



Sound Policy. Quality Care.

January 2, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Submitted electronically via Regulations.gov

RE: CY 2018 Updates to the Quality Payment Program

Dear Ms. Verma,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from 13 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

Today, the undersigned organizations of the Alliance write to express appreciation, share ongoing concerns, and provide additional input as you implement Year 2 of the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) under the Quality Payment Program (QPP) established as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

General Sentiments on Year 2 Implementation of the Quality Payment Program

The Alliance appreciates the many improvements and flexibilities CMS has provided to small practices, several of which will benefit specialty physician practices. We thank CMS for finalizing the small practice bonus and increasing the complex patient bonus. We also thank CMS for eliminating the burden of reporting data as part of the Advancing Care Improvement (ACI) performance category for small practices that may not have the resources to adopt certified electronic health record technology (CEHRT). We appreciate that CMS maintained its policy that reduces the burden of reporting through the Improvement Activities (IA) performance category by doubling the points available for high and medium weighted activities. Small, specialty-focused practices are poised to reap many other benefits and flexibilities as a result of the finalized policies dedicated to small practices.

MIPS Program

MIPS Eligible Clinicians

Definition of a MIPS Eligible Clinician

In the final rule, CMS explains that it received requests for additional clarifications on which specific Part B services are subject to the MIPS payment adjustment, as well as which Part B services are included for eligibility determinations. CMS clarified that “...*there are circumstances that involve Part B prescription drugs and durable medical equipment (DME) where the supplier may also be a MIPS eligible clinician...for those billed Medicare Part B allowed charges that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations.*”

We continue to be perplexed by CMS’ interpretation of the statute and decision to apply the MIPS payment adjustments to Part B drugs, especially after 26 Members of Congress and two Senators corresponded with Acting Secretary of Health and Human Services regarding their concerns about the policy. Indeed, a recent Avalere analysis found that some specialties will face financial adjustments as high as +/-16% based on performance in 2018, and +/- 29% based on performance in 2020 and beyond, given the inclusion of Part B drugs.

The prior quality reporting programs, such as the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM) and Electronic Health Record (EHR) Incentive Program, excluded Part B drugs from the payment adjustment. In addition, the APM track of the QPP does not include Part B drugs in the incentive payment. At a time when our country is debating issues related to the high cost of pharmaceutical treatments, and CMS is proposing to address issues related to the high costs of drugs in other proposed regulations, why would CMS reward or penalize clinicians based on the volume of medicines they prescribe to treat beneficiaries with debilitating, life-altering, and sometimes life-ending diseases?

Section 1848 of the Social Security Act (the Act) is entitled “payment for physician services” [emphasis added] and pertains to payment under the physician fee schedule (PFS). Had Congress meant for MIPS adjustments to apply to items and services outside the PFS, it would have stated so *explicitly*. Moreover, CMS never proposed a policy that would include Part B drugs in the MIPS payment adjustment, nor in its eligibility calculations. We believe CMS is in direct violation of the Administrative Procedures Act (APA), having never engaged in formal notice-and-comment rulemaking prior to implementation of this policy.

CMS must reconsider its policy and exclude Part B drugs from the MIPS payment adjustment and eligibility calculations beginning with the 2017 performance year.

Small Practice Definition

While CMS modified its definition of a small practice to mean a “practice consisting of 15 or fewer eligible clinicians,” the change did not have the intended affect. **The Alliance urges CMS to make a technical correction and again revise its definition of small practice to mean a “practice consisting of**

15 or fewer MIPS eligible clinicians,” ensuring only those clinicians who are eligible to participate in the MIPS program are counted toward the threshold.

CMS provides a number of incentives and flexibilities for small practices, which are important for many specialty practices that continue to struggle with MIPS engagement. We believe Congress intended the definition of small practice to capture the widest net of practices as possible, which is consistent with CMS’ “Cut the Red Tape” and “Patients Over Paperwork” Initiatives that seek to reduce regulatory burden on small practices, many of which are specialty-focused. CMS has the statutory authority to make this change, given the agency has already re-termed “MIPS eligible professionals” to “MIPS eligible clinicians,” and added new terms and definitions, such as “eligible clinician.”

CMS must revise its definition of small practice to mean a “practice consisting of 15 or fewer MIPS eligible clinicians,” which would allow more clinicians to qualify for the small practice bonus, eliminate the burden of reporting data as part of the Advancing Care Improvement (ACI) performance category, reduce the burden of reporting through the Improvement Activities (IA) performance category, and realize other benefits and flexibilities reserved for small practices.

Low-Volume Threshold

We thank CMS for finalizing its proposal to increase the low-volume threshold, which will allow more practices an opportunity to prepare for the transition into MIPS. Moreover, we appreciate CMS’ desire to develop and operationalize an opt-in process that is not burdensome to clinicians. As CMS considers further how to provide low-volume clinicians the ability to opt-in to the MIPS program, we urge CMS to ensure future policy holds harmless from penalties any clinicians opting in to MIPS. Clinicians opting in to MIPS should not be subject to penalties until they are required to participate. In addition, clinicians that are newly eligible in MIPS, such as those who suddenly exceed the low-volume threshold or are no longer newly enrolled in Medicare should be held to lower reporting requirements and alternative scoring in their first performance year, just as CMS offered “Pick your Pace” transition year policies to clinicians eligible to participate during the first year of the program. This “on-ramp” approach will help clinicians, especially those who are newly eligible, transition and integrate more easily into the MIPS program. **The Alliance would be pleased to assist CMS in establishing “on-ramping” policies, particularly as they apply to specialists.**

Group Reporting

CMS seeks comment on additional ways to define a group, not solely based on a tax identification number (TIN). For example, redefining a group to allow for practice sites to be reflected and/or for specialties within a TIN to create groups. We previously expressed our full support for CMS establishing group-related policies that would permit a portion of a group to participate in MIPS outside the group by reporting as a separate subgroup using a new identifier. Our only concern relates to the potential complexity and administrative burden associated with such a policy and the use of a new identifier. **Because subgroups could be a beneficial pathway for more meaningful specialty engagement in MIPS, the Alliance would be pleased to assist CMS in developing forthcoming proposals related to subgroup carve-outs and to remedy as many potential concerns as possible.**

MIPS Performance Category Measures and Activities

Submission Mechanisms and Scoring the Quality Performance Category

Given CMS' decision to allow reporting via multiple submission mechanisms beginning with the 2019 performance year, CMS finalized a modified version of its validation proposal to provide that CMS will validate the availability and applicability of quality measures only with respect to the data submission mechanism(s) that a MIPS eligible clinician utilizes for the quality performance category for a performance period, beginning with the 2019 performance period. Thus, MIPS eligible clinicians who submit quality data via claims only would be validated against claims measures only, and MIPS eligible clinicians who submit quality data via registry only would be validated against registry measures only. MIPS eligible clinicians who, beginning with year 3, elect to submit quality data via claims and registry would be validated against both claims and registry measures; however, they would not be validated against measures submitted via other data submission mechanisms. CMS did not propose or finalize any changes to the policy that if a MIPS eligible clinician submits any quality measures via EHR or QCDR, CMS would not conduct a validation process.

The Alliance greatly appreciates the clarification CMS has provided, however, we are concerned that scoring for the quality performance category is increasingly complex as a result of the multiple submission mechanism policy, the addition of “improvement” scoring, and the new data validation process. We urge CMS to proceed with caution and provide as much clarity to ensure clinicians understand how the agency arrived at their quality score, in year 3.

Cost Performance Category

The Alliance strongly opposes CMS' finalized policy to weight the cost performance category at 10% for the 2020 MIPS payment year. We understand why the agency felt that assigning a 0% weight to the cost performance category for the 2020 MIPS payment year may not provide a smooth enough transition for integrating cost measures into MIPS and may not provide enough encouragement to clinicians to review their performance on cost measures. However, as we stated in our comments on the proposed rule and countless times in the past, the Total Per Capita Cost and Medicare Spending Per Beneficiary (MSPB) measures are inappropriate for capturing the cost and resource use of specialty physicians and do not provide meaningful or actionable information that relates to the expert care they provide.

Specialists are working with CMS on the development of episode-based measures that are more applicable to the conditions and services they manage. However, at this time, only a few episode-based measures are available for a select few specialties. The Alliance looks forward to the implementation of a robust set of more focused episode-based cost measures, but until such time, the category should remain weighted at 0%. In the meantime, we will work with Congress on a legislative solution to address these concerns.

Advancing Care Information (ACI) Performance Category

We thank CMS for agreeing with the Alliance and finalizing a modified policy that would award 10 percentage points in the performance score for reporting to any single public health agency or clinical

data registry to meet any of the measures associated with the Public Health and Clinical Data Registry Reporting Objective (or any of the measures associated with the Public Health Reporting Objective of the 2018 Advancing Care Information Transition Objectives and Measures, for clinicians who choose to report on those measures), regardless of whether an immunization registry is available to the clinician.

CMS originally proposed that if a MIPS eligible clinician could not fulfill the Immunization Registry Reporting Measure, it would only award 5 percentage points in the performance score for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10 percentage points. The Alliance expressed concern that the proposal diminished the value of reporting to specialized and clinical data registries.

We appreciate that CMS revised its policy as a result of the Alliance's concerns. We look forward to providing useful input that will assist the agency as it continues to implement the QPP.

MIPS Payment Adjustments

Establishing the Performance Threshold

For the 2020 MIPS payment year, CMS finalized its proposal to set the performance threshold at 15 points. We remain concerned that CMS will soon be required to set the performance threshold based on mean/median performance on participating clinicians. While we are working with Congress on a legislative solution, **we urge CMS to propose and finalize policies that will improve long-term stability in reporting requirements and scoring mechanisms.** As explained in prior comments, the constant flux in reporting requirements year-after-year pose significant administrative burdens for physicians and their administrative staff, and are inconsistent with CMS' "Cut the Red Tape" and "Patients Over Paperwork" initiatives. **The Alliance would be pleased to share a list of existing policies that should be maintained in order to stabilize the MIPS program for the next several years.**

Review and Correction of MIPS Final Score

Performance Feedback Template

CMS continues to develop its performance feedback mechanism and invites clinicians and groups to share ideas or notify the agency if they would like to participate in user testing.

The Alliance would like to avail itself to collaborating with the agency and its contractors in the development and testing of its performance feedback for MIPS. As the agency will recall, between 2012-2013, the Alliance worked closely with CMS to make improvement and test the ability of specialty physicians to read and understand the early Quality and Resource Use Reports (QRURs) as part of the Physician Feedback Program through a collaborative effort known as the CMS/Alliance Value Modifier and QRUR "Super User" Network. Through this effort, specialty physicians and staff met with CMS program officers in Baltimore on multiple occasions, providing recommendations aimed at improving the QRURs so that clinicians would have meaningful, actionable information to assist in their efforts to improve the quality and cost of care rendered to Medicare beneficiaries. The Alliance also established and promoted a "QRUR Download Day" in support of CMS' efforts to encourage physicians to obtain and review their QRUR. Prior to the launch of the event, CMS engaged the Alliance in a closed User

Acceptance Testing (UAT) session, where our physicians identified a significant security issue. This helped CMS correct what would have been a potential violation of privacy and security laws on a large scale.

We extend ourselves to engage in a similar clinician-focused field testing to ensure the reports are user-friendly and provide specialists with meaningful and actionable data.

Third Party Data Submission

Qualified Clinical Data Registries (QCDRs)

Several Alliance organizations face overwhelming challenges with CMS' QCDR measure review process, forcing them to reconsider the hefty investment they've made in establishing these more relevant data collection and reporting tools for their members. This is unfortunate considering Congress ***explicitly*** encouraged the use of QCDRs for reporting quality measures as part of MACRA.¹

Below we outline the major concerns that must be immediately addressed. Otherwise, many specialty society registries may be forced to permanently end their programs.

- **Transparency:** The current process lacks transparency and consistency. While we greatly appreciate the flexibilities offered to QCDRs, CMS and its contractors seem to be operating in an increasingly arbitrary and disorganized manner with no apparent standardized guidelines. It is also challenging to understand the unique and varied role of each of CMS' contractors involved in the process, or who at CMS is responsible for the QCDR program.
- **Predictability:** Given the lack of transparency, it is difficult for specialty societies to predict various stages of the process and plan ahead. Specialty societies find themselves scrambling to update their platforms to account for last-minute measure tweaks requested by CMS, which causes delays in data collection, and confusion and added burden for clinicians. It also makes it more difficult for them to establish reliable benchmarks with consistent data.
- **Timelines:** Specialty societies are provided extremely short turnaround times for responding to questions/rejections related to their measures. In fact, some societies have been given just 24 hours to defend measures for inclusion in the MIPS program, even after they were told a few weeks earlier that their measures would be retained.
- **Contractors:** CMS uses multiple, disparate contractors to assist with its process. The contractors seem to have a serious misunderstanding of the clinical significance/implications of measures.
- **Feedback:** When specialty society staff seek assistance and clarification on QCDR issues, particularly those related to CMS' questions/rejections, the responses are intermittent and sporadic. These delays are problematic given the short turnaround time staff are allotted in responding to questions/rejections.
- **Measure reviews:** Specialty society staff provide materials to CMS and its contractors in advance of measure reviews. Alliance organizations note that CMS and its contractors are frequently unprepared, having not reviewed the materials prior to measure review conference

¹ Section 1848(q)(5)(B)(ii)

calls. In some instances, CMS staff and/or its contractors are taking these calls from remote locations or while driving and unable to look at the materials even if they are resent during the time of discussion. Moreover, final review seems to be dependent on one or two CMS medical officers, with little or no oversight.

We do not believe Congress envisioned a process that would lead specialty societies to contemplate ending their registry programs. On the contrary, legislators included language in MACRA to encourage the use QCDRs and allow them to flourish. Therefore, **the Alliance calls on CMS to implement a transparent, predictable multi-year measure approval process with clear timelines that allow for meaningful review and comment. We urge CMS to clarify the role and responsibilities of its various contractors in the measure review process, as well as that of its CMS program and medical officers, and improve oversight of the QCDR measure review process.**

We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons