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November 17, 2015

Andy Slavitt
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3321-NC
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Mr. Slavitt:

On behalf of the over 30 member companies of the Electronic Health Record Association (EHRA), we are pleased to submit our comments in response to the Request for Information (RFI) on new provisions in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA): Merit-based Incentive Payment System (MIPS), Alternative Payment Models (APMs) and physician-focused payment models (PFPMs).

The EHRA strongly believes that EHRs and other health information technologies are foundational to healthcare payment reform, specifically new payment models based on patient-centered outcomes, quality improvement, and reducing costs. The transition from fee-for-service to value-based care and other delivery reform models has accelerated the need for a more consistent and streamlined approach to measuring performance and quality. Health IT can substantially advance quality measurement and reporting by providing access to information not previously available and by automating data collection – all necessary to evolving alternative payment models (APMs).

We are enthusiastic about the opportunity to help providers optimize the use of technology as they transition to APMs. However, as you will see in our attached comments, we caution against over- reliance on the use of EHRs and health IT for collecting data that is outside the scope of EHRs, or is not currently defined and implemented today. For items that may be appropriate to add to an EHR for measuring or reporting, both vendors and providers need sufficient time to develop and implement new functionality or reporting capabilities, which may not be possible in time for the 2017 performance year.

The EHRA also recommends keeping the MIPS calculation as simple as possible, so that providers can successfully manage their performance throughout the year. If

providers cannot replicate the calculations in their own practices to track performance, they will likely feel frustrated and disenfranchised by the program.

As we commented in our response to the 2016 Medicare Physician Fee Schedule proposed rule, we urge CMS and ONC to continue the work already in progress with multiple stakeholders to make improvements to the electronic clinical quality measures (eCQMs), including the testing infrastructure and submission process, the standards utilized, and the process for annual measure updates. More time must also be devoted to ensure the reliability, validity, and feasibility of the eCQMs as we move towards a true pay-for-performance system. We have included several recommendations in our comments that we believe are important to address in order to improve these areas.

Finally, the EHRA does not support the creation of a new certification program for the alternative payment models (APMs) track. Technology requirements should be the same between MIPS and APMs so that incremental technology requirements are not a barrier to moving to the APM track. As an example, a provider meeting the 25% APM threshold should not be held in the MIPS track because they do not own an "APM certified" module that they did not need to successfully move 25% of their revenue to an APM. If they own and use the CMS-defined certified electronic health record technology (CEHRT) for the EHR Incentive Program, that should be sufficient.

The EHRA looks forward to working with CMS and other stakeholders to move these important proposals forward toward achieving our sharing goals of more effective, efficient healthcare services for all Americans.

Sincerely,

Leigh Burchell Chair, EHR Association

Allscripts

Sarah Corley, MD Vice Chair, EHR Association NextGen Healthcare

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

EHRA Detailed Comments

I. Background

Section 101 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare sustainable growth rate (SGR) methodology for updates to the physician fee schedule (PFS) and replaces it with a new Merit-based Incentive Payment System (MIPS) for MIPS eligible professionals (MIPS EPs) under the PFS. Section 101 of the MACRA sunsets payment adjustments under the current Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM), and the Electronic Health Records (EHR) Incentive Program. It also consolidates aspects of the PQRS, VM, and EHR Incentive Program into the new MIPS. Additionally, section 101 of the MACRA promotes the development of Alternative Payment Models (APMs) by providing incentive payments for certain eligible professionals (EPs) who participate in APMs, by exempting EPs from MIPS if they participate in APMs, and by encouraging the creation of physician- focused payment models (PFPMs). In this request for information (RFI), we seek public and stakeholder input to inform our implementation of these provisions.

General Comments

EHRs and other health information technologies are foundational to health care payment reform, specifically new payment models based on patient-centered outcomes, quality improvement, and reducing costs. The transition from fee-for-service to value-based care and other delivery reform models has accelerated the need for a more consistent and streamlined approach to measuring performance and quality. Health IT can substantially advance quality measurement and reporting by providing access to information not previously available and automating data collection — all necessary to evolving and alternative payment models (APMs). The EHR Association (EHRA) is enthusiastic about the opportunity to help providers optimize the use of technology as they transition to APMs. However, in our comments below, we caution against overreliance on the use of EHRs and health IT to report on MIPS performance categories that are outside the scope of EHRs, or are not currently defined and implemented today. Any new measures that can be appropriately captured and reported from an EHR will need to go through the same development and validation process as is being defined for eCQMs, to ensure results can be consistently captured and reported across EHR vendors without placing undue burden on providers.

- A. The Merit-based Incentive Payment System (MIPS)
 - MIPS EP Identifier and Exclusions
 We seek comment on what specific identifier(s) should be used to appropriately identify MIPS
 EPs for purposes of determining eligibility, participation, and performance under the MIPS
 performance categories. Specifically, we seek comment on the following questions:
 - Should we use a MIPS EP's TIN, NPI or a combination thereof? Should we create a distinct MIPS Identifier?
 - What are the advantages/disadvantages associated with using existing identifiers, either individually or in combination?
 - What are the advantages/disadvantages associated with creating a distinct MIPS identifier?
 - Should a different identifier be used to reflect eligibility, participation, or performance as a group practice vs. as an individual MIPS EP? If so, should CMS use an existing identifier or create a distinct identifier?
 - How should we calculate performance for MIPS EPs that practice under multiple TINs?
 - Should practitioners in a virtual group and virtual group practices have a unique virtual group identifier that is used in addition to the TIN?
 - How often should we require an EP or group practice to update any such identifier(s) within the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)? For example, should EPs

be required to update their information in PECOS or a similar system that would pertain to the MIPS on an annual basis?

Regarding the questions above related to whether to use a MIPS EP's TIN, NPI, or a combination; a new MIPS identifier; and the advantages/disadvantages of these approaches, the EHRA does not recommend adding a new MIPS identifier, as this approach could cause confusion and introduce inaccuracies and errors in the identification of MIPS EPs at a time when providers are already dealing with a tremendous change. Further, it does not seem efficient to create an identifier specific to any singular program, as providers may choose the MIPS path initially before transitioning to an APM, or they may participate in MIPS while also participating in a commercial payer's program, for example. As the NPI should be a unique number identifying each EP, we support the use of the NPI for identification of an individual EP, with expansion to any other providers covered under the MIPS that may not currently be required to have an NPI.

Regarding use of a TIN, consideration should be given to the fact that some providers may practice in multiple TINs, therefore, an EP may not have an association with just one TIN. In addition, there are different levels of TIN numbers associated with EPs/practices. This would seem to be a lesser solution.

Group identification becomes more challenging due to the different ways that a group may be defined. For example, in the CPCI program, a group is identified by a physical location. This introduces complexity in identifying an EP, as the EP may practice in multiple locations. The concept of a "virtual group" introduces further challenges to ensure that identification of a "group" is specific to the requirements of that definition.

When considering how to identify virtual groups, it will be important for CMS to provide clear guidance on how to handle instances where the providers don't share a common EHR platform or vendor. This will be critical in order to advance the use of electronic quality measurement and submission, and could be a potential barrier to the formation of virtual groups.

It is the EHRA's understanding that one of the primary drivers of the proposal to allow virtual groups is to assist small independent providers in their efforts to achieve the quality incentives under MIPS, which is a goal we applaud. In working towards this goal, however, it should not be assumed that these providers will have access to the more sophisticated health IT offerings that would accommodate this type of configuration and aggregation of data. The EHRA recommends that CMS consider these permutations and any others that may arise when determining the best way to identify a group practice and/or virtual groups.

Additionally, we note that depending upon the identifier(s) chosen for MIPS EPs, there could be situations where a given MIPS EP may be part of a "split TIN". For example, in the scenario where the identifier chosen for MIPS EPs is a TIN (as is utilized by the VM currently), and a portion of that TIN is exempt from MIPS due to being part of a qualifying APM, we will have a split TIN.

In the above scenario, what safeguards should be in place to ensure that we are appropriately assessing MIPS EPs and exempting only those EPs that are not eligible for MIPS?

We also recognize that depending upon the identifier(s) chosen for MIPS EPs, there could be situations where a given MIPS EP would be assessed under the MIPS using multiple identifiers. For example, as noted above, individual EPs are assessed under the PQRS based on unique

TIN/NPI combinations. Therefore, individual EPs (each with a unique NPI) who practice under multiple TINs are assessed under the PQRS as a distinct EP for each TIN/NPI combination. For example, under PQRS an EP could receive a negative payment adjustment under one unique TIN/NPI combination, but not receive it under another unique TIN/NPI combination.

- What safeguards should be in place to ensure that MIPS EPs do not switch identifiers if they are considered "poor-performing"?
- What safeguards should be in place to address any unintended consequences, if the chosen identifier is a unique TIN/NPI combination, to ensure an appropriate assessment of the MIPS EPs performance?

2. Virtual Groups

The virtual group option under the MIPS allows a group's performance to be tied together even if the EPs in the group do not share the same TIN. CMS seeks comment on what parameters should be established for these virtual groups. We seek comment on the following questions:

- How should eligibility, participation, and performance be assessed under the MIPS for voluntary virtual groups?
- 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?
- 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?
- 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?
- 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?
- Under the voluntary virtual group election process, what type of information should be required in order to make the election for a performance period for a year? What other requirements would be appropriate for the voluntary virtual group election process?
- Section 1848(q)(5)(I)(ii) of the Act provides that a virtual group may be based on appropriate classifications of providers, such as by specialty designations or by geographic areas. We seek comment on the following questions: 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?

3. Quality Performance Category

Section 1848(q)(2)(B)(i) of the Act describes the measures and activities for the quality performance category under the MIPS. Under section 1848(q)(2)(D) of the Act, the Secretary must, through notice and comment rulemaking by November 1 of the year before the first day of each performance period under the MIPS, establish the list of quality measures from which MIPS EPs may choose for purposes of assessment for a performance period for a year. CMS' experience under other quality

programs, namely the PQRS and the VM, will help shape processes and policies for this performance category. We seek comment on the following areas:

- a. Reporting Mechanisms Available for Quality Performance Category: We seek comment on the following questions related to these reporting mechanisms and criteria:
 - Should we maintain all PQRS reporting mechanisms noted above under MIPS?

The EHRA has previously provided feedback reflecting the comments our customers have made to us regarding the complexity of the PQRS program, with multiple reporting methods, quality measures, and submission requirements for providers to understand and adjust to in the midst of numerous other programmatic developments. Simplification and alignment of quality measures and reporting requirements would reduce the burden on both providers and the vendor community in the long term.

However, given the short timeframe for implementation of the MIPS for payment year 2019, we urge CMS to consider a gradually phased-in approach to streamline the reporting of quality performance in the MIPS. Adequate notification must be provided before removing or altering a reporting method, as that may negatively impact the ability of providers to successfully participate, especially in the initial reporting year of 2017. In addition, the time needed by software vendors to implement any software changes, including coding, testing, and software release, as well as for providers to implement those changes, must also be considered.

• If so, what policies should be in place for determining which data should be used to calculate a MIPS EP's quality score if data are received via multiple methods of submission? What considerations should be made to ensure a patient's data is not counted multiple times? For example, if the same measure is reported through different reporting mechanisms, the same patient could be reported multiple times.

As has been demonstrated in the validation pilot for the CMS Inpatient Quality Reporting (IQR) program, which compared manually-abstracted quality measure results with eCQM results for the same measure, measure results vary based on the reporting method due to differences in the way the data is collected, as well as in the measure specification itself. For this reason, the EHRA recommends that an EP's quality score be calculated using only the data from one method of submission in order to prevent duplicate reporting. There may be several methods to accomplish this goal, and we offer some alternatives. One method to consider is to count only the higher score if a provider submits data through more than one method. Another method would consist of having providers declare their reporting method prior to submission.

 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?

Please refer to our comments provided to the first question in this section regarding the reporting criteria. The appropriate number of measures depends upon the provider and their specialty and the number of applicable measures for the patient population they serve. A reasonable minimum could be established, similar to the minimum required for PQRS participation.

• Should we maintain the policy that measures cover a specified number of National Quality Strategy domains?

This question is more appropriately addressed by providers.

 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?

Although we fully support the move towards outcome-based measures, the initial requirements for MIPS should not rely heavily on this type of measure. Outcome-based measures are patient-centric, versus provider-centric, and require longitudinal data from various providers, care settings, and sources in order to accurately calculate performance. The most effective way to accomplish this aggregation is through interoperable health IT capabilities. This interoperability is not yet in full production, as it relies on providers utilizing health IT that complies with the meaningful use Stage 2 requirements. In addition, most measures today are process-based, and it will take time to migrate to a comprehensive set of outcome-based measures, as well as to ensure that the data can be aggregated effectively to demonstrate performance on these measures. Issues of attribution are particularly difficult with patient centric metrics and more study is needed on how to appropriately attribute long term outcomes if patients change physicians with regularity. The EHRA urges CMS and the measure developers to work with both the vendor and provider communities to evaluate the feasibility of any de novo eCQMs, especially any outcome-based eCQMs.

• Should we require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender?

The EHRA supports efforts to stratify reporting data, as well as the use of clearly-defined data elements to enable these capabilities. We urge that the data elements used for stratification be aligned among the various reporting programs, as well as the demographic and clinical data required by the EHR Incentive Program, so that one set of defined data elements can be leveraged by any program. In addition, any new requirements must be supported by the standard used for reporting (currently QRDA I and III) and should be data elements collected routinely for the care of the patient.

For the CAHPS for PQRS reporting option specifically, should this still be considered as
part of the quality performance category or as part of the clinical practice improvement
activities performance category? What considerations should be made as we further
implement CAHPS for all practice sizes? How can we leverage existing CAHPS reporting
by physician groups?

This question is more appropriately addressed by providers.

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?

The EHRA supports efforts to ensure that specialty physicians have measures that apply to their practice domain. At the same time, we urge CMS to consider methods to ensure that the organizations who are developing specialty-specific electronic clinical quality measure understand how to develop accurate, valid and feasible electronic specifications for those measures. The EHRA is concerned that some specialty organizations may have little to no understanding of the best practices employed to develop such measures, as well as little knowledge of the standards that are currently being utilized. This concern has been validated by conversations we have held individually with many of the specialty organizations, some of whom have asked for our guidance and professed little knowledge regarding how to develop CQMs.

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

The implementation of MIPS, with 2019 payments affected by 2017 CQM data, underscores the urgency of learning from our experiences to date, and to delay public reporting of EHR-reported data used to determine quality performance until the reliability and validity of the data can be assured. The EHRA fully supports CMS' stated goal to align the clinical quality measure requirements of the MIPS with other Medicare and Medicaid programs, and we support the expanded use of electronic clinical quality measures (eCQMs) in these efforts whenever appropriate. We agree that this alignment will eventually streamline the quality measure reporting process, reduce provider reporting burdens, and support the transition to a healthcare system focused on patient-centered outcomes measurement, quality improvement, and value-based care.

Recognizing that the industry is still in the early stages of migrating from claims-based measures to eCQMs, as well as from process-based to outcomes-oriented measures, we are concerned that moving too rapidly to transition to these relatively new methods of quality measurement will have a negative impact on both the performance measurement of each physician and the satisfaction that each physician has with their EHR. We reiterate our comments made to the 2016 MPFS proposed rule regarding our concern that it is too soon to utilize the eCQM data for an expanded approach to performance-based payments.

b. Data Accuracy

CMS' experience under the PQRS has shown that data quality is related to the mechanism selected for reporting. Some potential data quality issues specific to reporting via a qualified registry, QCDR, and/or certified EHR technology include: inaccurate TIN and/or NPI, inaccurate or incomplete calculations of quality measures, missing data elements, etc. Since accuracy of the data is critical to the accurate calculation of a MIPS composite score, we seek comment on what additional data integrity requirements should be in place for the reporting mechanisms referenced above. Specifically:

 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? The EHRA provided the following recommendations to the 2016 Physician Fee Schedule proposed rule to enhance CQM certification and to help address the recent findings of large numbers of errors in the eCQM submission data, and we reiterate them here:

- Timing of the annual eCQM measure updates as well as the release of any new eCQMs should be tightly correlated with the release of updates to the CMS Implementation Guide (which we assume will cover multiple CMS quality and incentive programs), as well as revisions to the validation tools used for electronic submission. This linkage should include adequate time for implementing any changes. Considering the short timeline between publication of any payment rules and the required usage dates, EHRA reiterates our recommendations that annual updates and revisions be limited to minor changes, which do not have a significant impact on clinician workflow or require software code changes or recertification of the EHR software.
- Currently, there are three different validation tools, which all are intended to validate the QRDA submission files in different ways (Cypress QRDA certification tool, CMS IG certification within Cypress, and Submission Engine Validation Tool (SEVT)). This set of multiple tools causes a great deal of confusion to the provider and vendor communities. There is also an expectation that any validation tools used would assure the vendor or provider of a high level of accuracy in the eCQM submission data but, as noted previously, the review by CMS of the submission data revealed a high number of errors. The EHRA strongly recommends that there should be a single validation tool for EPs and one for EHs, or at least the fewest needed to implement CMS and ONC policies; and that any validation tools incorporate the necessary changes to address the recent findings of significant errors in the CQM submissions for the 2014 reporting year and in general to flag the full range of foreseeable submission errors.
- As discussed at the August 2015 vendor summit, we also urge that CMS and ONC take
 more focused care to develop CQM-specific test data sets that are tuned to the
 specific CQM in question, while also maintaining the current approach of keeping test
 data sets as small as possible to reduce testing burden. Such more finely tuned test
 data sets will enhance the ability of certification and validation tools to increase the
 accuracy of specific CQM calculations.
- Both the implementation guide and the validator(s) should include any requirements
 for successful submission of the eCQM data. The large number of errors identified
 that were caused by requirements for submission that were NOT included in the
 certification process using Cypress, the CMS implementation guide, or the validators
 could be avoided if this were the case.

The EHRA also notes that there have been frequent revisions to the requirements for eCQM submission, including changes to the Cypress certification tool, updates to the version of QRDA expected to be utilized, and updates to the CMS implementation guide. In CY 2015 alone, revisions were made in January, April, and June. It is difficult for a vendor or provider to identify all the relevant documents and information to ensure that they are utilizing the most recent requirements. We urge CMS to continue to utilize and enhance the eCQI Resource Center as a "one-stop" area to include all relevant information and documentation for the eCQMs. We also urge CMS to reduce the number of revisions to the requirements, tools, and documentation for eCQM certification, validation, and submission in a given calendar year. Finally, the EHRA has provided numerous recommendations in the past regarding the need for more testing

and piloting of the eCQMs, the standards utilized, and the submission process. We reiterate the importance of this testing and validation process prior to requiring the use of new and revised eCQM specifications, along with the associated standards and tools.

CMS should consider collection of raw data rather than requiring EHRs to calculate measure performance. Raw data allows CMS to run their own reports and allows for flexibility in evaluating performance when guidelines change as they frequently do. If for example CMS collected the actual HGBA1c value rather than whether it was higher and lower than some value set by a measure, the reporting process is simplified and CMS has a much richer source of data for research and outcomes studies.

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?

The submission requirements for registries, including qualified clinical data registries, should be comparable to submission requirements for other entities, including use of the same standards, which is currently QRDA.

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?

The EHRA is concerned that CMS would require a separate process over and above the current ONC certification requirements. Adding additional review and/or qualification on top of the certification requirements creates unnecessary complexity in the program, and increases the burden on both providers and vendors in reporting quality performance. We reiterate our comments made in question 6i, regarding both the certification process and the CMS validation tools.

• 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 recalculate 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?

The EHRA notes that the calculation of performance rate should be a relatively simple step. We feel that if CMS does the calculation, it would allow them to perform the calculation to their specifications. For example, this would alleviate the problem found in 2014 submissions of having the wrong number of digits defined after the decimal point. We also recommend that CMS check the submission files for data accuracy and completeness during submission of data, before accepting the data, and reject any specific patient data files that do not comply. If the submission is in a QRDA I format,

CMS should accept any other files that are correct. CMS should also provide a report identifying any rejected files, and the reason for the rejection, and should allow this data to be resubmitted. Finally, ensuring that the data validator(s) allow testing of the submission files for any of these errors prior to final submission, as we have recommended previously, will improve the overall data integrity and accuracy rates. As noted above, having CMS calculate the performance rates has a number of positives and no obvious negatives.

• 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?

The EHRA feels that if many of our recommendations are put into practice, the number of files that are rejected should be minimal. In addition, if the submission process checks the files for accuracy prior to accepting the data, and rejects the file as described above, the provider, registry, or vendor will have the opportunity to correct any errors and resubmit the data. As far as any consequences to the registry or vendor, we are concerned that it is difficult to determine the root cause of many of these errors initially, and, in fact, some may be due to provider mistakes, such as incorrect mapping of data elements, or omission of data that is required. For example EPs have to populate some fields before submitting. We urge CMS to continue to work collaboratively and cooperatively with all stakeholders, as this is an evolving process.

- c. Use of Certified EHR Technology (CEHRT) under the Quality Performance Category Currently under the PQRS, the reporting mechanisms that use CEHRT require that the quality measures be derived from CEHRT and must be transmitted in specific file formats. For example, EHR technology that meets the CEHRT definition must be able to record, calculate, report, import, and export clinical quality measure (CQM) data using the standards that the Office of the National Coordinator for Health Information Technology (ONC) has specified, including use of the Quality Reporting Data Architecture (QRDA) Category I and III standards. We seek input on the following questions:
 - Under the MIPS, what should constitute use of CEHRT for purposes of reporting quality data?
 - 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?

4. Resource Use Performance Category

Section 1848(q)(2)(B)(ii) of the Act describes the resource use performance category under MIPS as "the measurement of resource use for such period under section 1848 (p)(3) of the Act, using the methodology under section 1848(r) of the Act as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Part D." Section 1848(p)(3) of the Act specifies that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs for purposes of the VM under the PFS. Section 1848(r) of the Act (as added by section 101(f) of the MACRA) specifies a series of steps and deliverables for the Secretary to develop "care episode and"

patient condition groups and classification codes" and "patient relationship categories and codes" for purposes of attribution of patients to practitioners, and provides for the use of these in a specified methodology for measurement of resources use. Under the MIPS, the Secretary must evaluate costs based on a composite of appropriate measures of costs using the methodology for resource use analysis specified in section 1848(r)(5) of the Act that involves the use of certain codes and claims data and condition and episode groups, as appropriate. CMS' experience under the VM will help shape this performance category. Currently under the VM, we use the following cost measures: (1) Total Per Capita Costs for All Attributed Beneficiaries measure; (2) Total Per Capita Costs for Beneficiaries with Specific Conditions (Diabetes, Coronary artery disease, Chronic obstructive pulmonary disease, and Heart failure); and (3) Medicare Spending per Beneficiary (MSPB) measure. We seek comment on the following questions:

- 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?
- How should we apply the resource use category to MIPS EPs for whom there may not be applicable resource use measures?
- What role should episode-based costs play in calculating resource use and/or providing feedback reports to MIPS EPs under section 1848(q)(12) of the Act?
- How should CMS consider aligning measures used under the MIPS resource use performance category with resource use based measures used in other parts of the Medicare program?
- How should we incorporate Part D drug costs into MIPS? How should this be measured and calculated?
- What peer groups or benchmarks should be used when assessing performance under the resource use performance category?
- CMS has received stakeholder feedback encouraging us to align resource use measures with clinical quality measures. How could the MIPS methodology, which includes domains for clinical quality and resource use, be designed to achieve such alignment?

Depending on how the new codes for episodes, patient condition, and patient relationship are defined, EHR and billing system changes may be necessary to support the capture, formatting, and transmission of these new data elements. The EHRA would like to remind CMS that, if software changes are needed, sufficient time needs to be provided between the finalization of the new codes and the activation date. The EHRA would be happy to consult with CMS on the code definitions to validate whether or not software changes would be needed and, if so, the amount of time that providers should be given to implement the new codes.

5. Clinical Practice Improvement Activities Performance Category
The term "clinical practice improvement activity" is defined under section 1848(q)(2)(C)(v)(III) of the
Act as an activity that relevant eligible professional organizations and other relevant stakeholders
identify as improving clinical practice or care delivery and that the Secretary determines, when
effectively executed, is likely to result in improved outcomes. In this RFI, we seek comment on other
potential clinical practice improvement activities (and subcategories of activities), and on the criteria
that should be applicable for all clinical practice improvement activities. We also seek comment on
the following subcategories, in particular how measures or other demonstrations of activity may be

validated and evaluated:

- A subcategory of Promoting Health Equity and Continuity, including (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b) accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) to provide comprehensive care for patients with disabilities.
- A subcategory of Social and Community Involvement, such as measuring completed referrals to community and social services or evidence of partnerships and collaboration with the community and social services.
- A subcategory of Achieving Health Equity, as its own category or as a multiplier where
 the achievement of high quality in traditional areas is rewarded at a more favorable rate
 for EPs that achieve high quality for underserved populations, including persons with
 behavioral health conditions, racial and ethnic minorities, sexual and gender minorities,
 people with disabilities, and people living in rural areas, and people in HPSAs.
- A subcategory of emergency preparedness and response, such as measuring EP
 participation in the Medical Reserve Corps, measuring registration in the Emergency
 system for Advance Registration of Volunteer Health Professionals, measuring relevant
 reserve and active duty military EP activities, and measuring EP volunteer participation
 in humanitarian medical relief work.
- A subcategory of integration of primary care and behavioral health1, such as measuring
 or evaluating such practices as: co-location of behavioral health and primary care
 services; shared/integrated behavioral health and primary care records; cross-training of
 EPs.

These practice improvement activities seem outside the scope of traditional practice improvement activities (expanded office hours, electronic communication with patients) and it would be more appropriate to label this section as activities to reduce disparities of care.

We also seek comment on what mechanisms should be used for the Secretary to receive data related to clinical practice improvement activities. Specifically, we seek comment on the following:

• 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?

The EHRA recommends that clinical practice improvement activities be reported to CMS via attestation. Many of the suggested sub-categories are not directly related to delivery of patient care and, therefore, would not be captured in the EHR. As we have learned with meaningful use, adding data capture requirements for the sole purpose of process-measurement reporting is frustrating to providers and creates inefficiencies in the caredelivery workflow. An example of a better approach would be to allow providers to set their own outcomes-focused goals resulting from clinical practice improvement activities, such as reducing readmissions for behavioral health patients with chronic clinical comorbidities.

If there are specific sub-categories for which CMS would like to use EHRs for reporting, the EHRA would be happy to consult with CMS to validate that the data is currently being captured in a standardized manner and can be consistently reported across EHR vendors.

We leave it to our clinician colleagues to comment on the potential negative impact on the viability of their practice if some of these laudable activities are undertaken.

- What information should be reported and what quality checks and/or data validation should occur to ensure successful completion of these activities?
- How often providers should report or attest that they have met the required activities?

As with other elements of MACRA reporting and MIPS scoring, we believe performance assessments within the clinical practice improvement arena should be assessed on an annual basis.

Additionally, we seek comment on the following areas of how we should assess performance on the clinical practice improvement activities category. Specifically:

• 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?

The EHRA advises against using counts or percentage-based measures for clinical practice improvement activity reporting. The use of such measures in meaningful use has been costly and burdensome to both vendors and providers, and has contributed to many of the complaints about the program. Given the natural complexity of the MIPS program, we believe reporting should be as simple as possible for providers and start with a yes/no attestation method.

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

As stated above, the EHRA suggests keeping the MIPS program as simple as possible at the start. Therefore, the weighting methodology should be kept simple and straightforward in the first years, to be modified, as needed, based on experience. The weighting should also consider that some categories are not relevant to certain specialties and that the co-location measure is not practical for practices with an existing single location. The impact of these "practice improvement" measures on a small practice should be carefully considered.

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

Lastly, section 1848(q)(2)(B)(iii) of the Act requires the Secretary, in establishing the clinical practice improvement activities, to give consideration to the circumstances of small practices (15 or fewer professionals) and practices located in rural areas and in HPSAs (as designated under section 332(a)(1)(A) of the PHSA). We seek comment on the following questions relating to this requirement:

- How should the clinical practice improvement activities performance category be applied to EPs practicing in these types of small practices or rural areas?
- Should a lower performance threshold or different measures be established that will better allow those EPs to reach the payment threshold?
- What methods should be leveraged to appropriately identify these practices?
- What best practices should be considered to develop flexible and adaptable clinical practice improvement activities based on the needs of the community and its population?

Many of the customers of EHRA members are small practices, and we are very sensitive to their needs and the burden that complex compliance programs can place on them. We believe that keeping the clinical practice improvement activity category flexible, with an attestation system for reporting, will allow small practices to perform as well as their larger counterparts on this MIPS category.

- 6. Meaningful Use of Certified EHR Technology Performance Category
 Section 1848(q)(2)(B)(iv) of the Act specifies that the measures and activities for the meaningful use
 of certified EHR technology performance category under the MIPS are the requirements established
 under section 1848(o)(2) of the Act for determining whether an eligible professional is a meaningful
 EHR user of CEHRT. Under section 1848(q)(5)(E)(i)(IV) of the Act, 25 percent of the composite
 performance score under the MIPS must be determined based on performance in the meaningful
 use of certified EHR technology performance category. Section 1848(q)(5)(E)(ii) of the Act gives the
 Secretary discretion to reduce the percentage weight for this performance category (but not below
 15 percent) in any year in which the Secretary estimates that the proportion of eligible professionals
 who are meaningful EHR users is 75 percent or greater, resulting in an increase in the applicable
 percentage weights of the other performance categories. We seek comment on the methodology
 for assessing performance in this 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.
 - Should CMS use a tiered methodology for determining levels of achievement in this
 performance category that would allow EPs to receive a higher or lower score based on
 their performance relative to the thresholds established in the Medicare EHR Incentive
 program's meaningful use objectives and measures? For example, an EP who scores
 significantly higher than the threshold and higher than their peer group might receive a
 higher score than the median performer. How should such a methodology be

developed? Should scoring in this category be based on an EP's under- or overperformance relative to the required thresholds of the objectives and measures, or should the scoring methodology of this category be based on an EP's performance relative to the performance of his or her peers?

- What alternate methodologies should CMS consider for this performance category?
- How should hardship exemptions be treated?

The EHRA discussed and carefully considered the questions posed here by CMS in light of our experience supporting providers with Stages 1-2 of the Meaningful Use EHR Incentive program.

Our experiences urge us to emphasize the following principles as CMS selects a scoring methodology:

- Simplicity. The methodology should be simple, so that it is easily understood by all
 participants in the program, and does not require extensive review or meaningful
 use knowledge. For example, the methodology should not require more than one
 page to describe.
- Predictability. The methodology should be predictable. EHR users ask for monitoring tools to determine their anticipated ability to meet MU thresholds, and we would like to be able to continue to provide such tools. If meaningful use achievement became comparative to peers, for example, it would be hard to predict any one individual's achievement.
- Interoperability. Interoperability is a key national goal, and one that EHRA strongly prioritizes and supports. Success with interoperability requires many providers to adopt appropriate technology and work on interoperability at the same time (since senders and receivers both have to participate). We are concerned that some methodologies CMS might consider could have the unintended side effect of allowing some providers to skip the interoperability requirements of the meaningful use program. We suggest that those remain required, even if other flexibility is enacted, to ensure progress on this key national goal.

Aside from those three goals, we defer to the provider community as to the methodology they consider most appropriate. Some EHRA members hear strong interest from their users in a methodology that awards partial points for achieving some, but not all, MU objectives.

We note that exceeding thresholds set by the meaningful use program does not have any proven value, and we are skeptical of incorporating that into a scoring methodology.

Regarding hardship exemptions, we defer to the provider community on the best approach. The fairest approach would seem to EHRA to be to base those providers' performance on their achievement in the other categories, effectively removing meaningful use points from both their denominator and their numerator.

7. Other Measures

Section 1848(q)(2)(C)(ii) of the Act allows the Secretary to use measures that are used for a payment system other than the PFS, such as measures for inpatient hospitals, for the purposes of the quality and resource use performance categories (but not measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians,

radiologists, and anesthesiologists). We seek comment on how we could best use this authority, including the following specific questions:

- 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?
- How could we leverage measures that are used under the Hospital Inpatient Quality Reporting Program, the Hospital Value-Based Purchasing Program, or other quality reporting or incentive payment programs? How should we attribute the performance on the measures that are used under other quality reporting or value-based purchasing programs to the EP?
- To which types of EPs should these be applied? Should this option be available to all EPs or only to those EPs who have limited measure options under the quality and resource use performance categories?
- How should CMS link an EP to a facility in order to use measures from other payment systems? For example, should the EP be allowed to elect to be analyzed based on the performance on measures for the facility of his or her choosing? If not, what criteria should CMS use to attribute a facility's performance on a given measure to the EP or group practice?

The EHRA cautions against using inpatient measures as part of the EP MIPS calculation. Attribution to an individual EP could be challenging, many EPs do not practice in a facility at all, and EPs may not have access to the inpatient measures throughout the year to monitor their individual performance. It will be important for providers to be able to monitor their performance throughout the year so that they can make any changes necessary to achieve the MIPS performance threshold with time to affect results.

- d. Additionally, section 1848(q)(2)(C)(iii) of the Act allows and encourages the Secretary to use global measures and population-based measures for the purposes of the quality performance category. We seek comment on the following questions:
 - What types of global and population-based measures should be included under MIPS? How should we define these types of measures?
 - What data sources are available, and what mechanisms exist to collect data on these types of measures?

It would be difficult to attribute global and population-based measures to an EP. These could be monitored to rate the success of the program as whole but would not be appropriate measures of an individual.

Lastly, section 1848(q)(2)(C)(iv) of the Act requires the Secretary, for the measures and activities specified for the MIPS performance categories, to give consideration to the circumstances of professional types (or subcategories of those types based on practice characteristics) who typically furnish services that do not involve face-to-face interaction with patients when defining MIPS performance categories. For example, EPs practicing in certain specialties such as pathologists and certain types of radiologists do not typically have face-to face interactions with patients. If measures and activities for the MIPS performance categories focus on face-to-face encounters, these specialists may have more limited opportunities to be assessed, which could

negatively affect their MIPS composite performance scores as compared to other specialties. We seek comment on the following questions:

- How should we define the professional types that typically do not have face-to-face interactions with patients?
- What criteria should we use to identify these types of EPs?
- Should we base this designation on their specialty codes in PECOS, use encounter codes that are billed to Medicare, or use an alternate criterion?
- How should we apply the four MIPS performance categories to non-patient-facing EPs?
- What types of measures and/or clinical practice improvement activities (new or from other payments systems) would be appropriate for these EPs?

We defer to the provider community.

- 8. **Development of Performance Standards:** Section 1848(q)(3)(B) of the Act requires the Secretary, in establishing performance standards with respect to measures and activities for the MIPS performance categories, to consider: historical performance standards, improvement, and the opportunity for continued improvement. We seek comment on the following questions:
 - 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? Should performance standards be stratified by group size or other criteria? Should we use a model similar to the performance standards established under the VM?
 - For the clinical practice improvement activities performance category, what, if any, historical data sources should be leveraged?
 - How should we define improvement and the opportunity for continued improvement?
 For example, section 1848(q)(5)(D) of the Act requires the Secretary, beginning in the
 second year of the MIPS, if there are available data sufficient to measure improvement,
 to take into account improvement of the MIPS EP in calculating the performance score
 for the quality and resource use performance categories.
 - How should CMS incorporate improvement into the scoring system or design an improvement formula?
 - What should be the threshold(s) for measuring improvement?
 - How would different approaches to defining the baseline period for measuring improvement affect EPs' incentives to increase quality performance? Would periodically updating the baseline period penalize EPs who increase performance by holding them to a higher standard in future performance periods, thereby undermining the incentive to improve? Could assessing improvement relative to a fixed baseline period avoid this problem? If so, would this approach have other consequences CMS should consider?
 - Should CMS use the same approach for assessing improvement as is used for the Hospital Value-Based Purchasing Program? What are the advantages and disadvantages of this approach?
 - Should CMS consider improvement at the measure level, performance category level (that is, quality, clinical practice improvement activity, resource use, and meaningful use of certified EHR technology), or at the composite performance score level?

- Should improvements in health equity and the reductions of health disparities be considered in the definition of improvement? If so, how should CMS incorporate health equity into the formula?
- In the CY 2016 PFS proposed rule (80 FR 41812), the Secretary proposed to publicly report on Physician Compare an item-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology. We seek comment on using this methodology for determining the MIPS performance standards for one or more performance categories.
- 9. Flexibility in Weighting Performance Categories Section 1848(q)(5)(F) of the Act requires the Secretary, if there are not sufficient measures and activities applicable and available to each type of EP, to assign different scoring weights (including the context of the conte

activities applicable and available to each type of EP, to assign different scoring weights (including a weight of zero) from those that apply generally under the MIPS. We seek comment on the following questions:

- 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?
- 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?
- What case minimum threshold should CMS consider for the different performance categories?
- What safeguards should we have in place to ensure statistical significance when establishing performance thresholds? For example, under the VM one standard deviation is used. Should we apply a similar threshold under MIPS?

The meaningful use program has been criticized for its all-or-nothing approach. Therefore, the EHRA recommends building flexibility into the weighting structure, to the extent that it can be easily supported without excessive complexity. Providers need to be able to track and manage their performance throughout the year, and if the measures and calculations are too complex, they won't be able to. We recommend keeping the program as simple as possible, especially in the first years.

10. MIPS Composite Performance Score and Performance Threshold Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS EP based on performance standards with respect to applicable measures and activities in each of the four performance categories. The methodology is to provide for a composite assessment for each MIPS EP for the performance period for the year using a scoring scale of 0 to 100. Section 1848(q)(6)(D) of the Act requires the Secretary to compute a performance threshold to which the MIPS EP's composite performance score is compared for purposes of determining the MIPS adjustment factor for a year...We are requesting information from the public on the following:

- How should we assess performance on each of the 4 performance categories and combine the assessments to determine a composite performance score?
- For the quality and resource use performance categories, should we use a methodology (for example, equal weighting of quality and resource use measures across National Quality Strategy domains) similar to what is currently used for the VM?
- How should we use the existing data on quality measures and resource use measures to translate the data into a performance threshold for the first two years of the program?
- What minimum case size thresholds should be utilized? For example, should we
 leverage all data that is reported even if the denominators are small? Or should we
 employ a minimum patient threshold, such as a minimum of 20 patients, for each
 measure?
- How can we establish a base threshold for the clinical practice improvement activities? How should this be incorporated into the overall performance threshold?
- What other considerations should be made as we determine the performance threshold for the total composite performance score? For example, should we link performance under one category to another?

11. Public Reporting

We also seek comment on what should be the minimum threshold used for publicly reporting MIPS measures and activities for all of the MIPS performance categories on the Physician Compare website.

In the CY 2016 PFS proposed rule (80 FR 41809), we indicated that we will continue using a minimum 20 patient threshold for public reporting through Physician Compare of quality measures (in addition to assessing the reliability, validity and accuracy of the measures). An alternative to a minimum patient threshold for public reporting would be to use a minimum reliability threshold. We seek comment on both concepts in regard to public reporting of MIPS quality measures on the Physician Compare website. We additionally seek comment on the following:

• Should CMS include individual EP and group practice-level quality measure data stratified by race, ethnicity and gender in public reporting (if statistically appropriate

12. Feedback Reports

Section 1848(q)(12)(A) of the Act requires the Secretary, beginning July 1, 2017, to provide confidential feedback on performance to MIPS EPs. Specifically, we are required to make available timely confidential feedback to MIPS EPs on their performance in the quality and resource use performance categories, and we have discretion to make available confidential feedback to MIPS EPs on their performance in the clinical practice improvement activities and meaningful use of certified EHR technology performance categories. This feedback can be provided through various mechanisms, including the use of a web-based portal or other mechanisms determined appropriate by the Secretary. We seek comment on the following questions:

- What types of information should we provide to EPs about their practice's performance within the feedback report? For example, what level of detail on performance within the performance categories will be beneficial to practices?
- Would it be beneficial for EPs to receive feedback information related to the clinical practice improvement activities and meaningful use of certified EHR technology performance categories? If so, what types of feedback?

- What other mechanisms should be leveraged to make feedback reports available? Currently, CMS provides feedback reports for the PQRS, VM, and the Physician Feedback Program through a web-based portal. Should CMS continue to make feedback available through this portal? What other entities and vehicles could CMS partner with to make feedback reports available? How should CMS work with partners to enable feedback reporting to incorporate information from other payers, and what types of information should be incorporated?
- Who within the EP's practice should be able to access the reports? For example, currently under the VM, only the authorized group practice representative and/or their designees can access the feedback reports. Should other entities be able to access the feedback reports, such as an organization providing MIPS-focused technical assistance, another provider participating in the same virtual group, or a third party data intermediary who is submits data to CMS on behalf of the EP, group practice, or virtual group?
- With what frequency is it beneficial for an EP to receive feedback? Currently, CMS provides Annual Quality and Resource Use Reports (QRUR), mid-year QRURs and supplemental QRURs. Should we continue to provide feedback to MIPS EPs on this cycle? Would there be value in receiving interim reports based on rolling performance periods to make illustrative calculations about the EP's performance? Are there certain performance categories on which it would be more important to receive interim feedback than others? What information that is currently contained within the QRURs should be included? More information on what is available within the QRURs is at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2014-QRUR.html.
- Should the reports include data that is stratified by race, ethnicity and gender to monitor trends and address gaps towards health equity?
- What types of information about items and services furnished to the EP's patients by other providers would be useful? In what format and with what frequency?

The EHRA agrees that providers will need feedback throughout the performance year to know how they are performing against target thresholds with sufficient time to make any necessary course corrections. Though some of the measures may be conducive to CMS providing interim reports for feedback, we do not believe that all MIPS performance metrics are; and once the metrics are defined, each will have to be evaluated for the ability for CMS to provide progress reports.

The EHRA is particularly concerned about interim reporting of meaningful use, clinical practice improvement activities, and eCQMs. It is invalid to assume that all EHRs can produce reports on-demand for a partial reporting period. Additionally, for the reports to be delivered to providers via CMS, the providers would first have to submit the data to CMS, likely in the same manner they do for attestation and quality reporting. We believe making providers report and attest throughout the year places an undue burden on providers.

For metrics where it is practical and meaningful to provide interim reporting, it may still not be possible to deliver that reporting in the 2017 performance year if software changes are needed to enable partial-period reporting. As the final rules for MIPs are expected in the fall of 2016, it is not feasible for EHR vendors to develop and distribute to customers new functionality by January 1, 2017.

In summary, we prefer a solution wherein providers can produce their own internal reports as a self-assessment, not required to be submitted to CMS and not a report-on-demand structure. Also, there would be little time to construct a new reporting system considering stated timelines for the advent of MACRA final rules and its projected start date.

A. Alternative Payment Models

1. Information Regarding APMs

Section 1833(z)(1) of the Act, as added by section 101(e)(2) of the MACRA, establishes incentive payments for EPs who are QPs with respect to a year. The term "qualifying APM participant" is defined under section 1833(z)(2) of the Act, and provides in part that a specified percent (which differs depending on the year) of an EP's payments during the most recent period for which data are available must be attributable to services furnished through an "eligible alternative payment entity" (EAPM entity) as that term is defined under section 1833(z)(3)(D) of the Act.

The term APM, as defined in section 1833(z)(3)(C) of the Act, includes: models under section 1115A of the Act (other than health care innovation awards); the Shared Savings Program under section 1899 of the Act; demonstrations under section 1866C of the Act (the Health Care Quality Demonstration Program); and demonstrations required by federal law.

Under section 1833(z)(3)(D) of the Act, an EAPM entity is an entity that: (1) participates in an APM that requires participants to use certified EHR technology and provides for payment for covered professional services based on quality measures comparable to the MIPS quality measures established under section 1848(q)(2)(B)(i) of the Act and (2) either bears financial risk for monetary losses under the APM that are in excess of a nominal amount or is a medical home expanded under section 1115A(c) of the Act.

For the years 2019 through 2024, EPs who are QPs for a given year will receive an incentive payment equal to 5 percent of the estimated aggregate Part B Medicare payment amounts for covered professional services for the preceding year. Under section 1833(z)(1)(A), the estimated aggregate Medicare Part B payment amount for the preceding year may be based on a period of the preceding year that is less than the full year.

a. QPs and Partial Qualifying APM Participants (Partial QPs)

Under section 1833(z)(2) of the Act, an EP may be determined to be a QP through: (1) beginning for 2019, a Medicare payment threshold option that assesses the percent of Medicare Part B payments for covered professional services in the most recent period that is attributable to services furnished through an EAPM entity; or (2) beginning for 2021, either a Medicare payment threshold option or a combination all-payer and Medicare payment threshold option. The combination all-payer and Medicare payment threshold option assesses both: (1) the percent of Medicare payments for covered professional services in the most recent period that is attributable to services furnished through an EAPM entity; and (2) the percent of the combined Part B Medicare payments for covered professional services attributable to an EAPM entity and all other payments made by other payers made under similarly defined arrangements (except payments made by the Department of Defense or Veterans Affairs and payments made under Title XIX in a state in which no medical home or alternative payment model is available under the State program under that title). These arrangements must be arrangements in which: (1) quality measures comparable to those used under the MIPS apply; (2) certified EHR technology is used, and (3) either the entity bears more than nominal financial risk if actual expenditures exceed expected expenditures or the entity is a medical home under Title XIX that meets criteria comparable to medical homes expanded under section 1115A(c) of the Act. For the combined allpayer and Medicare payment threshold option, the EP is required to provide to the Secretary the necessary information to make a determination as to whether the EP meets the all-payer portion of the threshold.

For 2019 and 2020, the Medicare-only payment threshold requires that at least 25 percent of all Medicare payments be attributable to services furnished through an EAPM entity. This threshold increases to 50 percent for 2021 and 2022, and 75 percent for 2023 and later years. The combination all-payer and Medicare payment threshold option is available beginning in 2021. The combined all-payer and Medicare payment thresholds are, respectively, 50 percent of all-payer payments and 25 percent of Medicare payments in 2021 and 2022, and 75 percent of all-payer payments and 25 percent of Medicare payments in 2023 and later years.

Under section 1848(q)(1)(C)(ii) of the Act, the statute specifies that partial QPs are those who would be QPs if the threshold payment percentages under section 1833(z)(2) of the Act for the year were lower. For partial QPs, the Medicare-only payment thresholds are 20 percent (instead of 25 percent) for 2019 and 2020, 40 percent (instead of 50 percent) for 2021 and 2022, and 50 percent (instead of 75 percent) for 2023 and later years. For partial QPs, the combination all-payer and Medicare payment thresholds are, respectively, 40 percent (instead of 50 percent) all-payer and 20 percent (instead of 25 percent) Medicare in 2021 and 2022, and 50 percent (instead of 75 percent) all-payer and 20 percent (instead of 25 percent) Medicare in 2023 and later years.

Partial QPs are not eligible for incentive payments for APM participation under section 1833(z) of the Act. Partial QPs who, for the MIPS performance period for the year, do not report applicable MIPS measures and activities are not considered MIPS EPs. Partial QPs who choose to participate in MIPS are considered MIPS EPs. These partial QPs will be subject to payment adjustments under MIPS.

b. Payment Incentive for APM Participation

To help us establish criteria and a process for determining whether an EP is a QP or partial QP, this RFI requests information on the following issues.

- How should CMS define "services furnished under this part through an EAPM entity"?
- 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?
- What policies should the Secretary consider related to estimating the aggregate payment amounts when payments are made on a basis other than fee-for-service (that is, if payments were made on a capitated basis)? What are the advantages and disadvantages of those policies? What are their effects on different types of EPs (that is, those in physician- focused APMs versus hospital-focused APMs, etc.)?
- What types of data and information can EPs submit to CMS for purposes of determining whether they meet the non-Medicare share of the Combination All-Payer and Medicare Payment Threshold, and how can they be securely shared with the federal government?

c. Patient Approach

Under section 1833(z)(2)(D) of the Act, the Secretary can use percentages of patient counts in lieu of percentages of payments to determine whether an EP is a QP or partial QP.

- 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?

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 privatepayer models?
- e. Medicaid Medical Homes or other APMs Available under State Medicaid Programs EPs may meet the criteria to be QPs or partial QPs under the Combination All-Payer and Medicare Payment Threshold Option based, in part, on payments from non-Medicare payers attributable to services furnished through an entity that, with respect to beneficiaries under Title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c) of the Act. In addition, payments made under some State Medicaid programs, not associated with Medicaid medical homes, may meet the criteria to be included in the calculation of the combination all-payer and Medicare payment threshold option.
 - What criteria could the Secretary consider for determining comparability of state Medicaid medical home models to medical home models expanded under section 1115A(c) of the Act?
 - Which states' Medicaid medical home models might meet criteria comparable to medical homes expanded under section 1115A(c) of the Act?
 - Which current Medicaid alternative payment models besides Medicaid medical homes are likely to meet the criteria for comparability of state Medicaid medical homes to medical homes expanded under section 1115A(c) of the Act and should be considered when determining the all-payer portion of the Combination All-Payer and Medicare Payment Threshold Option?

f. Regarding EAPM Entity Requirements

An EAPM entity is defined as an entity that (1) participates in an APM that requires participants to use certified EHR technology (as defined in section 1848(o)(4) of the Act) and provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) of the Act (the quality

performance category); and (2) bears financial risk for monetary losses under the APM that are in excess of a nominal amount or is a medical home expanded under section 1115A(c) of the Act.

- 1) Definition
 - What entities should be considered EAPM entities?
- 2) Quality Measures
 - What criteria could be considered when determining "comparability" to MIPS of
 quality measures used to identify an EAPM entity? Please provide specific examples
 for measures, measure types (for example, structure, process, outcome, and other
 types), data source for measures (for example, patients/caregivers, medical records,
 billing claims, etc.), measure domains, standards, and comparable methodology.
 - What criteria could be considered when determining "comparability" to MIPS of
 quality measures required by a non-Medicare payer to qualify for the Combination AllPayer and Medicare Payment Threshold? Please provide specific examples for
 measures, measure types, (for example, structure, process, outcome, and other types),
 recommended data sources for measures (for example, patients/caregivers, medical
 records, billing claims, etc.), measure domains, and comparable methodology.
- 3) Use of Certified EHR Technology
 - What components of certified EHR technology as defined in section 1848(o) (4) of the Act should APM participants be required to use? Should APM participants be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs or should CMS other consider requirements around certified health IT capabilities?

In consideration of the above questions, the EHRA offers the following recommendations to address the needs of APM participants. The EHRA supports the identification of a minimum subset of the current 2015 Edition certification criteria as applicable requirements for all APM participants. We believe the same certified EHR technology should be used for both EHR Incentive Programs and APM participants. The components we have recommended should support either the APM program or the EHR Incentive Program, and should not require any additional certification for use in the APM program.

We recognize that many providers and models will benefit from additional functionality which exists in the current certified technology and, as such, many providers may choose to select additional components to satisfy their needs. We do not recommend adoption of a large set of criteria due to the variability that exists across current models, and variability that will continue to exist as the payment models evolve. We discourage adoption of any components that may not be relevant to all providers and all APMs.

The EHRA recommends a narrow focus specifically on interoperability and patient engagement/care coordination criteria as essential components which should exist across all potential models. Selection of components to support APMs should offer reassurance that everyone will have the essential components to better reach their goals. Thus, the EHRA recommends the following as a the certification criteria that would best match the needs of the APM programs: (b)(1)Transitions of Care, (b)(6)Data Export, (e)(1) View, Download, and Transmit to 3rd Party, and (e)(2) Secure Messaging.

The EHRA suggests the ability of providers involved in different APMs to select any additional criteria which they may need to accomplish their goals from the current 2015 Edition Criteria which satisfy the EHR Incentive Program.

 What are the core health IT functions that providers need to manage patient populations, coordinate care, engage patients and monitor and report quality? Would certification of additional functions or interoperability requirements in health IT products (for example, referral management or population health management functions) help providers succeed within APMs?

As more experience occurs with population management, care coordination, and measurable outcomes based upon quality, we anticipate that innovation within the core health IT functions that will support APMs will continue to emerge. It is clear that functions which support interoperability across different care spectrums will be very important, but unclear exactly what will work best moving forward.

The EHRA discourages the creation of an additional set of certification criteria for APMs or any additional certification specifically for the APMs. Payment models are less mature and consensus has not been reached with regards to what will ultimately work best to achieve the desired outcomes. It would be premature to suggest additional requirements be written into the certification process when such an evolution is underway. We sincerely believe there must be sufficient time allowed for market demands to drive the innovation essential to determining core health IT functions for APMs. We are also concerned that adoption of additional criteria or required functions at this time could proliferate solutions which may not prove to be effective. In view of the 2015 Edition certification criteria, we also discourage the adoption of criteria, such as APIs from the EHR Incentive Program criteria or 2015 Edition optional criteria such as care plans, until the impact of such functions have been evaluated for their value within the current scope.

• How should CMS define "use" of certified EHR technology as defined in section 1848(o)(4) of the Act by participants in an APM? For example, should the APM require participants to report quality measures to all payers using certified EHR technology or only payers who require EHR reported measures? Should all professionals in the APM in which an eligible alternative payment entity participates be required to use certified EHR technology or a particular subset?

The EHRA agrees and supports the notion that adoption and use of EHR technology is essential to obtain desired cost reductions and population health improvements. To make it as easy as possible for providers to transition from the fee-for-service MIPS program to the more outcomes-focused APM model, we encourage alignment in the technology requirements for both programs. Technology adoption should not be a barrier to transitioning to the APM program.

APMs, by their nature, incent providers to better coordinate care, adhere to clinical best practices, and manage population health. Therefore, we believe it is not necessary to hold providers accountable to the level of rigor required by meaningful use. We suggest that "use" be defined as a limited set of meaningful use requirements that are most relevant to care coordination and more focused on real adoption than metrics of use. We also do not believe "use" requirements should apply to all providers, to avoid

the problems that some specialists, like radiologists, anesthesiologists, pathologists and others, have experienced with meaningful use. Because of the outcomes-focused incentive structure of APMs, we believe advanced and innovative use of technology will occur naturally and the need for administrative overhead to define and track technology use will diminish.

From a reporting standpoint, we encourage CMS to be mindful that some reporting programs do not require data submissions through the EHR. We recommend that this flexibility be maintained to allow for a greater variety of APMs providers could choose from or continue current participation in to satisfy MACRA APM definitions. Therefore, only payers who require EHR reported measures should be required to use CEHRT. In addition, it is important to remain mindful of the short timeframe between the release of a final rule, the current Stage 3 start date, and the start of this program in 2019, and not impose any new requirements for this program that will be difficult to implement within these constraints.

2. Information Regarding Physician-Focused Payment Models

Section 101(e) (1) of the MACRA, adds a new subsection 1868(c) to the Act entitled, "Increasing the Transparency of Physician-Focused Payment Models." This section establishes an independent "Physician-focused Payment Model Technical Advisory Committee" (the Committee). The Committee will review and provide comments and recommendations to the Secretary on PFPMs submitted by stakeholders. Section 1868(c)(2)(A) of the Act requires the Secretary to establish, through notice and comment rulemaking following an RFI, criteria for PFPMs, including models for specialist physicians, that could be used by the Committee for making its comments and recommendations. In this RFI, we are seeking input on potential criteria that the Committee could use for making comments and recommendations to the Secretary on PFPMs proposed by stakeholders. CMS published an RFI requesting information on Specialty Practitioner Payment Model Opportunities on February 11, 2014, available at http://innovation.cms.gov/files/x/specialtypractmodelsrfi.pdf. The comments received in Response to that RFI will also be considered in developing the proposed rule for the criteria for PFPMs.

PFPMs are not required by the MACRA to meet the criteria to be considered APMs as defined under section 1833(z)(3)(C) of the Act or to involve an EAPM entity as defined under section 1833(z)(3)(D) of the Act. However, we are interested in encouraging model proposals from stakeholders that will provide EPs the opportunity to become QPs and receive incentive payments (in other words, model proposals that would involve EAPM entities as defined in section 1833(z)(3)(D) of the Act). PFPMs proposed by stakeholders and selected for implementation by CMS will take time and resources to implement after being reviewed by the Committee and the Secretary. To expedite our ability to implement such models, we are interested in receiving comments now on criteria that would support development of PFPMs that involve EAPM entities.

- a. Definition of Physician- focused Payment Models
 - How should "physician- focused payment model" be defined?
- b. Criteria for Physician-focused Payment Models

We are required by section 1868(c)(2)(A) of the Act to establish by November 1, 2016, through rulemaking and following an RFI, criteria for PFPMs, including models for specialist physicians, that could be used by the Committee for making comments and recommendations to the Secretary. We intend to establish criteria that promote robust and well-developed proposals to facilitate implementation of PFPMs. To assist us with establishing criteria, this RFI requests information on the following fundamental issues.

 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.

The EHRA recommends that new PFPMs follow the MSSP ACO application model of having providers submit a plan for how they will use technology to achieve outcomes. We advise against propagating the meaningful use focus on "number of" and "percentage of" process metrics scored against an artificial threshold.

We also encourage consistency between the MIPS and APM technology requirements. Technology adoption should not be a barrier to transitioning from MIPS to the APM program.

- 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?
- What existing criteria, procedures, or standards are currently used by private or public insurance plans in testing or establishing new payment models? Should any of these criteria be used by the Committee for assessing PFPM proposals? Why or why not?
- c. Required Information on Context of Model Within Delivery System Reform
 This RFI seeks feedback on information that could be required of stakeholders proposing models to provide for the consideration of the Committee.

We are considering the following specific criteria for the Committee to use to make comments and recommendations related to model proposals submitted to the Committee. We are seeking feedback on whether these criteria should be included and, if so, whether they should be modified, and whether other criteria should be considered. Each of these criteria is considered for all models tested through the Center for Medicare and Medicaid Innovation (Innovation Center) during internal development. For a list of the factors considered in the Innovation Center's model selection process, see http://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf. We seek comment on the following possible criteria:

- We are considering that proposed PFPMs should primarily be focused on the inclusion of
 participants in their design who have not had the opportunity to participate in another
 PFPM with CMS because such a model has not been designed to include their specialty.
- Proposals would state why the proposed model should be given priority, and why a model is needed to test the approach.
- Proposals would include a framework for the proposed payment methodology, how it differs from the current Medicare payment methodology, and how it promotes delivery system reforms.
- If a similar model has been tested or researched previously, either by CMS or in the private sector, the stakeholder would include background information and assessments on the performance of the similar model.
- Proposed models would aim to directly solve a current issue in payment policy that CMS is not already addressing in another model or program.

d) Required Information on Model Design

For the Committee to comment and make recommendations on the merits of PFPMs proposed by

stakeholders, we are considering a requirement that proposals include the same information that would be required for any model tested through the Innovation Center. For a list of the factors considered in the Innovation Center's model selection process, see

http://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf. This RFI requests comments on the usefulness of this information, which of the suggested information is appropriate to consider as criteria, and whether other criteria should be considered. The provision of information would not require particular answers in order for a PFPM to meet the criteria. Instead, a proposal would be incomplete if it did not include this information.

- Definition of the target population, how the target population differs from the non-target population and the number of Medicare beneficiaries that would be affected by the model.
- Ways in which the model would impact the quality and efficiency of care for Medicare beneficiaries.
- Whether the model would provide for payment for covered professional services based on quality measures, and if so, whether the measures are comparable to quality measures under the MIPS quality performance category.
- Specific proposed quality measures in the model, their prior validation, and how they would further the model's goals, including measures of beneficiary experience of care, quality of life, and functional status that could be used.
- How the model would affect access to care for Medicare and Medicaid beneficiaries.
- How the model will affect disparities among beneficiaries by race, and ethnicity, gender, and beneficiaries with disabilities, and how the applicant intends to monitor changes in disparities during the model implementation.
- Proposed geographical location(s) of the model.
- Scope of EP participants for the model, including information about what specialty or specialties EP participants would fall under the model.
- The number of EPs expected to participate in the model, information about whether or not EP participants for the model have expressed interest in participating and relevant stakeholder support for the model. To what extent participants in the model would be required to use certified EHR technology.

We reiterate our position that it should be a subset of CEHRT used for the EHR incentive program as applied to MIPS, not a new certification program or new certification criteria focused on APMs.

- An assessment of financial opportunities for model participants including a business case for their participation.
- Mechanisms for how the model fits into existing Medicare payment systems, or replaces them in part or in whole and would interact with or complement existing alternative payment models.
- What payment mechanisms would be used in the model, such as incentive payments, performance-based payments, shared savings, or other forms of payment?
- Whether the model would include financial risk for monetary losses for participants in excess of a minimal amount and the type and amount of financial performance risk assumed by model participants.
- Method for attributing beneficiaries to participants.
- Estimated percentage of Medicare spending impacted by the model and expected amount of any new Medicare/Medicaid payments to model participants.

- Mechanism and amount of anticipated savings to Medicare and Medicaid from the model, and any incentive payments, performance-based payments, shared savings, or other payments made from Medicare to model participants.
- Information about any similar models used by private payers and how the current proposal is similar to or different from private models and whether and how the model could include additional payers other than Medicare, including Medicaid.
- Whether the model engages payers other than Medicare, including Medicaid and/or private payers. If not, why not? If so, what proportion of the model's beneficiaries is covered by Medicare as compared to other payers?
- Potential approaches for CMS to evaluate the proposed model (study design, comparison groups, and key outcome measures).
- Opportunities for potential model expansion if successful.
- C. Technical I Assistance to Small Practices and Practices in Health Professional I Shortage Areas. Section 1848(q)(11) of the Act provides for technical assistance to small practices and practices in HPSAs. In general, under section 1848(q)(11) of the Act, the Secretary is required to enter into contracts or agreements with entities such as quality improvement organizations, regional extension centers and regional health collaboratives beginning in Fiscal Year 2016 to offer guidance and assistance to MIPS EPs in practices of 15 or fewer professionals. Priority is to be given to small practices located in rural areas, HPSAs, and medically underserved areas, and practices with low composite scores. The technical assistance is to focus on the performance categories under MIPS, or how to transition to implementation of and participation in an APM. For section 1848(q)(11) of the Act—
 - What should CMS consider when organizing a program of technical assistance to support clinical practices as they prepare for effective participation in the MIPS and APMs?
 - What existing educational and assistance efforts might be examples of "best in class" performance in spreading the tools and resources needed for small practices and practices in HPSAs? What evidence and evaluation results support these efforts?
 - What are the most significant clinician challenges and lessons learned related to spreading quality measurement, leveraging CEHRT to make practice improvements, value based payment and APMs in small practices and practices in health shortage areas, and what solutions have been successful in addressing these issues?
 - What kind of support should CMS offer in helping providers understand the requirements of MIPS?
 - Should such assistance require multi-year provider technical assistance commitment, or should it be provided on a one-time basis?
 - Should there be conditions of participation and/or exclusions in the providers eligible to
 receive such assistance, such as providers participating in delivery system reform
 initiatives such as the Transforming Clinical Practice Initiative (TCPI:
 http://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/), or having a certain
 level of need identified?