AMERICAN PSYCHIATRIC ASSOCIATION

1000 Wilson Blvd., Suite 1825
Arlington, VA 22209

November 17, 2015

Andy Slavitt, MBA
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016

Re: CMS-3321-NC, Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Mr. Slavitt:

On behalf of the American Psychiatric Association (APA), the national medical specialty society representing over 36,000 psychiatric physicians and their patients, I am pleased to share APA's comments on the Request for Information on Implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). Effective MACRA implementation is critical for ensuring psychiatrists' ability to meaningfully participate in Medicare and patients' access to needed psychiatric care.

A. THE MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

1. MIPS EP Identifier and Exclusions

- Should we use a MIPS EP's TIN, NPI or a combination thereof? Should we create a distinct MIPS Identifier?

CMS should establish a simple and flexible process for identifying MIPS eligible professionals (EPs). To minimize potentially disruptive and administratively burdensome changes, the best approach may be to maintain identification by each EP's TIN/NPI combination, in place for the current physician quality programs.

- What are the advantages/disadvantages associated with creating a distinct MIPS identifier?

Requiring all EPs to register with CMS to create a new, distinct MIPS identifier would create a potentially insurmountable administrative burden for both EPs and for the agency. We are concerned with the ability of CMS' existing infrastructure to handle the creation of a new distinct MIPS identifier, especially ahead of the start of the MIPS reporting period and with enough lead time to allow all EPs to register. It is also not clear that CMS would be able to administer payments or penalties sufficiently through a new identifier separate from a TIN, and whether it would require an addition to the 1500 claims form.

2. Virtual Groups

- How should eligibility, participation, and performance be assessed under the MIPS for voluntary virtual groups?

EPs or small practices that practice in a certain specialty or sub-specialty may want to create a virtual group and report on the same quality measures and Clinical Practice Improvement activities. However, there should be no requirement that all EPs within a virtual group are within the same specialty. Allowing for the pairings of EP's within different specialties provides for an increased likelihood that these providers will meet the reporting criteria. It would be of value to establish an honest broker to designate pairings of the groups.

CMS may want to consider developing a separate identifier for each virtual group (especially virtual groups that do not already operate under a single TIN). This could be an "internal" identifier, solely for use by CMS, or an "external" identifier that the virtual group would also be required to use.

- Assuming that some, but not all, members of a TIN could elect to join a virtual group, how should remaining members of the TIN be treated under the MIPS, if we allow TINs to split?

EPs and small practices should be allowed to break away from larger TINs to form virtual groups. The remaining EPs within the TIN should be allowed to elect how they participate in MIPS or in APMs.

- Should there be a maximum or a minimum size for virtual groups? For example, should there be limitations on the size of a virtual group, such as a minimum of 10 MIPS EPs, or no more than 100 MIPS EPs that can elect to be in a given virtual group?

There should be maximum flexibility for physicians, small practices, and other EPs to form virtual groups. There should be no initial, annual, or other limits placed on the maximum number of virtual groups that could be approved each year. Setting limits on the establishment of virtual groups, including the maximum number of groups, minimum or maximum size, geographic proximity, or particular specialty, would have a chilling effect and discourage the EPs from pursuing this option. Such limitations could particularly harm the practices with limited resources and administrative support, which would most benefit from being in a virtual group.

- Should there be a limit placed on the number of virtual group elections that can be made for a particular performance period for a year as this provision is rolled out? We are considering limiting the number of voluntary virtual groups to no more than 100 for the first year this provision is implemented in order for CMS to gain experience with this new reporting configuration. Are there other criteria we should consider? Should we limit for virtual groups the mechanisms by which data can be reported under the quality performance category to specific methods such as QCDRs or utilizing the web interface?

As discussed in the previous question, limiting the number of virtual groups would inappropriately discourage participation. If there are concerns about the launch of virtual groups we instead recommend a pilot year prior to MIPS implementation to address any implementation challenges.

- If a limit is placed on the number of virtual group elections within a performance period, should this be done on a first-come, first-served basis? Should limits be placed on the size of virtual groups or the number of groups?

If limits are established, they should be arranged by specialty to allow various fields of medicine to identify whether this is a reasonable reporting option for these providers.

- Should there be limitations, such as that MIPS EPs electing a virtual group must be located within a specific 50 mile radius or within close proximity of each other and be part of the same specialty?

It would not be appropriate to set arbitrary geographic limitations, including a 50-mile radius, in particular as telemedicine is becoming more widely available. It also could hinder small groups of physician sub-specialties from joining together in a virtual group. Other limitations or parameters for being matched in a virtual group should be evident to the conveners and the eligible professionals. For example, a psychiatrist who predominantly treats patients with schizophrenia might find value in being matched with a psychiatrist who predominantly treats patients with depression. The clinician treating schizophrenia otherwise would be left without enough measures to report on and therefore fail their performance measurement requirement.

3. Quality Performance Category

a. Reporting Mechanisms Available for Quality Performance Category

- Should we maintain all PQRS reporting mechanisms noted above under MIPS?

Yes. This will allow for a more seamless transition to the new program. Additionally, psychiatrists have a low rate of adoption of EHRs and potentially limited access to registries, therefore maintaining the claims-based reporting mechanism ensures that at least a minimal number of measures may be reported on.

- Should we maintain the same or similar reporting criteria under MIPS as under the PQRS? What is the appropriate number of measures on which a MIPS EP's performance should be based?

Psychiatrists already encounter a limited number of applicable specialty-specific measures. We would not want to see an inflated number of required measures, unless they are specialty specific and directly relevant to improving the care of patients with psychiatric disorders.

- Should we maintain the policy that measures cover a specified number of National Quality Strategy (NQS) domains?

No. By requiring that the measures cover a specified number of NQS domains, psychiatrists are forced to report on clinically irrelevant measures. We therefore urge CMS to reconsider the current Physician Quality Reporting System (PQRS) requirement of 9 measures across 3 domains, which is an arbitrarily high standard that often results in reporting for the sake of reporting and subsequently data that is of little value. Maintaining the 9 measure reporting requirement also fails to recognize that the MIPS increases the total reporting burden of physicians with the addition of

the new category of Clinical Practice Improvement (CPI) activities. CMS should keep in mind that for some physicians and the psychiatric specialty in particular, some or all of the activities captured though this category may be more meaningful and accurate representations of quality than the current set of PQRS quality metrics. While APA supports the goal of identifying national strategy domains, including the need to ensure a balanced national scorecard for quality, it is sometimes challenging to fit measures into these discrete boxes and ensure that specialties, such as psychiatry, have an adequate suite of measures to meaningfully participate and comply with the program. The current domain assignment is very arbitrary and measures are moved from one domain to another from year to year. CMS should allow a measure to satisfy multiple domains. We also believe that by adding the new category of Clinical Practice Improvement, CMS will inherently target a wider array of quality interventions that satisfy the goals of multiple domains.

Consequently, we recommend that CMS consider doing away with the domain requirement and instead use domains to simply guide measuring national quality goals. Alternatively, if this is not possible, CMS should, at the very least, allow measures to be assigned and counted towards meeting multiple domains. We also would like to highlight that CMS' process of assigning domains and determining Measure Applicability Validation (MAV) clusters has historically occurred within a "black box." We urge CMS to give relevant stakeholders an opportunity to provide input into these determinations before domains and clusters are presented in proposed rules.

- Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

As discussed previously, this would pose challenges for specialties in which a limited number of measures exist. We oppose requiring that a minimum number of measures be outcomes-based and/or weighing outcome measures more heavily than other measures. APA cautions against any assumption that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their patient population. Holding physicians accountable for something that is not necessarily within their direct control would be imprudent. It also ignores infrastructure issues that may prevent the development or incorporation of appropriate outcome measures into CMS programs.

- How do we apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria? Should we maintain a Measure-Applicability Verification Process? If we customize the performance requirements for certain types of MIPS EPs, how should we go about identifying the MIPS EPs to whom specific requirements apply?

For specialties such as psychiatry that may not have enough measures, CMS should, in consultation with the affected specialty societies, use its authority to re-adjust the weights of the other MIPS categories. In particular, the Clinical Practice Improvement category may provide the most flexibility for many physicians to receive recognition for the quality improvement activities that are most relevant to their practice.
Additionally, because of the limited application of current quality measures eligible for reporting to psychiatry, a measure applicability verification (MAV) process is very much needed. However, the current MAV process has little to no utility for psychiatrists. The most commonly reported problem by APA members is that the MAV process does not occur until the end of the reporting year - when

it is too late for the clinicians to make a good-faith effort to correct and submit measures they might have missed. We therefore urge for improvements to this needed, but currently flawed, verification process.

- What are the potential barriers to successfully meeting the MIPS quality performance category?

Potential barriers to successfully meet the MIPS quality performance category include: psychiatric clinicians' low EHR adoption rate due to the cost of such systems and lack of systems that include specifications relevant to psychiatry; the reduction of claims-based measures available for reporting, and the low number of available psychiatric-specific performance measures. We in particular oppose any request that CMS not push forward with the development and maintenance of administrative claims based outcome measures. This would pose negative implications for psychiatry.

b. Data Accuracy

- What should CMS require in terms of testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product? How can testing be enhanced to improve data integrity?

APA recommends that a set of data unit tests with well-defined inputs and outputs be used in the testing of these products. These tests must be capable of demonstrating compliance to data calculation standards as defined in the data specification.

- Should registries and qualified clinical data registries be required to submit data to CMS using certain standards, such as the Quality Reporting Document Architecture (QRDA) standard, which certified EHRs are required to support?

APA recommends that registries and QCDRs be required to submit data to CMS using standards that, not only focus on the specific data elements, but also the semantics used to define the sent data's parameters. These semantics should be both broad and deep to allow for quality data to be collected in order to maximize the data's potential for highlighting clinical processes and outcomes. The QRDA would be an acceptable standard to be used, but might prove to be too cumbersome for some EPs' technical capabilities.

- Should CMS require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that CMS' form and manner are met? For example, CMS uses a specific file format for qualified registry reporting. The current version is available at: https://www.qualitynet.org/imageserver/pqrs/registry2015/index.htm. What should be involved in the testing to ensure CMS' form and manner requirements are met?

APA supports CMS' development of the basic document reporting schema as detailed above. We in particular urge for the development of a functional definition of the schema, so that components of the scheme (e.g., use cases) can be integrated across a variety of platforms in ways that are easily replicated and testable.

- What feedback from CMS during testing would be beneficial to these stakeholders?

Until the issues above are resolved (i.e., data specifications and semantics are selected), the type and amount of feedback produced in any desired testing scenario is unknown.

- What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data? For example, if a QCDR's calculated performance rate does not equate to the distinct performance values, such as the numerator exceeding the value of the denominator, should CMS re-calculate the data based on the numerator and denominator values provided? Should CMS not require MIPS EPs to submit a calculated performance rate (and instead have CMS calculate all rates)? Alternatively, for example, if a QCDR omits data elements that make validation of the reported data infeasible, should the data be discarded? What threshold of errors in submitted data should be acceptable?

We recommend that EPs use a system that is capable of transmitting to CMS both raw and calculated data. This would enable EPs to monitor the accuracy of their chosen system in calculating quality improvement and quality assurance variables while also comparing these values to CMS' calculations. This would increase QI/QA alignment between CMS and EPs participating in this process and also allow for better auditing processes fundamental to QCDR.

- If CMS determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet our data integrity standards, how should CMS assess the MIPS EP when calculating their quality performance category score? Should there be any consequences for the qualified registry, QCDR or EHR vendor in order to correct future practices? Should the qualified registry, QCDR or EHR vendor be disqualified or unable to participate in future performance periods? What consequences should there be for MIPS EPs?

APA understands that there should be consequences for registries, QCDRs, and EHR vendors who miscalculate their quality performance category score and transmit these results, inappropriately, to CMS. Rather than develop a consequence based on payment, it might be more prudent to develop a process whereby EPs can send a "soft score" for CMS to check and validate before accepting a final quality performance score for reimbursement processes. This would help identify errors in the reporting process and lead to better data outcomes, overall.

c. Use of Certified EHR Technology (CEHRT) under the Quality Performance Category

- Under the MIPS, what should constitute use of CEHRT for purposes of reporting quality data?

Until specific use cases are developed for CEHRT under MIPS, APA cannot offer constructive feedback for this question.

- Instead of requiring that the EHR be utilized to transmit the data, should it be sufficient to use the EHR to capture and/or calculate the quality data? What standards should apply for data capture and transmission?

It is unclear how CMS would monitor or use any data that is simply captured and calculated in the EHR, rather than requiring the EHR to transmit the data. Furthermore, all data captured and transmitted from an EHR to CMS should be in the format in which they are sent to CMS so that the comprising elements can be traced back to their canonical origins in the EHR.This will enable audits of the tracking and transmission logs to be completed in order to determine errors or problems with QI/QA.

4. Resource Use Performance Category

- Apart from the cost measures noted above, are there additional cost or resource use measures (such as measures associated with services that are potentially harmful or over-used, including those identified by the Choosing Wisely initiative) that should be considered? If so, what data sources would be required to calculate the measures?

APA supports the use by physicians of evidence-based clinical decision support systems to help guide their choice of treatment for particular conditions or patients. A growing number of specialties have developed and continue to expand and refine clinical guidelines and appropriateness use criteria (AUC). The "Choosing Wisely" campaign is a related but different specialty-driven program which was intended to promote a dialogue between patients and providers around potentially unnecessary tests, treatments and procedures.

Neither of these concepts should be considered absolute recommendations regarding the appropriateness of a given test, treatment or procedure. When presented with the general Choosing Wisely guidelines, a physician or patient may conclude that a particular recommendation is not appropriate in a given circumstance. Similarly, due to the nature of their practice, some physicians may conclude that particular recommendations do not apply to a subset of their patients. As a result, some legitimate variation in adherence to AUC and therefore average costs is to be expected. In addition, CMS' current attribution methods frequently hold the wrong physician accountable for the cost of a given service. Until such issues are resolved, it would be premature to judge physicians' resource use based on AUC or Choosing Wisely guidelines. Instead, physicians who use these should be given credit under the Clinical Practice Improvement category. However, individual specialties might decide to use AUC or "Choosing Wisely" guidelines in the creation of resource use measures applicable to their members. In these cases, CMS could then consider adoption of any that have a solid evidence base and were developed through a multi-specialty, clinician-led process. All specialties that provide the service in question would need to be consulted prior to adoption.

5. Clinical Practice Improvement (CPI) Activities Performance Category

APA urges CMS to allow for the broadest interpretation of CPI activities possible. The selection of activities should be optional. No category should be mandatory. Physicians should be given credit for CPI activities in which they are currently engaged, including those that are mandated or encouraged by Medicare and other government programs, as well as any institutions in which they practice, such as hospital activities related to Joint Commission Accreditation. Various activities of organizations representing physicians and medical groups should also be recognized as practice improvement. This would include accredited continuing medical education, board-certification-

related activities, and other initiatives aimed at improving clinical practice, such as opioid prescriber training and the provision of medication-assisted treatment of opioid use disorders.

- Should EPs be required to attest directly to CMS through a registration system, web portal or other means that they have met the required activities and to specify which activities on the list they have met? Or alternatively, should qualified registries, QCDRs, EHRs, or other health IT systems be able to transmit results of the activities to CMS?

Physicians should be able to demonstrate their performance of CPI activities through a simple attestation process. The attestation process would be best facilitated through a web portal that is simple to access and use. Transmission of CPI activity results also should be permitted, but not required, through EHRs and QCDRs when and where the capabilities exist. The physician or other EP should generally be responsible for documenting CPI activities. Participation in some activities could be reported on and/or collected from claims. Organizations and other entities that sponsor CPI activities should be required to maintain records for up to a certain period of time that can be used to verify physician or other eligible professional participation in a CPI activity. Where applicable, there should be an option of having participation in a CPI activity reported by the certifying agency rather than individual physicians. An APM Entity should be allowed to provide participation rates for physicians in the APM.

- How often should providers report or attest that they have met the required activities?

Attestations should occur annually. Some CPI activities (e.g., a certification) may be granted by the certifying organization for more than a one-year period. In such cases, physicians and other EPs should be allowed to attest to that activity for each of the years until the certification expires. After the initial year, the physician or other EP should not have to demonstrate anything additional in subsequent attestations until the certification expires, unless additional actions are required by the certifying organization.

- What threshold or quantity of activities should be established under the clinical practice improvement activities performance category? For example, should performance in this category be based on completion of a specific number of clinical practice improvement activities, or, for some categories, a specific number of hours? If so, what is the minimum number of activities or hours that should be completed? How many activities or hours would be needed to earn the maximum possible score for the clinical practice improvement activities in each performance subcategory? Should the threshold or quantity of activities increase over time? Should performance in this category be based on demonstrated availability of specific functions and capabilities?

CPI activity performance should be based on completion *or ongoing participation* in a specified number of clinical improvement activities, rather than hours. CPI activities should include those in which an individual physician or other EP can participate or complete, *or* activities in which participation or completion occurs at the group practice level.

- How should the various subcategories be weighted? Should each subcategory have equal weight, or should certain subcategories be weighted more than others?

At least initially, all CPI activities should be weighted equally. Physicians should not be required to attest to a CPI activity in every subcategory or any specific subcategory or activity. They should be able to pick and choose, so these would have to be weighted equally.

- How should we define the subcategory of participation in an APM?

The subcategory of participation in an APM should not be limited to qualified APMs. The definition of the APM subcategory under MIPS should include physician or other EP's participation in an APM "sponsored" by a commercial payer or Medicaid.

- How should the clinical practice improvement activities performance category be applied to EPs practicing in these types of small practices or rural areas?

Allowing for the broadest definition of CPI activities and least burdensome requirements will be needed to ensure that physicians in small or rural practices are able to participate. Ensuring that there are options which are free or low cost will also be crucial. For example, many physicians issue disease and population-specific notifications and perform other activities without the use of a certified electronic medical record, and this should be counted as CPI.

6. Meaningful Use of Certified EHR Technology Performance Category

- Should the performance score for this category be based be based solely on full achievement of meaningful use? For example, an EP might receive full credit (for example, 100 percent of the allotted 25 percentage points of the composite performance score) under this performance category for meeting or exceeding the thresholds of all meaningful use objectives and measures; however, failing to meet or exceed all objectives and measures would result in the EP receiving no credit (for example, zero percent of the allotted 25 percentage points of the composite performance score) for this performance category. We seek comment on this approach to scoring.

APA does not recommend an "all-or-nothing" approach to scoring for EPs' attempt to meeting meaningful use criteria. This method is self-limiting for psychiatrists (and other specialty groups) where the measures and objectives may lack relevance to the practice of psychiatry. Instead, the APA would rather that EPs demonstrate that they are using EHR technology "meaningfully" and to the greatest extent possible given how the measures and objectives overlap with their clinical practice. At the very least, lower thresholds or exceptions to the measures should be considered when meeting meaningful use standards so that EPs can attain the 25 percentage points with reasonable justification.

- What alternate methodologies should CMS consider for this performance category?

CMS should work with various specialties to determine how their varying scopes of practice impact the ability to meet performance thresholds and thus select measures that are reflective of actual practice. There should be significant flexibility in the type of hardship exceptions that are offered for Meaningful Use.

- How should hardship exemptions be treated?

Providers should not be penalized for taking a hardship exception. Many physicians are forced to take such an exemption through no fault of their own, e.g., their EHR vendor had delayed updates, inaccurate information, faulty software, etc. These providers should not be punished for the inability of their EHR software to complete Meaningful Use (MU) requirements, and therefore this should not affect their MIPS composite score. If a provider chooses to file a hardship exception, they should not be penalized in the MU performance category and should have options on how to reweight the other MIPS categories. Additionally, hardship exceptions should not be capped at five years, since many practices simply cannot participate due to their specialty, patient population, or aforementioned challenges with EHR software that is beyond their control.

7. Other Measures

- What types of measures (that is, process, outcomes, populations, etc.) used for other payment systems should be included for the quality and resource use performance categories under the MIPS?

While there is a dearth of outcomes measures specific to psychiatry, measures with intermediate outcomes are desirable. Additionally, to fill the gaps of outcome measures, there are several process measures that would address key clinical areas in psychiatry.

8. Development of Performance Standards

- Which specific historical performance standards should be used? For example, for the quality and resource use performance categories, how should CMS select quality and cost benchmarks? Should CMS use providers' historical quality and cost performance benchmarks and/or thresholds from the most recent year feasible prior to the commencement of MIPS?

If the purpose is to show improvement of the individual EP or virtual group, then benchmarks from the most recent year should be used. Consideration however must be given when there is a reduction or increase in available specialty-specific measures, in order to ensure an apples-to-apples comparison.

- For the clinical practice improvement activities performance category, what, if any, historical data sources should be leveraged?

If EPs or virtual groups have already successfully participated in a clinical practice improvement activity, their historical data should be used to designated this pre-existing activity and allow for this section to be weighted more heavily, when tabulating the composite score.

9. Flexibility in Weighting Performance Categories

- Are there situations where certain EPs could not be assessed at all for purposes of a particular performance category? If so, how should we account for the percentage weight that is

otherwise applicable for that category? Should it be evenly distributed across the remaining performance categories? Or should the weights be increased for one or more specific performance categories, such as the quality performance category?

There clearly are situations where certain EPs could not be assessed at all for purposes of a particular performance category. For example, if there are no measures specific to the conditions that a particular specialty treats and the type of care they provide, then physicians in this specialty would need flexibility regarding their quality component score. Quality activity needs to be meaningful and related to the actual services a physician personally delivers. General primary care measures should not be viewed as fulfilling the need for specialty-based measures. Also, hospital-based specialists who weren't eligible for incentives related to the Meaningful Use of EHRs should not be held accountable for that activity.

To account for the percentage weight that would have been applicable to the quality where performance measures are lacking, CMS should work with affected medical societies to determine how the percentage weight should be re-distributed and whether CPI activities could have their weight increased to make up for the lack of quality measures.

- Generally, what methodologies should be used as we determine whether there are not sufficient measures and activities applicable and available to types of EPs such that the weight for a given performance category should be modified or should not apply to an EP? Should this be based on an EP's specialty? Should this determination occur at the measure or activity level, or separately at the specialty level?

To identify the types of affected practitioners where insufficient measures would justify flexibility in the weighting, CMS could establish a process for pre-review whereby each practitioner could submit the measures and activities they believe are available to them. CMS would then give them a "pre-determination" regarding whether these would be sufficient for the given years' MIPS index. In the event that CMS found that the EP had not submitted all the existing activities available, CMS would provide them with a report as part of this pre-determination process.

As part of this pre-determination process, CMS would use the difference between the percentage of activities available to a practitioner versus 100 percent, to re-weight the other categories. CMS should also set up an appeals and communication process with EPs after they receive their quarterly feedback forms to ensure their progress towards 100 percent. Reweighting determinations should be based on specialty or sub-specialty rather than applied at the measure or activity level. The ability to be successful should be determined based on the measures and activities that are available for each EP in that given specialty or sub-specialty. As has been demonstrated in the Value-based Modifier program, the appropriate threshold will vary depending on the measure involved. There is no single threshold that is applicable for all measures within a category. CMS should keep in mind that measures developed for hospitals often require the use of minimum thresholds that make them inappropriate for use with most physician practices.

B. ALTERNATIVE PAYMENT MODELS (APMs)

1. Information Regarding APMs

b. Payment Incentive for APM Participation

- What policies should the Secretary consider for calculating incentive payments for APM participation when the prior period payments were made to an EAPM entity rather than directly to a QP, for example, if payments were made to a physician group practice or an ACO? What are the advantages and disadvantages of those policies? What are the effects of those policies on different types of EPs (that is, those in physician-focused APMs versus hospital focused APMs, etc.)? How should CMS consider payments made to EPs who participate in more than one APM?

A fundamental principle of all APMs is that they will advance teamwork among those involved in providing health care to a patient population. The methods that an APM Entity uses to distribute APM revenues to the physicians and other health professionals participating in the APM should foster collaboration among the team, not present a barrier to it. Proposals that are submitted for qualified APMs should explain how revenues will be distributed instead of CMS establishing requirements.

c. Patient Approach

- What are examples of methodologies for attributing and counting patients in lieu of using payments to determine whether an EP is a QP or partial QP?
- Should this option be used in all or only some circumstances? If only in some circumstances, which ones and why?

Eligible physicians should not be required to use either the patient or payments approach. They should retain the option to use the patient approach to calculating the share of their Medicare "business" that is attributable to one or more APMs instead of the revenue approach. Most physicians manage certain proportions of patients with one of several different conditions. Assuming that episode- and condition-based payment models are approved as qualifying APMs, the models will be applicable to some proportion of the patient population that each physician manages who has the conditions or episodes of care. Reporting the proportion of patients who are being managed within an APM may be a more patient-centered approach than summing up revenues from the services physicians provide. In some cases, it may be simpler to determine what proportion of a physician's patient population has conditions or episodes covered by APMs than to calculate revenues attributable to APMs. APMs may be designed around higher-cost conditions; however, so some physicians may be more likely to meet the MACRA thresholds using the revenue approach.

A related issue is what the minimum threshold of involvement in a patient's care should be in order for an APM physician to include a patient in their count. The attribution method used in the MSSP assigns patients to physicians if they have provided at least one primary service to the patient. Physicians in an APM could be contributing to the patient's care and the goals of the APM in other ways, however, besides face-to-face visits and procedures for patients. Psychiatrists, neurologists and other specialists could be consulting with primary care physicians on how to manage patients with substance use disorders, depression, Alzheimers or diabetes, for example, without seeing the patients themselves. Diagnosis, treatment, and management for many patients in the population served by an APM may involve multiple physicians, each of whom could potentially legitimately count the patient as their patient. CMS should require those proposing qualifying APMs to describe

how patients would be counted for purposes of establishing whether physicians are qualifying or partially qualifying APM participants.

d. Nominal Financial Risk

- What is the appropriate type or types of "financial risk" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity?
- What is the appropriate level of financial risk "in excess of a nominal amount" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity?
- What is the appropriate level of "more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures" that should be required by a non-Medicare payer for purposes of the Combination All-Payer and Medicare Payment Threshold under sections 1833(z)(2)(B)(iii)(II)(cc)(AA) and 1833(z)(2)(C)(iii)(II)(cc)(AA) of the Act?
- What are some points of reference that should be considered when establishing criteria for the appropriate type or level of financial risk, e.g., the MIPS or private-payer models?

To date, CMS has typically measured the financial risk associated with an APM using one yardstick: the total cost of care for a patient population. An ACO or other APM that does not have to pay CMS, if its patients' total costs of care exceed a CMS-developed financial benchmark, is considered by the agency to be upside only and is not recognized as being accountable for financial risk.

There are many financial risks that can be more than nominal that the typical CMS approach overlooks, including: start-up costs to get the APM off the ground such as data analysis and establishing procedures for coordinating care and sharing information, ongoing costs for new employees such as care managers, and foregone revenue from billable services that are reduced under an APM due to use of appropriateness guidelines and efforts to reduce exacerbations of patients' conditions requiring emergency department visits and hospitalizations. The practice may incur these costs with the goal of recovering them through savings on other services, but if the savings are not achieved elsewhere, the practice will incur losses. That can be a significant financial risk to the practice even if the practice is not required to make a payment to CMS.

An APM could be viewed as a product line being provided by a physician practice or other organization. The practice or APM Entity will incur costs associated with the product line and receive revenues from it. The financial risk to the practice or APM Entity is that the revenue from the APM may not cover the costs of participating in it. An APM that involves physicians taking the time to jointly develop treatment plans, reducing complications, improving the appropriateness of test ordering, hiring care managers, and participating in a clinical data registry may experience reduced fee-for-service revenues because they are providing high-value services which are not payable under the physician fee schedule and providing fewer or less expensive billable services.

The financial risk to the practice is that the payments from the APM will not be enough to cover these reduced fee-for-service revenues. The practice could be saving money for Medicare by reducing hospital admissions and expensive tests and procedures, but still be losing money for the practice. The definition of more than nominal financial risk should not be based on the relative gain or loss to the Medicare Trust Fund, but on how much the physician practice or APM Entity gains or loses.

Physicians will be much more willing to take accountability for costs that they can affect through their own performance, such as the costs of preventable complications, than they are to take on risk for the total cost of care for a large patient population. "More than nominal financial risk" should be defined in a way that allows physicians to take accountability for the services they can truly influence instead of requiring physicians to take responsibility for total Medicare spending on every health problem and service their patients get. Also, it is important that CMS allow sufficient time to achieve savings goals and not expect them to be reached in year one.

2. Information Regarding Physician-Focused Payment Models (PFPMs)

b. Criteria for Physician-focused Payment Models.

- What criteria should be used by the Committee for assessing PFPM proposals submitted by stakeholders? We are interested in hearing suggestions related to the criteria discussed in this RFI as well as other criteria.
- Are there additional or different criteria that the Committee should use for assessing PFPMs that are specialist models? What criteria would promote development of new specialist models?

The RFI notes that PFPMs proposed to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and recommended to HHS need not meet the same criteria that MACRA establishes for APMs, but CMS encourages proposals that will allow physicians to earn incentive payments available to participants in qualified APMs. APA agrees with this view. It is critical that the MACRA regulations establish a clear pathway for models to be proposed to the PTAC and for those models that are recommended by the PTAC to HHS to be implemented by CMS as qualified APMs.

CMS has stated that it has no obligation to test models that are recommended by the PTAC. We strongly disagree with this is extremely narrow perspective. For MACRA to succeed in reforming the delivery of care and improving value for patients and the Medicare Trust Funds, CMS must be willing to give serious consideration to proposed PFPMs that come through the PTAC and support their implementation. Within the MACRA law, establishment of the PTAC is under the title, "Promoting Alternative Payment Models." The PTAC subsection's purpose is stated as "increasing transparency of physician-focused payment models." This legislative language makes it clear that Congress intended for PFPMs to provide an alternative, more transparent avenue for the development of qualified APMs than the existing CMS process. It did not intend for PTAC-recommended models to receive comments from CMS and never be implemented.

The forthcoming regulations should establish an easy pathway for PFPM proposals to be adopted as qualified APMs. CMS should clearly outline the criteria that will be used to evaluate PFPM proposals. CMS and the PTAC should work collaboratively and in a transparent fashion with medical societies and other organizations developing proposals, provide feedback on drafts, and provide data up-front to help in modeling impacts.

The regulations should also make it clear that PFPMs that are recommended by the PTAC will be accepted by CMS. Although it is reasonable to have a more advanced application phase to work out the implementation details, stakeholders should not have to go through a separate proposal

process to first have their proposed PFPMs adopted by the PTAC and then to have them accepted by CMS. HHS should organize a reasonable process that will allow it to get good ideas for PFPMs from specialty societies and other organizations, ensure that they meet criteria that are known up-front to those preparing proposals, and then provide pathways for implementation that will allow participating physicians to earn MACRA incentive payments.

Implementation pathways should not be limited to small tests in a few communities. The APM incentive payments available under MACRA are for services furnished through an eligible APM entity during a six-year period only: 2019 through 2024. Physicians in all specialties and all geographic areas should have a meaningful opportunity to choose the APM pathway by having PFPMs available to them. In transmitting the PTAC's recommendations to CMS, HHS should direct CMS in how to implement the PFPM.

It is also important to recognize the linkage that MACRA established between the APM and MIPS pathways when it established the Clinical Practice Improvement (CPI) category within MIPS. In order for the new models in which physicians participate to be counted towards their CPI score, the models must be meet the MACRA definition of an APM. This is one more reason for the regulations to establish a clear means for PFPM proposals to be approved for implementation as qualified APMs.

PFPMs should support innovative approaches that give physicians the flexibility to deliver different services than they can within current payment systems. They should also ensure that the PFPM does not have so many administrative requirements that additional payments are all spent on administrative costs rather than helping patients.

Much of the focus on physician payment reform to date has been on three kinds of models: accountable care organizations, bundled payments for hospital-based episodes, and patient-centered primary care medical homes. But there are a number of other APMs that could improve patient care and reduce health care costs beyond these three. New PFPM proposals need to be developed by identifying opportunities to improve care for patients that will also reduce spending. For example, if better management of a patient's chronic disease can prevent the patient from being hospitalized, the patient is getting better care that also reduces spending. Other opportunities to improve care while reducing spending are to: provide preventive services that keep patients healthy; improve the appropriateness of test ordering; use lower-cost settings; and coordinate care with other physicians and facilities to improve accuracy of diagnoses, management of disease and reduce duplicative services and referrals. There are a number of barriers in current payment systems, however, that prevent physicians from being able to take advantage of these opportunities.

There are many high-value physician services that would benefit patients and help reduce avoidable spending, but the current payment system generally does not provide payment for them, for example:

- responding to a patient's phone call about a symptom or problem, even though that could help the patient avoid the need for far more expensive services, such as an emergency department visit;
- communications between primary care physicians and specialists to coordinate care, even though that can avoid ordering duplicate tests and prescribing conflicting medications;

- communications between community physicians and emergency physicians, and short-term treatment and discharge planning in emergency departments, even though that could enable patients to be safely discharged without admission;
- time spent by a physician serving as the leader of a multi-physician care team for patients with complex conditions;
- providing proactive telephone outreach to high-risk patients to ensure they get preventive care, even though that could prevent serious health problems or identify them at earlier stages when they can be treated more successfully;
- spending time in a shared decision-making process with patients and family members when there are multiple treatment options, even though that has been shown to reduce the frequency of invasive procedures and the use of low-value treatments;
- hiring nurses and other staff to provide education and self-management support to patients and family members, even though that could help them manage their health problems more effectively and avoid hospitalizations for exacerbations;
- providing palliative care for patients in conjunction with treatment, even though that can improve quality of life for patients and reduce the use of expensive treatments; and
- providing non-health care services (such as transportation) to help patients see the physician, even if that would avoid having them taken by ambulance to an emergency department.

Thank you again for the opportunity to comment on this important request for information. We look forward to working with you to ensure successful implementation of MACRA. If you have any questions or if we can be of further assistance, please contact Nevena Minor, Deputy Director of Legislative and Regulatory Policy at nminor@psych.org.

Sincerely,

Saul Levin, M.D., M.P.A.
CEO and Medical Director