition

We support CMS' proposal to amend the definition of a high priority measure to include quality measures related to opioids and classify intermediate-outcome and patient-reported outcome measures as outcome measures.

In terms of defining opioid use measures under the high priority definition, CMS proposes to solely focus on overuse and seeks comment on which aspects of opioids CMS should measure. Quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well-controlled and function improved without the need of high doses of opioids over a long period of time, that is an indication of good patient care; but a reduction in opioid dose alone is not an appropriate goal. Therefore, the AMA does not agree with the fundamental premise of a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics because on its own it is not a good indication of quality patient care. In fact, since the Centers for Disease Control & Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time but forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, and even suicide.

Identifying those patients for whom daily morphine milligram equivalents (MME) prescribed are considered high may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but not a mark of higher quality care. The CDC recommendations²⁸ allow for physicians to document a clinical rationale or justification when suggested dose levels are exceeded; yet, the existing measures that focus on MME do not capture if a justification exists nor do they provide a well-defined and targeted denominator.

If CMS implements a measure that focuses on MME it must adequately define the patients for whom higher doses of opioids may be appropriate. Otherwise, the measure may provide invalid representations of physician performance and CMS would be sending a signal to physicians that the government does not think physicians should prescribe these medications, and substituting its judgement about the risk benefit tradeoff for those of physicians. Therefore, CMS should consider and explore alternative measures or ones that provide complementary information on the quality of care such as the proportion of patients with acute or chronic pain whose pain was well controlled and/or function improved without needing high doses of opioids for lengthy time periods.

Quality Reporting, Requirements and Submission Criteria

- **Allow All Practices, Regardless of Size to Report through the Claims Collection Type**

CMS proposes to amend the definition of who is eligible to report through the claims collection type to only ECs in small practices beginning with the 2021 payment year. **While we support expanding the option to physicians who report under the group practice reporting option (GPRO) of 15 or fewer ECs, we do not support limiting it to individual ECs that are in practices of 15 or fewer.** Many multi-specialty practices participate in MIPS as individual ECs

²⁸Centers for Disease Control & Prevention. Guideline for Prescribing Opioids for Chronic Pain. 2016. Available at: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

and report through claims because it is the most flexible and least cost prohibitive option. The restriction would not be as much of a hardship if CMS allowed GPROs to report through sub-groups and provide flexibility with the measures that groups report and submit data on. However, if you report as a GPRO all physicians in the group, regardless of specialty or sub-specialty must report on the same set of measures, which is often impossible due to the varying scope of clinicians within a practice. Therefore, **we urge CMS to revise its proposal to allow all individual ECs, regardless of practice size to report through the claims collection type, as well as allow GPROs of 15 or fewer to report through claims.** Claims reporting is also the most popular reporting type so to restrict eligibility would further discourage meaningful and active participation in MIPS.

- **Reduce the Data Completeness Threshold to 50 Percent**

CMS proposes to maintain the data completeness threshold at 60 percent for successfully reporting on a measure in 2019. If a physician fails to meet the data completeness threshold they only receive one point (three for small practices) for reporting on a measure. We recognize that a larger threshold may increase the sample size of data; however, reducing the threshold to 50 percent does not prohibit physicians or practices from submitting more data. Maintaining a 60 percent threshold while physicians are upgrading to 2015 CEHRT, eliminating a sufficient number of measures and still learning the complex requirements for successful MIPS participation is premature and ignores the burden and hardship associated with increased reporting thresholds.

Increasing the threshold also discourages physicians from reporting on certain high priority measures, such as PROs due to the large administrative burden and cost associated with collecting information and reporting on all-payer data using a QCDR, registry, EHR or web-interface reporting mechanism. Maintaining the 60 percent threshold, coupled with the requirement of reporting on all-payer data, is especially burdensome for small practices that do not have the resources to hire an employee to collect and document such information. Even if the practice has an EHR, much of the information that supports the high priority measures are not captured within the EHR, but is collected through surveys and manual key entry.

The AMA strongly disagrees with the notion that a 50 percent threshold could lead to possible gaming. A 50 percent threshold still requires reporting on a majority of patients, which prevents cherry picking. The PQRS Experience Reports also routinely highlighted as a challenge that it is extremely difficult for physicians reporting through the claims option to achieve a 50 percent threshold. A 50 percent threshold is simply a more realistic reporting level that acknowledges common problems that may arise prior to or during the reporting period, such as the following:

- A vendor that fails to update measure specifications at the start of the reporting period.
- A delay in publication of CMS' approved qualified registries or QCDR list.
- A delay in CMS notification on a practice's reporting status (low-volume threshold, non-patient facing, facility-based, virtual group or APM eligibility).
- A delay in CMS releasing timely educational materials and updating the QPP website.
- A practice upgrading to 2015 CEHRT.
- Power outages or inaccurate coding.
- Implementing new 2019 Physician Fee Schedule payment policies.

Therefore, we urge CMS to reduce the quality reporting threshold to 50 percent.

Furthermore, we are concerned with CMS' desire to increase the data completeness threshold to 90 percent or 100 percent because routinely quality measurement is challenged by data integrity issues and an expectation of 100 percent leaves no room for errors that are often outside of a physician's control. Registries also would be particularly challenged since anything close to 100 percent of the population would require physicians to continue reporting and tracking submissions into the following year and leave less time for registry vendors to complete the data validation and quality assurance processes. The majority of registries have a data submission cut-off towards the end of January, after the reporting period has ended (and some earlier) because they need at least a month or two to process the data and submit to CMS. Therefore, a higher threshold of data completeness requires a significant amount of technical and administrative coordination which can take several months to properly validate, both for MIPS ECs in large practices and those in small and rural practice. Alternatively, CMS could consider shifting to a 90-day reporting period or a timeframe shorter than 12-months with a higher number of patients that must be submitted.

- **Eliminate the Requirement to Report on All-Payer Data**

As part of MIPS reporting, physicians are required to report on all-payer data (except if reporting through claims) to satisfy reporting on 50 percent of applicable patients. 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 takes away time from patient care and 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 potentially be used to satisfy their private payer pay-for-reporting requirements and obligations, then physicians might see the value in reporting on all-patients, regardless of payer.

We also note that CMS states that it wants to incentivize electronic reporting; however, the requirement to report all-payer data does the opposite. If you report measures through the claims option it is only based on Medicare Part B patients. CMS is placing the highest burden on physicians who choose to report via methods it should be incentivizing—EHR, qualified registry, or QCDR. Therefore, physicians may be deterred from adopting electronic reporting mechanisms.

In addition, the all-payer data requirement is especially burdensome for small practices that do not have the resources to hire a full-time or part-time employee to collect and document quality information, especially when reporting measures that require capturing patient information through surveys. Even if a practice has an EHR, much of the information that supports outcome and high priority measures is not captured within the EHR system, but instead is collected through manual key entry.

Therefore, we urge CMS to eliminate the all-payer data requirement and make it optional.

Alternatively, we encourage CMS to re-instate the PQRS requirement that physicians reported on a majority of Medicare Part B patients and submitted other payer data as the practice or reporting entity felt was appropriate.

- **Reduce the Quality Reporting Period Timeline to a Minimum of 90 Days**
We urge CMS to reduce the 2019 and future quality measure reporting period from a calendar year to a minimum of 90 consecutive days in order to reduce administrative burden. A reduced reporting period ensures physicians have sufficient time to implement after notification by CMS of their MIPS eligibility and special status, as well as performance feedback from CMS and educate the practice on performance year changes, including removal of measures or updates to measure specifications. In addition, the recommendation aligns with the PI and IA performance category timelines, especially since practices are required to upgrade and implement 2019 CEHRT.

While we acknowledge that certain reporting options, such as reporting certain outcome-based measures, may require a lengthier reporting period than 90 days to ensure statistical validity, we believe there is a substantial opportunity to reduce the cost and labor involved in reporting MIPS data to CMS by shortening the minimum data collection period to 90 consecutive days and allowing physicians to decide whether to report additional data. Our recommendation does not preclude practices from reporting more than 90 days, but allows practices the flexibility and recognition that being held to a January 1 start date is a challenge when CMS only finalizes policies November 1 of the previous year. For example, in 2018 the eCQM, *Functional Status Assessment for Total Hip Replacement* measures underwent significant updates to the measure specifications from 2017. Originally, the measure specifications looked at functionality assessments performed prior to hip surgery and 60-180 days after surgery. In 2018, the measure specifications changed to look at functionality assessments performed prior to hip surgery and 270-365 days after the procedure. Therefore, due to the significant modification and lack of timely release of the changes and implementation, physicians are forced to either begin reporting on an alternative measure, if possible or perform another functionality assessment and hope they will score well. If the reporting period were flexible, practices would have the time to make the necessary updates and better certainty that they could perform well under MIPS.

We also urge CMS to consider the timing of previous year MIPS feedback reports, which are released in July after the close of the reporting period (for example, 2018 MIPS Feedback reporting are released in July of 2019). Assuming CMS does not encounter delays in releasing feedback reports akin to its delay in releasing eligibility information, updating the website and that these reports are released in July, any necessary modifications will interrupt a 365-day reporting period. For instance, physician practices may need to conduct internal due diligence to identify quality performance variables, explore more clinically relevant reporting metrics and change data capture and input into the EHR, which would require action by third-party vendors who are not subject to the same payment penalties as physicians. If the reporting period were reduced to a 90-day minimum with the option to submit additional data, physicians and group practices would have greater flexibility to incorporate previous MIPS feedback into their 2019 performance and focus more of their attention on improving patient care as opposed to just reporting.

In addition, we foresee quality data integrity issues arising in 2019 because quality measurement reporting will be based on two versions of CEHRT (2014 and 2015). We expect many physician offices will transition to 2015 Edition EHRs throughout 2019. When a practice upgrades to CEHRT they must implement new data maps—essential for quality measurement—and hope their data housed in one version seamlessly integrates with the new version. In discussions with physician office Information Technology (IT) staff, we have been alerted to major issues that occur during EHR upgrades and changes in EHR versions. In most instances, the custom maps from one version of software are not identical to the new version and numerator/denominator calculations may be inaccurate and missing information. As one IT professional put it, “something always breaks when you go through a major software update on a complex application like an EHR.” We also often hear that when a practice goes through an upgrade they stop focusing on quality activities because the practice’s bandwidth is focused on a successful upgrade launch to lessen the loss in practice productivity. **We reiterate the need for a 90-day minimum so physician offices can accommodate these issues without sacrificing their ability to perform well in MIPS.**

- **Re-Instate Small Practice Bonus to Overall MIPS Score**

CMS proposes to only apply the small practice bonus to the quality category and states it is due to IA having special scoring, the ability to apply for a PI hardship exemption, and the fact that the cost does not require submission of data. We disagree with CMS’ proposal and strongly urge that CMS maintain the small practice bonus being applied to the overall MIPS performance score. Small practices do not only need assistance with scoring favorably under the quality category, but with the overall MIPS program. Small practices are consistently at a disadvantage as compared to larger health systems with respect to health IT and small practices are more likely to get penalized on cost measures given they have fewer cases to meet a minimum threshold. CMS’ own data shows that small practices are the least likely to participate in MIPS and changing the scoring rules would further disenfranchise them. Therefore, **we urge CMS to keep the small practice bonus points, as well as other bonus points, at the composite level.**

- **Make Outcome/High Priority Measures Optional**

Mandating that physicians report on an outcome measure, or high priority measure if an outcome measure is not available, may disadvantage certain specialties as well as rural practices and practices that treat high risk patients. As the AMA has highlighted in previous comment letters, there are a number of methodological issues that must be addressed before requiring reporting on outcome measures, such as the development of better risk-adjustment models at the measure level (not just the program level), benchmark methodology and stratification by specialty.

In addition, infrastructure challenges may prevent physicians from having the ability to report on outcome measures, such as not having appropriate data elements in the EHR. Practices may also experience interoperability issues that may interfere with the exchange of information needed to report outcome measures, or may be unable to do longitudinal tracking due to the lack of uniform patient identifiers and patient attrition when tracking outcomes. **Therefore, to make the program more equitable regardless of practice size or specialty, we strongly encourage CMS to make quality reporting more flexible by not requiring the use of any specific type of measure. Instead, CMS should recognize the importance of these measures through bonus**

points rather than a mandate. Removing the outcome measure requirement would ensure maximum potential achievement by all physicians, regardless of specialty, sub-specialty, practice size, or patient population. It would also simplify the overall calculation for scoring quality.

- **Eliminate the All-Cause Hospital Readmission (ACR) Measure Until It Has Been Refined and Deemed Valid at the Physician-level**

As we have stated repeatedly in previous comments, 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 the Hospital Readmission program and the associated measures, such as ACR, 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. As a result, the AMA sent a letter to CMS in February and reiterated in our 2019 IPSS proposed rule comments 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.**

Quality Data Submission Criteria and Scoring

- **Improving Electronic Data and Incentives to Use Electronic Clinical Quality Measures**

In order to improve electronic capture, calculation and reporting of quality measures, CMS should incent the use of standardized semantic content from recognized developers. In the development and specification of a quality measure intended for use in MIPS, the clinical concepts used in the measure could be incented to come from recognized clinical content models, such as those developed through the [AMA's Integrated Health Model Initiative \(IHMI\)](#). For example, if a measure is looking at blood pressure, and using the concepts as defined in the IHM, then QCDRs could be given incentives to use those concepts in the specifications they submit to CMS as part of the QCDR self-nomination process. In addition, it is worth continuing to note to CMS that EHRs do not uniformly calculate eCQM measures across vendors and practices due to the lack of specificity within CMS' Implementation Guides. **We also stress that any variations between data management in EHRs detracts from interoperability.** Incorporation of data requires the development, maintenance, and refinement of administrative codes such as the International Classification of Diseases (ICD), Current Procedural Technology (CPT®) and clinical vocabulary standards such as SNOMED Clinical Terms® (SNOMED CT®), Logical Observation Names and Codes® (LOINC) and RxNorm. Creating standards and mapping tools will facilitate working across these different codes and ensure consistency when data is exchanged. The AMA, through IHMI, is participating in activities to support ontological structures that will provide pathways for better data collection and analytics. **We encourage CMS to incorporate this work into its implementation guides to ensure eCQM calculations and benchmarks are accurate and that EHRs are accurately capturing eCQMs.** We stand ready to assist in this effort and look forward to engaging with CMS to improve data capture and exchange.

In addition, to encourage greater adoption of eQMs and electronic reporting CMS should maintain end-to-end bonus points and expand the definition. Currently, to achieve the bonus points on an individual measure, a physician must have the ability to: 1) record a measure's demographic and clinical data elements in CEHRT; 2) electronically export data to a third-party or transmit data electronically directly to CMS; and 3) the third-party can perform operations (e.g., aggregate, calculate, filtering) and submit data electronically to CMS. Essentially, for a physician to meet the bonus point requirements, data must always be managed electronically. Hand keying data into a registry's web portal would not count.

Given the high costs and limitations of today's EHRs, we are highly concerned that CMS is missing the mark and undervalues the usefulness of registries. Many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection. While end-to-end electronic reporting is a goal for many registries, it is essential that CMS does not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing registries, leveraging electronic capture, reporting where it makes sense, and using alternative methods when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a sometimes necessary manual data entry step.

In the spirit of incentivizing the reporting through electronic sources and following the intent of the law, **a physician should have the ability to report a mixture of eQMs and chart abstraction, and such actions should be rewarded regardless if it is completely "electronic" from end-to-end.**

- **Expand Protections for Reporting on New Measures and Measures Where CMS Cannot Calculate a Benchmark**

To encourage reporting on new measures, **CMS should institute protections that ensure physicians are not penalized for reporting on new measures.** Under the scoring criteria, CMS does not create a benchmark or provide associated achievement points on a measure until after receiving first year data. In addition, the maximum amount of points a physician can earn for reporting on a measure is three achievement points when CMS cannot create a benchmark due to fewer than 20 physicians reporting on the measure, or its calculation methodologies cannot handle complex measure structures (i.e., ratio, time sensitive measures, etc.). The AMA has repeatedly heard from physicians that they are discouraged from reporting on new measures because of the scoring rules. CMS is also contradictory because through the Meaningful Measures Initiative it wants to push reporting on new measures, such as outcome measures but it has set up a scoring system that disincentives reporting on the measures. To encourage reporting on new measures, **we recommend that CMS put in place some safe harbors when reporting on the measures, such as automatically award maximum achievement points or bonus points for reporting on new measures.**

- **Score Outcome Measures and High Priority Measures Equally**

Under the current scoring rules if a physician reports on additional outcome measures they receive two achievement points, but if a physician reports on additional high-priority measures

they only earn one achievement point. The inconsistency between the scoring rules is confusing, and CMS does not clearly distinguish the difference on the QPP website. Outcome and high priority measures are classified in the same category on the QPP website, and both are designated as high priority measures. In addition, to fully satisfy the quality requirements, a physician must report on an outcome measure. If they do not believe there is an applicable outcome measure for their practice, and they pick a high priority measure as an alternative, they are penalized in their scoring. To simplify the rules, CMS should make outcome measures and high priority measures optional and award bonus points to encourage and recognize the additional work that goes into reporting these measures. **Regardless of whether CMS maintains the outcome measure requirement, outcome measures and high priority measures should be scored the same. Physicians should receive two achievement points whether they report on an outcome or high priority measure.**

- **Remove High Priority Bonus Points from Web-interface**

The AMA supports CMS' proposal to remove high priority bonus points from web-interface reporters because reporting through the web-interface automatically satisfies the full quality reporting requirements and skews the program more favorably to large practices. Unfortunately, the web-interface reporting method is not applicable to all practices because the measures are primary care/internal medicine focused and practices must have a sufficient sample of patients to be eligible to report through the web-interface. CMS has also maintained much more consistency and stability with the web-interface since the measures and reporting mechanism have been in existence since the start of the PQRS program. Having the stability has resulted in a higher level of success under MIPS and PQRS.

Web-interface users are also not subject to capped points on topped-out measures, which further skew the program more favorably to web-interface users and large practices and automatically eligible for end-to-end electronic bonus points. Therefore, to make the program more equitable regardless of practice size or specialty, we encourage CMS to finalize its proposal to remove bonus points from the web-interface reporting mechanism.

- **Make Incentive to Use CEHRT/End-to-End Bonus Points More Flexible**

To encourage the use of CEHRT for quality improvement, CMS provides bonus points if a physician meets CMS' "end-to-end electronic reporting" standard when reporting on an individual measure. The bonus is available to all submission mechanisms except claims. However, to achieve the bonus points on an individual measure, a physician must have the ability to: 1) record a measure's demographic and clinical data elements in CEHRT; 2) electronically export data to a third-party or transmit data electronically directly to CMS; and 3) the third party can perform operations (e.g., aggregate, calculate, filtering) and submit data electronically to CMS. Essentially, for a physician to meet the bonus point requirements, data must always be managed electronically. Hand keying data into a registry's web portal would not count.

We support awarding a bonus point to encourage electronic reporting; however, given the high costs and limitations of today's EHRs, we are highly concerned that this incentive undervalues the usefulness of registries. Many registries still rely on both automated and manual data entry. A large percentage of EHRs cannot support all the necessary data elements needed for advanced

quality measures or analytics, and therefore registries still support a hybrid approach to data collection. While end-to-end electronic reporting is a goal for many registries, it is essential that CMS does not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing registries, leveraging electronic capture, reporting meaningful data, and using alternative methods to report data when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a manual data entry step.

In the spirit of incentivizing the reporting through electronic sources and following the intent of the law, a physician should have the ability to report a mixture of eCQMs and chart abstraction, and such actions should be rewarded regardless of whether they are considered to be completely “electronic” from end-to-end.

- **Data Completeness Requirement**

Under the current MIPS scoring rules, if a measure does not meet the case minimum requirement, does not have a benchmark, or does not meet the data completeness threshold a physician receives three points for reporting on the measure. We support this policy and encourage CMS to maintain the policy for future years and as proposed, not to eliminate it starting with the 2020 performance period. The floor provides some certainty with scoring and recognizes the effort that goes into reporting. We also continue to support the special scoring rules for small practices and urge CMS to maintain the policy in the future. As we highlighted earlier, we encourage CMS to move to reporting points, plus additional points for calculating achievement points against a benchmark.

- **Scoring Flexibility for Measures with Clinical Guideline Changes During the Performance Period**

Beginning with 2019, CMS proposes to suppress a measure without rulemaking, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns. As a result, CMS proposes to reduce the total available measure achievement points for the quality measure performance category by 10 points, which we support because a physician is not penalized when a measure is updated to reflect guideline changes or a patient safety issue arises. Under the proposal, CMS is reliant on the measure steward updating the measure to address guidelines changes, but it is unclear whether CMS would also rely on the steward to identify the issue and notify CMS. Therefore, we recommend that CMS clarify and allow multiple sources to flag issues and CMS work directly with the steward to determine the degree of the problem and change and whether it warrants suppressing the measure. Most, if not all, measure stewards will want to be responsive to the concern if they are made aware that the measure is causing harm.

We also seek clarification on the level of evidence needed to rapidly remove a measure(s) from a program without rulemaking due to a patient safety issue arising. For example, there is emerging evidence that the All-Cause Readmission measure may be leading to unintended consequences but CMS continues to include and score physicians on the measure.

- **Incentives to Submit More Impactful Measures on Outcomes**

CMS seeks comment on approaches to simplify scoring and incentives to submit more impactful measures that assesses outcomes rather than process. Please see *Revised Scoring and Quality Meaningful Measures Initiative sections* for details and recommendations on how to simplify the quality category and move to receiving more outcomes measures. In addition, throughout the AMA's quality comments we offer suggestions and recommendations to simplify existing requirements.

- **Measure Development Funding**

The AMA is becoming increasingly concerned with potential influence from pharmaceutical, medical device, and biotechnology industry through their financial support of measure development and we are unaware of CMS having restrictions within the CMS Measure Development Blueprint. We do not think that use of industry-funded or backed measures should be allowed within Medicare and other CMS programs. The potential of a conflict of interest is too great; if real, such conflicts could result in measurement benefitting industry, not patients. Therefore, we recommend that CMS update the CMS Measure Development Blueprint to specifically state that pharmaceutical, medical device or biotechnology financed measures are prohibited from CMS programs and request stewards to identify their funding source. At a minimum, for purposes of transparency, if a measure is funded by industry then there needs to be a disclaimer next to the measure steward's name highlighting their funding source.

- **Benchmark Methodology - Data to Show Differences in Performance and Improving the Benchmark Methodology**

To create benchmarks, MIPS awards quality measure achievement points to physicians based on their performance relative to decile-based categories calculated from historical data (when available). In an effort to improve and develop data that can show differences in performance and better determine physicians that provide high value care, we offer the following comments and concerns regarding the current MIPS benchmark methodology and offer illustrative examples using the 2015 Individual Physician Compare data downloaded from the CMS website. We also offer recommendations to improve the existing MIPS and Physician Compare benchmark methodologies. In addition, for greater transparency, it would be useful if CMS provided the minimum, average and maximum number of eligible clinicians who successfully reported on a measure, and the number of patients included in the denominator, as well as the number of eligible clinicians who attempted but did not successfully report on the measure, are provided with each benchmark.

Our primary concerns related to the MIPS benchmark methodology are as follows:

- 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 percent and be in the 4th decile while another physician scores 92 percent 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;

- There is a lack of consideration of the role played by random fluctuation, especially for small denominators;
- Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality;
- There may be significant changes to the population of physicians and groups between the time that the historical data represents (two years prior) to the time period to which the resulting thresholds are applied; and
- Under certain circumstances, physician performance score under MIPS may differ significantly from their performance under the *Physician Compare* methodology, even for the same measure.

Therefore, we urge CMS to revise the benchmark methodologies to allow measure thresholds to incorporate clinical knowledge, 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 highlight in Appendix C. *MPFS MIPS Benchmark White Paper*, this would allow for enough flexibility to address the above issues when they arise. 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.

vi. **Cost Performance Category**

In this rule, CMS proposes to: increase the weight of the cost category to 15 percent of the total score; retain two cost measures from the VBM; and add eight new measures based on episodes of care. In order to “measure as many clinicians as possible in the cost category,” the NPRM also raises the possibility of expanding the cost performance measurement period to two years, proposes a new attribution method for three of the new cost episode measures and maintains the previous reliability threshold of 0.4. As detailed in the text that will follow, **the AMA:**

- **Strongly urges CMS to retain a 10 percent weight for the cost category and remain flexible on weights for the next four years while the eight new episode-based cost measures are road-tested and more are developed and piloted;**
- **Is concerned that CMS’ desire to “capture” more physicians in the cost category will undermine reliability of and confidence in the measures;**
- **Is troubled by the paucity of data and analysis provided in descriptions of proposed policies and the rule’s impact section;**
- **Objects to the new attribution policy proposed for the three new acute inpatient condition measures; and**
- **Reserves judgment on whether cost measures should be based on two years of data rather than one.**

As observed in the proposed rule, the BBA authorized cost category weights at anything between 10 percent and 30 percent for each of the next four performance years. In response to the new legislative authority, CMS proposes “to modestly increase” the cost category weight to 15 percent in 2019 and anticipates an additional 5 percent increase each year until the 30 percent weight is reached in the 2022 performance year/2014 payment years. However, the agency also “considered maintaining the weight at 10 percent” because “clinicians are still learning about the cost performance category and being introduced to new measures.”

The AMA firmly believes that **the weight of the cost category should remain at 10 percent in 2019**. To be clear, the AMA supports the move to episode-based measures and greatly appreciates the effort that CMS and Acumen LLC have invested in creating a process that allows for significant clinical input in cost measure development and refinement. However, the initial eight measures will serve as a pattern for those that are to follow and we are convinced that a real-time road test and evaluation using the actual methodology that CMS proposes to implement is needed before this category becomes a larger part of the MIPS score. We note, for example that:

- The eight new measures have received only conditional support from the Measures Application Partnership (MAP) and have not yet been submitted to the National Quality Forum (NQF) for endorsement.
- CMS is proposing a very significant and untested change in the way acute inpatient conditions are attributed.
- The two cost measures carried over from the VBM have well known flaws and are now being refined by Acumen. However, the refined measures will not be available until 2020.
- The NPRM does not contain, and CMS does not appear to have conducted, data analysis that predicts the measures impact on different types of practices and would help avoid unintended consequences.
- More time is needed for development and testing of measures for additional procedures and conditions and to provide public and expert panel input on the methodological shifts that are proposed in the rule.
- CMS with the help of physician organizations needs to conduct additional education and outreach about the new measures.

The AMA is also troubled that in its desire to “measure as many clinicians as possible,” CMS is pushing forward with several policies that could compromise the integrity of MIPS cost scores. Chief among these are the continued use of a 0.4 minimum reliability standard and a proposed change in the attribution methodology for the inpatient condition measures, which already have reliability rates well below the 0.7 or 0.8 minimum reliability rate experts prefer when measures are to be used for public reporting or payment adjustments.

In general, the five procedural episode measures CMS is proposing to implement next year were easier to define and have higher reliability rates than the three inpatient conditions. For procedural measures, which require just 10 individual episodes in order to be scored, mean reliability scores were higher than 0.7 for all five measures when applied at the TIN (group) level and for three measures when applied at the individual physician level. To be scored on an inpatient condition measure, CMS has proposed a higher minimum case threshold of 20 episodes but mean reliability for these measures still was lower than for

the procedural measures for all but one measure—Intracranial Hemorrhage or Cerebral Infarction which achieved a mean reliability of 0.7 at the group level.

Of particular concern, mean individual level reliability for the new pneumonia episode measure barely met CMS' modest 0.4 standard level, and reliability was even lower than 0.4 for more than two-thirds of physicians measured as individuals. (Group level reliability was 0.64) In response to this “somewhat lower” reliability, a higher minimum case threshold of 30 episodes was considered but then rejected because it would have decreased the number of TINs that met the case minimum by 29 percent and the number of individuals by 84 percent. The AMA believes that this choice ignores the impact of unreliable measures on real physicians and their patients in order to increase the number of physicians who are subject to a measure that is likely to trigger inappropriate payment adjustments for a significant number of physicians. **If this measure is retained, the minimum case number should be raised and the attribution method should not be changed. As an alternative, the measure could be treated as optional or calculated with varying case minimum thresholds and provided to physicians for information only.**

In another effort to “measure as many clinicians as possible in the cost category,” CMS also wants to increase the number of physicians captured by an inpatient condition episode by modifying the way episodes are attributed. As originally designed and pilot tested, these episodes would have only been attributed to individual physicians if they were responsible for at least 30 percent of the inpatient E/M services in the episode. Under the new proposal, the 30 percent threshold would be applied at the TIN level (i.e., if members of the TIN participated as individuals rather than a group and the group as a whole met the 30 percent threshold, the full Part A and Part B expenditures associated with the episode would be attributed to any physician who provided even one inpatient E/M service during the episode). If physicians participated as a group, no episode would be counted more than once but if they reported as individuals, several members of the group could all be assigned the cost of the same episode and have it counted in their cost score if they had at least 19 other episodes for the same inpatient condition.

For such a major change in policy, there is remarkably little discussion of the rationale or impact of this proposal, which is covered in three short paragraphs in a very lengthy regulation. According to the proposed rule, the policy reflects stakeholder discussion “throughout the measure development process” of the “team-based nature of acute care.” However, there does not appear to have ever been any discussion of the newly-proposed attribution policy within the clinical panels that created the inpatient condition measures or the cost episode technical expert panel that provided general guidance. There are no projections on how many additional physicians and groups would be swept into the inpatient condition measures and how such a shift would affect reliability rates that are already far from ideal. There is no consideration of how the new attribution method would affect the viability of QPP's principle of allowing physicians to choose between individual or group participation. And no concern about the potential ramifications of undercutting the work of the clinical panels on the positive image the panels have created within the physician community.

It is not clear whether CMS knows, but chose not to publish, the attribution proposal's potential impact or whether the Agency is proceeding to implement it without any impact analysis. **In either case, we strongly believe that this new attribution method should not be implemented without a more granular analysis and public discussion of its likely effect.** In fact, cost category discussions throughout the NPRM seem to be shorter on data and specifics than the other MIPS categories. For example, neither the general cost performance section nor the impact section provide even a basic

estimate of how many groups (and size of the group) and physicians would likely have a cost measure applied to them. Other data that would enable CMS and stakeholders to make much more educated choices include: how many physicians would probably be subject to each of the new episodes; how much overlap there is between measures; and how much reliability, coverage and MIPS cost scores are expected to differ by: specialty; practice size, ownership and patient mix.

On the question of whether cost scores should be based on two years of data rather than one, the AMA is reserving judgment. Given that these scores are based on claims data, it should be possible to model and make public the impact on reliability and numbers of attributed groups and physicians with a two-year performance period versus a one-year performance period. Such a policy would be more acceptable if CMS also raised the reliability threshold than if the additional year of data is simply another means of extending the number of physicians who are subject to a measure that is still unreliable for many. We share CMS' concern that this approach would create an even longer gap between the performance and payment years. It also seems likely to create new complications such as what happens when new measures or policies are introduced between the two performance years. More years might also increase the number of practices that question their cost scores and have to undergo targeted reviews.

We have the following additional observations on the cost category:

- The AMA disagrees with the argument elsewhere in the rule that the small practice bonus should only apply to the quality category because these practices are not at any disadvantage in the cost category where scores are based on administrative claims and do not have to be reported. If the reliability table in this rule were expanded, as we believe it should be, to look at reliability across various sized practices, it likely would show that in almost all cases, cost measures are less reliable for small practices than large groups. It will also be more difficult for small practices to find the time and expertise to analyze their cost data and adjust their practices accordingly.
- Consistent with our Quality Category policy recommendation, cost measure data should not be reported until the measure has been in effect for three years.
- Any cost data reported in Physician Compare should have high reliability standards equal to the current Physician Compare standard.

The point of the MIPS cost category is to show physicians where there are opportunities for their practice to be more efficient. However, MIPS feedback reports this year did not include the detailed patient level information that was available in the predecessor Quality and Resource Use Reports (QRUR). Physicians tell us that the QRURs were much more useful and that the QRUR drop down data should be restored in the feedback reports. It is our understanding that CMS intends to add this data in the future and we hope that the next round of feedback reports will contain additional data.

vii. Improvement Activities Performance Category

Keep IA Nominations on a One-Year Cycle

CMS is proposing to change the performance year for which the nominations of prospective new and modified IAs would apply, such that IA nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible inclusion in a future year. **We oppose this policy change and believe it will reduce the timely inclusion of important activities in the IA**

Inventory. For example, it is incongruous for CMS to add a criterion for IAs to “place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities for inclusion in the Inventory, because their inclusion raises awareness for clinicians about the urgency of the situation and to promote clinician adoption of best practices to combat those public health emergencies”²⁹ while simultaneously proposing to change the program such that any new IA meeting this criteria will not be included in the program for almost two years. We fail to understand how CMS can accomplish the goal of raising awareness and promoting best practices in an expedient manner if there is a two-year gap between the time new IAs are proposed and the time they are incorporated into the IA Inventory. **CMS should keep IA nominations on a one-year nomination and inclusion cycle to ensure that the IA inventory includes activities that are timely, relevant, and meaningful to the evolving practice of medicine and the public’s health.**

Ensure Equity in Reweighting Policies

We continue to urge CMS to more evenly and fairly distribute the PI performance category weight across the other MIPS components if and when it is reweighted. Particularly in light of CMS’ goal to support small and rural practices and enable them to be successful in the QPP, we caution against forcing physicians to base their success in the program on, essentially, one category (quality, since cost is calculated by CMS). **In the spirit of fairness and maximizing a physician’s opportunity for MIPS success, we recommend reweighting the PI component entirely to the IA component such that IA would be worth 40 percent in 2019.**³⁰ We believe this structure still accomplishes CMS’ goals of prioritizing quality participation while balancing the flexibility and improved clinical outcomes associated with IAs. It also would incentivize physicians who take advantage of facility-based scoring to prioritize completion of IAs, rather than focusing exclusively on quality.

The IA category is no longer new to program participants, which warrants a more significant integration into the program. Moreover, MACRA defines IAs as activities that relevant eligible clinicians and other stakeholders identify as “improving clinical practice or care delivery” and are “likely to result in improved outcomes.” As such, increasing the weight of the IA category would have a strong synergistic effect on CMS’ Meaningful Measures Initiative, which cites improved outcomes as a key goal.³¹ Further, CMS has previously stated that IAs “have elements of quality and care improvement which are important to emphasize.”³² **We strongly urge CMS to increase the amount of weight it would distribute to the IA category to avoid creating an undue emphasis on only one category, help to create a more unified program, support CMS’ other Initiatives and demonstrate the value of the IA category while still prioritizing quality.**

Provide Positive Incentives for the Use of Health IT

CMS’ previous policy of providing bonus points in the PI category represented CMS’ understanding that health IT can play an invaluable role in improving outcomes and, to that end, incentivized physicians to incorporate health IT into their practice workflows and clinical activities. **We urge CMS to continue to incentivize—but not require—clinicians to use health IT as they accomplish IAs.** Given CMS’

²⁹ 83 FR 35907

³⁰ Please note that we are recommending that CMS maintain the 2018 MIPS category weights in 2019 as a baseline.

³¹ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>

³² 2018 Proposed Quality Payment Rule 82 Fed. Reg. 30,010, 30,145 (June 30, 2017).

proposal to remove the bonus score component of PI, CMS could continue to provide bonus points for certain activities and simply apply the bonus points at the composite score level. Doing so would avoid having to “reinvent the wheel” and would provide some consistency to physicians who have already adjusted their workflows to earn the PI bonus. The AMA would also support CMS applying high-weighting to any IA utilizing health IT.

Another way for CMS to incentivize the use of health IT in IAs is to provide multi-category credit. A multi-category credit scoring structure would provide physicians with credit across categories for performing certain activities that touch on multiple MIPS categories. For example, if a physician participates in a QCDR, the physician should receive credit in quality, IA, and PI. We refer you to earlier in our letter for more information about multi-category credit. We believe this approach would support future program policies aimed at increasing alignment of the PI, IA, and quality components of MIPS.

Regardless of which method(s) CMS adopts, **CMS should apply incentive policies to physicians who use both certified and non-certified health IT to enhance patient safety, beneficiary engagement, and security of health information.** This way CMS can avoid prescribing specific types of technology or limiting innovation.

Cybersecurity’s Role in IAs Utilizing Health IT

As CMS encourages the adoption and use of health IT, it must bear in mind that technology inevitably exposes its users to vulnerabilities. **Given increases in cyber threats, CMS should reward clinicians who are proactive in ensuring the safety of their electronic patient information, including actions that HIPAA may not address.** A 2017 AMA/Accenture-survey of 1,300 physicians across practices sizes and specialties showed that physicians overwhelmingly consider cybersecurity to be a patient safety issue.³³ It further revealed that four out of five physicians have experienced some sort of cyber attack.³⁴

The AMA has submitted several IA proposals intended to increase patient safety, enhance privacy and security of patient records, and provide education to patients around the use of health IT during CMS’ call for measures in both 2017 and 2018, yet none of them have been accepted by CMS for inclusion in its IA Inventory. **We struggle to understand CMS’ rationale in ignoring the importance of cybersecurity even as health information becomes increasingly valuable on the black market.**³⁵ **CMS requires physicians to use health IT to fully participate in the QPP, yet provides no incentives to do so in a secure manner despite such efforts being costly, time-consuming, and incredibly important to patient safety.** Examples of the AMA’s proposed cybersecurity IAs include the following:

- **Adopt voluntary cybersecurity best practices:** The eligible clinician adopts cybersecurity best practices identified by the security industry and federal government.
- **Initiate implementation of a cybersecurity framework:** Adopt a cybersecurity framework and identify an implementation process.
- **Provide patient education on accessing health information securely:** Provide written and/or face-to-face education to consumers about privacy and security considerations when electronically accessing health data.

³³ <https://www.ama-assn.org/about/medical-cybersecurity-patient-safety-issue>

³⁴ <https://www.ama-assn.org/about/medical-cybersecurity-patient-safety-issue>

³⁵ <https://www.forbes.com/sites/mariyayao/2017/04/14/your-electronic-medical-records-can-be-worth-1000-to-hackers/#5e78bd9250cf>

CMS should focus on integrating activities that utilize health IT in ways that demonstrate its prioritization of outcomes over means. Patient safety is one such outcome and, as demonstrated not only by our survey but also other HHS agencies,³⁶ cybersecurity is a patient safety issue. Adding these types of non-prescriptive activities to the IA Inventory would provide clinicians an opportunity to demonstrate their use of health IT in safe ways that improve their practices and assist their patients.

viii. Promoting Interoperability (PI)

The AMA applauds CMS' overhaul of the Advancing Care Information (ACI) category and supports many of the proposals within the PI program. We agree with CMS' goal of focusing the program on interoperability and improved patient access to health information as opposed to burdensome, prescriptive measures. However, CMS' continued proposed policy of an "all-or-nothing" scoring structure sustains the current, artificial, and flawed construct that assumes all measures work for all physicians. **We urge CMS to continue to limit data capture and measurement policies and other regulatory requirements in the PI program as physicians share data among themselves and with their patients.** We also suggest that CMS align the MIPS PI category with the hospital PI Program so that both hospitals and physicians achieve full PI credit upon scoring the same number of points.

We further note the importance of regulatory alignment across agencies with respect to data access and caution CMS against requiring physicians to transition too quickly to new measures in both 2019 and 2020 for reasons explained below.

Proposals the AMA Supports:

- **Measure reduction:** The AMA strongly supports CMS' proposal to eliminate a number of measures from the current ACI that are not meaningful, are administratively burdensome, and ultimately detract from patient care. The reduction of the number of measures on which a physician must report enhances a physician's ability to focus his or her time on providing patient care, as opposed to meeting and reporting on arbitrary requirements. To minimize burden on both physicians and Electronic Health Record (EHR) developers, CMS should ensure that the PI measures outlined in this proposal align with the PI measures for the recently finalized hospital PI program. CMS recognizes in its proposal that this alignment is needed. Physicians should not have to manage requirements of two different programs across practice settings, and vendors should not be forced to design technology for compliance with two different regulatory programs.
- **2019 Certified Electronic Health Record Technology (CEHRT) requirements:** The AMA supports the use of 2015 Edition CEHRT in 2019. We recognize the additional functionalities included in the new edition and agree that they will support improved patient access and interoperability. CMS should, however, closely monitor the availability of 2015 Edition CEHRT throughout 2018 to ensure physicians have sufficient choice of products and, as described further below, ensure that extreme and uncontrollable circumstances hardships contemplate situations in which 2015 Edition products are unavailable.
- **90-day reporting period in both 2019 and 2020:** 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

³⁶ <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm604500.htm>

flexibility in reporting PI measures and help practices successfully navigate their transition to 2015 Edition CEHRT.

- **Use of health information technology (IT) beyond CEHRT:** The AMA commends CMS' recognition, through the proposed Query of Prescription Drug Monitoring Program (PDMP) measure, that the use of health IT outside of CEHRT can be useful for physicians, improve patient outcomes, and enhance patient safety. Because increased interoperability and patient access will require new combinations of technologies and services, we continue to urge the U.S. Department of Health and Human Services (HHS) to reevaluate regulations that prioritize the use of CEHRT over other non-certified digital health tools. Patients, physicians, and other care team members should be empowered to make decisions based on what works best for their needs, and not what regulatory boxes must be checked. Any new PI measures should permit the utilization of not only CEHRT but also health IT that "builds on" CEHRT—a concept taken directly from CMS' priorities in its call for new PI measures.
- **Exclusion for the *Receive and Incorporate Health Information Measure*:** CMS should prioritize physicians sending health information over the incorporation of data received by other providers into the EHR. Just as CMS notes in the proposed rule that it is beyond a physician's control to require patients to access their information in a particular manner, CMS should recognize that physicians cannot require hospitals or other clinicians to send information to them. In fact, the EHR of a "sender" may not be able to communicate with a physician's EHR if the two parties have different edition EHRs, each of which utilizes different common clinical data architectures. Consequently, a physician will be reliant on another party to score well in the "Receive and Incorporate Health Information" measure. Furthermore, as CMS notes in the proposed rule, the Receive and Incorporate Health Information measure is new. This measure has not been tested in clinical practice and there is a lack of experience of how it will unfold in a real-world setting. For these reasons, we strongly support CMS' proposed exclusion for this measure.

Patient Access and Data Availability:

The AMA has long noted that physicians are unfairly penalized by CMS scoring physicians on measures that rely on the actions of others. We appreciate CMS' acknowledgment that, while physicians can encourage their patients to access information in a particular way (e.g., through a patient portal), the patient's ultimate actions are beyond a physician's control. As such, **we strongly support CMS' shift to scoring physicians on providing patients with access to their protected health information in a number of ways rather than scoring physicians on how patients access their information.**

However, the AMA also urges consistency across HHS as the agency sets policy to promote information sharing and prevent information blocking. For example, there is a discrepancy between the electronic patient information that is made available via the EHR (the common clinical data set, or CCDS) versus the information contained in a patient's designated record set as required by HIPAA. Particularly in light of MyHealthEData, an Initiative that the AMA generally supports, many patients will likely believe that application programming interfaces (APIs) will provide a "spigot" of data, enabling a free flow of all their information. This is not the case. In order to receive his/her entire medical record in an electronic format, a patient will likely still be given a CD or USB because APIs may not provide access to all of the information contained in an entire medical record. Furthermore, not all EHRs will be able to support any given app. If a patient has an app he would like to use, the physician's EHR may not support it, and the physician will have very little leverage against the vendor.

Because of the limitations of the API functionality, agencies across HHS must manage expectations about what information a patient can actually access through an app. The AMA will continue to work with the Office of the National Coordinator for Health Information Technology (ONC) and urge vendors towards developing an API that enables patients to pull more than just CCDS data. Moreover, ONC should work with OCR to specifically address this issue through guidance or an FAQ. This guidance should clarify that physicians are not information blocking in the event that patients cannot access their entire medical record through a mobile app and cannot receive their entire medical record in a format of their choosing (e.g., an app). In sum, **federal regulation and policy must balance patient data access with the limitations placed on physicians and patients by the design and development of health IT.**

Finally, CMS should make clear in the final rule or through guidance that patients are not required to sign-up for a patient portal for physicians to receive credit for this measure. The physician should only have to enable and turn on the functionality to receive credit in this measure and should not be held accountable for a patient's decision to create or not create a portal account. Vendors should be required to ensure that a physician's EHR can provide a patient with access to their records without special effort, including excessive fees, and regardless of whether a patient creates a portal account.

Scoring Recommendations:

CMS' expectation that physicians alone must continue to shoulder the burden of health IT measurement and reporting is inappropriate and unacceptable. While CMS has taken steps to reduce the burden of reporting program on physicians, more must be done. As such, the AMA has identified a strategy to improve MIPS PI. This strategy has both short- and long-term components. We believe these recommendations will better position the MIPS PI category to work more harmoniously with the other three components of MIPS.

- **For 2019: Align MIPS PI with the Facility-based PI Program's Scoring Standard**

CMS seeks comment on alternative approaches, flexibilities and methodologies to consider for scoring the PI component of MIPS.³⁷ The AMA supports CMS' desire to leverage alternative approaches that promote scoring flexibility in the PI performance category. CMS has also expressed a desire to align the requirements of the PI performance category with the requirements of the Medicare PI Program for eligible hospitals and CAHs ("PI Program").³⁸ We strongly agree with CMS that "aligning the requirements between programs would lessen the burden on health care providers and facilitate their participation in both programs."³⁹ **Therefore, the AMA recommends that CMS further align the two programs by extending the PI Program scoring standard of a 50-point minimum to the PI performance category under MIPS.** In other words, physicians who earn 50 points or higher in MIPS PI should be deemed to have satisfied the category's requirements. Such physicians should receive 100 points in the category, translating to 25 points towards a physician's final composite score. (See Example Score #1 below.) Physicians scoring 49.9 or fewer points should be scored according to the finalized scoring methodology (See Example Score #2 below.) This policy will reduce category complexity and physician burden, and will add flexibility for physicians, and can be adopted

³⁷ <https://www.federalregister.gov/d/2018-14985/p-1416>

³⁸ <https://www.federalregister.gov/d/2018-14985/p-1413>

³⁹ Id.

immediately. In fact, CMS already defines “successful” category performance as 50 percent of the total possible category points in its Physician Compare program.⁴⁰

The Inpatient Prospective Payment Systems (IPPS) final rule (CMS-1694-F) states that an eligible hospital or CAH must earn 50 points or more in the PI Program to satisfy the program’s requirements.⁴¹ CMS states that the “minimum Promoting Interoperability score is consistent with the current goals of the program that focus on interoperability and providing patients access to their health information.” CMS further states that it “understand[s] the constraints that health care providers face in providing care to patients and seek[s] to provide flexibility for hospitals to create their own score using measures that are best suited to their practice.” CMS believes it is “important to be realistic about what can be achieved” and that the “50-point minimum Promoting Interoperability score provides the necessary benchmark to encourage progress in interoperability.”⁴² **The AMA supports this approach and agrees that hospitals, CAHs, and the clinicians that work in these facilities need an appropriate balance among interoperability promotion, successful PI Program participation, and the current realities of using health IT.**

However, CMS’ proposed MIPS PI performance category scoring approach runs counter to CMS’ stated goal of program simplicity and consistency. For the MIPS PI performance category, CMS proposes a total value of 100 points across six measures. CMS is proposing a complex methodology including a maximum point value, numerator and denominator factor, performance rate, and sub-composite score calculation—all of which must then be multiplied by the PI performance category’s weighted MIPS factor. Many physicians have strained resources, limited support staff, and have expressed serious concerns with the category’s complex requirements to meet 100 points for full PI credit. While PI scoring for hospitals is more straightforward, eligible physicians must also navigate three additional MIPS components—all without benefiting from additional resources or support found in larger medical facilities (adding to the strain on participants is the fact that three out of the four program categories have requirements that are changing this year). We appreciate CMS’ move to reduce PI measures, but more must be done to ease the burden on physicians. **CMS should apply the same 50-point scoring standard enjoyed by facilities to the PI performance category of MIPS to better reduce physician burden, ease concerns with succeeding in PI, and further align program requirements across practice settings.** In other words, physicians who earn 50 points or higher in PI should be deemed to have satisfied the requirements of PI and should receive a 100 for the category, translating to 25 points towards a physician’s final composite score. Physicians scoring 49.9 or fewer points should be scored according to the finalized scoring methodology (which, as we explain below, should be on a yes/no attestation or objective-level basis).

We recognize that CMS may consider the PI performance category’s proposed scoring methodology analogous to the flexibility provided to hospitals. We recognize how CMS may view this as flexible since a physician’s PI score is a contributing factor in their overall MIPS score. However, this rationale ignores several issues.

⁴⁰ 82 CFR 53826.

⁴¹ <https://www.federalregister.gov/d/2018-16766/p-4889>

⁴² <https://www.federalregister.gov/d/2018-16766/p-4886>

CMS estimates a median PI performance category score of 73 in 2019—**less than three quarters of the 100 points CMS proposes requiring physicians to achieve to receive full PI performance credit (i.e., to satisfy PI requirements)**. CMS derived this number from proxy information from the 2016 Medicare EHR Incentive Program—a program whose objectives, measures, scoring methodology, technology requirements, and even name has changed multiple times over four years. While CMS assumes that “a large proportion of eligible clinicians who submit EHR Incentive Program data will likely achieve a Promoting Interoperability performance category score of 73 points,”⁴³ the AMA has strong concerns with CMS basing future physician performance in PI on a program that has gone through multiple iterations, including varying scoring requirements, since such numbers were calculated. Furthermore, concerns with the 73-point median calculation aside, CMS proposes to require 100 points for full PI credit in MIPS—50 points more than what is required for hospitals to satisfy the PI Program’s requirements. **In sum, hospitals—which have many more clinicians and many more financial and technical resources—are only required to meet 50 points to receive full PI Program credit, while physician practices with varying amounts of resources are held to a much higher standard. CMS should accommodate all providers equally and extend the 50-point minimum score across both PI programs.**

- **For 2020 and Beyond: Simplify PI and Reduce Burden Through Yes/No Measure Attestation and Require Health IT Vendor Reporting on Utilization of CEHRT Functionality**

CMS seeks comment on how the PI category should evolve in future years. We thank CMS for this solicitation and believe the following policy should be adopted as soon as possible—we believe it is possible to start in 2020—to provide significant burden relief to physicians and valuable information to the administration and health IT community. The policy has three components: yes/no measure attestation, objective-level scoring, and health IT vendor reporting on physician utilization of CEHRT functionality. (See Example Score #3 below.)

1. **CMS should only require physicians to attest to meeting the program’s measures—i.e., physicians should only be required to report “yes” or “no” on whether they had at least one patient in the numerator of each measure.** Each “yes” would be worth whatever that measure’s potential points are (e.g., under the current proposal, a “yes” attestation to e-prescribing would be worth 10 points). In addition to reducing reporting burden on physicians, a yes/no attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report, and could help prioritize both existing and future gaps in health IT functionality. It also capitalizes on changes made in the Bipartisan Budget Act of 2018, which removed the requirement, that HHS increase stringency of EHR measurement over time; Congress has clearly recognized that measuring EHR usage for measurement’s sake does not promote interoperability.
2. **CMS should require health IT vendors—not physicians—to report CEHRT functionality utilization levels.** Physicians should focus on meeting the PI program’s goals rather than worry about measurement and documentation. Opportunely, because EHRs

⁴³ <https://www.federalregister.gov/d/2018-14985/p-2655>

capture what functionalities are used to perform tasks, EHR vendors can easily provide such information to CMS and ONC. This data capture mechanism conveniently provides an audit trail for CMS to ensure that physicians actually did have at least one patient in the numerator of each “yes” attestation. Further, requiring EHR vendors to provide information directly to CMS and ONC on a physician’s real-world use of technology will provide insight into an EHR’s usability and conformance to certification. Adopting the attestation approach outlined above could also help the Secretary to meet its obligation to establish an EHR reporting program as required by the 21st Century Cures Act (see Section 4002).

CMS should score physicians at the objective level—that is, scored based on reporting one measure from each objective and receiving bonus points for any additional reported measures.

- 3. The AMA strongly opposes CMS’ proposal to require physician reporting on all measures to be deemed a meaningful user.** Not all of the measures work for all practices, as demonstrated by the continued number of necessary exclusions. We support CMS’ alternative approach, under which physicians would be scored at the objective level—that is, scored based on reporting one measure from each objective and receiving bonus points for any additional reported measures. Participants should be able to select among the measures within an objective on which they wish to report, allowing physicians to choose measures that are most relevant to their patient population and within their control.

Additionally, given that technology continues to evolve, current PI measures are likely to become quickly outdated or will fail to include more innovative uses of the EHR. Scoring PI at the objective level, coupled with an attestation approach, would provide flexibility to allow patients and physicians to efficiently test new uses of technology to see what does and does not work, while encouraging further innovation. **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.**

Accordingly, **we support CMS’ alternative proposal that CMS score measures at the objective level**, which conforms with HITECH’s requirement that meaningful users e-prescribe, exchange health information electronically, and report quality measures, and permits physicians to report on a subset of optional measures.⁴⁴

⁴⁴Of note, there is precedent for not requiring meaningful users to report on quality; the base score of the former PI/ACI component of MIPS did not require physicians to report to a clinical data registry. As such, we urge CMS to ensure that physicians are incentivized to conduct syndromic surveillance reporting or report to a clinical data registry, rather than required to do so. At the very least, a physician should only be required to report to one registry.

Example Score #1: 2019—Greater than 50 points (meets scoring minimum for full credit)

Objectives	Measures	Maximum Points	Numerator/Denominator	Performance Rate	Score
e-Prescribing	e-prescribing	10	200/250	80%	8
	Query of PDMP	5 (bonus)	150/175	86%	5 bonus
	Verify Treatment Agreement	5 (bonus)	N/A	0	0
HIE	Sending Health Information	20	135/185	73%	15
	Receiving / Incorporating Health Information	20	145/175	83%	17
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40	350/500	70%	28
Public Health / Clinical Data Exchange	Immunization Registry Reporting Public Health Registry Reporting	10		“Yes” responses to two registries	10
	Total Score				83*
	Total PI MIPS Score	Total Score ≥50 points			25

*Because the performance score is greater than 50, the total MIPS PI category score is the full 25 points.

Example Score #2: 2019—Fewer than 50 points (scored on performance)

Objectives	Measures	Maximum Points	Numerator/Denominator	Performance Rate	Score
e-Prescribing	e-prescribing	10	20/200	10%	1
	Query of PDMP	5 (bonus)	N/A	0	
	Verify Treatment Agreement	5 (bonus)	N/A	0	
HIE	Sending Health Information	20	40/160	25%	5
	Receiving / Incorporating Health Information	20	13/125	10%	2
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40	300/400	75%	30
Public Health / Clinical Data Exchange	Immunization Registry Reporting Public Health Registry Reporting	10	YES ATTESTATION	N/A	10
	Total Score				48*
	Total PI MIPS Score	Total Score is ≤ 49.9 points			.25*48=12

*Because the performance score is ≤ 49.9 points, the MIPS PI score is based on the proposed performance calculation.

Example Score #3: 2020 and beyond

Objectives	Measures***	Maximum Points	Attestation	Score
e-Prescribing	e-prescribing	10	Yes	10
	Query of PDMP	5 (bonus)*	No	
	Verify Treatment Agreement	5 (bonus)*	No	
HIE	Sending Health Information	20	Yes	20
	Receiving / Incorporating Health Information	20	No	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40	Yes	40
Public Health / Clinical Data Exchange	Immunization Registry Reporting Public Health Registry Reporting	10	No	0
	Total Score			70**
	Total PI MIPS Score	Total Score ≥50 points		25

* We are advocating for the opioid measures to remain as bonus measures beyond 2019.

**Because the attestation score is greater than 50, the total MIPS PI category score is the full 25 points.

***We would encourage CMS to increase the number of optional measures in each objective.

In sum, 2015 Edition EHRs are expected to improve interoperability and patient access—improvements that the AMA agrees are important. Through the adoption and implementation of 2015 EHRs, it is expected that physicians and patients will have new opportunities to engage with medical records and health data in a way that makes sense for the physician’s practice and their patients’ needs. **The approach of combining 2015 Edition EHR adoption along with shifting PI measure reporting to attestation will promote interoperability and reduce physician burden.** If CMS must use a performance-based scoring structure, it should limit such scoring to the Provide Patient Access and Sending Health Information measures. These are areas that CMS prioritizes (patient access and interoperability). As noted in our comments above supporting the measure exclusion, the Receive and Incorporate measure is new and, additionally, physicians should not be held accountable for performance scores that depend on actions of another party.

Discontinuation of Scoring the *Security Risk Analysis* Measure:

The AMA agrees with CMS that it is not necessary to score this measure as it is already required under the Health Information Portability and Accountability Act (HIPAA). Yet, the proposal still requires a physician to complete or review a security risk analysis to receive any score in the PI program. A physician’s success in the PI program should not hinge on his or her security risk analysis; rather, the physician should be held accountable for the privacy and security of his or her patients’ protected health information under HIPAA, which is regulated and enforced by the HHS Office of Civil Rights (OCR). **If CMS plans to condition a physician’s success in the PI program on whether he or she conducts or reviews a security risk analysis in accordance with HIPAA, a physician should receive a score that contributes to his or her overall PI score (e.g., 5 points for a “yes” attestation).** To be clear, the AMA

is not saying that a security risk analysis is unimportant. However, failure to conduct or review such an analysis is a matter for OCR, not CMS, to evaluate, and such failure should not preempt a physician's ability to score points in PI. At the very least, CMS should explicitly exclude the security risk analysis from any PI audits.

Interoperability Challenges:

HIE Measures:

CMS acknowledges the new PI criteria would “lead to lower scores due to fewer clinicians being able to report measures and achieve maximum performance for the Health Information Exchange (HIE) Promoting Interoperability Objective.”⁴⁵ After conferring with multiple medical specialties, the AMA fervently agrees the proposed HIE measures will be challenging for physicians. We highlight that 40 points out of the 100-point requirement for full PI credit is linked to success in the HIE Objective. The AMA supports CMS' intent with the HIE Objective, but is concerned that many physicians will be held accountable for HIE measure performance outside their control.

For instance, CMS' proposed HIE measures are calculated based on the number of referrals, transitions of care, patient encounters, documents sent, received and incorporated into the EHR. We stress that these measures are reliant on CEHRT's ability to correctly and consistently send, receive, and consume medical information with any and all certified EHRs. EHR vendors still do not agree on a consistent approach to implement all HIE measure standards. For instance, an EHR may still be certified by ONC without actually proving it will send, receive, and incorporate medical information with another CEHRT. Since EHR certification and testing is done in a controlled laboratory environment, products will be designated as “interoperable” by the federal government without even actually connecting to other certified EHR products. In fact, there is little assurance that two CEHRT products from the same vendor will be interoperable. This is further complicated by data intermediaries, other third-party products, Health Information Exchanges (HIE), patient matching issues, and the unique ways EHR vendors handle data. However, **CMS has made it the physician's responsibility to promote and ensure EHR-to-EHR interoperability. Physicians' HIE Objective success will hinge on a significant orchestration between dozens of developer and technology stakeholders—all of which have competing business interests.** Any inconsistencies—even with variations between 2014 and 2015 Edition EHRs—will exacerbate this undertaking, which will impact physicians' ability to succeed in CMS' HIE measures.

The AMA stresses that physicians have next to no control over their EHR's ability to interoperate. In addition to a myriad of administrative requirements that take away from patient care, physicians feel they are being tasked with health IT “project management.” We again reiterate that physicians are not interoperability experts. Promoting interoperability is a shared responsibility. While millions of documents are exchanged every day, data content, data quality, and data management are still challenges.⁴⁶ Clinician organizations, including the AMA, are actively addressing these issues; however, frontline physicians are feeling the brunt of federal requirements. CMS must do more to counterbalance PI requirements on physicians with health IT-centric issues outside of physician control.

⁴⁵Id.

⁴⁶Steven Lane, MD, Sutter Health, *Physician Perspective*, Content Interoperability Track, ONC Interoperability Forum, July 2018, available at https://drive.google.com/drive/folders/1TqN_C5R-hpSzb8jMi631nYp_sjMELLq9

There are significant costs associated with information exchange.^{47,48} Health IT vendors have a vested business interest in increasing physician exchange of documents.⁴⁹ To be clear, the AMA supports efforts to improve interoperability, but we are concerned that CMS' HIE measures will perpetuate vendors' "pay-for-reporting" business models. Health IT companies are more than willing to charge a fee for each and every physician requirement imposed by federal reporting programs. This puts all stakeholders in danger of promoting health IT as an industry first, and its use as a tool for patient care second. The AMA questions how CMS' PI performance category holds health IT vendors accountable for producing tools to advance care outcomes without continuing to burden physicians with exorbitant fees and a lack of usability. For example, members have reported that some EHR vendors do not allow physicians to turn on patient access functionalities without paying a fee—how does this promote interoperability and facilitate patient access? It does not; rather, physicians are made to pay large amounts of money to check boxes and report on measures while vendors collect. What incentives are in place to change health IT vendors' business practices? Adding requirements on physicians without addressing persistent issues related to health IT vendor action (or lack of action) does not promote patient-centric interoperability. This strategy will fail.

Again, the AMA recognizes the importance of promoting interoperability. **However, making physicians the sole mechanism to advance EHR interoperability adds to physician burden and burnout and does not equitably distribute the work required to become interoperable across all stakeholders.** CMS must be realistic about compounding federal reporting requirements and physicians' inability to control EHR and HIE capabilities or costs. Interoperability is a team sport. The AMA further encourages CMS to identify methods beyond just physician regulatory compliance to promote interoperability. We point CMS to our comments on the interoperability RFI.

We also caution that MIPS PI and PI Program disparity may drive physicians to grudgingly abandon their independent and private medical practices. We have heard from many of our members that the weight of federal program and administrative requirements are forcing them to consider hospital employment or early retirement. We would be concerned if this is CMS' intent. Physician independence is a critical component in providing patients choice and access to quality care. CMS must identify ways to level the playing field and provide physicians a clear and equitable path to success. **The AMA urges CMS to dissuade any notion that PI performance category success is only available to those who work in large facilities. We again urge CMS to extend the 50-point scoring standard to the PI component of MIPS.**

End-to-End Electronic Reporting

Additionally, we strongly recommend that CMS reconsider its requirement that clinical registry reporting be conditional based on "end-to-end" electronic reporting. Physician-led clinical data registries continue to highlight that some data may not be captured or reported easily from an EHR. It is an incorrect assumption that chart-abstracted or hand-keyed data has any less value than end-to-end electronically

⁴⁷Letter from the Physician Clinical Registry Coalition to James A. Cannatti III, J.D., Senior Counselor for Health Information Technology, Office of Inspector General, U.S. Department of Health and Human Services, Kathryn Marchesini, J.D., Chief Privacy Officer Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, (February 8, 2018), Available at <https://www.registrycoalition.net/wp-content/uploads/2018/02/PCRC-Letter-re-Information-Blocking-by-Electronic-Health-Record-Vendors-D0765240-2.pdf>, Accessed June 2018.

⁴⁸ONC Report to Congress, Report on Health Information Blocking, April 2015, available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

⁴⁹Id.

captured and reported data. Many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection.

While end-to-end electronic reporting is a goal for many registries, it is critical that CMS not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing registries, leveraging electronic capture, reporting where it makes sense, and using alternative methods when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a sometimes necessary manual data entry step. **The AMA recommends that CMS expand their Public Health and Clinical Data Exchange objective requirement to include a mixture of methods for data capture or reporting.**

The Query of Prescription Drug Monitoring Program Measure:

The AMA is committed to addressing the country's opioid epidemic and recognizes that PDMPs can provide valuable data to physicians who prescribe opioids. As such, **we support CMS' proposal to provide a bonus PI score to physicians who choose to utilize a PDMP when clinically appropriate and in accordance with state law.** While supporting this proposal, we must note that PDMPs alone cannot determine whether a patient is misusing or overusing opioids; rather PDMPs provide data on which physicians can make clinical judgments and evaluations. Similarly, we urge CMS to distinguish between data on pain clinic regulation and the use of data accessed through PDMPs throughout its policy-making process; notwithstanding the [CDC website](#) that CMS cites in its proposal, the AMA is not aware of data sufficiently demonstrating that PDMP use reduces overdose deaths.

The measure is new to physicians and there are a variety of unknowns in how the measure will be operationalized in physician practices. CMS should therefore carefully consider the implementation of this measure to ensure that it is not counterproductive to practice workflow. **CMS should ensure that a physician need only review the PDMP information as opposed to querying the PDMP itself.** If the measure is to count how many times a specific physician makes a PDMP query, then the physician's time is going to be spent "clicking" and looking at a computer screen as opposed to spending time on patient care. In practice, a physician assistant or nurse practitioner (or other authorized person in the office) typically performs the first query and enters the report or a note in the patient's pre-visit record for the physician to review so that PDMP information is a part of the clinical decision-making process. **The goal of the measure should be to review and interpret PDMP information, not to count how many times the physical act of the query itself occurs. Physicians should not be scored on how often they can click a button.**

CMS should continue to score this activity with bonus points in 2020 and beyond. By continuing to score this measure as a bonus, CMS can keep the Provide Patients Electronic Access measure's value at 40 points, which will underscore the agency's commitment to patient access while incentivizing physicians and the organizations in which they practice to become familiar with the PDMP measure and its integration into their workflow. This bonus structure would also provide flexibility with respect to state statutory and regulatory requirements related to PDMPs; approximately 40 states have some sort of query requirement and others have query exclusions (for example, physicians in some states do not need to check PDMPs for prescriptions of 7 days or less—requiring those physicians to change their workflow for a single federal measure would add considerable confusion and potential disruption to patient care). Additionally, there are a wide variety of PDMP technologies that operate differently across practices that

interface with a multitude of EHRs. There are also questions of how to best document the information gleaned from a PDMP into the EHR, in a secure manner that does not conflict with federal and state privacy laws, while ensuring that the information is associated with the correct patient.

If CMS finalizes its proposal to score this measure on a performance basis in 2020, we support CMS' proposed exclusion criteria for eligible clinicians unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. We also appreciate CMS' consideration of additional circumstances under which an exclusion may be justified and suggest that not only are cancer diagnoses and patients under care of hospice appropriate, but also other types of palliative care, acute pain prescribing for a limited duration, and emergency situations. CMS should also create an exclusion for physicians who do not prescribe Schedule II opioids at all (e.g., ophthalmologists). In other words, if a physician's denominator for that measure is zero, the weight for the PDMP measure would be redistributed to the electronic prescribing measure. Again, however, we urge CMS to keep the PDMP measure a bonus measure so that such redistribution is not necessary.

CMS acknowledges and seeks input on barriers to the implementation of electronic prescribing for controlled substances (EPCS). As the AMA described in a [March 2018 letter](#) to the Drug Enforcement Administration (DEA), the current EPCS regulations, which have been unchanged since 2010, prevent user-friendly devices that are widely available in medical practices from being deployed to meet the multifactor authentication standards in the DEA rules. The AMA letter outlined specific changes that are needed in the regulations for biometric devices in order to make it simpler and less expensive for physicians to adopt EPCS and have it integrated into their practice workflows. These requests are consistent with a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis that the DEA should increase EPCS to prevent diversion and forgery and revise the EPCS regulations. Although the numbers of [physicians checking PDMPs](#) has accelerated rapidly in recent years, the current low rate of adoption of EPCS means that tying a measure of PDMP utilization to use of EPCS is premature.

PDMP Integration With CEHRT:

CMS is seeking comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden. CMS is also seeking comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

In the rule's preamble, CMS acknowledges that PDMP integration with CEHRT is not widespread. Many physicians will likely need to enter data manually into CEHRT to document the completion of the query and conduct manual calculation of the measure. The AMA is aware that laws in several states do not permit PDMP data to be brought into and stored within CEHRT, thereby extending the need for manual data entry and manual calculation of the measure indefinitely. We also understand that the development of interfaces to connect CEHRT to the PDMP system is still ongoing. Until this is widely available, clinicians will be required to leave their workflow and log into a separate PDMP website where they can query the PDMP and view a patient's PDMP report. However, some members have reported that access to a PDMP via an EHR has resulted in compounding fees where the EHR vendor, PDMP vendor, and additional third-party intermediaries separately charge physicians. Furthermore, some states prohibit the use of certain sources of funding, thus limiting the potential range of funding mechanisms. For instance,

Florida law specifically prohibits the use of state funds to support the PDMP—further tying PDMP financing to physician-bound fees.⁵⁰

Physicians need access to interoperable and usable health IT that is well-integrated into their workflows. **Ultimately, PDMP systems and EHRs should standardize around a common approach for data exchange. The AMA recommends that CMS establish a coordinated approach, in consultation with clinicians, states, EHR and PDMP vendors, to reconcile variations in workflow, integration, and use of standards.** Not only will this reduce the disparity in PDMP usability, but it will also reduce costs, improve real-time data access, and better integrate PDMP data into health IT functions like clinical decision support and quality measurement.

The AMA cautions, however, CMS and ONC from going down the path of regulating technology. We view this concept as a microcosm of what has plagued the EHR Incentive Payment Program for much of its history: seeking to nationalize a prescriptive activity by leveraging health IT at a granular level. While we acknowledge a degree of benefit from this approach early in the nation’s journey towards digitized care, we question its effectiveness and the resulting unintended consequences that could impact the nation’s ability to combat the opioid crisis. **Rather than prescribing the use of certain technology and standards, the best approach is for CMS to continue promoting the use of PDPs with positive incentives and for ONC to focus its efforts on ensuring health IT vendors develop and implement open API interfaces in a standardized and consistent fashion.**

Participation in the Trusted Exchange Framework and Common Agreement (TEFCA):

The AMA is interested in the idea of considering participation in the TEFCA a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. We cannot comment fully, however, until the final TEFCA is released by ONC outlining what is required for participation. There are too many unknowns to make an informed decision at this time. For instance, the AMA seeks more clarity around the definition of “participation” and exactly how it would be measured. Would participation require both the physician and its health IT vendor to jointly sign the Common Agreement? Regardless, if participation in the TEFCA is finalized as a measure under the Health Information Exchange objective, it should be in addition to, not instead of, the other measures required under the objective. Furthermore, we recommend that CMS also consider similar trust agreements and not limit potential Health Information Exchange objective options to just the TEFCA.

Maintaining an Open API:

As stated throughout our comments, the AMA supports patient access and believes that an open API is an efficient and relatively non-burdensome manner of providing such access. We foresee APIs enhancing access to data in the EHR while concurrently expanding the opportunities for physicians and patients to use medical information in new and exciting ways. For this to occur, we believe a number of considerations must also be addressed, which are discussed in the interoperability RFI section of our comments. Nevertheless, once an EHR-enabled API is turned on and shown to provide improved access to data, physicians will want to maintain access—regardless of CMS-mandated reporting periods.

⁵⁰ Title XLVI, Section 893.055, Florida Statutes - Prescription Drug Monitoring Program.

While APIs have a lot of potential, enabling a new interface that provides access to sensitive or protected health information also increases the potential for unauthorized access to that information. Many physicians are still working through the complications and security requirements to limit the exposure surfaces on their EHRs. APIs will add to this by creating another threat vector for hacking or other cybersecurity attacks. The API is also a new EHR function which has largely gone untested in real-world use. As EHR vendors continue to update, patch, or make changes to the EHR, there will be instances where APIs will need to be brought offline for maintenance. Additionally, as with any complex technology, APIs may be interdependent with other health IT products. If those products fail, access to the API may also be compromised.

The AMA stresses that it is neither appropriate nor necessary to impose further requirements on physicians—beyond the proposed PI objective requirements—to maintain APIs once they are enabled. As described above, there are legitimate reasons why, for a short period of time, hospitals, physicians, or EHR vendors may need to disable APIs—resulting in temporarily limited data access—to defend, protect, or improve the security of patient data or the functionality of the EHR as a whole. We strongly urge CMS to take this into consideration and to limit any additional API requirements that would result in unintended consequences.

Extreme and Uncontrollable Circumstances:

The AMA continues to support CMS' proposal to include an extreme and uncontrollable circumstances policy, which acknowledges that there are occurrences that can make reporting infeasible for MIPS participants. **We urge CMS to clarify in the final rule or through guidance that a lack of available 2015 CEHRT in 2019 is a valid reason to claim this exception under the hardship application's "Vendor Issues" option.** Clearly, a physician will be unable to participate in PI in 2019 without access to 2015 Edition technology. While the AMA is supportive of the use of 2015 Edition technology, the fact remains that only a limited number of health IT products have been certified to 2015 Edition (according to ONC's Certified Health IT Product List, 429 products are 2015 Edition CEHRT, whereas 2148 products are 2014 Edition CEHRT). Unavailability of 2015 Edition CEHRT also will impact how physicians are able to report on Quality, given the category's year-long reporting period. **We also believe that issues with third-party intermediaries, such as EHR vendors and registries, warrant inclusion in this exemption.** The failure of these sources (including lack of vendor readiness) is completely outside the control of the participant and can prevent all data submission to CMS. Without the requested clarifications, CMS may have to make last-minute accommodations to address problems arising from these issues, which often require extensive resources, education on how it is being resolved, additional deadlines for participants, and other confusing changes to the program. Instead of dealing with these problems on a case-by-case basis as they arise, we believe CMS should establish a process now to leverage the extreme and uncontrollable circumstances policy to address these issues. This will simplify the category and avoid needing to handle these issues in a separate manner while participants are already trying to adapt to program changes.

Imbalances When Reweighting:

The AMA remains concerned that CMS continues to over-emphasize the Quality category under its reweighting policy. **We again urge CMS to more evenly distribute the performance category weights when participants claim a PI exception. Specifically, we suggest that CMS distribute PI's 25**

percent weight to IA for a total of 40 percent in IA, 50 percent in quality, and 10 percent in cost in 2019.⁵¹

ix. MIPS Scoring and the AMA's Scoring Proposal

One of the AMA's goals has been to make improvements to the MIPS program that will reduce complexity and allow physicians to spend less time on reporting and more time with patients. One area where we think the program could be significantly simplified is the scoring of each performance category to calculate a physician's final score.

Throughout 2018, the AMA met with a workgroup of medical specialty societies and state medical associations to develop potential improvements to the MIPS scoring methodology. The proposal that we developed and ultimately shared with CMS aims to remove performance category silos and harmonize the four performance categories to produce a more cohesive and holistic program. We are disappointed that CMS did not move toward a more simplified scoring methodology in this proposed rule, and only asked for feedback on several of our proposals. Therefore, we are sharing additional details of our scoring proposal and how it would improve the MIPS program, in the hope that we can continue to work with CMS to adopt this scoring methodology in future performance years. We urge CMS to move forward immediately to implement the AMA's scoring proposal.

Overall, we believe the scoring suggestions below would help to ensure that a physician's final composite score represents the care provided by physicians in a manner that is relevant, understandable, actionable, equitable, and transparent. We also believe it is important to work toward a scoring methodology that would create a glide path toward participation in MIPS APMs and Advanced APMs by encouraging physicians to focus on more clinically relevant measures that lead to quality improvement and better care for patients.

Multi-Category Credit

The AMA believes that the most effective action CMS could take to simplify MIPS scoring would be to allow multi-category credit for activities and measures that overlap performance categories. Specifically, we have recommended that CMS allow measures or activities in one performance category to "count" for credit in another performance category. We believe a scoring methodology such as a multi-category credit option is what Congress had in mind when it created a unified MIPS program out of the three previous siloed reporting programs (Physician Quality Reporting System (PQRS), Meaningful Use (MU), and Value Modifier (VM)) and new Improvement Activities category.

Advantages to Multi-Category Credit Scoring

The AMA believes that by allowing physicians to focus on activities that fit within their workflow and address their patient population needs, rather than focusing on segregated activities that fit into each individual performance category, the MIPS program could improve the quality of care and be more meaningful for physicians. Providing credit within the MIPS program for activities that span across the MIPS performance categories would also encourage increased participation in the MIPS program, make the MIPS program more relevant for physicians, and help reduce physicians' reporting burden.

⁵¹ Please note that we are recommending that CMS maintain the 2018 MIPS category weights in 2019 as a baseline.

CMS notes in the PI section of the proposed rule that in lieu of the improvement activities bonus score, it has looked at ways to link three of the performance categories under MIPS (IA, PI, and Quality) to reduce burden and create a more cohesive and closely linked MIPS program. CMS states that it could establish sets of new multi-category measures that would cut across the different program categories and allow physicians to report once for credit in all three performance categories. **While we strongly support CMS’ efforts to move forward with this proposal in future program years, we would also encourage CMS to expand the proposal to include the cost category in these multi-category measures, and ensure that the multi-category measures go beyond just PI measures as focus areas.** Allowing multi-category measures across all four categories could simplify the MIPS program and greatly reduce physicians’ reporting burden. Multi-category measures also would facilitate the development of new measures and activities that would: address key gap areas such as patient-reported outcomes (PROs); leverage health information technology in a more meaningful way; and target key cost drivers through use of tools such clinical decision support (CDS) and AUC. At a minimum, multi-category credits should apply to the cost category because the cost category has the fewest number of measures and is more of an unknown in terms of whether a physician or group will have a cost measure attributed to them.

For instance, CMS could develop or allow specialties to propose a multi-category measure set that focused on a topic related to cost, such as appropriate use, and incorporate it into the cost performance category.

Appropriate Use (AU)		Quality	Cost	PI	ACI
*Only included AU quality measures that have been classified as AU by CMS					
**Examples of AU quality measures that have been classified as AU by CMS					
Improvement Activities					
A_PSPA_29	Consulting AUC Using Clinical Decision Support when Ordering Advanced	X	X	X	
Quality Measures					
021	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin	X	X	X	
065	Appropriate Treatment for Children with Upper Respiratory Infection (URI)	X	X	X	
066	Appropriate Testing for Children with Pharyngitis	X	X	X	
091	Acute Otitis Externa (AOE): Topical Therapy	X	X	X	
093	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use	X	X	X	
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	X	X	X	
116	Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis	X	X	X	
145	Radiology: Exposure Dose or Time Reported for Procedures Using Fluoroscopy	X	X	X	
156	Oncology: Radiation Dose Limits to Normal Tissues	X	X	X	
185	Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	
224	Melanoma: Overutilization of Imaging Studies in Melanoma	X	X	X	

Multi-category credit that incorporates cost could also reduce the frequency with which categories such as PI and Cost would need to be reweighted. For example, allowing physicians who report or attest to measures and activities in the Quality, PI, and IA categories to also earn points in the Cost category decreases the likelihood that Cost would need to be reweighted to Quality. This approach could also allow more physicians to demonstrate performance in the Cost category while we wait for applicable episode-

based measures to be completed and would link all four categories in a way that is relevant and actionable.

In addition to the example CMS mentions in the PI section of the rule regarding closing the referral loop, which we appreciate and fully support, we believe there could be multi-category measure sets focused on topics such as diabetes, fall risk, hypertension or patient-reported outcome measures that would focus on specific clinical areas, while providing credit in the PI category for physicians who use technology to improve care in these areas. Therefore, we would encourage CMS to expand public health priority sets beyond the topic of general health and allow stakeholders to submit their own ‘priority sets’ of measures in various clinical topic areas so that a greater number of physician specialties could meaningfully report the priority sets of measures.

Example of Reducing Falls Risk measure set:

- Reports on MIPS #154 (Falls: risk assessment) and #155 (Falls: plan of care)
- Meets the case minimum for Medicare Spending per Beneficiary
- Attests to IA_PSPA_21 (Implementation of fall screening and assessment programs)

As a result, points by activity or measure would be achieved in the following categories:

Quality	Cost	PI	IA
MIPS #154	MSPB	N/A	IA_PSPA_21
MIPS #155			MIPS #154
IA_PSPA_21			MIPS #155

Physicians would not have to report on all of the measures in the multi-category measure set but if they report or attest to a measure in one category that spans another category, they would achieve credit in another (“multi-category credit”). CMS could identify and prioritize the activities that qualify for multi-category credit on the Quality Payment Program (QPP) website through color coding or some sort of flag.

The AMA believes that CMS should also develop multi-category measures focused on targeted topics around Patient-Centered Medical Homes (PCMHs) and Qualified Clinical Data Registries (QCDRs). For example, any PCMH could select the PCMH multi-category measure, which would include the reporting of quality measures through the PCMH, receiving full credit for IAs, and receiving full credit for PI as long as 50 percent of the physicians in the PCMH were using CEHRT. Physicians participating in a QCDR could also receive credit in all performance categories through a QCDR multi-category measure by reporting quality measures through a QCDR and using CEHRT, with no additional improvement activity or cost requirements given that QCDRs provide routine feedback on performance and areas of improvement that address the overall health of the physician’s patient population, which reduces cost over time.

CMS could present information in bundles for participants to use and develop targeted topics with the goal of improving patient care and achieving the highest MIPS score possible.

Measure/Activity	Quality	Cost	PI	IA
Qualified Clinical Data Registry (QCDR)				
Report Quality Measures Through QCDRs	5+	0	0	0
MSPB	0	5+	0	0
IA_PM_7	0	0	0	10**
PI_EP_1*			10	
PI Provide Patient Access (New Measure)*			10	
PI_HIE_Send	0	0	10	0
PI Use of A QCDR			10	0
Bonus Points For Reporting Targeted Topic	5	0	0	0
Total Report Points Across All Categories	75+ points			

* Included because we recommend CMS only require that physicians attest to one measure within each objective. The AMA opposes CMS' proposal to require reporting on every measure.

** Point distribution is based on our proposal where each measure gets 5 points for simplification purposes. It could change with further discussion or depending on the direction of the program. Please note that PI is double the weight of the other categories as CMS notes the importance of health IT across practice and quality improvement and outcomes.

CMS also asks for feedback in the PI section of the proposed rule on public health priority sets which would span all four performance categories. CMS notes that these public health performance sets would be built across performance categories and would decrease the burden of having to report for separate performance categories as relevant activities and measures are bundled. CMS mentions developing the first few public health priority sets around opioids, blood pressure, diabetes and general health and seeks comment on whether public health measure sets should be focused by specialty or clinical topics. The AMA strongly urges CMS to create measure sets that are focused by clinical topics, which would better recognize the diversity of physicians' scopes of practice and allow physicians to concentrate on managing a particular disease. Not all physicians within a specialty treat the same clinical conditions, so creating measure sets based on specialty alone would limit the relevancy of the sets.

Multi-Category Credit Under MACRA

The AMA strongly supports the movement toward multi-category measures and believes CMS has the authority under MACRA to develop measures that span all four performance categories of MIPS. As we have noted to CMS, the MIPS provisions in the MACRA statute recognize that the four performance categories have some conceptual overlap. For example, as to the overlap between the quality category and the PI category, (q)(2)(B)(iv) incorporates the provisions of (o)(2) on determining meaningful EHR use, and in turn (o)(2)(B)(i)(I) requires CMS to "provide preference to clinical quality measures that have been endorsed by the entity with a contract . . . under section 1890(a)."

CMS has previously used this overlap in their prior rulemaking and regulations, such as 42 CFR §414.1380 which provides that, in the scoring of the quality performance category, bonus points can be provided for using end-to-end electronic reporting. See 81 Fed. Reg. 77008, 77099, 77296 (11-4-2016).

In addition, nothing in the MIPS provisions of the MACRA statute prohibits CMS from awarding credit in multiple performance categories, as described in the above examples. Moreover, CMS has great

discretion in developing the methodology that is used to establish performance measures and score a physician's performance for purposes of the MIPS adjustment.

While it is true that (q)(2)(B) specifies particular types of measures that must be included for each of the four performance categories, a particular measure can be broad enough to cover activities in more than one category. As long as the physician's particular activity or multi-category measure satisfies the requirements in each of the multiple categories involved, the physician should receive credit in each of those categories. For example, to receive credit in both PI and Quality for reporting a quality measure through an EHR, CMS could simply develop a multi-category measure for reporting a quality measure through an EHR (e.g., PI_MCC_Quality). Please note that the AMA strongly urges CMS to move to a yes/no attestation of PI in 2020, which is described in detail in the PI section.

Points for Performance Category Based on Weight of Performance Category

CMS notes in the 'Final Score Calculation' section of the proposed rule that a few commenters suggested that it make the MIPS performance category weights equal to the number of points they will represent in the final score to minimize confusion. Specifically, the AMA asked that CMS align points with scoring and eliminate the use of percentages within each category and the need for physicians to undertake complicated calculations to determine their score in each performance category (e.g., *25 points*—not percent—for PI). CMS highlights several limitations it sees to adopting this scoring methodology, and seeks comments from stakeholders on how to simplify calculation of final scores.

First, CMS notes that various reweighting scenarios could mean that the weight of the performance categories for each MIPS eligible clinician may vary which makes it impossible for all MIPS eligible clinicians to have the same total number of points available in each category. While we agree that some physicians that have their performance category scores reweighted will still need to calculate their score for each performance category (as is done now), the majority of physicians and groups whose scores are not reweighted would have their final score methodology greatly simplified by aligning each performance category points with the performance category score. Creating multi-category credit measure sets that include cost and allowing reporting or attestation in one category to achieve credit in another ("multi-category credit") would also help physicians to understand how activities contribute to the physician's scores. For those participants who are reweighted, the number of potential points available in each category would simply shift up or down, providing clarity to those participants about the way their performance will be reflected in their final score.

CMS also notes that the quality category contains an extra measure for some groups of more than 16 physicians who are scored on the readmission measure. Given the AMA's concerns with the readmission measure (see quality category comments), we would recommend CMS remove it from the quality performance category to simplify scoring for physicians. Alternatively, CMS could only score the readmission measure under improvement points since only a limited number of physicians are eligible for the measure and many who are eligible are not scored on the measure because they do not have a sufficient number of patients attributed them.

The current scoring methodology that requires a physician to calculate their score in each performance category makes the program complicated and makes it difficult for individuals or groups to understand what potential score they may achieve and replicate the scoring methodology used by CMS. Moving to a system that aligns points with the weighting of each category increases scoring clarity and transparency.

Reporting Points and Attestation Based Scoring

To further reduce complexity and allow physicians to better predict how they will perform under MIPS, we recommend that CMS move to reporting points in the quality and cost category and attestation based scoring in PI and IA. For instance, in the quality and cost categories physicians would receive a set number of reporting or attribution points, such as five points for being attributed or reporting on each measure, plus additional points (up to five) based on their performance against the measure benchmark. They also could be eligible to receive reporting points for reporting on multi-category measures. IA scoring would continue to be attestation-based, but all activities would be weighted equally, such as each IA worth 10 points. PI measures would each be worth 10 points for attesting to having at least one patient in the numerator (see the PI section for additional details on our attestation-based scoring proposal). This higher point value is warranted as health IT is a significant investment for physician practices and needs to be continually updated, and as CMS has noted, the use of health IT can help with practice and quality improvement to result in better patient health outcomes.

Bonus Points at Composite Level

The AMA has also recommended that to simplify MIPS scoring methodology, CMS should move all of the program's bonus points to the composite score. Specifically, we have recommended that CMS shift bonus points for small practices, complex patients, reporting on a new quality or cost measure and outcome or high priority measures and other activities that Congress and or the Administration wishes to incentivize or protect to the composite score.

Many of the factors addressed in the bonus points are broadly applicable to an individual or group's ability to participate in MIPS and we support CMS' initial efforts to include additional points for small practices and complex patients in the composite score. CMS proposes to move the small practice bonus points to the quality performance category as it believes small practices are only disadvantaged in that category. The AMA strongly disagrees—small practices are consistently at a disadvantage as compared to larger health systems with respect to health IT and small practices are more likely to get penalized on cost measures given they have fewer cases to meet a minimum threshold. In addition, the measures CMS is using in the cost category are more likely to have very low reliability for smaller practices and are therefore more likely to lead to inappropriate payment penalties for these practices. Therefore, **we urge CMS to keep the small practice bonus points, as well as other bonus points, at the composite level.**

In addition, **transitioning improvement points in the quality category and eventually the cost category to the composite would simplify the scoring approaches within each category;** thereby increasing a physician's or group's ability to estimate the potential maximum score that could be achieved in a specific category. Moving these bonus points and improvement points to the composite score will further support the goal of simplifying and standardizing scoring.

See Appendix D, *MIPS Program: Revised Scoring Approach* for an overview of the changes.

x. MIPS Improvement Scoring

The MACRA statute requires that the MIPS program take into account improvement with respect to the quality and cost performance categories "if data sufficient to measure improvement is available" and the Bipartisan Budget Act of 2018 prohibits CMS from taking into account improvement from the cost

category until 2024. In 2018, CMS finalized that it would start measuring improvement in 2018 for the performance level for the quality category.

The AMA supports several of CMS' proposals with respect to improvement. In particular, we agree that improvement should be counted as bonus points and not used to penalize participants. Physicians should also still be able to receive full credit based on achievement so they are not penalized for their previous high performance. We also appreciate that CMS has maintained the policy that improvement can only increase, not decrease a physician's score. However, in a budget neutral system improvement-related bonuses for some physicians mean smaller bonuses for others.

In addition, we continue to believe that moving to measure improvement only complicates the MIPS program. **In particular, we do not believe two years of data on the MIPS program is sufficient to begin measuring improvement, as required by the statute. Especially in light of the fact that the data CMS utilizes to set benchmarks and model the program are based on PQRS performance.** CMS has not even released MIPS experience or detailed performance data and year one MIPS data may not be representative given the pick-your-pace approach that was adopted for the 2017 performance year. Also, this additional scoring consideration adds complexity to an already complicated program and requires physicians to factor in additional considerations when they are just trying to learn and adopt the program. For example, some practice may not understand that they must fully participate in the quality category in order to receive an improvement score. Therefore, we do not believe CMS will have sufficient data to analyze and score improvement until physicians have participated in the MIPS program for several years.

Improvement scoring also assumes that the quality measure benchmarks will remain stable from year to year, even if measuring at the category level only, when instead; the deciles will shift over time (see v. Quality, Quality Reporting, Requirements and Submission Criteria—*Benchmark Methodology* section for more details). Consequently, physicians may be improving their performance but this will not be captured in physician's overall points in the quality category. This will be further exacerbated if CMS finalizes its proposal to remove 34 quality measures, phase-out 94 percent of quality measures and subject QCDRs to yearly removal of QCDR measures. We recognize this is the trade-off of scoring improvement on a category versus measure basis, but without more experience with the MIPS program, we are unclear how often this will happen and if it warrants a different approach.

We are concerned that performance may differ across years as the number of physicians reporting on measures varies leading to potential increases or decreases in sample sizes and performance scores. In addition, differences may occur based on changes to reporting requirements across years, leading to a score that may not be reflective of true performance. It would be useful if CMS analyzed and released data on how benchmarks across years may shift to better understand whether the changes reflect more reliable data, such as a larger sample size or represent data that is insufficient for that year. If the latter, we are concerned that it further compromises CMS' ability to set reliable benchmarks for a specific year. **Therefore, we do not believe CMS has sufficient data to analyze and score improvement until physicians have participated in the MIPS program for several years.**

Furthermore, **we believe it is premature to set policy on improvement for the Cost category because physicians are only beginning to be measured on cost in 2018 and the category is undergoing significant modifications over the next few years.** In 2018, physicians are only measured on two cost measures, which are currently undergoing significant revisions and will only begin to be measured on a

limited set of episodes starting in 2019 and expansion of the episodes will occur over the next several years. CMS is setting policy before CMS has data on the new cost and episode measures and the overall impact on physicians. We are also concerned with the different improvement approaches CMS has finalized for the cost and quality categories. Two separate methods further add complexity to the MIPS program. Until a stable set of cost measures has been developed and in place for several years and until there is more data to base a decision on, we do not think it is possible to judge the impact or appropriateness of either of these two approaches.

We also **recommend that CMS consider other ways to score improvement.** For example, improvement points could be awarded when physicians report on a new quality measure or through our revised scoring approach, a physician receives reporting points, plus additional points for being scored against a benchmark. Improvement points could also be awarded for overall improvement of a participant's composite score, rather than just focusing on individual categories. CMS could also define improvement more broadly to encourage participants to report new aspects of the MIPS program, participate in pilots, use registries, or other tools that CMS seeks to promote.

In sum, we believe that continuing to move to measure improvement scoring at this time is premature. **We recommend that CMS continue to seek feedback and experience regarding improvement methodologies at least through the MIPS transitional period before adopting an approach which, once put into motion, may be difficult to change.**

xi. MIPS Payment Adjustment

Establishing the Performance Threshold

We do not support CMS' proposal to increase the performance threshold from 15 points in 2018 to 30 points in 2019. We find the 50 percent increase a drastic jump and not a modest increase, especially since CMS is utilizing hypothetical estimates from the legacy programs (PQRS, Value Modifier and Meaningful Use) to assume how physicians may perform. Basing assumptions on the value modifier (VM) is grossly inaccurate since the cost category includes new measures and attribution methodologies so really it is unknown how achievable it is to obtain a higher performance threshold. **We recommend CMS move to set the performance threshold based on a much smaller increase that is no higher than 25 and even increasing to 25 appears a stretch from 15 points.** Only in the later years, when the program is more stable and physicians have experience with participating in the program is it potentially more realistic for a physician or group to be able to achieve such a high threshold.

We are also concerned that CMS has not taken into consideration through its estimates and assumptions the impact the changing weights have on achieving a 30 point performance threshold. The discussion in the proposed rule only examines the increased performance threshold. There is no thought given to the ability to obtain the increased threshold when the category weights change at the same time. When setting the performance threshold, we encourage CMS to analyze performance year data (at a minimum, the prior year to the existing performance year) and look to see what is needed to achieve the existing threshold from one year to the next and the ability to improve one's score to achieve the increased threshold. In addition, as part of the analysis, the impact the altering of the weights and incorporation of cost measures have on scores from the existing year to the next.

Furthermore, CMS has not fully taken into consideration the feasibility of scoring more than three points on a quality measure given there are many measures, especially if reporting through a QCDR that do not have benchmarks or are considered topped out. CMS' examples in the rule assume all physicians have the ability to obtain maximum achievement points on every quality measure and find a relevant outcome measure when that is not the case.

- **Provide Data and Analysis Before Setting Future Performance Thresholds**

CMS seeks comments on the approach to estimating the performance threshold for the 2024 MIPS payment year, based on the estimated mean final score for the 2019 MIPS payment year. As noted in our previous comment letters, we do not believe that we have sufficient data to determine whether the mean or median is better or how selecting one may affect categories of physicians and their patients. We appreciate CMS providing analysis based on PQRS, VM and MU data and outlining based on the legacy programs that more physicians could score above the performance threshold if CMS based the threshold on the mean. Therefore, before setting and finalizing policy CMS must analyze actual MIPS data and set the performance threshold based on the mechanism that would ensure the least number of physicians could be penalized under MIPS. Specifically, CMS should run and publish analyses that detail how selecting the mean vs. median will affect the number of physicians who receive penalties and incentive payments, as well as if choosing one over the other would disproportionately impact certain specialties, small practices, or sites of service.

The statute also states that CMS should use data from a prior period when setting the performance threshold. **The AMA believes the choice of which clinicians to include in the calculation of data from prior performance periods could significantly impact the performance threshold.** We again ask that, once 2017 and 2018 data is available, CMS share it with stakeholders and highlight any trends in performance.

Overall, **we again urge CMS to focus the program away from penalties when making these decisions. If one alternative would result in more physicians receiving negative payment adjustments, we would generally urge CMS to select the opposite option.** At this early stage in the program with constant flux in the changes in weights, requirements and measures, we believe it is most appropriate to focus on holding participants harmless before creating larger penalties and incentives.

Finally, **once CMS establishes an appropriate performance threshold it should not be increased every year but should remain stable.** Constantly escalating the threshold will force physicians to change their reporting plan every year. Instead, the MACRA statute permits CMS to reassess the threshold every three years, creating a sense of consistency for participants. We also note that CMS is not required to change the threshold after three years but can merely reassess to see if the program warrants such a change.

Facility-Based Scoring

The AMA believes allowing physicians to select a facility based measurement option can reduce duplication and reporting burden by using quality and cost data that is already reported at the facility level to determine a physician's quality and cost score. However, **we have concerns about the proposal to automatically attribute a facility's score to a physician or group practicing in a facility, if they meet the facility based physician threshold requirements. Ideally, we prefer some form of an opt-in**

policy. Automatically attributing the facility score to facility based physicians eliminates any incentive for the facility to coordinate with individual physicians or specialties on meaningful quality measures or to seek the input of physicians of how they would like to participate in MIPS because the physician can potentially achieve at or above the performance threshold based on the facility's score in the hospital value based purchasing program. In addition, the facility is notified about its performance prior to the start of the MIPS performance period and has the option to ensure maximum success under MIPS to report through traditional MIPS.

We are also concerned that the point floor is potentially too high because facilities may not be incentivized to invest additional resources into physician-level quality reporting tools, which would create problems for physicians that choose to report separately from the facility. Therefore, CMS should reduce the 30 percent floor, especially if CMS does not finalize altering the category weights and maintains the 2018 weights and does not increase the performance threshold to 30 points to ensure the program is equitable for both facility and non-facility-based physicians. If CMS, maintains the 2018 category weights and performance threshold (or slightly increases the performance threshold), facility-based physicians will have an advantage over non-facility-based physicians.

We also encourage CMS to monitor this option to see if it leads to further consolidation of physician practices or other patterns in the health care marketplace.

- **Expansion of Facility-Based Measurement to Use in Other Settings**

We support CMS designing a facility-based measurement option for physicians that practice in facilities such as skilled nursing facilities (SNF), ambulatory surgical centers, and inpatient rehabilitation facilities. We especially encourage CMS to move forward with a facility based measurement option for physicians that treat patients in the post-acute care settings (PAC) because there are an extremely limited number of applicable quality measures and no relevant cost measures in MIPS and they have generally been excluded from the Meaningful Use program, now PI. We encourage CMS to consider attributing three to five of the quality and cost measures that are part of the IMPACT Act mandated program to facility-based PAC physicians.

Subgroups in Multispecialty Practices

CMS once again asks for comment on how to allow physicians in multispecialty practices to form subgroups for MIPS reporting, which we are supportive of and hope CMS will finalize this policy for 2019 MIPS reporting or at the latest by 2020. Currently, a physician must choose to report MIPS data individually or through the GPRO, which includes all MIPS ECs within a TIN. The AMA has heard from physicians that are part of a group practice that would like to report separately from the larger group, and supports allowing an option for a portion of a group to report as a separate subgroup. This would allow a specialty in a multispecialty group to form a subgroup to report on measures and activities that are more relevant to that particular specialty. To identify subgroups, CMS could create unique subgroup identifiers, like the virtual group identifiers. 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.

Application for Non-Assigned Claims for Non-Participating Clinicians

In this rule, CMS is proposing not to apply the MIPS payment adjustment to non-assigned claims for physicians who have elected Medicare's "non-participating" option rather than the "participating physician" option. Because "non-participating" physicians are not required to take all claims on assignment and may bill the patient up to 109.25 percent of Medicare's allowed charge, applying the MIPS adjustment to non-assigned claims for these physicians would result in an increase or a reduction of Medicare's reimbursement to the patient. The AMA strongly agrees that this would be a confusing and inappropriate result and we support this proposal. This is the policy that was applied under the value-based payment modifier and there is no indication that the policy had any impact on physicians' par/nonpar decisions.

xii. Third-Party Intermediaries

Qualified Clinical Data Registry (QCDR) Requirements and Deeming Process

Many medical specialty societies are developing tools such as Qualified Clinical Data Registries (QCDRs) to help physicians incorporate systems of learning into their practice to improve quality of care, provider workflow, patient safety, and efficiency. Capturing data through a registry allows for its collection and tracking across settings and disease states including, inpatient versus outpatient settings, acute episodes versus chronic disease, surgical versus nonsurgical interventions, and resource-intensive versus relatively inexpensive therapies. However, for the improvements to be made quality measurement must move beyond snapshots of care which focus on random individual measures to a learning system with a broad focus. Utilizing specialty-led QCDRs provides an opportunity to evaluate care within an entire specialty, as well as at the individual physician level.

To improve the QCDR process, 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 quality requirements, measure specifications or technology functionality. In addition, changing the QCDRs process and expectations of QCDRs on a yearly basis creates the perception among specialty-led QCDRs that the changes are arbitrary and lack evidence or reason. The annual changes are also administratively burdensome and do not allow sufficient time for implementation. Therefore, there must be consistency from year to year. As highlighted in our 2018 Final QPP comments, **it is unrealistic to expect that changes can be easily adopted by the start of the performance period when sponsors of QCDRs often only learn of the changes during the annual CMS QCDR "deeming" process or proposed rule. Therefore, at a minimum QCDRS should also be subject to a phased removal process.**

We continue to advocate and offer the following suggestions to improve the process:

- Develop a review process where CMS and its contractor consult with appropriate physician experts and QCDR stewards to ensure sufficient clinical expert review on the importance and relevancy of a measure. One entity suited to do this is the National Quality Registry Network (NQRN) through the PCPI, of which the majority of specialty society QCDR stewards are members. Importantly, PCPI membership, and participation in NQRN, is open to a broad range of health care industry stakeholders who contribute their diverse and well-informed perspectives to the QCDR review process. The NQRN is a network of individuals affiliated with PCPI member

organizations that are operating, planning, or otherwise interested in registries; using information from registries to improve patient outcomes; and providing technology and infrastructure such as registry platforms and data standards. The PCPI QCDR committee is another forum for addressing common issues.

- Develop a system to properly record and track ownership rights, including making ownership information CMS collects available to QCDRs to better facilitate sharing of QCDR measures between QCDR stewards.
- QCDR self-nomination application and materials should be updated to outline all of the information needed to determine QCDR status to avoid delays and misunderstandings.
- Provide at least a 60-day notice of any changes to the QCDR vetting process, including review of measures and a minimum of 30 days to appeal changes.

We once again urge CMS to work with specialty-led QCDR stewards to further improve the process and ensure a viable and private sector-run innovating reporting option. If changes are not made, many specialty QCDRs have stated they may not continue to seek QCDR status because of the escalating burden and arbitrary nature of the vetting process that often lacks evidence and operates on unrealistic timelines and expectations.

Update to the Definition of a QCDR

We support CMS' proposal to amend the definition of a QCDR, but do not believe the amended definition is sufficient to address the issue of some QCDR entities predominantly having a technical background and insufficient experience in medical quality and measure development. We recommend that CMS further refine the 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. The 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.

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.

QCDR Licensing

The AMA opposes the proposal to require a QCDR to enter into a license agreement with CMS permitting any QCDR to submit data on the QCDR measure for purposes of MIPS. The AMA understands that having multiple QCDRs report on the same QCDR measure allows CMS to collect a larger pool of measures, which statistically helps establish more reliable benchmarks and a wider performance range. However, this approach disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease-, condition-, procedure-, or therapy-specific patient populations.

Medical specialty societies devote extensive resources to measure development, data collection, and data validation. The data collected through QCDRs are used not only for MIPS reporting, but also for research and analysis used to support guideline development and quality Initiatives. Allowing CMS to permit any QCDR to report another QCDR's measures would place a significant strain on QCDR and medical specialty staff as any data collected from an outside source would have to be subject to the same extensive quality review process prior to use for research.

CMS should not finalize the requirement that QCDRs permit CMS to allow another QCDR to submit data on the first QCDR's measure. Should CMS finalize a revised QCDR definition as discussed above, this should limit the need for one QCDR to license another QCDR's measures because each entity would have its own measure development expertise. CMS must keep in mind that the QCDR reporting mechanism allows QCDRs to develop their own quality measures for use in the MIPS program. QCDRs should not be required to license a measure from another QCDR in lieu of developing their own measure.

QCDR Deeming/Application Process

The AMA is concerned that CMS is finalizing proposed changes to the 2019 QCDR application requirements in the 2019 MPFS-QPP proposed rule prior to publishing the final 2019 MPFS-QPP rule. It is our understanding that CMS is requiring QCDR stewards to attest to the proposed changes, such as the proposed licensing changes during the 2019 application process. The QCDR application timeline is currently open and closes on November 1, but the final rule is not published until November 1 and often later than November 1. CMS encourages groups to apply early to allow CMS time to provide feedback on the proposed measures and in turn, the QCDR steward ample opportunity to implement the final measures and ready to implement and go live on January 1. Therefore, the majority of specialty QCDR stewards are currently submitting QCDR applications, but are being held to a standard that is supposedly a proposal and specialty QCDR stewards do not support the changes. In the spirit of the rulemaking process and the opportunity for the public to comment, we strongly encourage CMS to hold off on making changes to the 2019 QCDR application requirements until after the final rule is released. Alternatively, CMS must allow for a nimble 2019 QCDR application process, including changes to the licensing standards given the significant changes CMS proposes for 2019.

Remedial Action and Termination of Third-Party Intermediaries

CMS proposes to amend the criteria when there is a deficiency or submission of inaccurate data by a third-party intermediary by removing the probation policy and replacing it with the "immediate or without advance notice the ability of a third-party intermediary to submit MIPS data on behalf of a MIPS EC, group or virtual group to CMS." While we recognize the need to ensure third-party vendors are adhering to standards and consistently submitting accurate data, we do not support a policy of immediate termination before a vendor has the ability to be placed on probation and the opportunity to implement a corrective action plan. Only after repeated problems and CMS directly notifying physicians, well in advance that the vendor is on probation would we support termination. Physicians must have ample opportunity ahead of a new performance period to research alternative submission mechanisms and vendors. If the termination occurs mid-performance period, CMS must also ensure it does not penalize a physician for a third-party intermediary compliance issue.

We also urge CMS to put in place a safe harbor policy for instances when a data issue occurs due to a third-party intermediary issue. Physicians should not be on the hook for a vendor problem that is

outside of the physician’s control. Therefore, if a data deficiency occurs due to a third-party, CMS should automatically consider the physician or group as satisfactorily satisfying the quality category. We envision with the 2019 performance period there might be a systemic problem with electronic data due to the transition and upgrade to 2015 CEHRT. We remind CMS that when practices had to upgrade to 2014 CEHRT in 2014 there were universal problems with eCQM and registry data and CMS had to deem the data unusable and consider all PQRS reporters as successful for purposes of the 2016 PQRS and Value Modifier payment adjustments.

We are aware of physician’s ability to submit a hardship exemption due to CEHRT upgrade issues, but the hardship does not transfer to quality and in fact CMS re-weights the PI category weight to the quality category—essentially doubling down on the quality category when physicians may already be at risk with data integrity issues due to EHR problems. Therefore, we are severely concerned that CMS has not proposed or put in place some sort of assurance or safe harbor policy related to CEHRT quality issues. To mitigate the issue and handle in the least burdensome way, **we recommend that if a physician files a CEHRT hardship and a quality issue occurs, they should be considered as successfully meeting the performance threshold.** Physicians should not be on the hook for having to file a Targeted Review. At a minimum, the CEHRT hardship exemption should also inquire about electronic quality measure issues as a way for CMS to preliminarily understand the problem. We welcome the opportunity to discuss this further with CMS and develop a proactive solution.

xiii. Public Reporting on Physician Compare

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; however, we are concerned with CMS’ direction due to the lack of consideration of MIPS program policies and methodologies and intersection with Physician Compare, as well as 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 the quality of care physicians provide. MIPS involve 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 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 *v. Quality, Quality Reporting, Requirements and Submission Criteria—Benchmark Methodology* section and Appendix C. *MPFS 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 measure score:** Under MIPS, a physician may report measures through multiple submission mechanisms or report more than the required number of measures. For purposes of avoiding a penalty CMS only considers the most successful method and measures. However, under Physician Compare, as long as a physician successfully satisfies MIPS quality reporting requirements, ALL data, regardless of whether the data was used to calculate the physician’s score, is publicly posted and included in the downloadable database.
- **Individual vs. Group Reporting:** Under MIPS, CMS calculates separate benchmarks and scores based on each reporting mechanism (claims, EHR, registry, QCDR and web-interface) and combines individual and GPRO data to calculate the benchmark and score. However, under Physician Compare, CMS calculates and displays separate scores for measures reported as an individual and measures reported as a group.
- **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 measure 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.” The AMA agrees a 50-point standard for measuring success in PI provides useful information to patients and caregivers without burdening individuals—including physicians. This concept also aligns with our recommendation (see our comments in the PI section of this letter) that physicians be deemed as successfully meeting PI requirements by scoring 50 points or more in their performance. Similarly, CMS should refrain from including EHR utilization performance information in Physician Compare. As we outlined earlier in this letter, EHR utilization performance is largely dependent on an EHR’s functionality—or lack thereof. For instance, physicians have next to no control over their EHR’s ability to interoperate, and including Health Information Exchange measure or objective performance in Physician Compare could provide patients false, incomplete, or information lacking context. We stress that checking a box on a computer screen does not constitute information exchange. Rather, it 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 their control.

The inconsistencies highlighted and demonstrated in our analysis outlined in Appendix C. *MPFS MIPS Benchmark White Paper* could result in physician frustration and further dissatisfaction, and ultimately lead to a lack of confidence in the MIPS program. Further, 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:** The AMA has repeatedly urged CMS to extend the preview period from 30-days to 90-days, in order for physicians to review and ensure the accuracy of their information. To expect physicians to access, review, and contest their Physician Compare data in 30-days ignores the demands of patient care and competing priorities physicians face on a daily basis. **The AMA urges CMS to extend the preview period to at least 90-days to allow physicians reasonable time to review and correct their data.** 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. As AMA has stated in previous comment letters, 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:** CMS has proposed to not publicly report first year quality measure for the first two years a measure is in use. The AMA is supportive of this change because previously CMS finalized that it would not report first year measures that have been in use for less than one year. However, as we have advocated previously, the AMA continues to urge CMS to expand this exclusion to measures that have been in use for less 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.

xiv. Proposed Alternative Payment Model (APM) Policies for 2019

The AMA greatly appreciates several of the proposed APM policies for 2019, which directly respond to recommendations made by the AMA in previous comment letters, and we urge CMS to finalize them:

1. the proposal to maintain the revenue-based financial risk requirement for Advanced APMs at no more than eight percent of revenues for an additional four years, from 2021 through 2024, which is consistent with AMA recommendations not to require APM participants to take increased financial risk in order to qualify as Advanced APMs;
2. the proposal to allow participants in Other Payer APMs to describe their compliance with requirements that APM physicians use certified electronic health record technology (CEHRT) instead of the policy previously outlined that would have mandated that APM payment contracts explicitly require use of CEHRT, which AMA had recommended;
3. the proposal to certify Other Payer APMs as meeting CMS APM requirements for up to five years—the AMA had recommended that CMS allow Other Payer APMs to be certified for multiple years instead of having to re-apply annually; and

4. the proposal to waive requirements for MIPS reporting and MIPS payment adjustments for physicians participating in Medicare Advantage APMs, effective in 2018, whether or not the physician also participates in APMs for Medicare fee-for-service patients, which is consistent with AMA recommendations to help physicians who practice in areas with an above-average proportion of Medicare patients in MA plans.

In addition to the above policies, the AMA welcomes several other APM policies and clarifications proposed in the 2019 rule. We support the CMS proposal to add a third option to assess whether physicians have met the All-Payer threshold for Qualified APM Participants at the practice level, based on their TIN, in addition to the individual level and the APM entity level. The AMA also appreciates the clarification that APM participants can meet Medicare and Other Payer participation thresholds using patient counts for one threshold and payment counts for the other threshold, whichever method is most advantageous to the physician. In addition, we thank the agency for making a technical correction to the regulations clarifying that Other Payer APM entities are required to bear financial risk for a minimum of three percent of expected expenditures, not four percent. Finally, while we support the new MA APM demonstration program, the AMA requests that CMS provide more information about the APMs that have been implemented by MA plans.

Use of CEHRT in APMs

In 2019 for Medicare APMs and 2020 for Other Payer APMs, CMS proposes to increase from 50 to 75 the percentage of an APM's participating physicians that will be required to use CEHRT in order for the APM to qualify as an Advanced APM. **The AMA recommends that new CEHRT requirements for Medicare APMs be deferred to 2020 like Other Payer APMs.** There is already a requirement to upgrade to 2015 edition CEHRT in 2019; physicians participating in APMs should not face too many new health information technology (health IT) requirements in a single year.

We also recommend that CMS take a different approach to assessing APMs' use of health IT to coordinate and improve patient care. CEHRT has come to be widely viewed as a tool for documenting, reporting and billing instead of as a tool for improving clinical care, coordination, and patient engagement. Furthermore, CEHRT is identified as contributing to physician burden and burnout (see, for example: <https://www.sciencedirect.com/science/article/pii/S0025619616302154> and <http://annals.org/aim/fullarticle/2546704>; <http://www.annfamned.org/content/15/5/419.short>).

To be successful in APMs, the AMA believes physicians need health IT that responds to and supports physician, patient, and care team interactions, not merely CEHRT. Instead of requiring that 75 percent of APM participants use CEHRT, **CMS should retain the current 50 percent requirement and allow APM entities to attest that an additional percentage of APM participants are either using CEHRT or using health IT that "builds on" or is an extension of CEHRT, such as plug-and-play modules, to achieve the specific goals of the APM.** Health IT that builds on or is an extension of CEHRT is a concept taken directly from CMS' priorities in its call for new PI measures. For instance, in addition to using certified EHRs, APMs would be able to attest to using customized messaging or care coordination technology developed for the unique needs of the patients in that APM. This approach balances the importance of using CEHRT while rewarding APMs for using innovative technology that meets physician and patient needs. This approach will also encourage significant improvements in technology to be developed that would lessen the burden on physicians. CMS needs to encourage health IT developers to

listen to APM participants and learn what they need to enter, retrieve, exchange, and analyze data, instead of developing technology that is only as advanced as the federal government requires.

The AMA is also concerned that physicians, including physicians participating in APMs, have little to no control over their EHR's ability to help achieve the APM's goals. Health IT companies frequently charge fees for each and every requirement imposed by federal reporting programs. Vendors need to be held accountable for producing tools to advance care outcomes without burdening physician practices or APMs with exorbitant fees and lack of usability.

Need for a More Robust APM Pathway

The AMA has significant concerns that as we enter the third QPP performance year, participation in APMs is still not a viable option for the majority of physicians. There is no national primary care medical home model, only about a quarter of the oncology practices who planned to participate in the Oncology Care Model became participants, the future of the Medicare Shared Savings Program is uncertain, just 10 percent of nephrologists participate in the Comprehensive End-Stage Renal Disease Care Model and, to date, none of the stakeholder models recommended to the Secretary by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) is being tested. Better APMs are needed that would address problems in the fee-for-service (FFS) payment system and correct important weaknesses in the current CMS models. Many specialty societies have been working to develop such APMs, and they need support from CMS to put them into operation.

APMs need to address key FFS barriers, such as lack of payment for many high-value services, including development of treatment plans, use of nurses to provide patient education about self-management of patients' conditions, intravenous hydration in the physician's office rather than in an emergency department, hospitalization at home, providing transportation to the physician's office rather than an emergency department, and palliative care for patients with advanced illnesses. These types of services, when used in the appropriate circumstances, could reduce total Medicare spending, but practices incur financial losses delivering them under FFS. Also, current FFS payment rates often are not high enough to cover the additional time needed to apply evidence-based guidelines and engage in a shared-decision making process with patients and other health professionals to ensure diagnostic accuracy and effective treatment plans. The more time physicians spend with an individual patient, the fewer patients they can see, so even though the additional time may result in more conservative care and Medicare savings, medical practices can lose money. Physicians and medical societies also lack access to timely, actionable data. Even when a practice or specialty thinks it knows how to save money on patient care through an APM, they do not have the data to make the business case for redesigning care delivery. They cannot justify hiring people to contact patients between visits, take after-hours calls, and coordinate with other providers without data showing the return on the investment. Most of the current Medicare APMs provide bonuses or penalties without changing the underlying FFS system, and the financial penalties physicians can face from changing care delivery under FFS often outweigh the available APM incentives.

In addition to addressing the barriers in the FFS system, new APMs need to be put in place that will improve problematic aspects of the current CMS models. For example, even though CMS now recognizes that MIPS adjustments should only apply to physician services, APM financial risk rules still require physicians to take risk for the price of drugs and other cost factors that are beyond their control. In addition, CMS definitions of risk fail to take into account start-up costs and operating expenses, nor has CMS adopted the AMA's previous recommendation to establish lower APM financial risk

requirements—below the eight percent standard—for small and rural physician practices. Lack of good risk adjustment models hurts practices with more complex patients and patients who have poor functional status or lack caregiver support at home. CMS attribution methods limit patients’ access to the benefits of APMs and they keep physicians guessing which of their patients are in APMs and uncertain as to which patients are eligible for available waivers of Medicare rules like the three-day inpatient stay preceding a covered skilled nursing facility stay.

We encourage CMS to again review our previous comment letters and consider how the physician community and the agency can better collaborate to improve the availability of APMs, the number of physicians participating in them, and the number of Medicare patients receiving care through APMs. The AMA and the physician community stand ready to assist CMS in any way we can to establish a more robust APM pathway under the QPP.

E. Other Issues

i. Medicare Diabetes Prevention Program (MDPP)

The AMA strongly urges CMS to launch a demonstration to test a virtual Medicare Diabetes Prevention Program (MDPP). There are a number of clinical studies that evidence the clinical efficacy of virtual DPP including in cohorts similar to the Medicare beneficiary demographic, but a demonstration will provide CMS with a rich source of data to address a number of key questions raised by the Agency. In short, CMS will be able to assess whether such services are cost savings or cost neutral while also ensuring a number of measures are tested to ensure program integrity. The AMA welcomes the opportunity to work with CMS to advance this important effort to expand access, particularly to rural areas that lack access to in-person MDPP.

The AMA has carefully considered a number of key questions raised by policymakers when evaluating whether coverage of virtual MDPP is warranted. These questions have centered largely on program integrity—as opposed to efficacy. As a threshold matter, the primary program integrity issues raised concerning virtual DPP are the same whether the service is delivered through a virtual modality or in-person programs including whether a payment claim is filed for a Medicare beneficiary and the services were actually rendered. Virtual MDPP program integrity can be optimized in a well-established and straightforward manner. Specifically, in most cases the same controls utilized to protect against breaches in program integrity for in-person services would apply to virtual programs. And, there are a number of possible options for leveraging the electronic footprint and automated signatures of virtual programs to enhance program integrity.

The following are examples of either existing measures already deployed by virtual DPP providers to optimize program integrity, while others are possible measures that the AMA would welcome working with CMS and virtual DPP providers to initiate a demonstration.

First-time non-providers participating in the MDPP. The program integrity issues surrounding first-time non-providers are the same whether the service is in-person or virtual. The DPP provider that hires the non-providers (coaches) must have proper internal controls surrounding screening and identification, authentication, and authorization protocols for access to any web-based portal. Compared to existing programs where non-providers participate (e.g., home health, personal care), virtual MDPP would be better equipped to identify program integrity issues because (1) more data is available to digitally track

the activities of non-providers and their interactions with beneficiaries; (2) when provided user identifications for log ins, organizations and federal oversight entities will know which individual virtual MDPP non-provider interacted with a beneficiary (which is different than some state's personal care service programs); and, (3) being virtual in nature, physical patient harm and abuse (can be captured due to digitization and quantified).

Shared monitoring (including coaches that are not medical staff) and how can it be verified. Monitoring can be verified through data that is captured by the system including log-ins, time stamps, what information is viewed, and communication between individuals with shared monitoring responsibilities.

Coach-to-beneficiary ratio. If CMS were to test coach-to-beneficiary ratio, this would allow an assessment of efficacy and savings. A coach-to-beneficiary ratio should be evidence-based and a demonstration would provide valuable information to assess this issue. It is notable that provider-to-beneficiary ratios exist in some state Medicaid programs for home health/personal care or for service definitions in Medicaid regarding group therapy that is tied to a certain provider-to-beneficiary ratio. Coach-to-beneficiary ratio would create a data point to identify aberrant ratios through data analytics for further follow-up and investigation.

Response times to beneficiary questions. Virtual MDPP could be as good as or even better than in-person MDPP because response time to beneficiary questions can be tracked, logged, and made immutable. In the digital world, the beneficiary's and provider's computers must communicate by passing data and information to each other (e.g., header, packet information). This "background" data is generally made outside the control or knowledge of the parties and can be captured and monitored by the virtual MDPP entity. Furthermore, the system can be set up to record time-stamps for when a lesson starts, progression or interaction, log-ins, weigh-ins, meals, and messaging with an individual and coach.

Weight verification and measuring outcomes. Weight loss can be verified through recorded, time-stamped weigh-ins. Each scale that is issued is calibrated to each beneficiary so all weights are measured accurately and uniformly. The scale itself is web-linked to prevent error and bias in self-reporting of manual entry. The scale is pre-assigned to each participant's identification to accurately attribute all weigh-ins. The weight data itself will be logged frequently from the home scale to build a true picture of progress. In a demonstration, CMS could consider additional measures to test in a demonstration including (1) an initial in-person weigh-in either virtually with a MDPP coach or in-person; (2) an individual could use video capture or a store and forward photograph with weigh-in; or (3) other use of other technologically enabled modalities.

Medically unlikely edits. CMS is also able to test the utilization of medically unlikely edits (MUE).

In sum, there are a number of options for structuring a demonstration for virtual DPP that is designed to address the key question of whether services are cost saving or cost neutral and allow CMS to assess various program integrity measures. The AMA welcomes working with CMS on this important effort.

ii. Improving Utilization of Chronic Care Management (CCM) Services

To improve utilization of CCM services by Medicare patients, the AMA recommends that CMS eliminate the cost-sharing requirements for these services. Although utilization of CCM has been increasing in recent years, patient cost-sharing remains a barrier. Trying to promote participation in a care

management program to patients, and then having to talk about patients' cost-sharing obligations, puts physicians in an uncomfortable position. To make matters worse, for those enrolled in Medicare Advantage, the costs to the patient can be prohibitive. Because these patients often have high deductibles, they can end up paying the full cost of the program. As a result, patients are reluctant to consent to participate in CCM, and if they do, they frequently complain about the cost. These concerns often lead to them withdrawing from the program.

iii. Adaptive Behavioral Assessment Services

For 2019, the CPT Editorial Panel approved a comprehensive set of new Adaptive Behavior Assessment and Treatment codes. These eight new codes and revisions to two existing Category III codes represent a large change for the providers of these services and the AMA was disappointed that CMS failed to neither list the new codes in Addendum B nor discuss the codes at all in the text of the Proposed Rule. This has led to considerable confusion within the provider community, as to the intentions of CMS are unclear. We understand that the RUC did not submit specific recommendations on these family of services, but in the past the Agency has at the very least published the codes in Addendum B, so that providers are notified of the codes. **The AMA recommends that CMS publish the following adaptive behavior assessment and treatment codes in Addendum B of the Medicare Final Rule as well as clearly state their coverage intentions for these services for 2019.**

- 97X51 Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face, analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan.
- 97X52 Behavior identification supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face, with the patient, each 15 minutes.
- 97X53 Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes.
- 97X54 Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes.
- 97X55 Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face, with one patient, each 15 minutes.
- 97X56 Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes.
- 97X57 Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes.
- 97X58 Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes.

- 0362T Behavior identification supporting assessment, each 15 minutes of technician’s time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient’s behavior.
- 0373T Adaptive behavior treatment with protocol modification, each 15 minutes of technician’s time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient’s behavior.

III. Request for Information (RFI)

A. Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare and Medicaid Participating Providers and Suppliers

CMS requests comments on how it could use the CMS health and safety standards required for providers and suppliers participating in Medicare and Medicaid (i.e., Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to “further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers.”

CMS notes that it might consider revisions to CoPs for hospitals such as: “requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.”

In general, we do not believe that a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information is necessary in the context of other current and forthcoming policies. We are concerned that compliance fears and costs associated with new standards could hinder investments and actions to enhance interoperable data exchange. Further, health care stakeholders have not had sufficient time to evaluate the impact of forthcoming regulations and enforcement around information blocking, the impact of the PI program, and the operations of TEFCA and U.S. Core Data for Interoperability (USCDI)—each of which will affect interoperability going forward.

Alternatively, we strongly suggest CMS examine fundamental issues that continue to hinder interoperability and identify the appropriate methods to address these issues. This concept is further explored below. CMS should address priority elements of health information exchange and consider actions to promote the electronic availability of pertinent clinical information, rather than focusing on pure “data exchange.”

Clear Regulatory Goals

Evolving health IT and sources of data have become central components of managing patient care and have the potential to enhance and refine physicians' understanding of patient health. Patient information, including social determinants of health and genomic data, will further add digital definition to patients' stories. We also expect the expansion of consumer health applications to add patient generated health data to the already complex domain of clinical data—offering new methods for patients to engage with their physicians.

However, systems today are unable to reliably and completely capture and exchange clinically meaningful and essential information. Despite the large amounts of health data being gathered today, it is not always meaningful, organized, or structured in a way that can easily be used, accessed, or shared by people and systems. Health care data is fragmented, incomplete, incompatible, and often not in forms easy to exchange and aggregate. Furthermore, critical information on patient function, status, goals, social determinants of health, as well as patient and device-generated data is often inaccessible by clinicians and health systems. Current technical standards mostly specify how to exchange data, not what the right information to exchange is, and physician data entry burden is increasing to the point of becoming unsustainable.⁵²

While industry adoption of EHRs has increased, the amount of health data captured and the expectation that EHR adoption would transform health care has failed to materialize. This is due to the fact that federal regulations have driven EHR design and use. CMS and ONC have historically focused their regulatory policy on measuring a physician's use of technology. To date, this approach has heavily influenced EHR development by focusing EHR design on documentation, reporting and regulatory compliance. Due to the misplaced emphasis on data capture and reporting, rather than data exchange, most patient health information is still “locked” inside the physician's office—only today it is in an EHR rather than a paper chart. Physicians and patients alike are eager to remove barriers that block access and exchange of EHR health information.

The AMA is encouraged that CMS is refocusing its efforts on promoting interoperability and access to information. **To ensure this momentum does not stall, the AMA urges CMS to further leverage appropriate regulation that advances outcomes and goals.** Rather than simply requiring data to be exchanged, CMS should eliminate regulation that drives health IT development and use, and instead focus on regulation that emphasizes patient care goals and the availability of the pertinent data to support those goals. **For instance, CMS should establish a focused interoperability strategy with the goal of clinical necessity, rather than exchanging data simply for reporting requirements.** We further recommend that this approach examine the burden of data collection and aspire to return time back to physicians to provide patient care. This course correction is necessary to reduce physician burden and to improve the quality of data for both physicians and patients.

⁵² Sinsky, Christine A. et al, Professional Satisfaction and the Career Plans of US Physicians. Mayo Clinic Proceedings, Volume 92, Issue 11, 1625-1635

Information Blocking

Both the AMA's and ONC's own report to Congress have identified that health IT vendors engage in information blocking—activities interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.⁵³ The AMA has received numerous complaints from physicians of health IT vendors blocking information through financial, technical, and contractual means. Through the QPP, CMS already requires physicians to attest they will not engage in information blocking activities. However, to resolve information blocking problems, vendors must be held accountable as well.

While we understand that HHS' Office of Inspector General (OIG) and ONC are developing rulemaking to implement information blocking requirements, EHR vendors continue to create barriers to access patient information. These barriers interfere with and materially discourage physician and patient access to information. Our members report that some EHR vendors refuse to enter into negotiations for the transfer of patient information to clinical data registries. While some EHR vendors have negotiated with physicians and third-party software companies, other EHR vendors tack on large fees to send data from the EHR to clinical data registries or to even connect to a health information exchange (HIE). For instance, Cerner and Epic charge fees of \$30,000 and \$20,000 (respectively) for sending data abstraction from their EHR to clinical data registries, and Allscripts charges \$1,000 to \$1,500 per clinician for reporting under the MIPS Program.⁵⁴ We are also aware of vendors requiring physicians to purchase intermediary software systems, owned by the EHR vendor, just to enable data exchange. While certified EHR vendors are required to acknowledge the existence of fees, they are not required to publish the actual dollar amount, or even list a range of costs. In the spirit of transparency, and to better inform health IT consumers, we urge CMS and ONC to establish a method to collect, list, and publicize actual fees EHR vendors charge customers. **In addition, CMS should use this information to make publicly available the real-world cost estimations for physicians and hospitals to participate in all EHR-related reporting programs' measures and objectives.**

Additionally, we foresee information blocking becoming a major obstacle in the newly emerging area of EHR applications (apps). ONC's 2015 Edition Certification Final Rule and the 21st Century Cures Act contemplate the importance of application programming interfaces (API) and their potential to empower both physicians and patients with access to data using apps. Many emerging apps are based on SMART (Substitutable Medical Apps & Reusable Technology), an open, standards-based technology platform that enables innovators to create apps that seamlessly and securely run across the health care system. SMART apps based on the FHIR (Fast Healthcare Interoperability Resources) standards framework are designed to be interoperable across EHRs and easily installed or removed. However to realize the full potential of APIs and apps, EHR vendors must configure their software to use the same version of the FHIR standard. When vendors use slightly different versions of technical standards, or tweak standards to make them unique, interoperability breaks.

⁵³ Office of the National Coordinator for Health Information Technology, Report to Congress: Report on Health Information Blocking, Washington, DC: Department of Health and Human Services, (April 2015), Available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf, Accessed June 2018.

⁵⁴ Letter from the Physician Clinical Registry Coalition to James A. Cannatti III, J.D., Senior Counselor for Health Information Technology, Office of Inspector General, U.S. Department of Health and Human Services, Kathryn Marchesini, J.D., Chief Privacy Officer Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, (February 8, 2018), Available at <https://www.registrycoalition.net/wp-content/uploads/2018/02/PCRC-Letter-re-Information-Blocking-by-Electronic-Health-Record-Vendors-D0765240-2.pdf>, Accessed June 2018.

Essentially, “fitting a round peg into a slightly round hole” allows vendors to assert they are conforming to a standard while still stretching the standard’s flexibility to fit their own business needs—effectively curbing data access, use, and exchange. The AMA is concerned that, without the appropriate transparency, testing, and assurances, EHR vendors will extend current interoperability issues into their next generation products. While we recognize CMS has limited influence on EHR vendor conformance to standards, we believe this issue will negatively impact the potential benefits of API-enabled EHRs. Furthermore, clinicians have little influence or capability to fix these interoperability issues and should not be held liable for issues outside their control. **Therefore, we urge CMS to establish “hold harmless” exceptions for physicians and hospitals when EHRs are suspected of or found to be information blockers. This should include instances when EHR vendors knowingly and willfully introduce uniqueness in their API development that is found to detract from, rather than improve, patient and physician access to data.**

Access to All Relevant Information Without Burden

In order to promote interoperability, CMS needs to prioritize patient and physician access to data and help ensure that the data is consistent, understandable, and usable. **Therefore, AMA recommends that CMS establish a plan with proper stakeholder feedback to focus interoperability efforts on promoting data consistency and access.**

Data Access

Patients and physicians need access to all relevant patient information to support wellness and high quality care. While studies have evaluated EHR usability issues, research has primarily focused on the burden of entering data or documenting information in the EHR.^{55, 56} A physician or hospital’s inability to pull information out of an EHR or to extract entire medical records, caused by vendor claims of data ownership, business interests, or technical limitations, is also a major impediment to data access.⁵⁷

EHRs often contain most of the information that makes up a patient’s electronic medical record, yet accessing a complete record—particularly from the patient’s point of view—is overly complicated. The HIPAA privacy rule defines the designated record set as a group of patient medical and billing records maintained by or for a covered entity—which may include enrollment, payment, claims, adjudication, and any additional information used in whole or in part to make care-related decisions. The digitization of medical records should have reduced the friction of collecting and organizing this data. From a practical sense, EHRs and health IT should ultimately provide secure electronic access and use of the designated record set in order to facilitate each patient’s longitudinal health record. The 21st Century Cures Act reinforces this concept.⁵⁸

However, many EHRs only provide a subset of this information—limiting access and exchange of the patient’s designated record set. Health IT vendors can provide data beyond the required minimum, but

⁵⁵ Arndt B, Beasley J, Watkinson M, Temte J, Tuan W, Sinsky C, Gilchrist V, Annals Journal Club: Tethered to the EHR: Primary Care Physician Workload Assessment Using EHR Event Log Data and Time-Motion Observations *Ann Fam Med* September/October 2017, 15:419-426; doi:10.1370/afm.2121

⁵⁶ Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, et al, Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties, *Ann Intern Med*, 2016;165:753–760. doi: 10.7326/M16-0961

⁵⁷ AMA Board of Trustees Report 11-A-16. Principles for Hospital Sponsored Electronic Health Records (Resolution 825-I-14), (Nov. 2015), Available at <https://www.ama-assn.org/sites/default/files/media-browser/public/hod/i15-bot-reports.pdf>, Accessed June 2018.

⁵⁸ 21st Century Cures Act, H.R. 34, 114th Cong. (2015).

have historically not gone above and beyond ONC certification requirements. Today, the data that is “exposed” by an EHR is often a subset of what most would consider a complete medical record. For example, the CCDS is a grouping of 20 data classes that is meant to act as a “floor” of data for certified EHRs. Yet, ONC has identified at least 50 additional data classes that should be made available electronically.⁵⁹

The AMA views the discrepancy between what is legally required, (i.e., the designated record set) versus what EHRs provide (i.e., the CCDS, as having major implications for health care). First, lack of access to the full record limits the physician’s ability to see a complete picture of their patient’s story, reduces their ability to use supportive health IT tools (e.g. clinical decision support systems), and contributes to physician burden by requiring re-documentation for quality measurement, reporting, or clinical registry reporting. Additionally, there are growing concerns that physicians may be held accountable or considered “data blockers” if patients cannot access their entire designated record set via new features like APIs and apps of their choice.

Patients are also disadvantaged by this inconsistency. While many stakeholders (including the AMA) have expressed support for APIs in the 2015 Edition EHRs, we are concerned that, in practice, many updated and new EHRs will overwhelm patients. We foresee issues where APIs will only provide access to a curtailed medical record, or provide access to more information only if using specific applications favored by the health IT vendor. Furthermore, we also question what—if any—efforts are underway to educate patients about the security, privacy, and usability of this data.

Data Consistency

Importantly, not only should a complete record be accessible, but also the data contained therein must also be consistent, understandable, and usable. For this to occur, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, the translation from data to knowledge can only occur if the meaning of data is consistent. However, levels of semantic interoperability vary greatly in the health care system. Physicians agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care.⁶⁰ As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the less useful it is to physicians and patients.

This leads to another piece of the interoperability puzzle that the industry must address: data mapping. Mapping is needed so transmitted data can be used by the receiving EHR rather than just viewed. For example, if a patient has a problem identified as “hypertension,” a simple interface can move this text to another system where it can be viewed. However, to be useful in automated alerts and care planning, mapping must translate this information so that it has the same “meaning” in the receiving system. To create the appropriate meaning, the “hypertension” text typically must be put into the correct part of the receiving EHR’s database so that EHR “knows” the patient has this condition. Additionally, problems like hypertension often are comprised of many different attributes, all of which should be captured, stored and transmitted in a common format. While this example may seem simple, the proprietary nature of

⁵⁹ The Office of the National Coordinator for Health Information Technology, Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process, (Jan. 2018), Available at <https://www.healthit.gov/sites/default/files/draft-uscdi.pdf>. Accessed June 2018.

⁶⁰ Stanford Medical, How Doctors Feel About Electronic Health Records National Physician Poll by The Harris Poll, (June 2018), Available at <http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-Poll-Presentation.pdf>. Accessed June 2018.

EHRs, and the lack of an agreed upon medical data model, makes this difficult—even with the increased use of standardized codes.

Furthermore, EHRs typically do not identify components of the office note in the same manner. For instance, when a physician sees a note drafted in a Cerner EHR shown in an Epic EHR the information gets rearranged, misconstrued, or lost. This is because information stored in Cerner's terminologies and logic is not machine-readable by Epic's technology. For the information to interoperate between the two systems, the information must be translated into a standard terminology while, at the same time, preserving all the exchanged information's content and context. Providers spend hours documenting and searching for needed information when they lack access to interoperable and usable digital information.

To address this issue, the AMA has launched the Integrated Health Model Initiative (IHMI). The IHMI is a digital platform for stakeholder collaboration and clinical review to build a unified data model to organize data in an interoperable fashion. Utilizing the IHMI, different computer systems will be able to exchange data with unambiguous, shared meaning and be fully comprehensive across systems and clinical environments—enabling a true longitudinal patient health record independent of the data's originating source.

The IHMI will also support improvements in quality measurement. Currently, EHRs do not uniformly calculate eQOMs across different vendors and practices due to the lack of specificity within the ONC's CEHRT program. Incorporation of data requires the development, maintenance, and refinement of administrative code sets such as the ICD, Current Procedural Terminology[®] and clinical vocabulary standards such as SNOMED Clinical Terms,[®] Logical Observation Names and Codes[®] (LOINC), and RxNorm. Creating standards and mapping tools will facilitate working across these different codes and ensure consistency when data is exchanged. The AMA, through its IHMI, is participating in activities to support ontological structures that will provide pathways for better data collection and analytics.

We recognize that CMS alone cannot incentivize the health IT market to expose or standardize information. However, more needs to be done to increase access to all appropriate medical information—for both patients and physicians. Access to granular data that is available, consistent, and retains the same meaning is a crucial element in improving health and lowering costs—and is ultimately the foundation of interoperability. This will require a coordinated approach involving clear objectives with a singular focus, planning and prioritization. **The AMA strongly recommends that CMS establish a plan, in conjunction with stakeholders and other federal agencies, to focus interoperability efforts on promoting data consistency and access. This must include balancing policy goals with a sensible timeline. CMS should align future reporting programs around clinically led efforts—like the IHMI—that aim to advance terminologies, data elements, coding, and common data models to promote interoperability.**

Health Data Cybersecurity

The AMA is deeply concerned that our nation's health care providers and patients have been insufficiently prepared to meet the cybersecurity challenges of an increasingly digital health care system. Cybersecurity is a national priority and physicians, other health care providers, and patients need tools to secure sensitive patient information in the digital sphere. As clinical adoption of digital medicine tools accelerates with new innovations, and in light of increased public and commercial insurer coverage of

digital medicine tools and services, there is increased urgency to advance policies that remedy vulnerabilities in cybersecurity.

The health care community must recognize that cybersecurity is not only a technical issue, but also a patient safety issue. The AMA recently completed a first of its kind cybersecurity survey of 1,300 physicians.⁶¹ The top three cybersecurity concerns that physicians identified were interruption to EHR access, EHR security (including compromised patient data), and general patient safety concerns. This survey underscores the importance of considering the potential harm to patients and interruption to their care when making the cost-benefit analysis of data security, privacy, and interoperability.

Physician practices spend a substantial amount of money on cybersecurity. For example, as noted in the AMA's cybersecurity study's qualitative review, a nine-physician practice spent \$250,000 per year and a 50+ physician regional medical center spent \$440,000 per year. We further note that only one in five small physician practices have an in-house security official. Thus, small practices need extra help in navigating cybersecurity challenges to help them prepare for cyber attacks and ensure patient data remains confidential as it is exchanged. **CMS must consider the added complex interplay of agency policies and their impact on physicians and interoperability.** For instance, the OCR, the OIG, ONC, and the Food and Drug Administration have differing perspectives on and authority over security.⁶² Absent alignment across the federal government on these issues, health IT developers, health systems, and physicians will increasingly encounter conflicting guidance, which stymies innovation and adoption.

Finally, cybersecurity impacts the entire health care ecosystem. Technology has increased connectivity and collaboration in all facets of the health care delivery system. Indeed, the AMA's cybersecurity survey shows that 85 percent of physicians believe it is "very" or "extremely" important to share data to provide efficient, quality care but are concerned about how to share it securely. This integration is increasingly important as the industry moves towards value-based care and provides more care outside the four walls of a brick-and-mortar health care practice.

The AMA encourages CMS to reframe its view of data security from punitive requirements to an opportunity for positive incentives to encourage cybersecurity activities that will protect practice continuity and patient information. **We strongly urge CMS to introduce positive incentives in Medicare programs that promote good cyber hygiene.** For example, the AMA has recommended that CMS adopt Improvement Activities in the QPP related to good cyber hygiene.

Additionally, the AMA recently requested that the OIG create an anti-kickback safe harbor and CMS create a Stark exception that allows for the sharing of cybersecurity items and services with detailed suggestions into the structure of a potential safe harbor, including definitions, scope, donors, recipients, value of technology, and appropriate safeguards similar to the current EHR safe harbor and Stark exception.⁶³ Overall, the AMA stresses that any cybersecurity anti-kickback safe harbor or Stark exception be easy to understand, interpret, and enforce so that donors and recipients can readily

⁶¹ AMA, *Medical Cybersecurity: A Patient Safety Issue*, (Dec. 2017), Available at <https://www.ama-assn.org/about/medical-cybersecurity-patient-safety-issue>, Accessed June 2018.

⁶² Letter from the Hon. Greg Walden, Hon. Frank Pallone Jr., H. Comm. on Energy and Commerce, Hon. Patty Murray S. Hon. Lamar Alexander, S. Comm. on Health, Education, Labor, and Pensions to The Hon. Alex Azar Sec'y US Dep't of Health and Human Services, (June 5, 2018), Available at <https://energycommerce.house.gov/wp-content/uploads/2018/06/20180605HHS.pdf>, Accessed June 2018.

⁶³ AMA, *Letter to OIG in Response to Solicitation of Safe Harbors*, (Feb. 2018), Available at <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-2-26-Letter-to-Levinson-re-Draft-OIG-Annual-Solicitation.pdf>, Accessed June 2018; AMA, *Letter to CMS in Response to Stark RFI* (Aug. 2018).

distinguish permissible activities from those that violate the Anti-Kickback Statute. This concept is reflected in the HHS Cybersecurity Task Force Report Recommendation 1.5, which “strongly encourage[s] Congress to evaluate an amendment to [the Stark Law and Anti-Kickback Statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy.”⁶⁴ While OIG has the regulatory authority to create an anti-kickback safe harbor, CMS must show no program or patient abuse in creating Stark exceptions. We understand this Stark standard is difficult for CMS to meet and has caused other proposed regulatory Stark exceptions to fail. **Thus, we urge CMS to consider methods similar to those that allowed for an EHR Stark exception-to extend their legislative interpretation to include cybersecurity services and technology or to amend the definition of remuneration to exclude the sharing of cybersecurity items and services.**

B. Price Transparency: Improving Beneficiary Access to Providers and Supplier Charge Information

The AMA appreciates the opportunity to provide feedback to CMS in response to its request for information regarding price transparency to empower patients, improve the quality of care and lower health care costs. The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients are increasingly becoming active consumers of health care services. Achieving meaningful price transparency can help lower health care costs and empower patients to make informed care decisions. The AMA supports efforts to ensure price transparency, but recognizes that providing meaningful price and cost information to patients in the current environment is challenging.

Charge Information Versus Out-of-Pocket Cost Information

When it comes to information regarding the costs of health care services and procedures, patients are most concerned with what their financial responsibility will be. In other words, patients want to know their out-of-pocket costs for a given office visit or procedure. Charge, or list price, information may play a limited role in greater price transparency because the true out-of-pocket cost varies vastly from cash price because of the complexity of third-party payers including discounted fees, negotiated rates, use of in-network providers, deductibles, and co-payments. Even self-paying patients may have a different out-of-pocket cost from the cash price because the patient may receive charity care or prompt pay discounts. Patients with health insurance rarely pay the physician’s listed charge for services—they pay a pre-determined portion of the rates that their physician has negotiated with their health plan, or in the case of Medicare, the price Medicare pays as listed on the fee schedule for that service adjusted to reflect the variation in practice costs based on geographic area. For patients with insurance, the most relevant data is what portion of those payment rates for which they will be responsible, including any co-payment, co-insurance, or deductible amount. This information is the most likely information to impact treatment decisions by cost-sensitive patients.

Self-paying patients, however, pay directly for their medical services, and typically will not have access to the discounted fees of insurers for in-network physicians, hospitals and other providers. Alternatively, they pay the “cash price” for their respective medical service or prescription drug. Self-paying patients can seek the “cash prices” from their respective providers and pharmacies. Providers can communicate

⁶⁴ Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry* (June 2017), Available at <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>. Accessed June 2018.

such information to individual patients, and hospitals can be encouraged to adopt, implement, monitor and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make access to those programs readily available to patients.

Role of Providers, Suppliers, and Payors in Providing Cost Meaningful Cost Information

Providers, suppliers, and payors all have an important role to play to enabling patients to best use charge and cost information in health care decision making. **Payors, in fact, play the most important role in helping patients understand and use cost information.** As mentioned above, the most critical data point to patients is their out-of-pocket costs, and payors are best positioned to easily provide that information to patients. Currently, patient benefit and formulary information is not readily accessible at the point-of-care. In order for physicians to best help patients in understanding this information and using it to inform treatment decisions, the AMA recommends that payors work to make this information available through platforms such as electronic health records. If patient out-of-pocket cost information were to be made available at the point-of-care, patients and physicians could have fully informed conversations about the best course of treatment.

For patient cost-related inquiries that may occur outside of a care setting, platforms should be made available where patients can easily access estimates of their out-of-pocket costs for services and procedures. As providing these types of tools is a relatively new consideration for a number of payors, the AMA strongly recommends that CMS engage in market research to help determine exactly what type of information is most meaningful to patients and how that information is best communicated to patients. Generally, however, the information should be easy to access and easy for the average Medicare or Medicaid beneficiary to understand. That may include simple explanations and definitions of items such as co-payments, co-insurance, deductibles, etc., to help patients better understand the information they are being presented. Price information should not simply be a list of codes with associated payment rates, as this information will be meaningless to most beneficiaries.

Any information made available to patients should also be clear that any out-of-pocket cost estimates are estimates only, and that the provision CMS should also strongly consider creating a patient-friendly online platform, as well as a mobile application, for patients to access this information. Medicare has a website that provides pricing information on services covered by the Medicare Physician Fee Schedule. It provides more than 10,000 physician services, the associated relative value units, and a fee schedule status indicator. The pricing amounts are adjusted to reflect the variation in practice costs based off of geographic area. While available, the information itself is difficult to obtain and interpret. For example, a patient would have to know the HCPCS code, know whether a modifier is required, and the Medicare Administrative Contractor (MAC) locality in order to get specific information as to price for the service. MAC locality is a drop-down list sorted by a number identifier and not in alphabetical order by state or by specific geographic area. Even then, the patient would need to interpret whether the non-facility price, facility price, and whether the limiting charge amount applies.

The AMA also recommends that **CMS create a guide for beneficiaries that helps them understand health care cost information**, provides assistance as to how to utilize any price transparency tools made available to them by CMS, and provides guidance about how to discuss price and cost information with their providers and suppliers. This information may be useful to include as part of the beneficiary Welcome to Medicare information.

While the AMA strongly supports physicians playing an active role in assisting patients in acquiring cost information, we are concerned about discussions regarding new requirements for physicians to provide this information. As discussed above, physicians are currently ill-equipped to readily provide this information to insured patients without a significant added administrative burden on their practice. For physicians to incorporate discussions with patients regarding health care cost information in to treatment planning, patient benefit and formulary information needs to be available at the point-of-care. Ideally, this information would be made available by payors for easy access through a patient's EHR. However, currently, the only way for a practice to assist a patient in finding this information would be for practice staff to contact a patient's health plan directly to inquire about a patient's share of costs for a particular service or procedure. As one can imagine, if physicians were required to do this for every patient for every visit, it would add an overwhelming administrative burden to physician practices. A requirement for physicians to engage in an activity this burdensome would be unreasonable given the current capabilities to access this type of information.

CMS should also note that providing accurate information regarding the costs, out-of-pocket or otherwise, is extremely difficult before patients are furnished the needed services. Anticipating the need for health care services is often difficult. It is not uncommon for a service or procedure to encounter secondary conditions or otherwise unanticipated complications that would be impossible for a physician practice to foresee at the time cost information would be provided. The intensity and scope of service required often leave patients without time or ability to evaluate their options prior to receiving care. For these reasons, providers and suppliers should not be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service. Instead, the cost information provided to patients would be an estimate of charge information to help patients better understand what their potential financial liability might be for services they obtain and to enable patients to compare charges for similar services.

IV. Appendix

A. Estimated Impact of CY2019 Evaluation and Management Proposed Policy by Medicare Specialty

**Includes CPT Codes 99201-99215, GCG0X, GPC1X, GPD0X and GPD1X, but does not include GPRO1 - prolonged service; Analysis uses Estimated CY2017 Medicare Utilization and CY2019 Medicare CF for both "Current Method" and "Proposed Method"; E/M MPPR Estimate based on 2016 Medicare Carrier 5% Standard Analytic File; Excludes specialties with less than \$1 million in CY2017 allowed charges for 99201-99215 or claims with unknown specialty designation*

Medicare Designated Specialty	Total Medicare Payment for Office Visits w/o Policy Changes (Using CY2018 Total RVUs)	Change in Payment Due to Proposed E/M Collapse Policy (includes G codes*)	Additional Change in Payment Due to E/M MPPR Policy	Net Change Due to E/M Collapse and E/M MPPR Policies	Total Medicare Payment for Office Visits Under Proposed Method (E/M Collapse and E/M MPPR) (Using Proposed CY2019 Total RVUs)	Percent Change in Payment for Office Visits (Both E/M Collapse and E/M MPPR Policies)
TOTAL	\$ 23,298,623,446					
HOSPICE AND PALLIATIVE MEDICINE	\$ 6,491,871	\$ (1,278,816)	\$ (21,072)	\$ (1,299,888)	\$ 5,191,983	-20%
HEMATOLOGY	\$ 35,814,877	\$ (5,616,074)	\$ (76,952)	\$ (5,693,026)	\$ 30,121,850	-16%
GYNECOLOGY/ONCOLOGY	\$ 28,857,336	\$ (3,997,258)	\$ (547,163)	\$ (4,544,421)	\$ 24,312,915	-16%
MEDICAL ONCOLOGY	\$ 217,094,796	\$ (31,098,224)	\$ (182,736)	\$ (31,280,960)	\$ 185,813,836	-14%
NEUROPSYCHIATRY	\$ 3,342,298	\$ (410,887)	\$ (23,423)	\$ (434,310)	\$ 2,907,988	-13%
NEPHROLOGY	\$ 366,158,222	\$ (47,203,589)	\$ (302,888)	\$ (47,506,478)	\$ 318,651,744	-13%
NUCLEAR MEDICINE	\$ 3,261,367	\$ (405,925)	\$ (12,208)	\$ (418,133)	\$ 2,843,234	-13%
CARDIAC ELECTROPHYSIOLOGY	\$ 123,640,581	\$ (15,324,933)	\$ (146,856)	\$ (15,471,789)	\$ 108,168,792	-13%
CRITICAL CARE (INTENSIVISTS)	\$ 35,990,339	\$ (4,325,639)	\$ (100,505)	\$ (4,426,144)	\$ 31,564,195	-12%
RADIATION ONCOLOGY	\$ 85,243,662	\$ (9,893,434)	\$ (574,960)	\$ (10,468,394)	\$ 74,775,268	-12%
PODIATRY	\$ 645,600,644	\$ (10,733,858)	\$ (65,687,368)	\$ (76,421,226)	\$ 569,179,418	-12%
INTERVENTIONAL CARDIOLOGY	\$ 230,977,054	\$ (25,262,896)	\$ (255,653)	\$ (25,518,549)	\$ 205,458,505	-11%
PULMONARY DISEASE	\$ 519,566,122	\$ (56,585,347)	\$ (692,200)	\$ (57,277,547)	\$ 462,288,575	-11%
CARDIAC SURGERY	\$ 23,265,687	\$ (2,414,967)	\$ (60,075)	\$ (2,475,041)	\$ 20,790,646	-11%
THORACIC SURGERY	\$ 34,448,176	\$ (3,351,307)	\$ (95,221)	\$ (3,446,528)	\$ 31,001,648	-10%
SLEEP MEDICINE	\$ 18,791,073	\$ (1,820,388)	\$ (3,618)	\$ (1,824,006)	\$ 16,967,067	-10%
INFECTIOUS DISEASE	\$ 87,007,974	\$ (7,183,264)	\$ (765,556)	\$ (7,948,821)	\$ 79,059,153	-9%
GERIATRIC MEDICINE	\$ 62,649,142	\$ (5,263,125)	\$ (425,824)	\$ (5,688,949)	\$ 56,960,193	-9%
COLORECTAL SURGERY	\$ 32,609,046	\$ 2,177,018	\$ (4,743,104)	\$ (2,566,086)	\$ 30,042,961	-8%
SURGICAL ONCOLOGY	\$ 18,788,106	\$ (1,078,188)	\$ (285,170)	\$ (1,363,357)	\$ 17,424,749	-7%
PHYSICAL MEDICINE AND REHABILITATION	\$ 296,738,502	\$ (4,498,950)	\$ (11,065,012)	\$ (15,563,961)	\$ 281,174,540	-5%
DERMATOLOGY	\$ 883,036,919	\$ 209,244,544	\$ (251,123,409)	\$ (41,878,865)	\$ 841,158,054	-5%

NEUROLOGY	\$ 670,721,588	\$ (24,948,472)	\$ (5,341,041)	\$ (30,289,513)	\$ 640,432,075	-5%
PERIPHERAL VASCULAR DISEASE	\$ 3,031,756	\$ (80,774)	\$ (35,394)	\$ (116,168)	\$ 2,915,588	-4%
OPHTHALMOLOGY	\$ 515,715,805	\$ 3,971,043	\$ (23,714,332)	\$ (19,743,289)	\$ 495,972,516	-4%
ANESTHESIOLOGY	\$ 169,519,002	\$ (204,291)	\$ (5,065,536)	\$ (5,269,827)	\$ 164,249,175	-3%
SPORTS MEDICINE	\$ 42,181,673	\$ 3,583,247	\$ (4,861,167)	\$ (1,277,920)	\$ 40,903,753	-3%
GERIATRIC PSYCHIATRY	\$ 5,170,221	\$ (156,210)	\$ -	\$ (156,210)	\$ 5,014,011	-3%
CERTIFIED CLINICAL NURSE SPECIALIST	\$ 29,322,926	\$ (747,025)	\$ (17,505)	\$ (764,530)	\$ 28,558,397	-3%
EMERGENCY MEDICINE	\$ 164,829,846	\$ (37,175)	\$ (3,767,129)	\$ (3,804,304)	\$ 161,025,541	-2%
GASTROENTEROLOGY	\$ 494,407,166	\$ (9,707,187)	\$ (1,359,395)	\$ (11,066,582)	\$ 483,340,584	-2%
PREVENTIVE MEDICINE	\$ 6,380,418	\$ 107,663	\$ (244,648)	\$ (136,985)	\$ 6,243,434	-2%
CERTIFIED REGISTERED NURSE ANESTHETIST	\$ 1,206,868	\$ (17,505)	\$ (6,755)	\$ (24,260)	\$ 1,182,608	-2%
ADDICTION MEDICINE	\$ 4,621,434	\$ (63,406)	\$ (6,164)	\$ (69,570)	\$ 4,551,864	-2%
PATHOLOGY	\$ 2,881,831	\$ 331,366	\$ (373,663)	\$ (42,297)	\$ 2,839,534	-1%
RHEUMATOLOGY	\$ 375,417,278	\$ 13,205,481	\$ (17,540,236)	\$ (4,334,755)	\$ 371,082,523	-1%
PEDIATRIC MEDICINE	\$ 25,857,819	\$ 269,554	\$ (484,578)	\$ (215,024)	\$ 25,642,796	-1%
ENDOCRINOLOGY	\$ 374,423,628	\$ (1,129,450)	\$ (186,831)	\$ (1,316,281)	\$ 373,107,347	0%
INTERNAL MEDICINE	\$ 3,871,679,750	\$ 31,325,279	\$ (24,729,341)	\$ 6,595,938	\$ 3,878,275,688	0%
INTERVENTIONAL RADIOLOGY	\$ 9,484,370	\$ 469,734	\$ (413,873)	\$ 55,861	\$ 9,540,231	1%
NEUROSURGERY	\$ 116,272,265	\$ 1,791,395	\$ (323,774)	\$ 1,467,620	\$ 117,739,886	1%
HEMATOLOGY/ONCOLOGY	\$ 697,545,442	\$ 10,699,495	\$ (986,631)	\$ 9,712,865	\$ 707,258,306	1%
FAMILY MEDICINE	\$ 3,606,747,571	\$ 113,138,550	\$ (56,711,076)	\$ 56,427,473	\$ 3,663,175,044	2%
OSTEOPATHIC MANIPULATIVE MEDICINE	\$ 20,490,031	\$ 761,315	\$ (365,507)	\$ 395,808	\$ 20,885,840	2%
ORTHOPEDIC SURGERY	\$ 947,571,929	\$ 121,325,332	\$ (94,947,028)	\$ 26,378,304	\$ 973,950,233	3%
CARDIOLOGY	\$ 1,673,787,386	\$ 50,259,515	\$ (1,261,621)	\$ 48,997,894	\$ 1,722,785,281	3%
PSYCHIATRY	\$ 428,733,813	\$ 13,881,946	\$ (31,113)	\$ 13,850,833	\$ 442,584,645	3%
GENERAL SURGERY	\$ 331,303,718	\$ 24,316,111	\$ (9,332,412)	\$ 14,983,698	\$ 346,287,416	5%
NURSE PRACTITIONERS	\$ 1,441,181,453	\$ 93,149,384	\$ (25,035,363)	\$ 68,114,021	\$ 1,509,295,474	5%
HAND SURGERY	\$ 61,951,012	\$ 10,538,938	\$ (7,241,524)	\$ 3,297,414	\$ 65,248,426	5%
DIAGNOSTIC RADIOLOGY	\$ 12,237,942	\$ 907,940	\$ (232,960)	\$ 674,980	\$ 12,912,923	6%
PHYSICIANS ASSISTANT	\$ 880,931,609	\$ 100,911,145	\$ (51,442,398)	\$ 49,468,747	\$ 930,400,356	6%
OTOLARYNGOLOGY	\$ 483,766,537	\$ 120,847,876	\$ (92,891,766)	\$ 27,956,110	\$ 511,722,647	6%
ORAL SURGERY	\$ 8,519,498	\$ 808,496	\$ (304,336)	\$ 504,160	\$ 9,023,658	6%
GENERAL PRACTICE	\$ 181,231,116	\$ 13,894,726	\$ (3,084,777)	\$ 10,809,949	\$ 192,041,065	6%
VASCULAR SURGERY	\$ 115,959,089	\$ 9,653,737	\$ (1,658,179)	\$ 7,995,558	\$ 123,954,646	7%
PAIN MANAGEMENT	\$ 166,806,512	\$ 21,764,031	\$ (6,627,973)	\$ 15,136,058	\$ 181,942,570	9%
OPTOMETRY	\$ 273,100,554	\$ 26,752,277	\$ (1,697,949)	\$ 25,054,327	\$ 298,154,881	9%
INTERVENTIONAL PAIN MANAGEMENT	\$ 168,203,323	\$ 22,545,559	\$ (6,788,185)	\$ 15,757,374	\$ 183,960,697	9%

PLASTIC AND RECONSTRUCTIVE SURGERY	\$ 55,565,227	\$ 10,280,479	\$ (4,526,105)	\$ 5,754,374	\$ 61,319,601	10%
UROLOGY	\$ 752,497,473	\$ 126,343,272	\$ (41,574,022)	\$ 84,769,250	\$ 837,266,723	11%
ALLERGY/IMMUNOLOGY	\$ 95,801,235	\$ 13,194,385	\$ (603,585)	\$ 12,590,800	\$ 108,392,035	13%
CERTIFIED NURSE MIDWIFE	\$ 2,144,561	\$ 312,479	\$ (20,735)	\$ 291,744	\$ 2,436,305	14%
OBSTETRICS/GYNECOLOGY	\$ 225,275,520	\$ 47,309,295	\$ (9,018,841)	\$ 38,290,454	\$ 263,565,974	17%
MAXILLOFACIAL SURGERY	\$ 4,558,435	\$ 978,386	\$ (146,599)	\$ 831,787	\$ 5,390,222	18%

B. MPFS Legal Concerns: Analysis of Whether Certain E/M RVU Changes Violate the PFS Statute

In the portion of the CY 2019 PFS proposed rule concerning E/M CPT codes for office and other outpatient visits, the Centers for Medicare & Medicaid Services (CMS) states that its purpose is to simplify payment and related documentation. As explained below, however, the proposed changes are contrary to the basic RBRVS premise of section 1848 of the Social Security Act, are contrary to the statutory restriction concerning the permissible annual percentage reduction in the combined total RVU for a given physician service, and are contrary to the statutory prohibition against variations among types of physicians in the number of RVUs for a given service.

I. Statutory Requirement to Base PFS Payments on Relative Resources Used

The Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) required that Medicare physician payments be based on a fee schedule using a “resource based relative value scale” (RBRVS).⁶⁵ With respect to payments for evaluation and management (E/M) office and other outpatient visits, the CY 2019 proposed rule for the Medicare physician fee schedule and other Part B payment policies⁶⁶ fails to follow these RBRVS requirements.

Specifically, OBRA 1989 added section 1848 to the Social Security Act (SSA).⁶⁷ That section requires CMS to base physician payments on a methodology that combines the work, practice expense, and malpractice relative value units (RVUs).⁶⁸ For each physician service, CMS must take into account⁶⁹ “the portion of the resources used in furnishing the service that reflects physician time and intensity” (the work component); “the portion of the resources used in furnishing the service that reflects the general categories of expenses” other than those relating to malpractice (the practice expense component); and “the portion of the resources used in furnishing the service that reflects malpractice expenses” (the malpractice component, also known as the professional liability insurance, or PLI, component).⁷⁰

The preamble to the PFS proposed rule states that “there are five levels of E/M visit codes in the office or other outpatient setting based on . . . complexity”.^{71,72} CMS continues:

Current PFS payment rates for E/M visit codes increase with the level of visit billed. As for all services under the PFS, the rates are based on the resources in terms of work (time and intensity), PE and malpractice expense required to furnish the typical case of the service.⁷³

The above approach is consistent with the statute. CMS, however, would “simplify the payment for [office-based and outpatient E/M] services by paying a single rate for the level 2 through 5 E/M visits.” In

⁶⁵ See Conference Report to Accompany H.R. 3299, Omnibus Budget Reconciliation Act of 1989, Report 101-386 (November 21, 1989), page 741. See also pages 110, 758, 763, and 764 of the conference report.

⁶⁶ 83 Fed. Reg. 35704, 35832-35848 (July 27, 2018) (PFS proposed rule).

⁶⁷ 42 U.S.C. 1395w-4.

⁶⁸ SSA section 1848(c)(2)(A)(i).

⁶⁹ SSA section 1848(c)(1)(A)-(C).

⁷⁰ Under SSA section 1848(c)(2)(C), the practice expense and PLI RVUs were phased in. Since 2002, the practice expense component has been based entirely on relative resources. Since 2000, the PLI component has been based entirely on relative resources.

⁷¹ PFS proposed rule at 35832.

⁷² Neither SSA section 1848 nor the regulations in 42 CFR part 414 refer to “complexity” with respect to physician services generally; however, the preamble to the PFS proposed rule, as well as other Medicare guidance (including documents provided through the Medicare Learning Network), make clear that the work RVU is based on “complexity”, which relates to time and intensity.

⁷³ PFS proposed rule at 35832.

addition, the agency would “develop a single set of RVUs under the PFS for E/M office-based and outpatient visit levels 2 through 5” (with one set of codes and RVUs for new patients and one for established patients).⁷⁴

Under this proposal, a physician would be paid the same for level 2 work as for level 5 work, even though level 5 work is much more complex than level 2 work. For CY 2018, for example, the level 5 work RVU for new patients (3.17) was 340% of the level 2 work RVU for new patients (0.93). But the PFS proposed rule would reduce this level 5 RVU from 3.17 to 1.9, the same as the proposed level 2 work RVU.

This level 5 work RVU for new patients would be a 40% reduction. For established patients, the reduction for the level 5 work RVU would be 42%. All physicians should be very concerned that CMS will consider their most complex E/M work for Medicare patients to be of substantially less value in CY 2019 than such work was in CY 2018. In stark contrast, work RVUs for the much less complex level 2 office visits would rise by 104% for new patients and by 154% for established patients.

Clearly, these proposals for changes in the E/M work RVUs are not resource-based and are inconsistent with the statute. The proposals do not adequately take into account “the portion of the resources used in furnishing the service that reflects physician time and intensity”, as required by SSA section 1848(c)(1)(A).

Moreover, CMS is basing these single RVUs for levels 2 through 5 (new and established patients) on the basis of the average of the relative inputs for the RVUs,⁷⁵ even though the agency stated (as noted above) that the PFS payments rates are based on the resources in terms of the work, PE, and PLI expense required to furnish the typical case of the service. The concepts “average” and “typical” are not the same.

Another RBRVS issue is the situation in which an E/M code is billed for the same day as a procedure code for the same patient. The proposed rule notes that that E/M services are generally paid in one of two ways—as standalone visits using E/M visit codes, or included in global procedural codes.⁷⁶ CMS continues that there are “existing policies under the PFS where we reduce payments if multiple procedures are furnished on the same day to the same patient.”⁷⁷ The agency therefore takes the following approach:

[W]e are proposing that, as part of our proposal to make payment for the E/M levels 2 through 5 at a single PFS rate, we would reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier–25.⁷⁸

This proposal dramatically reduces payment and fails to adequately take into account the resources that the physician (or a group practice) devotes to a patient in providing separate services that occur on the same day. Moreover, in most cases, this proposed 50% reduction would in fact apply to the visit, thereby greatly increasing the payment reductions already triggered by making a single average-weighted

⁷⁴ Id. at 35839.

⁷⁵ Id. at 35840.

⁷⁶ Id.

⁷⁷ Id. at 35841.

⁷⁸ Id.

payment for levels 2 through 5 visits. For example, the combined impact of the two proposals on level 4 and level 5 RVUs for new patients would be 68% and for established patients 69%.

Again, in proposing these substantial reductions, CMS is not adequately taking into account “the portion of the resources used in furnishing the service that reflects physician time and intensity”, as required by SSA section 1848(c)(1)(A).

In addition, the proposed rule does not use a resource-based approach to the practice expense (PE) component or the PLI component. CMS would reduce most RVUs—work, PE, and PLI—by 20% to 50%.⁷⁹ Resources in terms of the work, PE, and PLI expense required to furnish the typical cases of these E/M services cannot have changed to this degree from CY 2018 to CY 2019.

CMS seems to recognize these legal problems because it is also proposing to create “add-on” codes to “better capture” the variety of resource costs among E/M visits.⁸⁰ As discussed in more detail below, however, these add-on codes do not cure the legal defects because not all physicians will qualify for them.

II. Annual Percentage Reduction in RVUs

As noted, CMS states in the PFS proposed rule that its proposals are intended to simplify the payment for office-based and outpatient E/M services by paying a single rate for level 2 through 5 E/M visits. In addition to violating the overall RBRVS requirements in SSA section 1848, this proposal would, as explained below, violate a specific statutory provision intended to mitigate the effects of significant changes in the RVUs.

According to charts in the proposed rule for level 4 and level 5 for new patients, the proposal would decrease reimbursement from \$167 and \$211, respectively, to \$135.⁸¹ For established patients for level 4 and level 5, the proposal would decrease reimbursement from \$109 and \$148, respectively, to \$93.⁸²

These are significant adverse changes for levels 4 and 5. In order to mitigate the effects of such changes, SSA section 1848(c)(7) provides as follows:

Effective for fee schedules established beginning with 2016, for services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2-year period.

For new patients, the dollar reductions for level 4 and level 5 are approximately 19% and 36%, respectively. For established patients, the dollar reductions for such levels are approximately 14% and 37%, respectively. Again, these are significant reductions.

It should be noted, however, that the above annual reduction limit is couched in terms of the percentage decrease in RVUs, not the percentage decrease in the dollar amount. For levels 4 and 5, CMS is proposing

⁷⁹ For level 5 PE RVUs, for example, the reduction would be 29% for new patients and 32% for established patients. For level 5 PLI RVUs, for example, the reduction would be 52% for new patients and 47% for established patients. (As noted, for level 5 work RVUs, the reduction would be 40% for new patients and 42% for established patients.)

⁸⁰ PFS proposed rule at 35839-35840.

⁸¹ *Id.* at 35840.

⁸² *Id.*

to reduce work, PE, and PLI RVUs. Under SSA section 1848(c)(7), the annual reduction in the combined total RVU for these components must be under 20%.

With respect to the combined total of RVU reductions for levels 4 and 5 (work, PE, and PLI):

- New patients: The proposed rule would decrease it from 4.65 and 5.85, respectively, to 3.73, which are reductions of approximately 20% and 36%, respectively.
- Established patients: The proposal would decrease it from 3.04 and 4.10, respectively, to 2.55, which are reductions of approximately 16% and 38%, respectively.

Of these four combined total RVU reductions, three decrease RVUs in a single year by more than the annual percentage reduction allowed by the statute (again, annual reductions must be under 20%). Under SSA section 1848(c)(7), these three RVU reductions are required to be “phased-in over a 2-year period,” therefore, these three proposed changes cannot be implemented in January 2019.

As noted, CMS is also proposing to create add-on codes to “better capture” the variety of resource costs among E/M visits. These add-on proposals, however, have no legal relevance to SSA section 1848(c)(7). That statutory provision concerns the “total relative value units for a service”. A “service” equals a code, and for each code there are associated RVUs. Each base E/M code must be considered in isolation, without regard to any add-on codes. The level 4 and 5 CPT codes for new patients are 99204 and 99205, respectively. For established patients, the level 4 and 5 codes are 99214 and 99215, respectively. For three of these four services (codes), the proposed RVU reductions would violate the statute by reducing the combined total RVUs for the service by more than the allowed annual percentage reduction. The creation of add-on codes by CMS is not relevant to these violations. In other words, the add-on codes do not cure these legal defects.

Moreover, moving beyond the statutory limit on annual RVU percentage reductions (SSA section 1848(c)(7)), these proposed RVU reductions ranging from 20% to 52% would clearly be inconsistent with the general RBRVS requirements of section 1848 because (as discussed in section I above) they are inconsistent with a resource-based approach. Resources in terms of the work, PE, and PLI expense required to furnish the typical cases of these E/M services cannot have changed to this degree from CY 2018 to CY 2019. And the add-ons would not be universally available.

III. “No Variation” Statutory Provision on Number of RVUs

The PFS proposed rule would make RVU changes that have the effect of treating various types of physicians differently. These distinctions are inconsistent with the “no variation” provision, SSA section 1848(c)(6), which provides as follows:

The Secretary may not vary the conversion factor or the number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.

This statutory provision refers to varying the number of RVUs for a service (or the conversion factor, which is not relevant to this discussion). As noted, a “service” is identified by a CPT code. The no-variation provision is saying literally that, for example, CPT code 99214 (level 4 for established patients) must have the same number of RVUs regardless of the type of physician billing that code. In other words, the statute takes a universal approach.

The no-variation issue in the PFS proposed rule stems from the approach that CMS is taking with respect to add-on codes for particular types of physicians. The proposal would create certain add-on codes for levels 2 through 5 for primary care, and for some types of specialists but not others.

These include “HCPCS G-code add-ons to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits [and also] an additional prolonged face-to-face services add-on G code.”⁸³

For primary care, the proposed rule would create the “continuous care” add-on code GPC1X, but this HCPCS code is available only with respect to established patients, not new patients.⁸⁴

As to specialists, CMS states that “[t]he distribution of E/M visits is not uniform across medical specialties. We have found that certain specialists, like neurologists and endocrinologists, for example, bill higher level E/M codes more frequently than procedural specialists, such as dermatology.”⁸⁵

CMS therefore is “proposing to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches we believe are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding.”⁸⁶

This add-on HCPCS code, GCG0X (visit complexity), would be available only for the following specialties: endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care.⁸⁷

These payment distinctions between primary care and specialist care, and one type of specialist versus another type of specialist, violate the no-variation statutory provision. For example, when a physician bills CPT code 99214 (level 4 for established patients), the payment for that code will be the same as a physician who claimed level 2, 3, or 5 for established patients. The physician may bill an add-on for primary care. A different physician may bill that same level 4 code and seek an add-on for specialty care. Another specialist billing that code, such as a dermatologist, cannot bill the specialist add-on because that specialty is not on the above add-on list of specialties. In other words, all physicians billing this particular E/M code would not have the same number of RVUs.

For specialists who do not practice a specialty included in the add-on list, the proposed rule violates the no-variation provision because that specialist will not have the same number of RVUs as other physicians billing that code. And even though CMS takes the position that a specialist may in some cases qualify for the primary care add-on,⁸⁸ this would not be true in all cases—again, some specialists would not have the same number of RVUs as other physicians billing the code.

⁸³ Id.

⁸⁴ Id. at 35842.

⁸⁵ Id. at 35841.

⁸⁶ Id. at 35842.

⁸⁷ Id.

⁸⁸ Id.

Moreover, even a physician providing primary care to established patients, or practicing a specialty on the add-on list, will not always meet the criteria to qualify for the add-on; therefore, impermissible RVU variations would occur among physicians.

The E/M problems created by the proposed rule are also evident with the particularized approach taken for podiatrists:

We propose that, rather than reporting visits under the general E/M office/outpatient visit code set, podiatrists would instead report visits under new G-codes that more specifically identify and value their services. We propose to apply substantially the same documentation standards for these proposed new podiatry-specific codes as we propose above for other office/outpatient E/M visits.⁸⁹

In other words, CMS proposes to disqualify podiatrists from the use of E/M codes entirely. Instead, for podiatrists, those 10 codes (levels 1-5 for new patients and levels 1-5 for established patients) would be replaced with two new G-codes, HCPCS codes GPD0X and GPD1X.⁹⁰

Therefore, podiatrists would be treated differently than almost all other types of physicians (as defined for Medicare purposes in SSA section 1861(r)). For an office or other outpatient visit with a given patient, a podiatrist will not be able to choose the appropriate level among the 10 E/M codes, and will not have the possibility of qualifying for an add-on code in addition to the base E/M code.

The proposed rule would also create related problems for psychiatric services because psychiatrists would not have the possibility of qualifying for the add-on codes.⁹¹

These proposed changes for podiatrists and psychiatrists are inconsistent with the no-variation provision.

The purpose of SSA section 1848(c)(6) is to require a universal approach. Each physician must have the same number of RVUs for a given service, regardless of whether the physician practices primary care or a specialty, or one type of specialty rather than another. The PFS proposed rule does not comply with this statutory requirement.

C. 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

⁸⁹ *Id.* at 35838-35839.

⁹⁰ *Id.* at 35843.

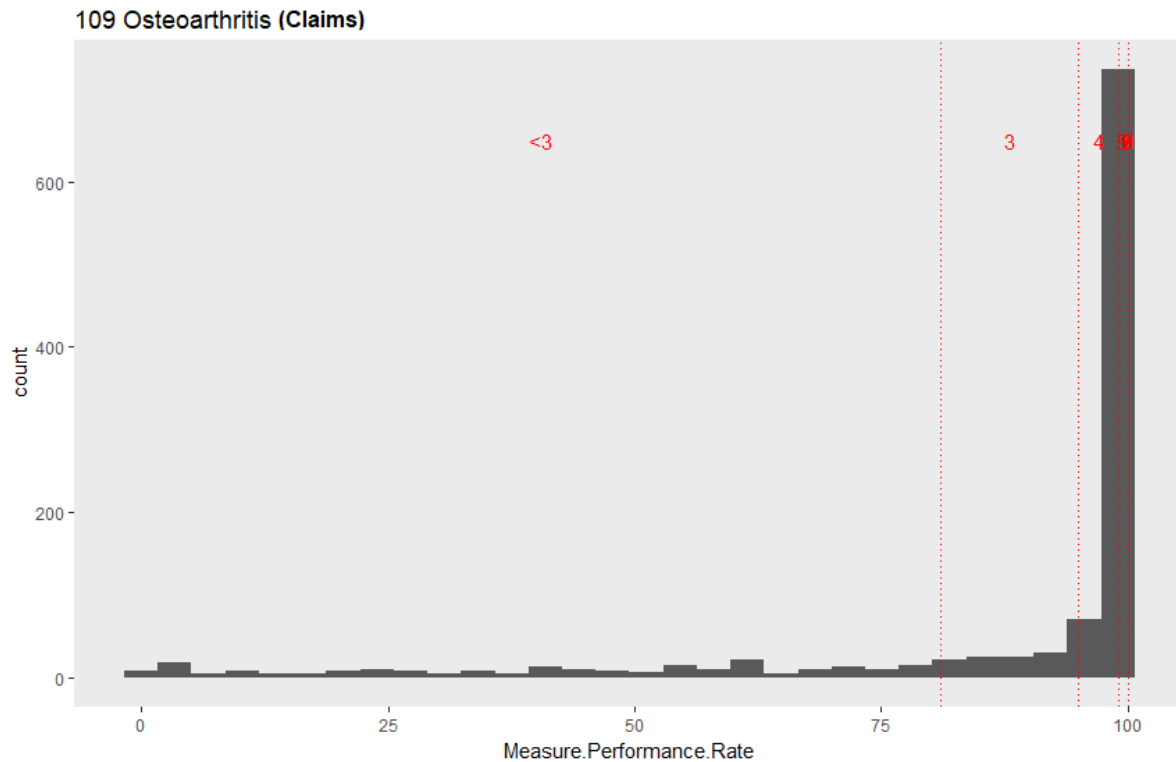
⁹¹ *Id.*

- 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.



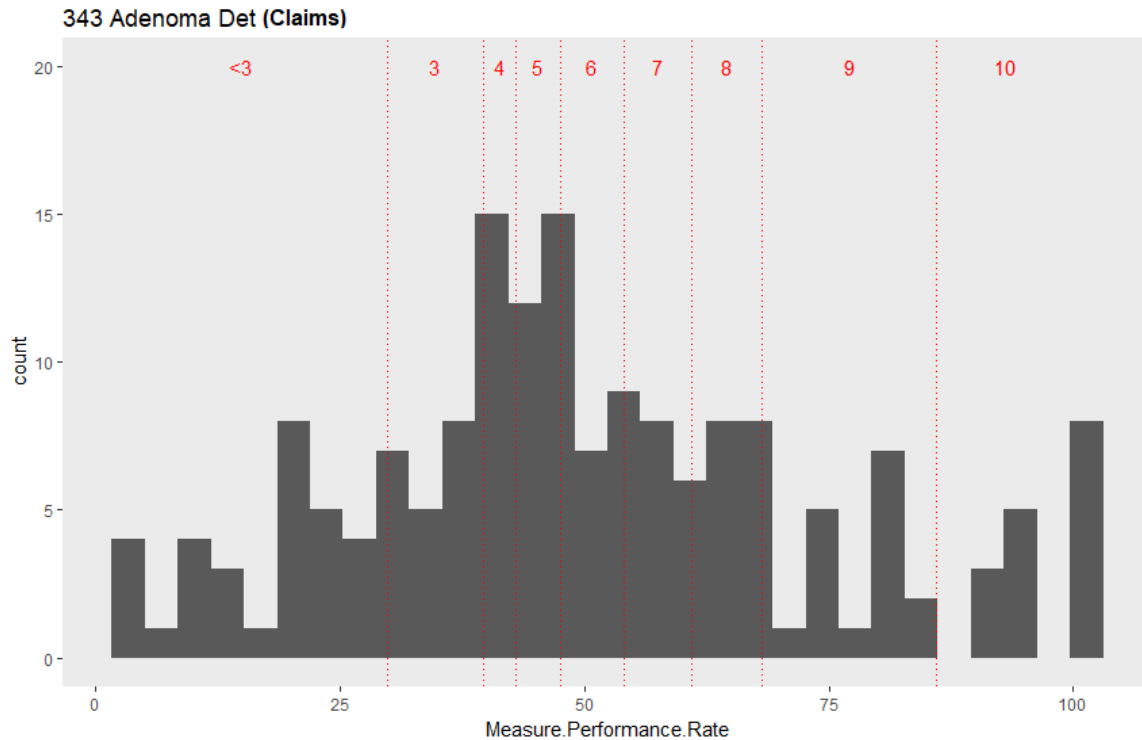
This is a concern because based on points awarded using these benchmarks, it suggests that physicians who score in the low 90s (3rd decile) are closer in quality to those who score 1% (lowest decile) than they are to those who score 100% (highest decile). Or, from the standpoint of encouraging performance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

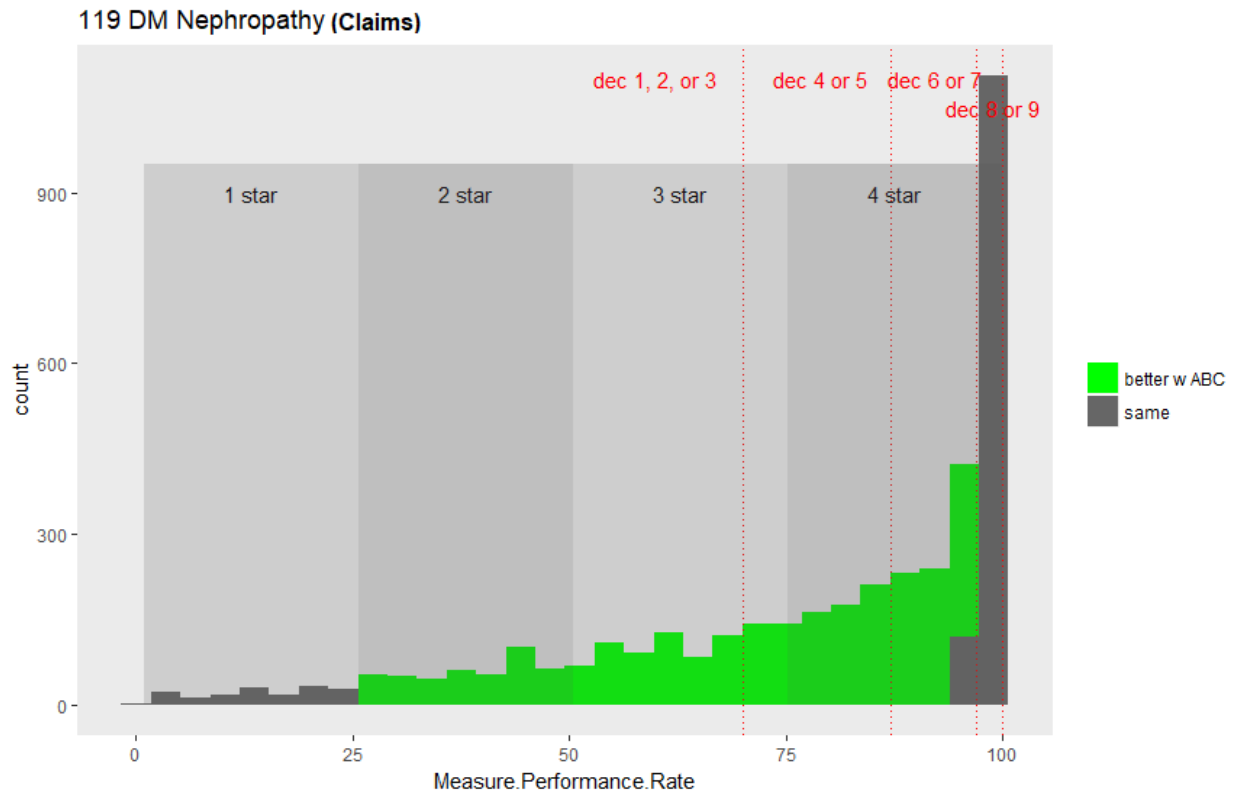
116 = Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

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.

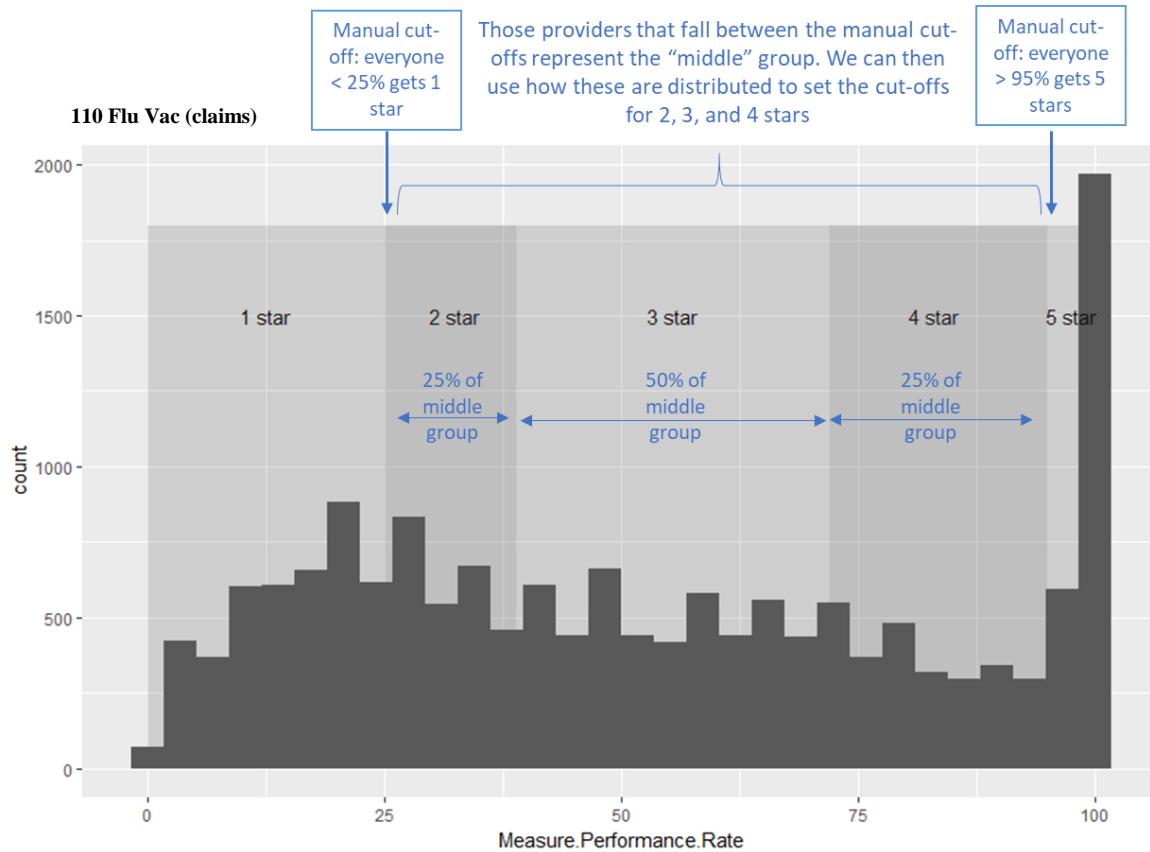
5. **Under certain circumstances, physician performance score under MIPS may be significantly different from their performance under the Physician Compare methodology, even for the same measure.** In the graph below, in addition to MIPS-based deciles, we calculated 5-star categories using the Physician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

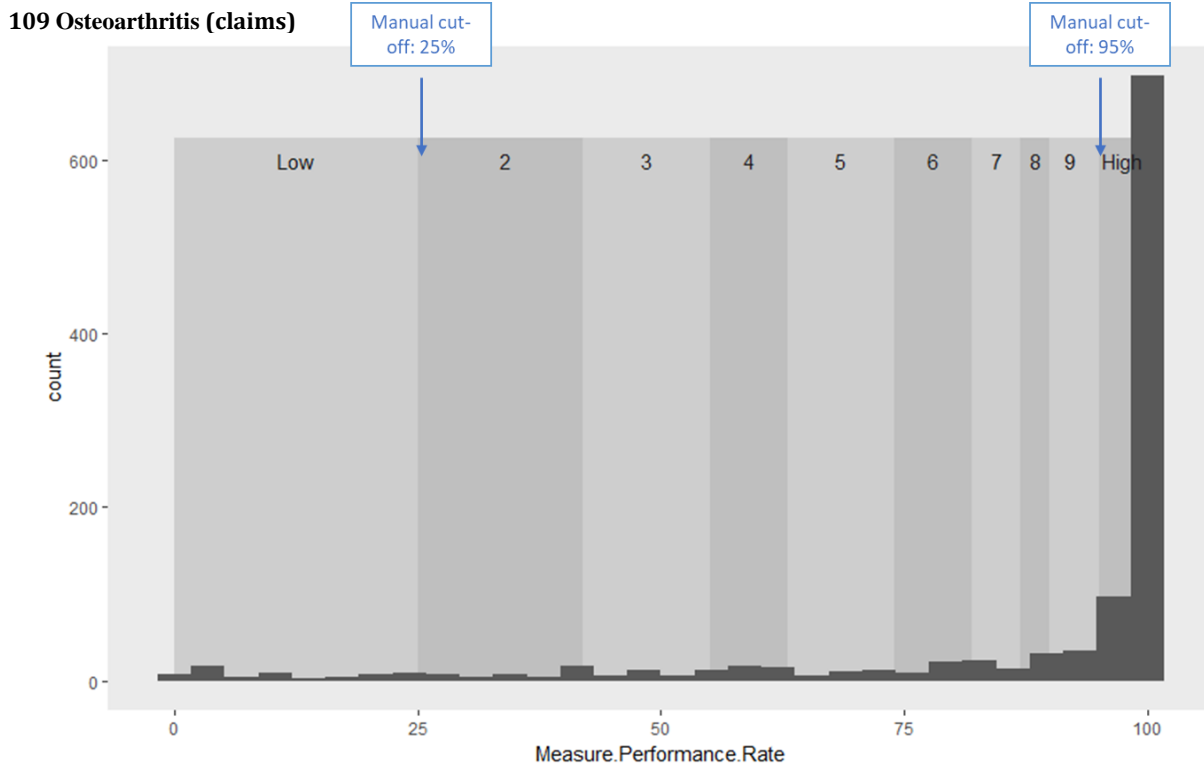
A Revised Methodology:

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.

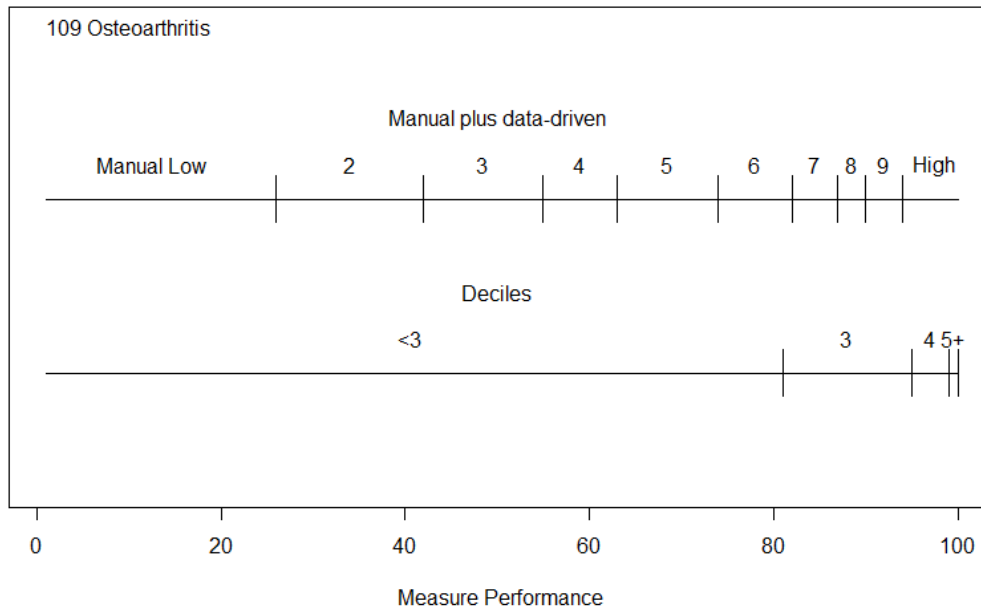


Obviously, this is not the only way to combine manual and data-driven thresholds, but it is easy to see how it could quickly alleviate many of the challenges imposed by the current methodology.

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



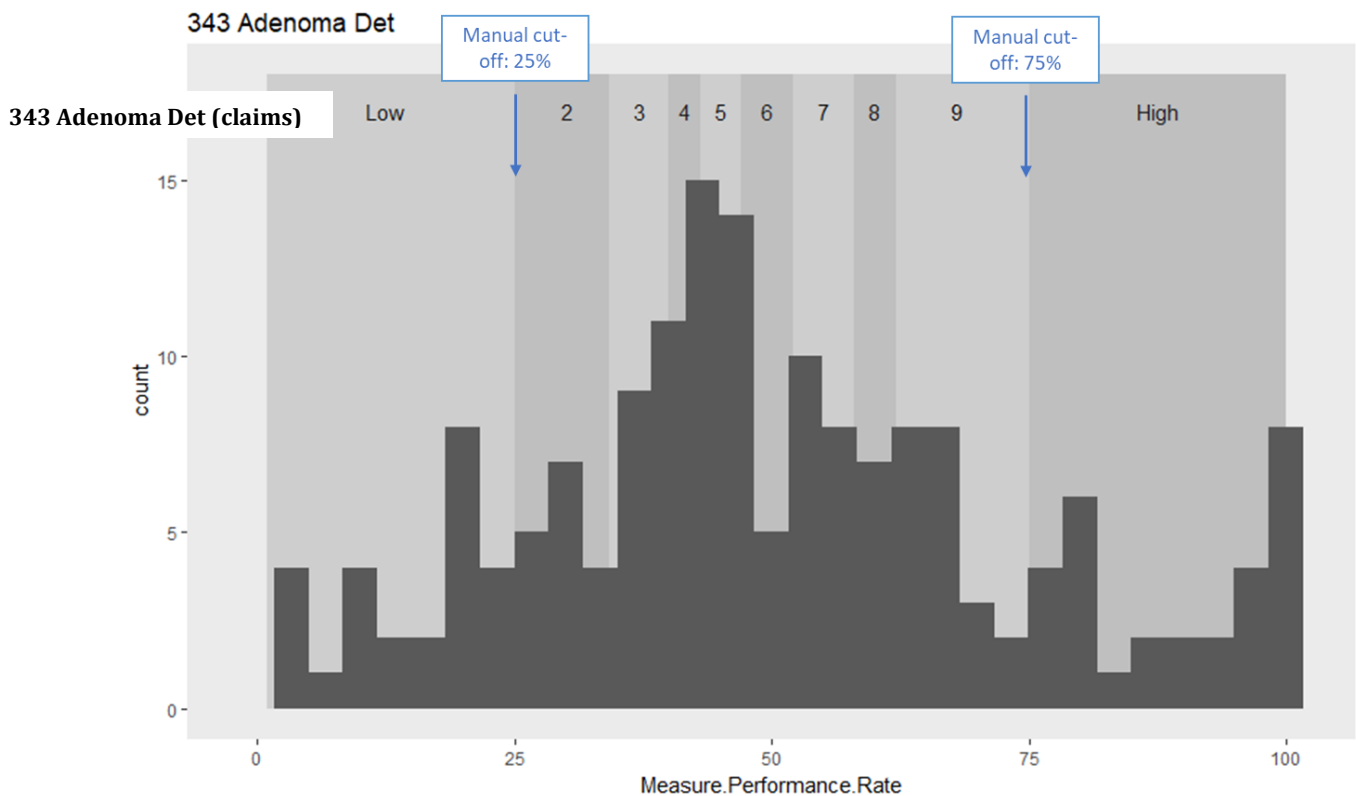
Compared with the current decile method, the M+DD method allows for greater spread across all categories and eliminates the need for physicians to score 100% to be in the highest category. A comparison of the cut-offs to those created by the current MIPS decile method is as follows:



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.

D. MIPS Program: Revised Scoring Approach

The goal of this scoring approach is to reduce administrative complexity, allow physicians to spend less time on reporting and more time with patients and on improving care, and create a more sustainable MIPS program. The proposal aims to remove the category silos and harmonize the four categories to produce a more cohesive and holistic program. It also sharpens the focus on outcomes as opposed to just reporting.

Overview of changes:

- Uses the weighting finalized for 2018*

- Assigns points to each category that align with the percent weight of each category
- Moves all bonus points to composite score
- Allows reporting or attesting in one category to receive automatic credit in another (“multi-category credit”)
- Changes the focus of each category to points for reporting points with additional points based on performance in the Quality and Cost categories
- Requires only yes/no attestation for PI measures and scores at the objective level (i.e., physicians do not need to report on all measures)
- Maintains attestation for IA measures.

**We do not believe CMS should change the category weights in 2019 and should maintain 2018 weights*

Category	Proposed Refinements
<p>General Requirements and Reporting Across MIPS Categories</p>	<p>A physician or practice would have to meet the performance threshold to avoid a penalty. Any physician who achieves a score above the performance threshold would be eligible for an incentive.</p> <p>All bonus points would now be calculated at the composite score level. Bonus points would include:</p> <ul style="list-style-type: none"> • Small practices • Complex patients • Improvement in quality category • Improvement in cost category • Reported an outcome or high priority measure • Reported a new quality or cost measure • Multi-Category Credit
<p>Quality</p>	<p>Weight: 50 %</p> <p>Maximum points: 50</p> <p>Requirements:</p> <ul style="list-style-type: none"> • Explore whether a case minimum approach (e.g., 20 consecutive Medicare patients) or minimum reliability score of 0.80 or other alternatives to be determined would simplify reporting requirements while also ensuring that comparisons across reporting options and specialties are equitable (e.g., benchmarks should be determined separately for QCDRs and qualified registries) <p>Reporting points:</p> <ul style="list-style-type: none"> • Receive 5 points for each measure that is reported • Can receive automatic credit in additional measures if report on a related multi-category credit measure

Category	Proposed Refinements
	<p>Additional points based on:</p> <ul style="list-style-type: none"> • Performance against benchmarks on quality measures <ul style="list-style-type: none"> ○ Benchmarks should be reevaluated to ensure that comparisons across reporting options (e.g., QCDR vs. qualified registry) and specialties are equitable and aligns with the methodology used for the five-star ratings in Physician Compare.
<p>Cost</p>	<p>Weight: 10%</p> <p>Maximum points: 10</p> <p>Requirements:</p> <ul style="list-style-type: none"> • Case minimum based on a minimum reliability score of 0.80 • Regardless of whether a cost measure applies, the physician or group would still be able to achieve credit for multi-category activities/measures • If no cost measure or multi-category credit applies, then it will be offset by the Quality category <p>Reporting/Attribution points:</p> <ul style="list-style-type: none"> • Receive 5 points for at least one cost measure • Can receive automatic credit in additional measures if report on a related multi-category credit measure <p>Additional points based on:</p> <ul style="list-style-type: none"> • Performance against benchmarks on cost measures <ul style="list-style-type: none"> ○ Benchmarks should be reevaluated to ensure that comparisons across specialties are equitable and aligns with the methodology used for the five-star ratings in Physician Compare.
<p>Promoting Interoperability (PI)</p>	<p>Weight: 25%</p> <p>Maximum points: 25</p> <p>Requirements:</p> <ul style="list-style-type: none"> • Yes/No attestation on at least one measure in each objective (yes = at least one patient in the numerator) for 90 consecutive days • Reweighting due to the three specified reasons still applies (i.e., insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over availability of CERHT) <p>Reporting points:</p>

Category	Proposed Refinements
	<ul style="list-style-type: none"> Each measure is worth 10 points Can receive automatic credit in additional measures if report on a related multi-category credit measure
Improvement Activities (IA)	Weight: 15% Maximum points: 15 Requirements: <ul style="list-style-type: none"> Attest to at least 1 IA over 90 consecutive days All IAs are the same weight Can still report using the approved reporting options Reporting points: <ul style="list-style-type: none"> Receive 10 points for each IA Can receive automatic credit in additional measures if report on a related multi-category credit measure
Composite Score	Quality: 50% = 50 points Cost: 10% = 10 points PI: 25% = 25 points IA: 15% = 15 points

Examples of Scoring

Each of these examples outlines the proposed scoring approach focused on reporting/attribution points only, particularly showing where measures or activities could be designated as multi-category credit and provide automatic credit in other performance categories. These examples do not include additional points that could be achieved based on benchmarks or the bonus points applied at the composite score. Points could change based on the weights.

Example 1

A practice focuses on reducing the risk of falls across its patient population:

- Reports on MIPS #154 (Falls: risk assessment) and #155 (Falls: plan of care)
- Meets the case minimum for Medicare Spending per Beneficiary (MSPB)
- Attests to IA_PSPA_21 (Implementation of fall screening and assessment programs)

Measure/Activity	Quality	Cost	PI	IA
MIPS #154	5+	0	0	0
MIPS #155	5+	0	0	0
MSPB	0	5	0	0

IA_PSPA_21	0	0	0	10
Bonus Points For Reporting Multi-Category Credit Measures	5			
Total Report Points Across All Categories	35+ points			

Example 2

In this example, a practice determines that it will focus on patient-reported outcomes using its EHR and patient portal for the reporting year.

- Reports on Multi-Category Credit Quality Measure: MIPS # 398 (Varicose vein treatment with saphenous ablation: outcome survey)
- Does not have any applicable cost measures
- Attests to IA_BE_1 (Use of certified EHR to capture patient reported outcomes)
- Attests to PI measure “Provide Patient Access”

Measure/Activity	Quality	Cost	PI	IA
MIPS #398	5+	Reweighted to Quality	0	0
IA_BE_1	0		0	10
PI Provide Patient Access	0		10	0
Bonus Points For Reporting Multi-Category Credit Measures	5			
Total Report Points Across All Categories	35+ points			

Example 3

A cardiology practice focuses on appropriate use and implements efforts around some key drivers of cost:

- MIPS #323 (Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention [PCI]) and MIPS #324 (Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients)
- Meets the case minimum for Total Cost of Care (TCC)
- Attests to IA_PM_13 (Chronic care and preventative care management for empanelled patients) and IA_PSPA_17 (Implementation of analytic capabilities to manage total cost of care for practice population)
- Attests to PI Sending Health Information and PI Receiving and Incorporating Health Information

Measure/Activity	Quality	Cost	ACI	IA
MIPS #323* (Now a Cost and Quality measure)	5+	5	0	0
MIPS #324 * (Now a Cost and Quality Measure)	5+	5	0	0
TCC	0	5	0	0
IA_PM_13	0	0	0	10
IA_PSPA_17	0	0	0	10
PI Sending Health Information	0	0	10	0
PI Receive/Incorp Health Information	0	0	10	0
Bonus Points For Reporting Multi-Category Credit Measures	5			
Total Report Points Across All Categories	70+ points			

Example 4-Targeted Topics

CMS could present information in bundles for participants to use and develop targeted topics with the goal of improving patient care and meeting at least the performance threshold.

- Participation in a patient-centered medical home.
- Use of a qualified clinical data registry.

Measure/Activity	Quality	Cost	PI	IA
Qualified Clinical Data Registry (QCDR)				
Report Quality Measures Through QCDRs	5+	0	0	0
MSPB	0	5+	0	0
IA_PM_7	0	0	0	10**
PI_EP_1*			10	
PI_Provide Patient Access (New Measure)*			10	
PI_HIE_Send	0	0	10	0
PI_Use of A QCDR			10	0
Bonus Points For Reporting Targeted Topic	5	0	0	0
Total Report Points Across All Categories	75+ points			

* Included because we recommend CMS only require that physicians attest to one measure within each objective. The AMA opposes CMS' proposal to require reporting on every measure.

** Point distribution is based on our proposal where each measure gets 5 points for simplification purposes. It could change with further discussion or depending on the direction of the program. Please note that PI is double the weight of the other categories as CMS notes the importance of health IT across practice and quality improvement and outcomes.