Alliance of Specialty Medicine

Sound Policy. Quality Care.

September 13, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted online via regulations.gov

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

Dear Administrator Verma:

On behalf of more than 100,000 specialty physicians from 15 specialty and subspecialty societies, and dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care, the undersigned members of the Alliance of Specialty Medicine (the "Alliance") write in response to proposals outlined in the aforementioned proposed rule, which includes proposals to update the Medicare physician fee schedule for CY 2020 and the Quality Payment Program in Year 4.

PROVISIONS OF THE PROPOSED RULE FOR PFS

Determination of Malpractice RVUs

Specialty physicians pay some of the highest professional liability (PLI) premiums and the Alliance is in agreement with the AMA/Specialty Society RVS Update Committee (RUC) regarding a number issues in the calculation of the malpractice (MP) RVUs in the CY 2020 MPFS proposed rule that require correction. Below we highlight our key concerns:

Non-physician Health Care Professional Premium Rates. The Alliance notes that CMS has improved the crosswalk for 5 non-physician provider groups by obtaining updated premium information. However, 11 non-physician provider specialties continue to be crosswalked to the physician specialty with the lowest premiums, Allergy Immunology. This significantly exceeds the actual premium costs for these providers. As the percentage of non-MD providers billing Medicare for services increases, this distortion becomes increasing problematic, given budget neutrality, and fails to accurately reflect relative resource costs for

this important component of the MPFS. The RUC has provided CMS with a potential source of non-physician provider data. ***Until CMS has better data for the 11 non-physician providers, we agree with the RUC recommendation that the crosswalk should be to optometry. While this may still exceed actual costs, it would be much closer than the current crosswalk to Allergy/Immunology.***

Surgery Service Risk Group – Minor vs. Major Surgery. CMS proposes to combine minor surgery and major surgery premiums to create the surgery service risk group, which it claims will yield a more representative surgical risk factor. CMS states they will consider surgical services with physician work values greater than 5.00 RVUs as "major surgery" for this analysis. We are concerned that this definition is arbitrary and does not account for a number of situations. For example, the RUC has identified 157 codes with a ZZZ global period (sometimes referred to as "add-on" codes) and work RVUs of less than 5.00 that are clearly a component of major surgery and should be designated as such. We would like to draw special attention to Table 8.B. *Volume-weighted Distribution of 2019 Physician Work RVUs by Service Risk Type by CMS Specialty*, which contains errors for several specialties. For example, the table indicates that both neurology's and neurosurgery's share of total "work RVUs–no surgery" is 70%. This figure is inaccurate for both neurosurgery and neurology. Neurosurgery's share of surgery RVUs (codes in 10000-69999 range) is 80%, leaving 20% as the correct share of total "work RVUs – no surgery." Neurology's share of total "work RVUs – no surgery" is 95%. Moreover, the numbers shown in line 13-Neurology and 14-Neurosurgery of table 8.B across all columns are exactly the same, indicating a likely "copy and paste" error. ***The Alliance urges CMS to review these issues with surgical service risk group computation and correct the obvious errors.***

Imputation Methodology. CMS has made improvements in obtaining premium data for many specialties. However, the data set is not complete for all specialties and an "imputation methodology" has been derived to fill in the gaps that contains numerous inaccuracies for some specialties. Of the 23 CMS specialties that are subject to total imputation, sixteen are mapped to Allergy/Immunology. We join the RUC in urging CMS to collect premium data for these specialties and, in the meantime, to work with the RUC to better identify appropriate crosswalks. For example, the contractor has mapped the specialty of sleep medicine to general practice when neurology would actually be more appropriate clinically and in terms of MP risk. In addition, Table 8.C.1 includes manifestly flawed mappings, showing neurosurgery PLI premiums imputed from neurology. Clearly this is incorrect. ***The Alliance asks the agency to rectify these errors in the "imputation methodology" for PLI crosswalks.***

MP RVU Valuation for Low and No Volume Services: We commend the agency for accepting the RUC specialty designation "overrides" for very low volume services to prevent significant variation in year-to-year MP RUVs. The issue of valuing PLI RVUs for low volume codes has long been a concern for specialties with high PLI payments. Some codes are so rarely performed or have such low Medicare volume for a particular year that the dominant specialty may be incorrect and, therefore, may not accurately reflect the risk. We agree with the RUC that code-specific "overrides" are essential when the claims data are inconsistent with the specialty that would be reasonably expected to furnish the service. Some procedures may be very low volume for Medicare but have greater volume for Medicaid or other payers, further propagating errors. In the CY 2019, MPFS CMS failed to appropriately account for low-volume procedures, leading to large decreases in MP RVUs for some specialties. CMS did correct most of these errors in the July 2019 Quarterly Update but ***we urge CMS to ensure that the low-volume overrides are correctly applied for 2020 and to work with the RUC to identify appropriate specialty assignments for these codes.***

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

CMS proposes changing the statutory "ASP plus six percent" used to reimburse providers for Part B drugs to "ASP plus no add-on" for Part B drugs furnished by Opioid Treatment Programs (OTPs). We object to CMS's underlying philosophy that "limiting the add-on will incentivize the use of the most clinically appropriate drug for a given patient." As specialties that administer Part B drugs, we strongly disagree with this sentiment. More importantly, the evidence contradicts CMS position; physicians do not profit on Part B drugs under the ASP methodology and it does not provide an incentive to choose high-cost treatment inappropriately.

Even the Medicare Payment Advisory Commission (MedPAC) acknowledges in its report that the ASP plus 6 was designed to account for "handling and overhead costs and/or for additional mark-up in the distribution channels that are not captured in the manufacturer-reported ASP."[1] We believe OTPs may be unable to afford Part B drugs without the add-on to cover those costs. Given the importance of addressing the country's opioid crisis, the administration should be overly cautious to ensure the success of these programs. We recommend that CMS include the add-on payment for Part B drugs administrated by OTPs.

Physician Supervision for Physician Assistant (PA) Services

CMS proposes to redefine the physician supervision requirement for services delivered by a PA, including to defer to state scope of practice and to create a looser standard than the "general supervision" requirement that currently exists for PAs practicing in states without laws governing physician supervision of PA services. ***The Alliance opposes this proposal.*** With respect to those states without supervision laws, CMS' proposal to consider the "PA's approach to working with physicians" in furnishing services fails to meet the statutory requirement that PAs must furnish services under the supervision of a physician. Additionally, CMS' proposal would create unnecessary variation in standards for care furnished by PAs, based on differences in states laws, that we believe would not be appropriate for a federal program. As such, ***we recommend that CMS not finalize this policy, and instead retain the general supervision requirement that is currently in place.***

Review and Verification of Medical Record Documentation

CMS proposes to establish a general principle to allow the physician, the physician assistant, or the advance practice registered nurse who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or other members of the medical team. ***The Alliance supports this proposal, which we believe would further clarify and build upon the policies CMS has put in place to reduce documentation burden for teaching physicians, while still maintaining safeguards to ensure that medical records include necessary information to demonstrate medical necessity and accurately document clinical findings, treatments, and ongoing care planning, as applicable.***

Care Management Services

CMS proposes separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. As described in the rule, CMS

[1] MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65–72.

expects that, in most instances, initiation of PCM would be triggered by an exacerbation of the patient's complex chronic condition or recent hospitalization such that disease-specific care management is warranted. Of note, CMS anticipates that in the majority of instances, PCM services would be billed when a single condition is of such complexity that it could not be managed as effectively in the primary care setting, and instead *requires management by another, more specialized, practitioner* [emphasis added].

While the Alliance greatly appreciates CMS' recognition of the important and necessary role of more specialized practitioners in the diagnosis, management and treatment of chronic diseases, we have concerns about potential overutilization of this service without appropriate billing and coding guardrails. More importantly, there seems to be considerable overlap in the various care management codes and the new complexity add-on code, particularly now that the office visit codes were just revalued to include time spent three days prior and seven days following each office visit. ***Consistent with the AMA RUC, we recommend CMS work with the relevant specialty societies to submit PCM services for consideration by the AMA CPT Editorial Panel and Relative Value Services Update Committee (RUC).*** Member organizations of the Alliance would be pleased to work with the relevant specialty societies through this process.

Should CMS disagree with this recommendation and finalize these codes for CY 2020, ***we urge the agency to work with the Alliance to establish appropriate billing and coding criteria and associated educational materials that clearly describe the differences in and appropriate scenarios for coding and billing care management services, the complexity add-on code, and revised E/M services. CMS' educational materials should also clarify that use of PCM services is not limited by specialty type.*** This will ensure specialty physicians apply these codes correctly and avoid unwanted audits.

Comment Solicitation on Consent for Communication Technology-Based Services

CMS seeks comment on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services, in which the practitioner would make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. ***We support a single advance beneficiary consent, which should allow practices to seek beneficiary consent for any combination of existing communication technology-based services for no less than one-year from the date the beneficiary consent is obtained.*** Additional program integrity efforts should not be necessary as CMS' current audit programs should identify unusual billing practices associated with these services.

Comment Solicitation on Opportunities for Bundled Payments under the PFS

CMS requests comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS to improve care while lowering costs. The Alliance is deeply concerned about efforts to expand bundled payments in the PFS given challenges associated with existing bundled payment and similar programs. For example, we are concerned with CMS' continued reliance on all-cause readmissions as this measure is not an accurate reflection of quality of care. More importantly, as we've stated elsewhere in these comments, ***we do not support the use of population-based administrative claims-based measures for a clinician-focused program such as MIPS.*** These measures do not result in meaningful or actionable feedback for specialists, require a large sample to produce reliable results, and do not provide a complete picture of quality due to the limitations of claims data. Of note, while CMS attempts to risk adjust its readmission measures, we remain concerned that it will not have enough of an impact to overcome the inherent flaws with the readmissions measures.

Also of note, we have concerns with transparency in the existing bundled payment programs and other alternative payment and delivery models. As we've stated previously, and most recently in our comments on the Patients Over Paperwork RFI, ***we urge CMS to release data on specialty participation in APMs, including bundled payment programs.***

As a result of our concerns, ***the Alliance recommends that CMS assess existing bundled payment programs (and other alternative models of delivery and payment) to ensure quality is accurately measured and maintained, and that cost-savings are truly being realized, before expanding bundled payments in the PFS.***

Payment for Evaluation and Management (E/M) Visits

CMS proposes significant modifications in coding and payment for E/M services that, if finalized, would have a stark impact on overall reimbursements to various specialties. While each Alliance specialty is impacted differently (positive and negative), as a coalition dedicated to the development of sound federal health care policy, we are concerned with the precedent CMS would be setting if it "de-linked" E/M values from the E/M services delivered as part of codes with global periods, while maintaining the link between E/M values and other PFS services. As a matter of policy, we believe it is grossly inappropriate to "pick and choose" when to apply established E/M values in the valuation of other services that incorporate E/M visits, or in this case, based on the context in which E/M services are delivered. If finalized as proposed, CMS would be establishing a policy that may have unintended consequences for future valuation decisions in many other areas. ***We, therefore, urge CMS to reverse its decision to exclude the updated E/M values in codes with global periods, which is inconsistent with the AMA RUC recommendations.*** The Alliance of Specialty Medicine believes that CMS should strive to maintain the integrity of the statutorily mandated resource-based relative value system (RVS) by ensuring that codes that have values derivative of the office and outpatient E/M codes are updated commensurately, including codes with global periods.

OTHER PROVISIONS OF THE PROPOSED REGULATIONS

Open Payments

While CMS does not specifically solicit comments about existing payment categories, we remain concerned about the nature of payment category "Education" and how it is defined. Specifically, under the current definition of education, CMS includes medical journal articles provided by applicable manufacturers about its products, despite the fact that these materials directly benefit patients.

As we shared previously, it is common for manufacturers to provide grants or other funding to physician societies and other CME providers to develop hand-out materials such as compendia of abstracts or pocket guides of guidelines. Since these materials are compiled by the societies as adjunctive materials to meetings, the Alliance feels strongly that they should be categorized as exclusions as they are intended to benefit patient care.

We urge CMS to revise the definition of education to exclude these items.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

While we recognize the importance of protecting the Medicare program and beneficiaries from potential harm, we believe that CMS' enrollment policies concerning improper prescribing and patient harm do not strike the right balance with the goal of ensuring access to specialized care; are duplicative of current safety mechanisms; and create excessive uncertainty and burden for clinicians as they engage in the practice of medicine.

With respect to CMS' proposal to specify that CMS may revoke Medicare enrollment for providers who have a pattern of improper prescribing of Part B drugs (in addition to Part D drugs), we are concerned that some specialties will be unfairly targeted and prevented from legitimate prescribing. As we have previously commented, what may be considered excessive prescribing for the general population could be clinically appropriate given a patient's individual circumstances, particularly in pain management and palliative care. We note that many "off-label" uses are clinically appropriate and represent the standard of care.

Furthermore, we are concerned with CMS' proposal to add a new revocation and denial reason based on the actions of other government bodies or oversight entities in order to address patient harm, which we believe represents overreach on the part of CMS. To begin, the list of sanctions or disciplinary actions from these entities that CMS would consider, such as license restriction(s) pertaining to certain procedures or practices, required compliance appearances before state oversight board members, required participation in rehabilitation or mental/behavioral health programs, required abstinence from drugs or alcohol and random drug testing, administrative/monetary penalties; or formal reprimand(s), are not necessarily indicative of patient harm. Furthermore, CMS fails to articulate clear standards for how it will determine, based on its assessment of the proposed factors, whether there are sufficient grounds to revoke or deny enrollment based on patient harm. Based on the policy as proposed, for example, CMS could potentially revoke or deny enrollment to an individual clinician based on a single compliance appearance before a state oversight board. Additionally, CMS' inclusion of "any other information that CMS deems relevant to its determination" as a factor in making a revocation or denial determination provides overly broad authority to CMS in making enrollment decisions. Given the consequence of enrollment revocation or denial on a practitioner's livelihood – including mandatory termination of participation in Medicaid and certain other federal health programs – as well as the potential impact on the availability of specialty physicians across the country including underserved areas, we believe that that CMS' proposed standard is unacceptable and must not be finalized.

For the reasons detailed above, we continue to oppose CMS' improper prescribing policies and CMS' new enrollment revocation and denial proposals.

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

CMS makes a series of proposals related to the advisory opinion process administered by the Agency related to application of the physician self-referral law (i.e. the Stark Law). In particular, CMS proposes that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would "preclude the imposition of sanctions . . . with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued." CMS goes further to propose that "the Secretary will not pursue sanctions . . . against any individuals or entities that are parties to an arrangement that CMS determines is

indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion" that received a favorable opinion.[2]

The Alliance continues to support agency efforts to maintain the integrity of the Medicare program through implementation of laws and regulations related to fraud and abuse. However, we are concerned that the Stark Law and its supporting regulations have become outdated and must be reviewed for relevance given changes and improvements in the health care delivery system since its passage and subsequent updates. This is underscored as the health care system attempts to move providers into arrangements focused on value-based care and with the push to increase participation in alternative payment models (APMs). We believe the agency must take significant steps to modernize the regulations related to the Stark Law. In the meantime, however, ***the Alliance supports the CMS changes related to the Agency's Stark law advisory opinion process***. We believe that entities' abilities to rely on favorable agency advisory opinions will be welcomed as providers contemplate new payment and delivery arrangements.

CY 2020 Updates to the Quality Payment Program

MIPS Value Pathways (MVP) Framework

In this rule, CMS proposes to apply a new MIPS Value Pathways (MVPs) framework to future proposals beginning with the 2021 MIPS performance year. According to CMS, MVPs would create a more cohesive and meaningful participation experience for clinicians by moving away from siloed activities and measures and toward an aligned set of measures that are more relevant to a clinician's scope of practice, while further reducing reporting burden and easing the transition to APMs through enhanced and timely performance feedback. Under the framework, CMS would develop multiple pathways that focus on specific specialties or conditions. A clinician or group would be in one MVP associated with their specialty or with a condition, reporting on the same measures and activities as other clinicians and groups in that MVP. MVPs would include measures and activities covering all four MIPS performance categories are addressed, including but not limited to administrative claims-based population health, care coordination, patient-reported (which may include patient reported outcomes, or patient experience and satisfaction measures), and/or specialty and condition specific measures. Each performance category would be scored according to its current methodology and current MIPS performance measure collection types would continue to be used to the extent possible. CMS envisions a program where eventually all MIPS eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory but instead would be required to report on measures and activities in a specialty- or condition-focused MVP. CMS also contemplates assigning clinicians and groups to MVPs. CMS states that these and other details would be addressed in next year's rulemaking cycle based on stakeholder feedback.

To guide future development of MVPs, CMS sets forth the following principles:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.

[2] CMS also adds "*[i]f parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request to query whether a referral is prohibited under section 1877 of the Act because the arrangement is materially indistinguishable from an arrangement that received a favorable advisory opinion*."

2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible and by linking cost and quality measurement.

The Alliance very much appreciates CMS' interest in simplifying MIPS, creating a more cohesive and meaningful participation experience, reducing clinician burden, and providing a glide path to Advanced APMs. Nevertheless, we are concerned that the MVP framework, as currently envisioned, does not go far enough in terms of addressing some of the most fundamental problems with MIPS and relies on what sounds like a mandatory assignment process that does not preserve clinician choice. Most notably, the framework fails to truly deconstruct the silos that currently separate each performance category. Instead, it simply attempts to connect the performance categories under a common theme but maintains a structure where each category still has a distinct set of measures/activities and a unique set of reporting and scoring rules. It is absolutely critical that the MVP framework focus primarily on unifying the MIPS performance categories through streamlined reporting and scoring strategies and providing cross-category credit that alleviates duplicative reporting and allows clinicians to spend more time tracking their performance rather than tracking compliance. In the absence of a better unification plan, the MVP framework will simply perpetuate confusion and what is becoming a pattern of disengaged compliance versus meaningful participation. The Alliance recognizes that CMS faces statutory limitations related to MACRA, but we also believe there is enough flexibility in the current statute for CMS to adopt more cohesive and less intricate policies that also simultaneously incentivize more innovative and meaningful demonstrations of high quality, high value care. It is equally critical that CMS preserve clinician choice and that participation in MVPs remains voluntary.

CMS poses multiple questions to the public to help it flesh out the MVP framework. Below are comments and concerns that are of greatest interest to the Alliance:

- ***Preserve clinician choice***. It is critical that clinicians have the ability to:
    - Participate in either an MVP or remain in the traditional MIPS pathway.
    - Voluntarily select the most appropriate MVP rather than CMS automatically assigning an MVP to a clinician or group.
- ***Work with relevant clinician stakeholders on an ongoing basis to develop MVPs in a transparent and collaborative manner***. The current framework lacks numerous critical details, many of which cannot be resolved through this rushed rulemaking cycle. We urge CMS to have an ongoing dialogue with stakeholders throughout the coming year, and subsequent years, to ensure careful and thoughtful consideration of these complex issues.
- ***Implement the MVPs gradually through pilot testing that focuses initially on relatively simple conditions/procedures impacting relatively homogenous patient populations that also have existing measures and activities***. Our volunteer members are already spread thin assisting CMS with activities such as the development of episode-based cost measures, and they have little available bandwidth to devote to yet another comprehensive development project that starts from scratch. CMS should rely on existing measures and activities to the greatest extent possible. At the same time, if a specialty expresses interest in bringing its own innovative measures to the table (e.g., cost measures), the MVP framework should accommodate the consideration of such measures.

- ***Consider condition- or procedure-specific MVPs rather than specialty-specific MVPs*.** Many specialties are divided into sub-specialties that have important distinctions in terms patient populations, procedures, and patterns of care. For example, within neurosurgery, there are surgeons that focus almost exclusively on cerebrovascular care (i.e., stroke) and surgeons that focus almost exclusively on spine care. It would be inappropriate to hold all of these surgeons to the same set of metrics. Even among spine surgeons and other sub-specialists, if could be challenging to identify a common set of metrics that would apply universally to all procedures and conditions. At the very least, we urge CMS to consider the use of separate or stratified benchmarks to accurately account for this diversity and ensure apples-to-apples comparisons of performance. As stated earlier, it is critical that CMS consult with specialty society experts to develop specific MVPs and to ensure appropriate measure selection and benchmarking methodologies.
- ***Incentivize meaningful engagement by specialists by preserving choice and simplifying program requirements and scoring policies*.** In its discussion of the MVP framework, CMS asserts that MIPS presents clinicians with too much complexity and choice, causing unnecessary burden; that it is difficult for clinicians to choose measures that are meaningful to their practices and have a direct benefit to beneficiaries; and that the program does not allow for sufficient differentiation of performance across practices due to clinician quality measures selection bias. The Alliance would like to clarify that it is not the wide choice of measures or activities that makes this program so confusing and difficult to navigate but, rather, the complicated set of reporting requirements and scoring rules, which differ from one category to the next. These include multiple conflicting eligibility and determination periods, some of which do not result in final determinations until late in the performance year; numerous distinct thresholds serving a variety of purposes—from scoring to eligibility; bonus points applied for different purposes and at different levels (category versus final score level); scoring caps tied to specific, detailed criteria; and disparate exclusions and exceptions, some of which are automatic and some of which require the submission of applications. Other policies are problematic in that they further discourage meaningful engagement by specialists. These include the ongoing removal of numerous specialty-specific MIPS and QCDR quality measures, increasingly stringent qualified clinical data registries (QCDR) criteria, and scoring caps for measures that lack benchmarks. In order for this program to produce data that will drive improvements and inform patient decision making about specialty care, CMS must preserve choice in terms of MIPS measure selection and participation options and adopt flexible policies that incentivize meaningful engagement by specialists rather than policies that marginalize them. We also fear the implications to specialists' successful participation in any quality component of MVPs based on CMS' aggressive proposals to remove topped out measures from the MIPS program. Historically, CMS has not allowed measure developers to re-tool measures removed from the program into specialty or procedure-specific measures, even when meaningful gap-in-care data can be provided and even though CMS does not analyze or publicly report data on topped out measures stratified by practice size, type, or specialty.
- ***Avoid the use of administrative-based population health measures***. Although these measures are meant to reduce reporting burden since they are calculated automatically by CMS, they are not meaningful and do not result in actionable feedback for specialists. They also do not typically provide an accurate or complete picture of a clinician's quality due to the limitations of billing data. Furthermore, they require a large sample to produce reliable results, which makes them potentially appropriate for facility-level or accountable care organization (ACO)-level programs, but present challenges in a clinician-focused program such as MIPS. Most specialists would prefer to use measures that produce valuable and actionable feedback, even if they

require an investment of time and resources to collect, versus meaningless population-focused administrative-based performance data calculated automatically by CMS. If CMS continues to see value in administrative-based population health measures, then it should provide them in the form of confidential feedback to clinicians rather than for purposes of accountability and payment updates.

- ***Customize Promoting Interoperability requirements.*** CMS should work with specialty societies to develop an inventory of Promoting Interoperability measures that look beyond EHR functionality and instead recognize diverse and innovative ways of sharing and otherwise making use of electronic health data to improve clinical outcomes (e.g., implementation of practice improvements based on clinical data registry data that incorporates EHR data). Clinicians working with CMS to develop MVPs, as well as clinicians continuing on the traditional MIPS pathway, should be able to choose the most relevant measures from this inventory similar to how clinicians may currently select from an inventory of over 100 Improvements Activities. We appreciate CMS moving in this direction with the addition of the voluntary Query of a Prescription Drug Monitoring (PDMP) measure, which provides MIPS clinicians with the flexibility to query a PDMP using data from CEHRT in any manner allowed under their State law. We urge CMS to continue to adopt measures that follow this more adaptable model.
- ***Use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by specialists and subspecialists in group practices.*** The Alliance continues to believe that MIPS group participation options should not be restricted according to a clinician's tax-ID number (TIN). Rather, a portion of a group should be able to ***voluntarily*** report as a separate sub-group on measures and activities that are more applicable to the sub-group and be scored accordingly based on the performance of the sub-group. As such, we appreciate CMS' consideration of the use of the MVP framework as an alternative way to expand participation options for specialists and subspecialists through sub-group reporting. To ensure that specialists can take advantage of this innovative participation option, it is critical that CMS simultaneously address other policies, discussed earlier, that continue to disincentivize more meaningful engagement by specialists. We also believe that any decisions related to specialist or sub-specialist participation within a larger group practice should be voluntary and made by the members of the group.
- ***Continue efforts to provide enhanced and timelier clinician feedback***. CMS expresses interest in providing more meaningful performance feedback to clinicians, but its proposed vision seems to focus on enhanced claims-derived feedback. While specialists would appreciate enhanced access to claims data, this data must be presented in a timely-fashion (preferably real-time) and in a manner that helps clinicians better understand their practice patterns in terms of both cost and quality so that they are better prepared to potentially transition to APMs. Data provided by CMS to date has been untimely and difficult to interpret. For example, the current cost measures seem to represent a double standard set by CMS. Feedback is only provided by CMS once, and only during the post-submission targeted review period, which is in direct opposition to the program requirement for QCDRs to provide snapshots of quality measures at least four times during the performance period to allow reporting clinicians the chance to integrate quality improvement into their practice patterns and workflows. CMS should continue to work with stakeholders to refine the format in which this data is presented and to consider ways to merge claims data with existing clinical data collected form registries to ensure a more complete picture of care.
- ***To better assist patients with healthcare decision making, MVPs must capture data on specialty care.*** The Alliance supports CMS' goal of helping patients to make more informed health care decisions and believes that if MVPs are constructed with relevant stakeholder input

and in a manner that captures specialty care, they can come closer to achieving that goal. We support the use of patient-reported clinical outcome measures so long as the MVP framework recognizes the time and resources required to collect this type of data. For example, CMS could provide cross-category credit for such measures (e.g., patient-reported outcomes collected via a patient portal connected to a registry or EHR and used to improve practice could be eligible for credit under the Quality, Promoting Interoperability, and/or Improvements Activity categories) or reduce the number of required measures in a MVP when a patient-reported outcome measure is included. On the other hand, we request that CMS approach patient experience and satisfaction measures more carefully given their subjective nature and variability. CMS discusses potentially reporting on Physician Compare a "value indicator" representing each clinician's performance on cost, quality, and the patient's experience of care. We do not believe that publicly reporting patient experience measures would be appropriate at this time. We also caution against making too many data points available to public since this could confuse patients and clinicians.

MIPS Policies Proposed for 2020 and Beyond

As CMS continues to work with stakeholders to develop the MVP framework and address more fundamental reforms to MIPS, CMS should also ensure that the traditional MIPS track remains as consistent as possible. Each year since its inception, CMS has made significant changes to the program that not only confuse clinicians and patients, but also divert limited resources to administrative processes that do little to improve patient care or experience. Importantly, these constantly shifting targets prevent accurate long-term assessments of the feasibility of program policies, as well as other participation and performance trends.

Performance Category Weights. For the 2020 performance year, CMS proposes to decrease the Quality category weight to 40 percent and to increase the Cost category weight to 20 percent, and to continue on this path until both categories are weighted at 30 percent for the 2022 performance period. The Alliance appreciates CMS' attempt to gradually shift these weights in order to prepare clinicians for the sixth year of the program, when CMS is required by statute to assign a weight of 30 percent to each of these categories. Nevertheless, ***we oppose CMS raising the weight of the Cost category at this time due to ongoing concerns regarding the existing set of cost measures (see additional comments in the Cost section below) and the fact that clinicians continue to have far more direct control over quality measures than they do over cost measures***.

Quality Category: Removal of Measures. In this rule, CMS proposes to eliminate 55 quality measures for 2020, which represents over 20 percent of the measures in the program. Many of these measures are specific to specialty care and if removed, will further erode the choices available to specialists and further limit their ability to participate fully and meaningfully in the program. This proposal, paired with CMS' simultaneous decision to scale back on the number of QCDR measures, further impacts the ability of specialists to participate fully and meaningfully in MIPS and sends a signal to our member societies to reconsider future investment in the development of new measures. ***We strongly urge CMS to reconsider the removal of these measures, particularly those that are being proposed for removal due to topped out status or an ongoing lack of benchmark***. These specific issues are discussed in more detail below.

Quality Category: Topped Out Measures. ***The Alliance continues to oppose the elimination of topped out measures for multiple reasons***. For one, current determinations of topped out performance may not be accurate due to shifting program requirements from year to year. They also might only reflect the performance of a portion of clinicians who self-select the measure because of expected high performance, rather than true performance across all eligible clinicians. Furthermore, high performance rates do not necessarily mean that a measure is no longer meaningful to patients and clinicians and should stopped being tracked. In fact, removal of such measures could lead to serious unintended consequences if declining performance becomes difficult to track over time. For example, CMS proposes to remove the following two cataract surgery outcome measures for 2020 due to topped out status without accounting for the clinical relevance of these measures: #192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures; and #388: Cataract Surgery with Intra-Operative Complications. Cataract surgery is a highly-successful procedure and complication rates are extremely low; therefore, even slight increases in an individual surgeon's rate of complication are concerning and captured by these measures. Maintenance of these measures would allow cataract surgeons real-time awareness of complication rates and provide real opportunities for quality improvement where necessary. We urge CMS to conduct more thorough analyses of factors potentially influencing topped out performance. CMS should consider factors such as whether performance varies by group versus individual reporting, by practice setting, by geography, by volume of cases, or by physician experience with quality reporting.

CMS seeks feedback on potentially increasing the data completeness threshold for extremely topped out measures that it retains in the program. The Alliance has concerns about this policy since it would not sufficiently address the aforementioned issues that impact the potential accuracy of current topped out determinations. Adopting yet another threshold also adds to the complexity of the program, rather than helping to simplify it. To maintain program stability and choice, we urge CMS to maintain these measures over time so that it can conduct more thorough analyses of what is contributing to topped out performance. Simultaneously, CMS should consider ways to maintain topped out measures in the context of MVPs, such as by folding them into composite measures or requiring a greater number of measures when a MVP relies on topped out measures.

Quality Category: Measures with No Benchmark. Beginning with the 2020 performance period, CMS proposes to remove quality measures that do not meet case minimum and reporting volumes for benchmarking for two consecutive years (i.e., do not have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size of 20 applicable cases). This policy would apply to traditional MIPS measures, as well as QCDR measures. As we noted earlier, ***the Alliance strongly opposes this and other policies that disincentivize meaningful participation by specialists***. Currently, measures that meet data completeness, but do not have benchmark are capped at 3 points, which discourages clinicians from selecting these measures and creates a cycle where it is nearly impossible to accrue enough data to calculate a benchmark. CMS needs to consider the effect of these policies as a whole. For example, none of the measures in the Urology Specialty Measure Set have been reported sufficiently to achieve benchmarks. If this proposal is finalized, all of these urology measures could be removed from the program, leaving Urologists with few relevant participation options. Before attempting to remove measures without a benchmark, CMS should first adopt more flexible policies that encourage additional clinicians to report them. This includes removing the low cap on points that can be earned on measures without benchmarks and permitting subgroup-like reporting to incentivize specialists in multi-specialty groups to select these

more meaningful measures. Until these changes are made and clinicians have a fair opportunity to report these measures and build a benchmark, it is unreasonable to remove them. We also remind CMS that low reporting rates are not always an indication that the measure is not of value to patients. Some measures may only be reported by a small number of clinicians (e.g. pediatric specialists) and yet represent a significant percentage of the clinicians caring for the patients to which the measure applies.

Quality Category: Data Completeness Criteria. Starting with the 2020 performance year, CMS proposes to increase the quality measure data completeness threshold, which is the percentage of eligible patients that a clinician must report on for each quality measure, from 60 percent to 70 percent. While CMS presented 2017 data showing that, on average, clinicians are already reporting on more than 70 percent of applicable patients, ***we oppose this proposal for multiple reasons since it represents yet another moving target when what this program needs more than anything is consistency***. Additionally, it is unclear from the data presented in the rule whether the average data completeness rate reflect Medicare only reporting or reporting across all payers. If the former, it might not be an accurate reflection of national reporting trends. It is also based on 2017 data, when the Pick Your Pace option was available, which might distort the results. The data that has been provided by CMS further fails to distinguish between practices reporting their data manually or through an electronic health record. Raising the data completeness threshold specifically targets manual data entry clinicians who are already burdened by the lack of available EHR technology to complete this process and will now have to divert more staff time and financial resources to be successful in the program. Furthermore, increasing this already arbitrary threshold will further impact specialists who practice in multiple sites under a single TIN. Oftentimes, not all sites participate in MIPS or use the same registry or EHR, which makes it more challenging to capture a higher percentage of applicable patients.

CMS previously finalized that beginning in 2020, clinicians other than small practices will receive zero points on a measure that does not meet the data completeness threshold. ***We oppose this inflexible policy and request that CMS reverse it since it would not provide any credit to clinicians who attempt to submit data. We also believe that it would be inappropriate to simultaneously adopt a higher data completeness threshold while at the same time implementing a policy to award zero points to clinicians who fail to meet the threshold.***

Quality Category: Administrative Claims-Based Population Health Measures. Currently, the MIPS program has one administrative claims-based quality measure, the all-cause readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum. In this rule, CMS proposes to add a second administrative claims-based measure— an All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure— to MIPS in 2021. ***As we discussed in our MVP comments above, we do not support the use of population-based administrative claims-based measures for a clinician-focused program such as MIPS***. These measures do not result in meaningful or actionable feedback for specialists, require a large sample to produce reliable results, and do not provide a complete picture of quality due to the limitations of claims data.

Cost Category. For 2020, CMS proposes to incorporate revised versions of the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) measure, to maintain the eight episode-based cost measures approved for 2019, and to add the following ten episode-based cost measures:

1. Acute Kidney Injury Requiring New Inpatient Dialysis
2. Elective Primary Hip Arthroplasty

3. Femoral or Inguinal Hernia Repair
4. Hemodialysis Access Creation
5. Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
6. Lower Gastrointestinal Hemorrhage
7. Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels
8. Lumpectomy Partial Mastectomy, Simple Mastectomy
9. Non-Emergent Coronary Artery Bypass Graft (CABG)
10. Renal or Ureteral Stone Surgical Treatment

We appreciate CMS' efforts to work with stakeholders to develop and refine these measures, including updates to the TPCC measure to ensure it focuses exclusively on primary care; however, we have concerns about the implementation without validity testing to ensure appropriate attribution.

For the TPCC measure, the MAP Coordinating Committee provided a final recommendation of "do not support for rulemaking with potential for mitigation" due to multiple ongoing concerns, including the lack of available information on the measure's validity testing. In regards to the revised MSPB measure, although the MAP conditionally supported it pending NQF endorsement, it cited various ongoing concerns with the measure, such as the need for ongoing testing to ensure the measure demonstrates validity and reliability at the individual clinician level. The MAP also voiced concern that neither the original nor revised version of the measure has been reviewed by NQF, limiting the public's ability to determine the validity of the changes to the measure. Furthermore, the MAP raised concerns about double counting clinician costs across the TPCC, MSPB and episode-based cost measures and challenges it faced getting access to field test data.

Overall, despite efforts by CMS to improve these measures, the Alliance continues to question the appropriateness of using both the TPCC and the MSPB measure in a clinician level accountability program. Most clinicians still lack a clear understanding of these measures, question whether the measures capture costs over which they have direct control, and question how they can use the data to make practice improvements. Further, QCDRs with signed data use agreements handling submission for practices have no means to access centralized cost data during the post-submission targeted review period, other than through manual contact of every practice. This is particularly egregious given CMS' proposals to increase the requirements for QCDRs to act as quality improvement educators.

In regards to the episode-based cost measures, our members support the development of more focused cost measures and appreciate CMS' efforts to be transparent and inclusive to date in the development of these measures. However, both the development process and the field-testing period remains rushed, which has caused confusion among even our most engaged members and has prevented them from providing meaningful feedback. We strongly recommend that CMS continue to make improvements to the field-testing period, including better education and outreach to clinicians not involved in the development process and a longer field testing and feedback period.

We are also concerned that only three of the 18 episode-based cost measures proposed for 2020 have been endorsed by the NQF. Among the Wave 1 measures, which are currently being used in MIPS, only three were endorsed by the NQF.[3] The other five measures were brought to the NQF, but did not pass

[3] The following episode-based cost measures are currently under review by NQF: Routine Cataract Removal with Intraocular Lens Implantation, Screening/Surveillance Colonoscopy, and Knee Arthroplasty.

muster with the Scientific Methods Panel and thus, did not move on to a formal evaluation by the Cost committee. In terms of the ten Wave 2 measures proposed to be added to MIPS in 2020, none have been reviewed yet by the NQF. This seems to be at odds with CMS' other proposals as they relate to QCDR measure testing requirements at the NQF standard, and sets a dangerous double standard within the program.

Given these ongoing issues with all of the cost measures, we strongly recommend that CMS maintain the 15 percent weight for the Cost category in 2020, and remain flexible with the weight of this category over the next three years. Such flexibility would recognize the ongoing work and evaluation related to these measures and the need for additional education and outreach so that clinicians can better understand these measures.

Improvement Activities Category. CMS proposes to revise the attestation requirements for group practices participating in this category. Starting in 2020, a group or virtual group would be able to attest to an Improvement Activity only if at least 50 percent of MIPS eligible clinicians (in the group or virtual group) participate in or perform the activity. CMS clarifies that at least 50 percent of a group's NPIs must perform the same activity for the same continuous 90 days in the performance period. CMS also clarifies that a TIN could submit a single attestation affirming that these criteria were met.

The Alliance opposes this proposal because it adds another layer of complexity by once again shifting the rules of the program. Importantly, it also does not reflect the realities of clinical practice, where a specific Improvement Activity might only be relevant to a single specialist in a multi-specialty practice, yet that intervention might impact a large portion of the group's patients. Furthermore, it would be logistically challenging and impractical to expect all of these clinicians to perform the activity over the same 90 day period. Finally, this proposal does not align with the APM track of the Quality Payment Program in that APMs are not held to a similar threshold that takes into consideration how many clinicians within the APM completed the activity. Ideally, we would recommend that CMS maintain its current policy where if at least one clinician in the group performs the activity for a continuous 90 days, the entire group may get credit for that activity. If CMS insists on adjusting this policy, it should at least modify it so that a certain percentage of clinicians in the group (ideally less than 50 percent) must complete any single activity, rather than the same activity, over the performance year, rather than over the same 90 day period.

Promoting Interoperability Category. ***The Alliance appreciates CMS' effort to streamline the reporting requirements of this category over the last year. Nevertheless, as we discussed earlier in our comments on the MVP framework, this category could benefit from even fewer rigid requirements and a larger inventory of measure options that are more relevant to specialists***. This should include measures that look beyond EHR functionality and instead recognize innovative ways of sharing and otherwise making use of electronic health data to improve clinical outcomes (e.g., implementation of practice improvements based on clinical data registry data that incorporates EHR data). Clinicians working with CMS to develop MVPs, as well as clinicians continuing on the traditional MIPS pathway, should be able to choose the most relevant measures from this inventory similar to how clinicians may currently select from an inventory of over 100 Improvements Activities. CMS' decision to add the voluntary Query of a Prescription Drug Monitoring (PDMP) measure last year, which provides MIPS clinicians with the flexibility to query a PDMP using data from CEHRT in any manner allowed under their State law, shows its willingness and ability to think outside the box. Moving forward, we urge CMS to consider adopting similarly unique measures that are not directly tied to EHR functionalities and represent diverse activities related to the exchange of health-related data. We also recommend that

CMS rely on Yes/No measure attestations for this category as much as possible, which would minimize clinician reporting burden and align with how clinicians attest to Improvement Activities.

Promoting Interoperability Category: Hospital-Based Group Definition. CMS proposes to revise the definition of a hospital-based "group" so that such a group would be identified as hospital-based and eligible for reweighting of the Promoting Interoperability category if more than 75 percent of the NPIs in the group meet the definition of a hospital-based individual MIPS eligible clinician (versus the current definition of 100 percent). ***The Alliance supports and appreciates this modification since it consistent with the threshold used for groups in the definitions of facility-based MIPS eligible clinician and non-patient facing MIPS eligible clinicians.***

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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 Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions