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November 17, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3321-NC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Mr. Slavitt:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to respond to the *Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models* (RFI) that was published in the *Federal Register* on October 1, 2015. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice.

**Background**

This is a large and complex RFI, reflecting the extensive and substantive program implementations with which the Centers for Medicare & Medicaid Services (CMS) have been tasked. Because CMS has yet to provide detailed proposals, we are unable to provide complete responses to all the questions posed. However, we appreciate this opportunity to provide input both now and in the future as the Merit-based Incentive Payment System (MIPS) and alternative payment model (APM) initiatives continue to evolve. At this early stage, both initiatives are works in progress. As these initiatives develop, we urge CMS to continue to dialogue with stakeholders to facilitate rapid cycle

ongoing refinement and improvement of the implementation of MIPS and APMs.

With respect to both MIPS and APMs, we urge CMS to build transition processes and reasonable timelines into all regulatory, reporting, and payment implementations of these initiatives given that it is possible that neither CMS nor providers will immediately be able to implement a perfect system. Also, because parameters and benchmarks will be changing as these initiatives develop, thoughtful transitions and timelines are necessary to allow providers to prepare in advance, learn and implement a data capture strategy, budget for costs, and make meaningful changes in performance. As a general principle when developing MIPS and APM policy, we consider it better to be inclusive and flexible rather than prescriptive and rigid in order to foster innovation and generate widespread stakeholder engagement. We also believe that both initiatives would be helped immeasurably by a mandate from CMS for true and widespread electronic health record (EHR) interoperability. In addition, as with any substantial change in policy, we ask that CMS monitor the total regulatory burden being placed on individual practitioners. The requirements of multiple programs are already a major demand of time and energy that takes time away from patient care, which is an unintended consequence for providers and beneficiaries.

## Solicitation of Comments

### *A. The Merit-Based Incentive Payment System (MIPS)*

The ACS appreciates this opportunity to comment on the development and implementation of the MIPS program, and we hope to help guide some of CMS' decisions by drawing from our successes and lessons learned both from our own quality improvement efforts and our members' experience to date with the various CMS quality programs, including the EHR Incentive Program, the Value Modifier (VM), Physician Compare, Physician Quality Reporting System (PQRS), and other hospital incentive programs.

For more than 100 years, ACS has led national and international initiatives to improve quality in hospitals as well as the more specific fields of surgical quality, trauma, and cancer. The ACS Inspiring Quality Campaign was more recently launched to drive awareness of innovative quality improvement programs across the country including the Commission on Cancer, the

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Committee on Trauma and the ACS National Surgical Quality Improvement Program (ACS NSQIP). These initiatives are built on four key principles: setting the standards, building the right infrastructure, using the right data and verifying with outside experts. Together, these principles implemented through our various clinical data registries form a continuous loop of quality improvement in which organizations and providers learn to improve and keep improving. Our recommendations to CMS are largely based on the successes we have seen in our own quality initiatives. Below are some major themes that we believe will be key to the success of the MIPS program:

Meaningful and timely feedback: To avoid repeating the mistakes of current programs, we suggest that CMS first work on carefully designing the MIPS system; accrue a minimum foundation of data using the new system; confidentially share that data with practicing physicians, provide transparency to algorithms used in an easy to understand format with the ability to drill down to the case level; and transition toward real-time feedback with cloud-based technology so that providers can use data to make decisions at the point of care, thereby preventing many negative outcomes.

Quality and cost connection and appropriate attribution: The ACS has voiced concerns about the ongoing disconnect between what is being measured on the quality side and cost side of the equation of the VM. Moving forward, CMS must be able to clearly attribute cost to the individual eligible provider (EP) with appropriate risk adjustment. This could be accomplished with episode-based cost measures to help ensure more fair comparison. It is critical that providers understand the cost of their care before the MIPS program becomes punitive.

One challenge in the creation of episodes for general surgery is the diversity of care and settings in which care is delivered. General surgeons treat patients across a variety of settings, (acute versus elective practice environments) with varying volumes, encompassing many different diseases/treatments (trauma, bariatrics, breast, colorectal, pediatric, endocrine, transplant, hepatopancreaticobiliary, oncologic, and general/gastrointestinal). We encourage a partnership between CMS and ACS to best account for the diversity in the care delivered by general surgery to ensure meaningful measurement which accurately classifies the care delivered.

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Measurement across the phases of surgical care: The ACS believes quality measurement should consider five phases of surgical care: preoperative, perioperative, intraoperative, postoperative, and post-discharge, along with care coordination. These phases begin with the decision to operate in a preoperative phase. During this first phase, care coordination and optimal patient preparation for surgery are universal for all patients. The perioperative phase represents the last preoperative check prior to surgery. The intraoperative phase relates to the surgical team in the operating room, and the postoperative phase considers acute care in the postsurgical window. The post-operative phase considers the re-entry of the patient into care coordination with the primary care team. Recognition of these phases with clinical metrics and registries would build a safer, higher quality of care as a standard.

Meaningful engagement: At the early stages of the MIPS program, the ability to participate and "achieve" is far more important than attainment of the highest standard. To accomplish this, flexibility across programs, including virtual groups, will be critical. CMS must encourage meaningful engagement and measurement that drives improvement in patient care rather than reporting for the sake of reporting. As providers become engaged in the program, the level of improvement and the distribution of incentive payments should become increasingly higher stakes.

Use of physician-led clinical data registries: In general, we believe measures from specialty registries have proved to be more relevant, clinically appropriate, and actionable for surgeons when compared to the measures currently available as reporting options through PQRS and the EHR Incentive Program. Encouraging the use of clinical data registries will facilitate strategic and focused quality improvement, achieve value while reducing reporting burden on the physician community, and allow for an easier transition toward real-time feedback.

## Eligible Professional (EP) Identifiers

### Key Ideas

To account for the broad range of practice types, there should be flexibility in how EPs can report and how patients are attributed to them. Providers should be given the choice to be assessed at either the individual or group level based on the care they provide. This flexibility is particularly important if MIPS is

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truly intended to serve as a quality improvement program. The MIPS program must be flexible enough to allow physicians and physician groups to organize in ways that ensure patients receive high quality and efficient care, while limiting negative financial impacts that could diminish their ability to continue making improvements. It is critical that EP identifiers are developed to promote a level playing field for all sizes and types of practices including large groups, small practices, hospital and university-based physicians. For example, if there are mechanisms that favor large groups, EPs who are in small practices in healthcare shortage areas may be pushed toward larger groups in densely populated areas thereby decreasing access to care in rural areas.

By relying only on tax TIN/NPI combinations, CMS will limit the utility of the data and incentives provided under MIPS. For this reason, it is important to allow physicians to determine the group configurations that make the most sense for quality improvement. EPs should have the option to rely on a single source to reconcile the various aspects of accountability—whether this can be resolved by a MIPS identifier will be up to CMS to determine with input from stakeholders. In order to understand the operational nuances of implementing EP identifiers and other administrative decisions, and to provide the level of feedback requested in many of the questions below, ACS would be interested in surveying our members. This survey could be done with a grant from CMS.

**Should CMS use a MIPS EP's TIN, NPI, or a combination thereof?**

ACS encourages CMS to consider the pros and cons of each identifier (TIN/NPI/combination) as they begin to implement different aspects of the program. For example, TIN-based analysis offers administrative simplicity, but NPI level analysis offers granularity. Additionally, TINs/NPIs are intended for payment purposes and might have limitations in terms of capturing quality. There is also the current problem with individual EPs not knowing if their group has opted to participate in PQRS, which has resulted in a loss of autonomy. As discussed above, EPs should have the OPTION to rely on a single source to sign in to reconcile various aspects of accountability by knowing exactly how they are being evaluated —whether this can be resolved by a MIPS identifier will be up to CMS to resolve with input from stakeholders. The key issue is that EPs should be able to rely on a single source to access information on their performance with minimum burden.

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**What are the advantages/disadvantages associated with using existing identifiers either individually or in combination?**

As CMS creates the parameters for MIPS, we believe that it must use guiding principles that make the program understandable, efficient, actionable, and straightforward.

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

As discussed above, a MIPS-specific identifier as an OPTION may address cases where a physician has multiple TINs or combination of NPI and TIN reporting. However, if CMS were to opt to create a MIPS-specific identifier, it must resolve its current enrollment process issues so as not to create even greater administrative burden on practices.

**Should a different identifier be used to reflect eligibility, participation, or performance as a group practice vs. an individual MIPS EP? If so, should CMS use an existing identifier or create a distinct identifier?**

Discussed above.

**How should CMS calculate performance for MIPS EPs that practice under multiple tax ID numbers (TINs)?**

In general, ACS has concerns regarding the measurement of specialty care crossing various facilities or primary care physician (PCP) affiliations (hospitalists, Accountable Care Organization (ACO) affiliated groups, Federally Qualified Health Centers (FQHC), unrelated multi-specialty group practices and independents), and how this care is attributed. Currently, CMS policy in the PQRS only allows for one type of reporting methodology. As discussed above it is important that EPs are given the OPTION for their performance to be tracked by either NPI, TIN, or a MIPS-specific identifier, and this choice might vary depending on the MIPS category. For example, an EP might want to report quality measures as a group but be recognized as an individual for clinical practice improvement activities (CPIAs).

**How often should CMS require an EP or group practice to update identifier(s) in PECOS (the Medicare enrollment system)? Should EPs be**

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

Administrative streamlining and "paperwork reduction" should guide these decisions. Many of our members have had a lot of difficulty updating this information and find Provider Enrollment, Chain and Ownership System (PECOS) to be very problematic and dysfunctional.

**In situations where a MIPS EP could be assessed using multiple identifiers (e.g. under current PQRS assessment where an EP is assessed under each distinct NPI/TIN 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?**

CMS will need to be able to capture all NPIs associated with performance across TINs/ MIPS identifier (if implemented) exempted practice etc., and attribution should be linked in a meaningful way to an episode of care.

## Virtual Groups

### Key Ideas

ACS believes that the MIPS virtual group option has the potential to more meaningfully align measurement based on care delivery models. We believe the following will help guide the development of Virtual Groups:

- As this program is implemented, ACS supports minimum standards to ensure that the members of a virtual group are working toward a common goal or otherwise have a mutual interest in quality improvement. For example, virtual groups could facilitate meaningful measurement for rural surgeons who are either not part of a group practice or are in a small group.

- It will be critical to maintain flexibility in responding to changes in virtual groups as this program is implemented. EPs should have the option to be tied to their hospital or ASC for quality reporting purposes.

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- EPs should also have the flexibility to change virtual groups if their current group is not optimal for reporting quality.

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

Due to the unique nature and composition of each virtual group, ACS recommends that CMS not pit virtual groups against each other when measuring performance, and instead look at annual self-improvement (at least initially). For example, if the virtual group is all participants in a specific registry, did their aggregate performance improve from year 1 to year 2?

Virtual groups could be organized similar to the current PQRS group practice reporting option (GPRO), with the flexibility to select both quality and eventually resource use measures, once they are developed. EPs could elect to be in a virtual group. Examples of how virtual groups could be organized include:

- Registries: ACS recognizes virtual groups as an opportunity for EPs who participate in clinical data registries to allow for meaningful and cross cutting comparisons across specialties.

- Clinical service lines: Virtual groups could be organized across clinical service lines such as a cancer group, cardiac care group, or chronic disease management in a primary care medical home (PCMH) group—or more broadly in an integrated clinical group practice.

**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 CMS allows TINs to split?**

ACS supports the concept of allowing for split TINs. Split TINs could drive improvement by allowing for the recognition of high performers.

**Should there be a maximum or minimum size for virtual groups? (E.g. a minimum of 10 MIPS EPs or no more than 100 MIPS EPs that can elect to be in a given virtual group?)**

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It is critical that CMS maintain flexibility and allow EPs to form virtual groups based on the care they deliver, with the ability to participate as part of multiple different virtual groups. For example, flexibility is needed for general surgeons who encounter patients in an acute environment as well as through emergent settings. These providers will need to have multiple affiliations in areas that cross care (different groups, hospital systems, etc. that even cross state lines at times).

Given the diversity of care delivery, limiting the number of EPs allowed to participate in a group or number of groups is arbitrary and may limit innovative ways to measure care. CMS should focus on encouraging participation.

**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? (CMS is 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 CMS should consider?**

Discussed above.

**Should CMS limit for virtual groups the mechanisms by which data can be reported under the quality performance category to specific methods (e.g. QCDRs or utilizing the web interface)?**

All reporting options and mechanisms should be maintained, including the qualified clinical data registry (QCDR). In fact, we believe that virtual groups could be of particular utility for surgeons to whom measures included in the web interface, for example, are not applicable. Limiting the reporting mechanisms available to virtual groups will undermine one of the primary benefits of virtual groups: allowing groups to organize under MIPS in a manner congruent with how care is delivered to be able to report on the most meaningful measures for that group.

**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?**

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Limiting the number of EPs allowed to participate in a virtual group is arbitrary. We urge CMS to focus on increasing participation, rather that limiting the number of virtual group elections.

**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?**

As discussed above, ACS believes that CMS should encourage participation in MIPS and allow for flexibility in the formation of virtual groups. We recommend against restrictions on specialty or geographic location, for example:

- Geographic location: Rural surgeons may want to join groups with others across state lines for more meaningful peer-to-peer comparisons. Allowing rural surgeons the opportunity to partner with other surgeons in quality improvement and cost reduction efforts will provide a care improvement opportunity previously unavailable to these providers.

- Cross-specialty: A vascular surgery group may want to form a virtual group with interventional radiologists.

**<u>Quality: Reporting Mechanisms & Criteria</u>**

**Should CMS maintain all PQRS reporting mechanisms currently available for MIPS?**

To minimize confusion and encourage participation in the initial stages of the program, MIPS should maintain all PQRS reporting mechanisms currently available.

**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? (E.g., if the same measure is reported through different reporting mechanisms, the same patient could be reported multiple times).**

ACS agrees that there must be a mechanism to ensure that EPs do not get credit for using the same measure for the same patients across multiple reporting

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mechanisms. This may be especially challenging when a given patient is in both a registry and an EHR. CMS must work to simplify and educate EPs to increase the transparency of various reporting mechanisms.

Furthermore, the program should be designed to incentivize robust measures in future years. One way to accomplish this is to transition toward giving additional credit/weight for more robust measures, such as outcome measures or measures reported via registries versus claims. Otherwise, specialties with more outcome measures could be at a disadvantage when compared to specialties which report process measures in order to score adequately. However, this must be a phased approach to allow for the development of measures for the various specialties.

**Should CMS 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?**

The PQRS reporting requirement for individual measure reporting on nine measures, including one cross-cutting measure, across three National Quality Strategy (NQS) domains is arbitrary and onerous. We have heard from many of our members that they view PQRS as "reporting for the sake of reporting" because the majority of the measures are meaningless to surgeons. Additionally, CMS must account for the higher reporting burden that EPs will face under MIPS with the inclusion of CPIAs—and that CPIAs might be more relevant and meaningful to their practice. To this end, CMS should lower the threshold, but work with providers to identify measures that are actionable and have a greater impact on improving care. Surgical outcome measures or measures of appropriateness have the potential to drive significant improvements in quality.

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

The NQS domain requirement is arbitrary. ACS supports the overarching goals of the domains, but requests that NQS domains be used as a guide for measure selection and not a requirement. If CMS does opt to maintain the domain requirement, it should: 1) adopt a more transparent process for assigning domains, allowing for relevant clinical expert input; and 2) allow for

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measures to be assigned to multiple domains simultaneously, where appropriate, to offer EPs more flexibility.

**Should CMS require that certain types of measures be reported? (E.g, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?**

Although ACS agrees that certain types of measures such as outcome measures and measures of appropriateness can be more meaningful and have a greater impact on care, CMS must make greater investments in developing these types of measures. As discussed above, we agree that EPs should be given more credit for outcome measures or appropriateness measures reported via registry versus claims. However, due to the financial implications of MIPS, and the methodological issues that still must be worked out in regard to outcome measures, the weights should be gradually phased in because it is not equitable to assign greater weight to certain types of measures until all EPs have meaningful and robust measures to choose from. Additionally, CMS must further develop its capacity to 1) accept appropriate risk-adjusted data; and 2) make comparisons of those outcomes across homogenous procedure groupings.

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

Yes, CMS should require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender, assuming minimum case thresholds are met to make the stratifications meaningful for quality improvement. However, stratified data should only be provided to the EP as part of the feedback report for internal quality improvement. Stratified data should not be released to the public or be used to determine payment. Reporting mechanisms must also allow for risk adjustment, where appropriate.

**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?**

ACS strongly encourages including the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey measure (S-CAHPS) as an option for either the CAHPS survey in PQRS or as a CPIA. An EP should be able to

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elect to get credit for CAHPS under one category or the other, but not both (at least not for the same patient).

It is also important to note that the ACS continues to urge CMS to consider including the S-CAHPS as an individual, voluntary PQRS measure. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which are important from the patient's perspective and for which the patient is the best source of information. We remind CMS that the National Quality Forum (NQF) Measure Applications Partnership (MAP) recommended the inclusion of S-CAHPS in PQRS for two consecutive years, starting in 2013, yet CMS still continues to claim that it is not technically feasible to include the S-CAHPS measure in PQRS. We strongly encourage CMS to prioritize the time and resources needed to include the S-CAHPS as a PQRS measure. To satisfy the measure, EPs should attest to the administration and review of the survey.

**What considerations should be made as CMS further implements CAHPS for all practice sizes? How can CMS leverage existing CAHPS reporting by physician groups?**

As discussed above, ACS continues to feel that CMS has not made much progress in implementing a CAHPS survey that serves the surgical patient. We strongly recommend the S-CAHPS as a CAHPS option, and we also encourage CMS to make investments into patient reported outcome measures (PROs) for the surgical patient.

**How should CMS apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria?**

Specialists should not be negatively affected as a result of having fewer measures that are applicable to the care they provide. CMS must focus on the impact of a given measure, not the number of measures.

**Should CMS maintain a Measure-Applicability Verification (MAV) Process?**

ACS agrees that CMS should maintain the MAV process, as it will likely be important during the early days of MIPS. However, it is critical that CMS increase the transparency of the MAV program, as many providers view it as a

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"black box." We believe CMS can increase transparency in the following ways: 1) work with specialists in a transparent manner to choose the measures—these measures should have a public comment period; 2) post the chosen measures in a timely manner and; 3) educate EPs on the measures for which they will be evaluated, as well as the process for evaluation. CMS should continue to exclude cross-cutting measures from trigger clusters.

**If CMS customizes the performance requirements for certain types of MIPS EPs, how should CMS go about identifying the MIPS EPs to whom specific requirements apply?**

CMS should work with professional society organizations to customize the performance requirements for certain types of MIPS EPs. Regarding surgery, ACS has submitted a Measures Group for inclusion in PQRS 2017 which represents a complete surgical program across the various phases of surgical care. This Measures Group is applicable to the majority of major surgical procedures, and could be further specified for given disciplines using registries as the program matures.

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

The potential barriers to successfully meeting the MIPS quality performance category include:

- The rapid timeline will exacerbate confusion for providers and systems.
- Certain aspects of the MIPS program are opaque to providers and lack specificity, controllability, and demonstrated effect.
- There is a high reporting burden.
- There are various informatics challenges, including a lack of interoperability between EHRs and registries.
- There are gaps in the ability of CMS to accept risk-adjusted data.
- Feedback reports are difficult to understand and are not actionable due to the data lag and ineffective presentation.

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- There is a lack of meaningful measures for given practice types, including the ten different types of general surgical practices (trauma, bariatrics, breast, colorectal, pediatric, endocrine, transplant, hepatopancreaticobiliary, oncologic, and general/gastrointestinal).

**Quality: Data Accuracy**

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

It is critical for CMS to develop a system for data to be submitted in the appropriate format based on the type of data—CMS should accept data which is normalized and risk-adjusted, when appropriate.

**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?**

- Data should not be submitted to CMS until appropriately risk-adjusted and protected from uses other than those for which it was intended, similar to the CMS Qualified Entity Program. Data submitted to CMS should be protected from release under the Freedom of Information Act (FOIA) and should not be subject to reinterpretation for separate publication by non-approved entities, particularly if this could misinform the public. Reuse of this data cannot be controlled and may not always be in the best interest of patient care.

- ACS fully supports the move toward data standards, such as QRDA or National Quality Registry Network (NQRN) standards, with the eventual goal of a single standard for both registry and EHR data. However, this transition will take time and therefore CMS must maintain flexibility in the formats accepted during this transition, as discussed above.

- ACS is willing to serve in partnership with CMS in a yet-to-be defined open public−private partnership for creating standards to define reliable, authentic and valid registries.

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In regard to testing data, ACS recommends that CMS work with registries and vendors to allow for a mandatory test submission of data prior to the CMS deadline. A test submission will ensure that CMS can accurately accept data, including risk adjusted data. However, until this process is established, CMS must accept data in the format that registries believe is the most reliable format to prevent the misclassification of care. These data should not be made public until there is comparability among data.

Additionally, CMS should require the following to improve data integrity:

- A secure authentication method that increases the usability of the data for evaluation and quality improvement;
- Verification by each registry and EHR of processes as part of external peer review;
- Transparency of data elements, performance measure specifications, and risk adjustment methodologies (if relevant), achieved by publishing or otherwise making this information publicly available;
- Provision for data sharing agreements between CMS and registries/EHR products that state that the specialty registry or individual provider will retain ownership of reported data, not CMS. This is intended to create a restricted covenant to prevent others from using the data for unintended purposes but it would not prevent CMS from obtaining data for a specific use;
- Eventual transition toward a direct feed from EHRs/registries; and
- Prohibition of vendor information blocking or introducing steep charges for the transfer of data, thereby limiting interoperability. It is critical that vendors are prevented from becoming so proprietary that participating in a registry or EHR product leads to impediments to driving improvements in patient care.

**Should CMS require that qualified registries, QCDRs, and HIT systems undergo review and qualification by CMS to ensure that CMS' form and manner are met? (E.g., CMS uses a specific file format for qualified**

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**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?**

As discussed above, "one form fits all" may not translate for each registry. Therefore, when developing forms for data submission, it is critical that CMS work with registries to ensure that CMS can accept formats which allow registries to demonstrate embedded risk adjustment. ACS supports a process that is modeled after the current QCDR self-nomination process.

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

The following feedback from CMS would be beneficial during testing: acceptability, methodology (including methodological changes), and assessment of reliability and validity.

**What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data? (E.g, if a QCDR's calculated performance rate does not equate to the distinct performance values, such as the numerator exceeding the value of the denominator, should CMS re-calculate the data based on the numerator and denominator values provided?)**

It is important that CMS work closely with any QCDR should it need to perform recalculations to ensure integrity. In order to promote data accuracy, completeness, and reliability, CMS should consider the following:

- Random sampling with audits should be required. Appropriate sampling can be just as effective as reviewing complete data sets.
- There should be a mechanism to remove duplications.
- It is important to note that reliability and validity varies according to each measure.

**Should CMS not require MIPS EPs to submit a calculated performance rate (and instead have CMS calculate all rates)?**

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ACS strongly believes that CMS should not recalculate the performance rate unless the QCDR or Qualified Registry provides authorization because certain measures must be submitted by programs as complex risk-adjusted metrics. Specifically, QCDRs and Qualified Registries should have the option to submit their performance assessments as suitable performance rates. Collaboration with CMS could help improve CMS' familiarity with ongoing ACS registry quality improvement efforts. This partnership could also work toward increased data sharing which could provide the opportunity to enable real-time feedback to EPs.

**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?**

It is important to note that error thresholds will differ across registries but should not exceed 5 percent in general. More mature registries are likely to have lower error thresholds, whereas registries in their infancy may have higher thresholds.

In the event that a QCDR omits data elements, the QCDR should be given the opportunity for dispute resolution or appeal. Subsequent to appeal, if there is no resolution, data should be discarded.

**If CMS determines that the MIPS EP (individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet CMS 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?**

If CMS determines that the MIPS EP has used a data reporting mechanism that does not meet CMS data integrity standards, feedback from CMS should be provided to the Qualified Registry/QCDR/EHR to allow for correction. If data is not corrected, the Qualified Registry/QCDR/EHR could be put on a probationary period to fix the data inaccuracies. It is important that the EP is not at fault if their vendor has a data accuracy issue. In this instance, the EP should be held harmless and other MIPS categories could be weighted more

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heavily. As noted above, a mandatory test submission of data may help alleviate or remedy these issues prior to the submission deadline.

**Quality: Use of CEHRT**

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

The streamlining of CMS quality programs, including the Medicare EHR Incentive Program, into a single MIPS program provides an opportunity to broaden our understanding of what constitutes meaningful use of certified electronic health record technology (CEHRT). The College believes that CMS should look at the concept of meaningful use more in terms of use of the data, rather than use of the EHR technology itself. This meaningful use of CEHRT may come in many forms, including through moving data into alternate methods of reporting performance measures to CMS.

To provide for the greatest level of flexibility, CMS should develop a continuum of acceptable pathways through which the use of CEHRT may be demonstrated. Such methods should have demonstrated reliability, validity, and an audit trail and be used for accountability and determining incentive payment. The digital use of clinical data must be leveraged for better, more optimal care.

One such example of flexibility would be reporting of electronic clinical quality measures (eCQMs) through a QCDR rather than via the EHR. We urge CMS to allow use of a QCDR to serve in place of reporting eCQMs via the EHR for purposes of demonstrating meaningful use. Broadening the definition of meaningful use to allow for this, could also allow for QCDR reporting to constitute use of CERHT for purposes of reporting quality data under MIPS.

**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?**

As noted above, ACS believes that there should be great flexibility in the use of health information technology (HIT) provided that the data are valid and available for use in fulfilling multiple requirements, quality improvements efforts and research purposes. CMS should work closely with The Office of the National Coordinator for Health Information Technology (ONC) in developing

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standards for this activity that ensure that data are mutually intelligible and that transmission of data is free from unnecessary hurdles. Therefore, ACS feels that capture and transmission should be separate and "capture and calculate" is appropriate for the initial stages of the MIPS program. In time, the data should be transmissible and shared with a broad audience of stakeholders via the EHR system or potentially other certified technology.

**Resource Use**

**Apart from the cost measures currently utilized as part of the Physician Value Based Payment Modifier, 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?**

The ACS continues to be concerned about the relevancy of the quality and cost measures used to calculate the VM, the ongoing disconnect between what is being measured on the quality side and cost side of the equation, and the inadequacy of the program's attribution and risk adjustment methodologies. In regard to the disconnect, CMS relies on PQRS measures to calculate a portion of the quality composite, which focuses on very specific procedures or services (such as discontinuation of prophylactic antibiotics) while the cost measures are very broad and evaluate total cost— (i.e., total per capita costs, as well as the cost of services performed during an episode that comprises the period immediately prior to, during, and following a patient's hospital stay). Broad-based attribution does little to provide meaningful and actionable information to providers. As a result, the measures have no clinical relevance for many physicians. While some physicians have no costs attributed to them, others are tagged with costs for services they had no opportunity to control. CMS must be able to provide actionable, meaningful resource use performance data to individual EPs that allows EPs (individually or collectively) to manage resource use in the context of providing high quality care. Specific episode-based cost measures will help ensure more fair comparisons and alleviate the need for many of the complex adjustments to data that are required when looking at total per capita costs.

It is no coincidence that MACRA initially grants this category only 10 percent of the total MIPS score. Congress understood that the current VM

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methodology is seriously flawed and that time is needed to improve it. ACS agrees with that assessment and stands ready to work with CMS to improve measurement of physician resource use.

**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)?**

Specific episode-based cost measures will help ensure more fair comparisons and alleviate the need for many of the complex adjustments to data that are required when looking at total per capita costs. It is critical that when these more targeted cost measures are available for resource use measurement that they replace, rather than supplement the current flawed, broad-based cost measures.

Within these episodes, the ability to drill down to more relevant feedback could be very informative as well, including diagnostics, post-acute services, pharmaceuticals, etc. Examples include: total resource use for a cancer bundle for a colorectal cancer, trauma bundle or a total joint bundle. This is an area where there needs to be a great deal of development and where CMS should focus their resources. We look forward to providing additional input in response to CMS' recently released request for comments on episode groups.

**How should we incorporate Part D drug costs into MIPS? How should this be measured and calculated?**

CMS must implement a mechanism to account for all pharmaceutical costs when evaluating physician resource use. It is also important to identify scenarios where savings can be achieved by prescribing less expensive yet equally effective drugs.

The current cost measures used in the VM program specifically exclude Part D costs, which puts physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order/prescribe drugs covered under Part D, since the former would appear to have higher Medicare expenditures than the latter. While use of the Hierarchical Condition Categories (HCC) model may account for some conditions that require Part B drugs and are therefore more costly, it does not distinguish between the appropriateness of Part D drugs versus Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for

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their patient. ACS believes the current methodology has the potential to influence treatment decisions as physicians are perversely incentivized to prescribe Part D drugs when Part B drugs may be more appropriate for the patient. The development of a measure that incorporated Part D costs would need appropriate risk adjustment and also attribute the Part D cost to the prescribing physician.

**What peer groups or benchmarks should be used when assessing performance under the resource use performance category?**

Specific episode-based cost measures, as discussed above. It is also important for CMS to ensure that practices are being compared to similarly situated practices (geography, specialty mix, patient mix, etc.).

**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?**

Physicians should not be held accountable for cost performance, in particular, until CMS has developed and carefully tested more focused episode-based cost measures that more accurately evaluate care over which a physician has control and allow for more equal comparisons of patient populations. The ACS is very involved in this work and looks forward to assisting CMS with the implementation of more specialty-specific episode-based cost measures, and we encourage a more rapid timeline for rolling out the episode-based grouper.

To this end, ACS strongly urges CMS to distribute MACRA funding (section 102) for quality measure development. MACRA specifically authorizes $15 million per year for each of fiscal years 2015 through 2019, for a total of $75 million, to fund the development of physician quality measures for use in the MIPS. We encourage CMS to give priority to efforts generated by or in collaboration with the medical profession—this will be key to achieving the legislation's goal of the availability of an adequate portfolio of appropriate quality measures.

Additionally, ACS encourages the continuation of PQRS Measures Groups which can allow EPs to organize measures in a way that could keep the resource measures clinically aligned with particular services, procedures, or even clinical service lines.

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## CPIA

***Key Ideas***

The Clinical Practice Improvement Activities category of MACRA "gives credit to professionals working to improve their practices and facilitates future participation in APMs." The MACRA legislation provided for six CPIA performance categories. Specifically those are: 1) *Expanded practice access*, 2) *Population health*, 3) *Care coordination*, 4) *Beneficiary engagement*, 5) *Patient safety and practice assessment* and 6) *Participation in an APM*. Though not explicitly requested or outlined in the RFI, ACS would like to take this opportunity to comment on the original six categories and submit requests for consideration on behalf of surgeons relative to same.

The ACS has a long and successful history in the development of accreditation and verification programs to improve the quality of care for surgical patients. In addition, the numerous quality programs developed by the ACS, including NSQIP, Trauma Quality Improvement Program (TQIP), and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) are well recognized as promoting the highest standards of surgical care through evaluation of surgical outcomes in clinical practice. More information on these efforts can be found at: https://www.facs.org/quality-programs. Because the goal of these programs drives to the heart of the intent of the CPIA component of MIPS, we firmly believe that surgeons who actively participate in such should accordingly receive CPIA credit under the category of *Patient safety and practice assessment* for their efforts.

ACS would also specifically request that surgeons who utilize the ACS Surgical Risk Calculator for shared decision making in surgery receive credit toward their CPIA score under the category of *Beneficiary engagement*. The Risk Calculator can be found at http://riskcalculator.facs.org/ . Similarly, we would also ask that surgeons who utilize the evidence-based guidelines for decisions relative to surgical care found at http://ebds.facs.org receive credit toward their CPIA score under the category of *Patient safety and practice assessment*. ACS expects that both of these resources will be operational and linked into the CMS-qualified Surgeon Specific Registry (SSR) before the data for the first year of MIPS is collected in 2017. ACS also believes that CPIA credit under the category of *Patient safety and practice assessment* should be provided to surgeons for successfully meeting the maintenance of certification

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requirements (MoC) of their applicable specialty board and that the credit should apply for the period of time for which the MoC is valid.

Participation in a QCDR is specifically mentioned in MACRA as meeting the criteria for CPIA credit under the subcategory of *Population management*. We would note that two ACS QCDRs, namely the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program and the ACS SSR QCDR – Trauma Measures Option, have been approved by CMS to provide registry-based quality reporting. However, we also believe that participation in other physician-led clinical data registries that might not (yet) be a QCDR such as public health registries, and registries implemented at local institutions, should be considered for CPIA credit. In recognition of the extra investment of time and resources that must be made by physicians who opt to collect and report data through a clinical data registry, we would ask that surgeons successfully reporting via QCDRs as well as physician-led clinical data registries receive specified CPIA credit in addition to receipt of credit under the quality measures category of MIPS.

Should the Secretary ultimately decide to provide CPIA credit under the subcategory of *Expanded practice access* to those providers and practices which offer same day appointments for urgent needs and/or after-hours access to clinician advice, ACS respectfully asserts that surgeons who provide call coverage and make themselves available to emergency departments and other facilities providing after-hours access, whether on a voluntary or mandatory basis, should also similarly receive credit for their analogous efforts in providing such access to after-hours clinician advice and service.

Lastly, ACS would call attention to the pending publication of its *Optimal Resources for Quality Surgical Care*, which is a reference and standard setting volume developed by experts nationwide and coordinated by ACS. We look forward to working with CMS in the future to consider providing CPIA credit to surgeons for successfully incorporating components derived from this publication into their practices.

With regard to ACS' responses below to the specific CPIA questions posed in CMS' Request for Information, ACS notes that those responses were drafted based on two premises:

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1) MIPS was designed in such a way as to reduce administrative burdens by coalescing all of the current Medicare quality initiatives into one entity.

2) The CPIA component of MIPS was specifically designed to not only improve performance in MIPS, but also to encourage participation in alternative payment models.

***CPIA: Questions***

**Proposed Additional Subcategory: Promoting Health Equity and Continuity**

ACS has no objection to the inclusion of this additional subcategory. We would suggest that CMS consider giving credit to providers who accept Medicaid and who treat the underserved. If CMS chooses to give CPIA credit to these providers, it will be important to account for the variability in Medicaid eligibility across states.

**Proposed Additional Subcategory: Emergency Preparedness and Response**

ACS strongly supports the creation of this additional subcategory as it would serve as a means of providing CPIA credit to surgeons who serve in the armed forces reserves and the National Guard. We would urge the criteria for credit be created so as to be broad enough to include those EPs who also participate in other state-based emergency and disaster preparedness activities and other volunteer initiatives sponsored by medical specialty societies such as ACS' Operation Giving Back: http://operationgivingback.facs.org.

**Proposed Additional Subcategories: Social and Community Involvement, Achieving Health Equity and Integration of primary care and behavioral health**

In general, ACS has no objection to the inclusion of these additional categories but we would note there seems to be limited applicability for participation by surgery EPs.

**Data Collection: 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?**

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**Or alternatively, should qualified registries, QCDRs, EHRs, or other HIT systems be able to transmit results of the activities to CMS?**

Attestation through a simple, accessible, web-based portal should be a valid option for all providers. However, given that this is a new and developing category, reporting requirements should be kept simple and inclusive enough to accommodate a broad range of options. Specifically, ACS would suggest that in addition to annual attestation through a web-based portal, acceptable options should include QCDRs and EHRs, and where applicable, there should be an option of having participation in a CPIA reported by the certifying agency, rather than by the individual physician. This range of options would provide the opportunity for specialty societies and/or QCDR sponsoring entities to create what are essentially specialty-specific dashboards designed to provide feedback to EPs across all of the MIPS performance categories. Such would offer the means by which to tie measurement in one category to measurement in other categories, (e.g. ensuring that quality and resource measurement are occurring in the same clinical spectrum), reduce physician administrative burden related to reporting, streamline CMS efforts to receive performance data in each performance category, and allow for alignment of measure reporting with other non-Medicare reporting requirements such as those related to MoC or private payer initiatives.

**Data Collection: What information should be reported and what quality checks and/or data validation should occur to ensure successful completion of these activities?**

In order to facilitate CPIA reporting, ACS would suggest that whenever possible, reporting should be automatic and performed as part of utilization of an EHR, participation in a QCDR or use of other health information technology. In most instances, ACS believes that simple attestation, perhaps with auditable documentation should be sufficient.

**Data Collection: How often providers should report or attest that they have met the required activities?**

Attestation should be required on an annual basis.

**Data Collection: What threshold or quantity of activities should be established under the clinical practice improvement activities performance category?**

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Until more information on the specific number of requirements and possible options for fulfillment of such are available, it is difficult to provide firm opinions and recommendations here. That said, ACS does believe participation at the outset of the program would be greatly facilitated by imposing straightforward structural measures. It is our understanding that under MACRA, full CPIA credit is provided to those who participate in a PCMH and that participation in an approved APM provides at least fifty percent of the maximum CPIA score possible. It is also our understanding that providers are not required to perform activities in all of the outlined CPIA categories to receive full credit. Accordingly, we would suggest that EPs be required to successfully complete or participate in activities in no more than three of the total number from the menu of activities ultimately prescribed in order to receive full CPIA credit.

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

Until such time as we have a better understanding of what is being measured, it is not feasible to make meaningful suggestions with regard to an appropriate weight to be assigned. That said, ACS believes there must be a compelling rationale for providing differentials in the weight assigned to the list of subcategories ultimately available.

**Performance Assessment: How should CMS define the subcategory of participation in an APM?**

As stated above, it is our impression that the intent of the CPIA component of MIPS is, in large measure, to encourage and facilitate the adoption of APMs. Accordingly, in order to facilitate such we strongly suggest that APM participation, even at low levels, should qualify for credit. Specifically, we would suggest that receipt of a minimal amount of payment, e.g. two percent, through an APM be sufficient to receive credit for APM participation in the early years of the new program. Additionally, we suggest those that receive a somewhat higher percentage of payment through an APM, perhaps ten percent, should receive full credit in the CPIA component. In order to further encourage participation in an APM, we would suggest that both of these thresholds could be met with either Medicare or all-payer calculations. While this amount is obviously not enough to meet the prescribed threshold to be

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considered fully qualified as an APM participant and therefore, excluded from most MIPS requirements, we believe such would both encourage participation in APMs and also serve to balance the prescription that those who participate in a patient centered medical home receive full CPIA credit.

**Small Practices in Rural Areas and HPSAs: How should the clinical practice improvement activities performance category be applied to EPs practicing in these types of small practices or rural areas?**

Rather than simply lowering the threshold for small and rural practices, ACS believes it would be preferable to include a broad enough range of approved activities so as to provide ample opportunities for all providers. In order to facilitate participation at the outset of the program, we would suggest an initial focus on structural measures and that simple attestation, perhaps through the use of the EHR or other health information technology, be sufficient for credit.

**Small Practices in Rural Areas and HPSAs: Should a lower performance threshold or different measures be established that will better allow those EPs to reach the payment threshold?**

Per our response above, rather than focusing on a lower performance threshold, ACS suggests that efforts concentrate on the provision of an ample set of options to be reported such that practices of a variety of sizes, located in geographically diverse regions of the country, will have reasonable opportunity for success. At the outset, such should likely concentrate on structural measures reported through the electronic health record or a web-based portal. Keeping in mind the policy intent of the CPIA to encourage participation in an alternative payment model, we would also reference our response above to the question relative to the definition of the subcategory of participation in an APM, e.g. the provision of full CPIA credit to those who receive a modest portion of payment through an APM.

## Meaningful Use

### Key Ideas

Meaningful use and interoperability are ultimately about data liquidity leading to complete patient records, informing physician workflows, and improving quality at the point of care. The EHR Incentive Program, has done much to expand the use of EHRs but little to attain these goals. The streamlining of

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CMS quality programs, including the Medicare EHR Incentive Program, into a single MIPS program provides an opportunity to broaden our understanding of what constitutes meaningful use, looking at the concept more in terms of use of the data, rather than use of the EHR technology itself. This meaningful use may come in many forms, which may extend beyond EHRs themselves as the sole source for defining meaningful use, be it through registries, apps running on platform technology, QCDRs, pop-up alerts, etc.

ACS does not believe that such a broadening of the definition of meaningful use would require eliminating all current requirements. Certain efforts such as eRx and data exchange standards have had a beneficial impact on patient safety, quality of care, and ensuring interoperability and should therefore be maintained.

Finally, in consideration of the coming changes to the EHR Incentive Program due to passage of MACRA, we believe that the recently finalized Stage 3 rule should not be implemented until details of how meaningful use will be integrated into the MIPS program are better understood.

**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 (e.g., 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 (e.g., zero percent of the allotted 25 percentage points of the composite performance score) for this performance category).**

ACS strongly believes that the MU component of MIPS should allow providers to earn partial credit for partial attainment. The low attainment rate for MU Stage 2 has demonstrated the folly of the all-or-nothing approach. Appropriate credit should be allotted for partial success and improvement in meeting the goals of meaningful use.

The performance score for this category should be flexible, with scores based on achievement of meaningful use to different degrees and through different methods. Partial credit coupled with a broader definition of what constitutes

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meaningful use will help alleviate ongoing problems surgeons have faced under Stages 1 and 2 of the program.

Partial credit could be based on a number of criteria including reaching a lower threshold for each current individual measure or objective, achieving success on specific number of measures or objectives, use of data collected through EHRs to populate registries, or inform surgical workflows at the point of care to improve quality, increase accountability, influence payment, or some combination of these approaches.

**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 over performance 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?**

As mentioned above, ACS feels strongly that the MU category of MIPS should be flexible and allow for a range of scores and is not opposed to the concept of a tiered approach. If such an approach is adopted, the ACS would urge that tiers be defined in the context of the broader definition of meaningful use described above, and the definition of these tiers should be accomplished with additional input from the specialty societies. Given the relatively low level of attainment of MU Stage 2, we feel that it would be appropriate to provide credit based on an EP's performance relative to his or her peers, however, under no circumstances should those who have successfully achieved the current stringent required thresholds under the terms of the current EHR Incentive Program receive lower than the full score possible under the section.

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

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As mentioned above, this is an opportunity to broaden our understanding of what constitutes meaningful use, looking at the concept more in terms of how data is leveraged to improve care. The original intent of the Health Information Technology for Economic and Clinical Health Act (HITECH) was to expand the use of electronic medical records through federal investment, and ensure that these new systems were interoperable. The program has been highly successful in expanding the use of the technology, but less successful in making the data collected in these records meaningful to patients and physicians. In the years since the program began, the technology has surpassed the law, and now platform technology and cloud based applications have the potential of taking this data and using it to improve quality and efficiency at the point of care. If the concept of meaningful use were reimagined in a modern framework in line with how these data are already being used in many health systems throughout the country, and credit could be given for use of data in registries and QCDRs or through platform based applications that pull data from multiple sources to inform decision making at the point of care, then the program would be greatly improved and more providers and patients would recognize the value of the system.

One concrete example that would represent a modest, yet still meaningful step in the right direction would be to allow the use of a QCDR to report eCQMs rather than using the EHR itself. This would also reduce reporting requirements on physicians.

**How should hardship exemptions be treated?**

Hardship exemptions will remain an appropriate method of addressing unavoidable situations where technical barriers make performance in this category impracticable. There should be significant flexibility in the type of hardship exceptions that are offered for the MU category. Many physicians face unique situations that may not fall into an established hardship exception category, but cause the provider to be unable to meet MU requirements. Those who have an approved exemption due to hardship should not have any weight assigned to this category. Ideally, the provider should be able to reassign the weight of this category toward a category of their choice. For example, if a provider has an approved hardship exemption for MU, they should be able to choose to reassign the weight of this category to quality, resource use, or

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CPIA, at their discretion. Alternately, the weight of this section could be spread proportionally over the other categories.

**"Other Measures": Measures from Other Medicare Payment Systems (Quality or Resource Use)**

**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?**

Providers will need a mix of all types of measures. Even structural and process measures closely associated with outcomes can be critical to promoting quality on the local level.

ACS supports a movement toward team-based measures which allow a surgeon to be tied to the overall score of a given clinical discipline, as demonstrated in the NSQIP or as effectively implemented in various bundled payment programs (Bundled Payments for Care Improvement (BPCI), Comprehensive Care for Joint Replacement).

Registry-based measures which encompass the five phases of surgical care (preoperative, perioperative, intraoperative, postoperative, and post-discharge) coupled with care coordination will be meaningful and important to both surgeons and surgical patients. Defining process measures along this continuum is an effective way to derive a single report for a single patient which encompasses impactful measures and patient-focused care.

**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?)**

If CMS chooses to implement a policy which permits the use of facility-based measures, it is critical that EPs have the option to report these measures (or otherwise receive credit for the facility's performance), and that they are not a requirement, given the implications for payment and public reporting.

**"Other Measures": Global Population-based Measures (Quality)**

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**What types of global and population-based measures should be included under MIPS? How should CMS define these types of measures?**

If CMS chooses to implement a policy which permits the use of global and population-based measures, it is critical that EPs have the option to report these measures (or otherwise receive credit for the facility's performance), and that they are not a requirement, given the implications for payment and public reporting.

If the EP elects to have these types of measures linked across programs, team based measures for surgery should be attributed to the surgeon, the peri-operative team, and the facility.

**Non-Face to Face Practices**

**Key Ideas**

In reference to the series of questions posed on this topic, it is ACS' understanding that the target group for which this section is directed is primarily providers such as radiologists and pathologists who may have little actual personal interaction with patients. That said, we want to ensure that surgeons who may utilize telehealth as an integral part of their practice, those in rural practice or burn surgery as examples, are neither excluded nor face any additional barriers based on whatever criteria are ultimately established.

**Performance Standards : Historical Performance**

**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 CMS use a model similar to the performance standards established under the VM?**

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ACS supports movement from individual historic baselines which should be either prior year or several year average and eventually toward a blended regional or national benchmark (+/- regional cost indexing) to avoid penalizing high performers. During this transition, it is critical that CMS balance incentives so that historically high performers as well as those who have not invested as much in quality improvement (QI) have a chance to succeed and to be recognized for their commensurate investments in QI. CMS may need to account for group size by moderating risk associated with normal variability. Additionally, it is important to account for new technologies and new guidelines which could impact the future numerator.

**Performance Standards: Improvement**

**How should CMS 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.**

It is critical that CMS conduct pilot testing to define improvement for the MIPS program. CMS must account for the different types of practices and the type of improvement needed by those practices before this program becomes punitive. For example, improvement will be defined very differently for a small rural practice versus an inner city trauma center.

It is also inappropriate to apply lessons learned from ACO or hospital program scoring systems for use in the MIPS program without pilot testing.

**How should CMS incorporate improvement into the scoring system or design an improvement formula?**

Discussed in "Quality: Reporting Mechanisms & Criteria" section.

**What should be the threshold(s) for measuring improvement?**

Discussed in "Quality: Data Accuracy" section.

**How would different approaches to defining the baseline period for measuring improvement affect EPs' incentives to increase quality performance?**

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- **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?**

In order to continue to drive improvement, it is critical that benchmarks move over time with careful consideration for how rapidly benchmarks change.

ACS encourages CMS to develop the MIPS program to move toward the achievement of a certain level of outcome with the incorporation of various domains focusing on improvement and appropriateness. In this example, the score would roll up into a composite that incorporates topped out metrics so that performance is maintained while new differentiators are increasingly demonstrating greater improvement/importance. However, if an EP performs adequately or exceptionally and does not improve over time, they should not incur a penalty. To this end, it is critical to balance incentives so that historically high performers, as well as those who have not invested as much in QI, have a chance to succeed and to be recognized for their commensurate investments in QI.

**Should CMS consider improvement at the measure level, performance category level (i.e., quality, clinical practice improvement activity, resource use, and meaningful use of certified EHR technology), or at the composite performance score level?**

Improvement should be rewarded both at the individual measure level and the performance category level. The individual measure level is important because it will reward those who recognize specific areas in need of improvement and undertake efforts to increase their performance in the following reporting period. Considering improvement at the performance category level allows for rewarding improvement in instances where measure groups change from year to year.

**<u>Performance Standards: Methodology</u>**

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**In the CY 2016 PFS proposed rule, CMS proposed to publicly report on Physician Compare an item-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology. CMS seeks comment on using this methodology for determining the MIPS performance standards for one or more performance categories.**

ACS seeks clarity regarding the ABC methodology's benchmark, which is based on the mean of the best performers on a given measure representing at least 10 percent of the patient population. Specifically, how was validity and reliability determined for the best performers across all PQRS measures? Does the 10 percent cut point represent statistically significant differences in performance and account for the strength of adequate confidence intervals? We also seek further clarity on how the cut point of 10 percent was determined—does this indicate that the 10 percent includes the minimum value for inclusion as a "best performer," and all other EPs would otherwise be penalized with a poor rating?

The ACS is also unsure to what extent the ABC methodology would adequately account for patient mix and ensure apples-to-apples comparisons of physician performance. Unlike cost measures used under the VM, there are currently no adjustments applied to PQRS quality measures to account for the specialty mix of those reporting the measure. CMS simply compares performance across any and all physicians who report the same measure, regardless of their specialty, practice setting, or patient mix.

When calculating performance benchmarks, it is critical that CMS account for the varying circumstances of physicians who may choose to report the same measure, including their specialty (and sometimes even their subspecialty, such as in the case of trauma vs. non-trauma surgeons), patient mix, practice setting, and the care/procedure they are actually providing. Since these are not simple tasks, we recommend that CMS begin by testing benchmarking methodologies on measures for which there is little variability in the patient population to which the measure applies and in the physicians who report the measure. Another alternative would be for CMS to initially focus only on individual physician or group practice self-improvement over time rather than attempting to solve all of these issues associated with more complex benchmarks that attempt to compare performance across a diverse population of providers.

**<u>Weighting Performance Categories</u>**

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**Are there situations where certain EPs could not be assessed at all for purposes of a particular performance category? If so, how should CMS account for the percentage weight that is otherwise applicable for that category? Should it be evenly distributed across the remaining performance categories? Or should the weights be increased for one or more specific performance categories, such as the quality performance category?**

There is a great need for further development of meaningful and actionable measures for EPs within specialties. In the early stages of the MIPS program, EPs should not be penalized for having a lack of relevant measures. To this end, we encourage CMS to implement a phased approach to allow for specialty measure development. As the MIPS program rolls out, EPs should receive full credit even if an EP does not have measures to report due to a lack of measures for his or her specialty. As the MIPS program matures with new measures, those EPs should use the new measures and receive less credit if they have not developed measures.

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

As the MIPS program matures, measures that demonstrate greater strides in improving patient health should be given more weight. For example, outcome and appropriateness should be given more weight than structure or process; PRO measures should be given more weight than CAHPS; cost measures must be further developed before they are more heavily weighted. A public-private multi-stakeholder partnership should be established to develop measure weights.

**What case minimum threshold should CMS consider for the different performance categories?**

The case minimum threshold should be based on reliability and validity. Because there will often be low case numbers for patients encounters on the individual EP level, it will remain difficult to reliably measure EPs. ACS is

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concerned that reliability for the MIPS program seems exceedingly low—any level of discrimination commonly accepted by the medical profession, such as a 95 percent confidence interval or >0.70 (or even >0.40) reliability will result in very few discriminations for CMS's purposes. Furthermore, using a fixed standard deviation does not reflect reliability.

To increase case thresholds, we recommend two possible solutions: 1) CMS should measure EPs over a greater time period, or 2) allow for a multi-payer mix of data. Additionally, CMS should work with specialty societies to expand on measures that do not rely on intrinsically limited procedure-specific measurements. For instance, broadly applicable patient-reported outcome measures can alleviate this challenge.

**What safeguards should CMS have in place to ensure statistical significance when establishing performance thresholds? For example, under the VM one standard deviation is used. Should CMS apply a similar threshold under MIPS?**

Discussed above.

**Composite Performance Score and Performance Threshold**

**How should CMS assess performance on each of the 4 performance categories and combine the assessments to determine a composite performance score?**

The law specifies the weight of each of the four performance categories to begin the MIPS program—50 percent for quality; 10 percent for resource use; 25 percent for MU; and 15 percent for CPIA. If there is a situation where an EP cannot be assessed for performance of a particular category, EPs should not be penalized for having a lack of relevant measures, as discussed above. To this end, we encourage collaboration between CMS and professional societies to determine whether each specialty has sufficient relevant measures in each category.

**For the quality and resource use performance categories, should CMS 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?**

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ACS strongly recommends against using a methodology similar to what is currently used for the VM. As discussed in the "Resource Use" section, the ACS continues to be concerned about the relevancy of the quality and cost measures used to calculate the VM, the ongoing disconnect between what is being measured on the quality side and cost side of the equation, and the inadequacy of the program's attribution and risk adjustment methodologies.

ACS believes that more specific episode-based cost measures will help ensure more fair comparisons and alleviate the need for many of the complex adjustments to data that are required when looking at total per capita costs. Episode-based cost measures will also allow for a focus to be placed on improved patient outcomes. Additionally, it is important to encourage improvements in medicine without stifling innovation by focusing solely on cost.

**What minimum case size thresholds should be utilized? For example, should CMS leverage all data that is reported even if the denominators are small? Or should CMS employ a minimum patient threshold, such as a minimum of 20 patients, for each measure?**

Discussed in "Weighting Performance Categories" section.

**How can CMS establish a base threshold for the clinical practice improvement activities? How should this be incorporated into the overall performance threshold?**

At a minimum, for the first two years of the MIPS program, the CPIA category participation should be based on attestation.

## Public Reporting

### Key Ideas

Since MIPS is an opportunity to avoid repeating the mistakes of the past, including hurried implementation, we suggest that CMS first work on carefully designing the MIPS system; accrue a minimum foundation of data using the new system (e.g., at least 2 years of data); confidentially share those data with practicing physicians in a clear, easy to understand format while simultaneously conducting research into what information and format consumers find useful; and then consider sharing the information with the

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public via Physician Compare or a similar site. There are currently too many ongoing and largely unresolved problems related to risk adjustment, attribution, appropriate sample sizes, and the ongoing lack of relevant specialty measures which make public reporting premature.

**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? (For example, CMS is currently 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).**

Regardless of what mechanism is used, reliability of quality measures needs to be taken into account when quality information is used for public reporting and accountability. In the shorter term, it might be easier to rely on minimum patient thresholds with the understanding that meaningful and accurate representative samples will vary across measures and even specialties. If CMS considers the use of composite scores for reporting on Physician Compare, it is important to remember that composite scores can be helpful to consumer understanding as a way to summarize care, but composite measures do not always increase the reliability of a physician's performance score, and may result in less actionable data for quality improvement. Statistical "shrinkage" of evaluations is an option to address reliability and false signal generation, though it typically results in lesser discrimination.

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

While ACS shares the goal of providing high quality care to all patients and the goal of reducing socioeconomic disparities in care, the current need is to address more foundational challenges with public reporting; stratifying by these factors would only potentially complicate these challenges at present. Furthermore, targeting health disparities at the individual physician level might not be realistic due to small sample sizes and other methodological issues that might result in misleading and confusing information for the public. Targeting these potential disparities are larger system goals that might need to be

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addressed with systems-based measures, not measures that are reported at the level of the individual practitioner.

**Feedback Reports**

**Key Ideas**

The most critical change that will help engage physicians in driving improvements in care is timely feedback linking cost and quality based on highly reliable and trusted data. A two-year gap between performance and incentive payment with cost data limited to total cost of care is simply not actionable (many EPs change practices in a two-year period). Furthermore, the majority of current PQRS measures relevant to surgical care are viewed as untrusted and meaningless by the surgical community.

In order to achieve significant improvements in care, a transition toward real-time feedback is critical. Feedback in real time will allow for the prevention of negative medical events/outcomes from occurring. A current day example of this can be illustrated with GPS vehicle navigation applications: on-demand feedback is critical for preventing a wrong turn, whereas a report of the wrong turns provided to a driver two years after taking a trip is not helpful. Providers see the current lag in quality measurement in a similar way.

To resolve these issues, ACS sees the following solutions: 1) real-time quality measurement feedback through the use of clinical data registries; 2) An all-payer composite feedback report to give physicians a more comprehensive view of their performance.

While we transition to registries, the following steps could be taken to work toward a better feedback system:

- A collaboration with CMS and other payers to understand and establish the cost of care.

- ACS strongly encourages CMS to consult with providers, across specialties, on an ongoing basis to ensure feedback reports present data accurately and meaningfully.

- Reports should be proactively forwarded to providers. EPs and practices continue to face challenges when trying to access reports. While we appreciate CMS' efforts to keep these reports secure and

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confidential, this process should not result in the diversion of valuable time away from the patient.

We thank CMS for recent efforts to improve the readability of these reports, including additional drill down tables, but remind the agency that many of the PQRS measures are inherently flawed. A large part of increasing the usability these reports will be improving the underlying measures and performance calculation methodologies.

**What types of information should CMS 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?**

For purposes of confidential feedback reports, data should be as granular as possible so that EPs can fully understand exactly that on which they are being measured. At the same time, this level of detail should not compromise data interpretability and actionability. Simply sharing large amounts of data with individual EPs who do not have database personnel to parse the information into a useful format is of limited efficacy.

Lastly, it is not clear from the current Quality and Resource Use Reports (QRURs) how a given EP could intervene to decrease costs. Feedback reports need to do a better job at parsing out resource use that is in the direct control of the EP. Resource use data should also focus on more discrete clinical bundles or episodes so that all services included, whether by the EP or other providers, are related to a common goal (versus the current Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost measure, which are much too imprecise in their focus).

**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?**

Physicians would find value in reports that summarized an EP's progress toward satisfying both of these MIPS categories and clearly flagged areas where an EP might be deficient. Since the CPIA category could span a variety of activities, CMS will likely have to consult with professional societies and other entities to gather and verify this data and to ensure it is being presented accurately.

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**What other mechanisms should be leveraged to make feedback reports available?**

- **Should CMS continue to make feedback available through the web-based portal currently used for PQRS, VM, and the Physician Feedback program?**
- **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?**

ACS agrees that CMS should work toward all-payer composite feedback reports since this would give physicians a more comprehensive view of their performance. However, this should be a longer term goal. For the immediate future, CMS should focus on making the current reports more user-friendly and available on a more frequent basis such as real-time dashboards.

At the same time, we do believe that QCDRs should maintain control over providing quality data feedback to their participants. CMS should not attempt to reinterpret this data or otherwise re-purpose it to fit within its own QRUR format since this might affect the soundness of the data.

**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?**

The current requirement that only allows an "authorized group practice representative" to access these reports often restricts an individual EP's ability to directly access his/her own report. While we very much value the need to ensure secured access to these reports, the EPs who are being evaluated in the report should each have independent access to the reports.

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**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 CMS 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.)**

Reports should evolve into "dashboards" that are made available to EPs in as real-time as possible, but at the very least, on a quarterly basis. As discussed, the current annual distribution strategy and the two-year gap between performance and payment, greatly reduce the utility and value of these reports. Feedback reports should meaningfully guide improvements in practice.

**Should the reports include data that is stratified by race, ethnicity and gender to monitor trends and address gaps towards health equity?**

The task of addressing gaps in health equity might not best be solved through individual measurement. Efforts to stratify based on these factors at this early stage would only serve to further complicate an already complex endeavor.

**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?**

As discussed above, feedback reports need to do a better job at parsing out resource use that is in the direct control of the EP. Resource use data should also focus on more discrete clinical bundles or episodes so that all services included, whether by the EP or other providers, are related to a common goal

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(versus the current MSPB and Total Per Capita Cost measure, which are much too imprecise in their focus).

***B. Alternative Payment Models***

**APM Background**

***Patient care first***

The ACS appreciates this opportunity to comment on the development of APMs and physician-focused payment models (PFPMs). The ACS has long supported policy changes that increase the accuracy of physician reimbursement and improve quality, and we appreciate CMS' efforts toward that goal. The mission of the ACS is to put patient welfare first above all else. We urge CMS to do the same and to view these and other new payment policies through the lens of any potential impact on patients by focusing first on the care delivery model and then developing appropriate payment models within those care delivery models. In addition to providing new payment models, it is crucial that APMs should first and foremost lead to better patient care. As CMS, along with providers and other stakeholders, develop criteria, quality metrics, payment methodologies, and the model design for APMs, CMS should put patient interests first. In addition, given that there is potential for beneficiaries to be faced with increasingly complicated choices and value judgements about where to seek care as these new models develop, it is important that patients are educated and informed about their options.

***PFPMs should qualify as APMs***

Ambiguity exists in CMS' interpretation of MACRA as to whether PFPMs approved by the Physician-Focused Payment Model Technical Advisory Committee (TAC) also qualify as eligible APMs under MACRA. Congressional intent in including the PFPM section was to create a clear pathway for the development of eligible APMs for specialties that lacked applicable models sufficient to meet the thresholds to become qualifying APM participants under MACRA. Therefore, we urge CMS to streamline this process and ensure that the criteria developed for assessing PFPMs be in line with the requirements for eligible APMs. Payment models approved as PFPMs should also be eligible for approval as an APM on an expedited basis without the need to meet additional criteria or requirements. If a model meets the

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PFPM requirements, then the Centers for Medicare and Medicaid Innovation (CMMI) should make it a demo without additional requirements.

***Kinds of APMs***

Creating enough APMs so that all physicians have the option to participate is complicated because there are so many physician subspecialties. In general surgery, for example, there are surgeons who do predominantly, trauma, transplant, bariatric, endocrine, breast, pediatric, oncologic, colorectal, and true general surgery. APMs will eventually require a threshold of at least 75 percent of all Medicare payments or patients attributable to services furnished under an APM entity in 2023 and later years. In addition, the models that CMS currently recognizes as eligible APMs, such as ACOs and medical homes, have so far found it very difficult to incorporate specialists, particularly surgeons, into these models. This presents a significant challenge to create sufficient applicable APMs for each physician subspecialty. One way to address this hurdle is for CMS to approve APMs in which a broad group of specialists could participate. As such, we suggest that CMS create criteria for a continuum of APMs, which span the range from bundled payments around a specific condition to capitated payments for care of a population related to a specific condition, patient population, or desired health outcome, and which should all be structured around variation in quality or cost. For example:

- ***Procedure-specific APMs*** that address a procedural episode triggered by the need for the procedure. For example, a procedure-specific APM could be developed around mastectomy. The time window could be three days prior to the mastectomy and 60 days after the procedure. The services could be all the Part B services provided in that time window related to the mastectomy.
- ***Condition-specific APMs*** that address a specific condition. For example, a condition-specific APM could be developed around breast cancer. The time window could be one year from the breast cancer diagnosis and could include all the Part B services provided to a patient in that time window related to the diagnosis.
- ***Population-based APMs*** that include all the patients in a given population for a specified type of care. The physicians participating in this type of APM would be responsible for the care of an entire population of patients with respect to a health care service line and

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would be paid a "per member per month" payment for any care that is needed (or not needed) related to that service line covered by the APM. This would be similar to a managed care model but is limited to a specific type of care. For example, a population-based APM could be developed around total breast care. There would not be a specified time window, rather the APM would include an ongoing "per member per month" payment for each of the lives included in the model, regardless of whether they require care or not. The payments are the same whether the patients receive no care, preventative care only, or treatment for breast cancer or other diseases of the breast. Such a model would include quality metrics to ensure patients were not being under treated, and payments would be set at a risk-adjusted level designed to incentivize the physician to ensure patients were provided recommended screenings and kept healthy.

Although procedure-specific APMs, or bundled payments for hospital-based episodes, have been the focus of current model development, population-based APMs will eventually be able to provide a pathway for a larger percentage of physicians within a subspecialty to participate in an APM. As such, we urge CMS to consider population-based APMs that can include specialty care as well as primary care when developing APM and PFPM criteria.

**APM RFI Questions**

1. **How should CMS define "services furnished under this part through an [eligible alternative payment] EAPM entity"?**

The definition of services furnished under an APM would vary based on the type of APM that is developed. We describe three types of APMs: procedural, condition, and population-based. The services furnished through an APM entity should include the clinical service lines associated with each type of APM.

2. **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 qualified professional (QP) (For example, if payments were made to a physician group practice or an ACO?)**

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**a. What are the advantages and disadvantages of those policies?**
**b. What are the effects of those policies on different types of EPs (that is, those in physician-focused APMs versus hospital-focused APMs, etc.)?**
**c. How should CMS consider payments made to EPs who participate in more than one APM?**

Claims for Medicare physician services are generally submitted by an organization with a taxpayer identification number (TIN) comprising one or more physicians that are separately identified through their National Provider Identifier (NPI). If Medicare provides payment amounts to the TIN for an APM involving multiple physicians, then the APM should be required to provide information to CMS, either by revenues or patient counts, regarding the shares attributable to each eligible physician participating in the APM as identified by the NPI.

Given that different APMs will have different methodologies for attribution and paying participants, we suggest that CMS require, at least in the first few years, that APMs report to CMS the equivalent fee-for-service (FFS) amounts associated with the services that the physicians provided through the APM as the aggregate payment amounts paid under the APM. This is important because we believe that it will be much more straightforward if the APM incentive is based on the value of services that the physician actually provided, rather than the value-based payments, or amounts that take bonuses or penalties into consideration.

With respect to payments made to QPs who participate in more than one APM, we believe CMS should consider the combined payments for purposes of calculating the incentive. Because a large percentage of physicians are highly specialized, they might have to participate in more than one APM to be considered qualifying APM participants. Any payments made to QPs under an APM model should be included in the incentive calculation.

3. **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)?**

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a. **What are the advantages and disadvantages of those policies?**
b. **What are their effects on different types of EPs (that is, those in physician-focused APMs versus hospital-focused APMs, etc.)?**

Please see # 2, above.

4. **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?**

Given that the combination all payer and Medicare payment threshold option does not begin until 2021, we urge CMS not to rush the process of developing this policy. Instead of requiring specific non-Medicare APM payment data in the early years of this program we recommend instead that CMS require physicians to provide attestations regarding this information. CMS has a history of allowing attestations or other methods not requiring data validation in the early stages of program implementation (e.g. the EHR Incentive Payment Program), and we believe this would be another area where starting with attestations would be appropriate in the beginning years.

5. **Should the option of attributing and counting patients in lieu of using payments to determine whether an EP is a QP be used in all or only some circumstances? If only in some circumstances, which ones and why?**

We urge CMS to provide as much flexibility as possible for physicians to qualify as QPs or partial QPs. As such, we recommend that eligible physicians always have the option of using either the patient approach or the revenue approach to determine whether they qualify as an APM participant. We do not believe that using the patient approach should be limited to any particular circumstances. Most physicians manage certain proportions of patients with several different conditions. If a range of APMs such as procedure, condition, and population-based APMs are approved, certain models will be applicable to some proportion of the population that each physician manages. Reporting the proportion of patients who are being managed within an APM could be a more patient-centric approach compared to summing up the revenues from each

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service that physicians provide as they relate to an APM. In some cases, it could be simpler to determine what proportion of a physician's patient population has the procedures or conditions covered by the APM. In addition, APMs based on populations would require the patient counting approach to be successfully implemented.

6. **What is the appropriate type or types of "financial risk" to be considered an EAPM entity?**

Financial risk should be limited to the types of risk that the delivery system can affect or that physicians and providers can exercise control over. Specifically, the risk should be limited to the clinical risk associated with the type of procedure, condition, or population addressed by the APM. Insurance risk or risk for anything unrelated to the APM would not be appropriate for the APM entity.

Financial risk associated with a procedural APM, for example, can include costs for an episode defined by a specified trigger to start (most likely the procedure) and a timeframe in which it would end. Investments in the APM, including the initial investment and start-up costs, should also go toward the definition of "financial risk." These could include data analyses and establishing procedures for coordinating care and sharing information and ongoing costs for new employees such as care managers. If the administrative costs are not considered, many potential participants will not choose to be a part of an APM. For instance, for many EPs, costs of compliance with the EHR Incentive Program and PQRS were greater than the bonus payments associated with these programs.

7. **What is the appropriate level of financial risk "in excess of a nominal amount" to be considered an EAPM entity?**

We urge CMS not to require downside risk in defining "nominal amount" for purposes of determining an eligible APM entity. CMS has taken the approach of not initially requiring downside risk with APMs such as the Medicare Shared Savings Program, the Comprehensive Care for Joint Replacement Model, and the first phase of the Bundled Payment for Care Improvement Initiative. All participants in these models should be considered to meet the financial risk criterion.

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We urge CMS to proceed with caution when determining nominal financial risk and to start with a very low percentage of 1-2 percent in the early years and adjust the risk over time. If the risk is too high, providers will either not participate in APMs or might refuse high-risk patients. We cannot stress enough the need for CMS to make the financial risk and performance goals reasonable, especially in the early stages of the APM option. For example, Dartmouth-Hitchcock, the entity at the forefront of developing and implementing Accountable Care Organizations (ACOs), and other entities recently dropped out of the Pioneer ACO program because it was unable to meet the specified savings and performance goals.[1]

Again, CMS should also consider the fact that in order to participate in APMs, providers will need to make substantial investments resulting in additional administrative burden, additional personnel, provider and staff training, and other necessary infrastructure, thereby already taking on considerable downslide risk. Requiring providers to take on sizable additional risk, especially in the early stages, may not be reasonable.

8. **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?**

We urge CMS to require that the level of "more than nominal financial risk" for the combination all-payer and Medicare payment threshold be the same as the level of "more than nominal financial risk" for Medicare-only APMs. This same level of risk is necessary to ensure that these new payment structures do not influence access to care based on payer.

9. **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?**

When determining comparability of state Medicaid medical home models to medical home models expanded under MACRA, two areas of importance are comparability of quality measures and risk adjustment.

[1] Evans, Melanie. "Two More Pioneer ACOs Exit as new CMS Model Emerges." November 4, 2015. http://www.modernhealthcare.com/article/20151104/NEWS/151109941.

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10. **What entities should be considered EAPM entities?**

CMS should place as few restrictions as possible on the types of entities that can be considered APMs. APM entities could include physician practices, independent practice associations, physician-hospital organizations, and other organizations. At the very least, CMS should not require that an APM entity include a hospital because it is important that physician-led groups would have the opportunity to participate as well. In short, we recommend that any type of entity should be eligible for qualifying as an APM as long as it meets the basic criteria that CMS sets forth for APMs. Such criteria could include assuming the care of the patients covered by the APM, meeting certain agreed upon quality measures, and providing care for the determined services based on agreed upon payment arrangements. APM entities should not be limited by facility type, group type, or how the entity is organized legally.

If an APM entity is a hospital or other entity that is not physician-owned, then it should be required to provide a means for physicians to influence the governing policies of the organization, such as through meaningful practicing physician representation on the governing board.

11. **What criteria could be considered when determining "comparability" to MIPS of quality measures used to identify an EAPM entity?**

We recommend that CMS consider measures that are used in all CMS programs, not just PQRS, as available measures for APMs. CMS' efforts to align PQRS with other Medicare quality reporting programs makes all CMS program measures eligible for being considered "comparable." We believe that the pool of available measures should be as broad as possible and should also include those measures used in QCDRs.

Given the diversity of APM models that could be developed, we urge CMS to define "comparable" measures to include measures that are tied to the APM's procedure, condition, or population and address quality and resource use, even if these measures are not specifically available under MIPS. One major benefit of APM participation is that providers will no longer need to comply with MIPS. Requiring APMs to include only MIPS performance measures would counteract this benefit.

For consideration in specific APMs, the agreed upon measures should be meaningful and lead to better patient care and be specific to the services

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provided. Providers should understand the process for satisfying the measure for purposes of improvement. The reporting process should be as streamlined as possible and should not require multiple reporting requirements.

The ACS also continues to urge CMS to consider including S-CAHPS as an individual, voluntary PQRS measure and as a measure for APMs. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which are important from the patient's perspective and for which the patient is the best source of information. We remind CMS that the NQF MAP recommended the inclusion of S-CAHPS in PQRS for two consecutive years, starting in 2013, yet CMS still continues to claim that it is not technically feasible to include the S-CAHPS measure in PQRS. We strongly encourage CMS to prioritize the time and resources needed to include the S-CAHPS as a PQRS measure and also as a measure available for APMs.

12. **What criteria could be considered when determining "comparability" to MIPS of quality measures required by a non-Medicare payer to qualify for the Combination All-Payer and Medicare Payment Threshold. (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.)**

With respect to the combination all-payer and Medicare payment threshold, we stress the importance of consistency and harmonization in quality across payers to be inclusive of all the reporting options available in MIPS. We urge CMS to harmonize the use of measures and APMs across payers.

13. **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 consider other requirements around certified health IT capabilities?**

The goal of including the use of CEHRT in an APM should be to improve care of the patient. This can be accomplished in many ways, such as by providing better information to the physician at the point of care, or providing tools to the

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patient to allow them to make more informed decisions about their health. There should therefore be great flexibility in the adoption of HIT to allow for innovation in improving quality and efficiency and APM participants should not be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs.

14. **What are the core HIT 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 HIT products (e.g. referral management or population health management functions) help providers succeed within APMs?**

For APMs to be successful, the APM participants need access to real-time clinical data to inform clinical decisions and improve the efficiency of care and patient outcomes. Performance feedback is also necessary for participants to understand how their actual expenditures compare to expected expenditures. Feedback should be provided at a minimum on a quarterly basis, but preferably monthly and, ideally, on demand. Other core HIT functions include the ability to easily link to each beneficiary all services, drugs, devices, DME and sites of care used for the reporting time period.

Patient engagement will require tools that are usable and easy to understand by beneficiaries across the spectrum of healthcare literacy and across language barriers. Providers should also be able to use HIT to generate automatic reminders and recalls based on well-established criteria (for example, surveillance colonoscopy). Another core function is automatic scheduling of referrals and follow up visits. Such services could be provided through the EHR or through applications running on other platform technology.

15. **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?)**

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The goal of the EHR Incentive Program was to expand the use of CEHRT and ensure that such technology was being used in a meaningful manner. The true goals of meaningful use and interoperability, however, should ultimately be about data liquidity leading to complete patient records, informing physician workflows, and improving quality at the point of care. The streamlining of CMS quality programs, including the EHR Incentive Program, into a single MIPS program provides an opportunity to broaden our understanding of what constitutes meaningful use of CEHRT. CMS should look at the concept of meaningful use more in terms of use of the data, rather than use of the EHR technology itself. For purposes of becoming a qualified APM participant, use of CEHRT may come in many forms, provided that it meets the goals above and is flexible enough to allow for innovation. CMS should develop a flexible continuum of acceptable manners through which use of CEHRT may be demonstrated, provided these methods have demonstrated reliability, validity, and an audit trail and be used for accountability and payment.

16. **How should physician-focused payment models be defined?**

PFPMs should be defined as broadly as possible so as to encourage innovative ideas and to encompass a broad enough range of models to cognitively engage a wide range of specialties. As long as a model uses a payment method other than traditional FFS (or a payment model other than FFS in combination with traditional FFS) and achieves certain agreed-upon quality metrics, it should be considered a candidate for approval. A narrow definition, or one with too many restrictive criteria, will inhibit innovation and development of such models.

In addition, if a model meets the PFPM requirements, then CMMI should make it a demonstration without additional requirements. Recognizing the reality of limited resources, the ACS strongly urges that at the very least, models favorably reported by the TAC should receive expedited consideration by CMMI. We understand that CMS believes there is ambiguity in the interpretation of the statute as to whether a payment model that is approved by the TAC as a PFPM would also qualify as an eligible APM under MACRA. We urge CMS to streamline this process and allow payment models approved as PFPMs to be also eligible for approval as an APM without the need to meet additional criteria or requirements. We believe that creating a pathway for development of such models by specialty societies and others so that all

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physicians have options to participate in eligible APMs was the intent of Congress when drafting this legislation.

17. **What criteria should be used by the TAC for assessing PFPM proposals submitted by stakeholders? (CMS is interested in hearing suggestions related to the criteria discussed in this RFI as well as other criteria.)**

MACRA contains a number of incentives for APM participation ranging from CPIA credit, to the 5 percent incentive and exemption from MIPS requirements, and ultimately separate conversion factor base payment updates for MIPS participants and qualified APM participants beginning in 2026. Therefore, the ACS believes it is important for all physicians to have the opportunity to be able to participate in an eligible APM. Creating APMs for all physicians is complicated because there are so many physician subspecialties. In general surgery, for example, there are surgeons who do predominantly, trauma, transplant, bariatric, endocrine, breast, colorectal, oncologic, and true general surgery, yet they are all considered "general surgeons" by Medicare. APMs will eventually require a threshold of at least 75 percent of all Medicare payments attributable to services furnished under an APM entity in 2023 and later years. This presents a significant challenge to create APMs for each physician subspecialty. The criteria used by the TAC for assessing PFPMs should therefore be harmonized with the requirements for eligible APMs under MACRA, while leaving the greatest level of flexibility practical to allow for innovation.

One way to address this hurdle is to develop criteria that would allow for APMs in which a broad group of specialists could participate. As such, we suggest that CMS create criteria for a continuum of APMs, which span the range from bundled payments around a specific condition to capitated payments for care of a population related to a specific condition or desired health outcome, and which should all be structured around variation in quality or cost. For example:

- ***Procedure-specific APMs*** that address a procedural episode triggered by the need for the procedure. For example, a procedure-specific APM could be developed around mastectomy. The time window could be three days prior to the mastectomy and 60 days after the

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procedure. The services could be all the Part B services provided in that time window related to the mastectomy.

- ***Condition-specific APMs*** that address a specific condition. For example, a condition-specific APM could be developed around breast cancer. The time window could be one year from the breast cancer diagnosis and could include all the Part B services provided to a patient in that time window related to the diagnosis.
- ***Population-based APMs*** that include all the patients in a given population for a specified type of care. The physicians participating in this type of APM would be responsible for the care of an entire population of patients with respect to a health care service line and would be paid a "per member per month" payment for any care that is needed (or not needed) related to that service line covered by the APM. This would be similar to a managed care model but is limited to a specific type of care. For example, a population-based APM could be developed around total breast care. There would not be a specified time window, rather the APM would include an ongoing "per member per month" payment for each of the lives included in the model, regardless of whether they require care or not. The payments are the same whether the patients receive no care, preventative care only, or treatment for breast cancer or other diseases of the breast. Such a model would include quality metrics to ensure patients were not being under treated, and payments would be set at a risk-adjusted level designed to incentivize the physician to ensure patients were provided recommended screenings and kept healthy. As we noted above in question #5, counting patients instead of payments would be required for this type of APM.

We strongly believe that physicians of every specialty should have at least one type of APMs available for calculating their payment. The population-based APMs are the most difficult to develop but will be crucial given the narrow focus of many practices since they can encompass many different physician specialties all focused on improving care to a specific population.

In addition, as the TAC assesses PFPM proposals submitted by stakeholders, CMS should develop a process whereby PFPM applicants can receive feedback at certain points during the review and development process of their model as to whether they are on the right track or if they need to make changes in order

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to qualify as an eligible APM. One approach CMS could take would be to allow a pre-application information review process. This is important given that model development is likely to require a substantial investment in time and resources. At the very least, if a model is not accepted, the TAC/CMS should be required to give the rationale for rejecting the model and suggestions for improving the model. This would help avoid the problems that have occurred with measure development and the NQF process. Without appropriate feedback, PFPM applicants stand to lose their entire investment.

18. **Are there additional or different criteria that the TAC should use for assessing PFPMs that are specialist models? What criteria would promote development of new specialist models?**

Please see #17, above.

19. **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?**

The lack of transparency of private payer plan information makes informed commentary difficult or impossible for this and similar issues. Aligning public and private payers could have great value but the opacity of private payer processes is a major impediment to such alignment.

20. **Should CMS propose that 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?**

While we agree that CMS should consider whether the decision-making capacity of a particular specialty is fully recognized/utilized in an already existing model, we do not believe that PFPMs should be primarily focused on the inclusion of participants in their design who do not have the opportunity to participate in another model. We understand that APMs are meant to facilitate a new physician payment update to replace the SGR, not primarily to fill a gap in alternative payment methodologies. We strongly urge CMS not to reject a potential PFPM due to the fact that the physicians who are able to participate have another PFPM in which they could participate as well.

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21. **Should proposals be required to state why the proposed model should be given priority, and why a model is needed to test the approach?**

From a transparency perspective, it seems reasonable that proposals should state why the proposed model should be given priority and why a model is needed to test a particular approach. But as we stated above, we do not believe that PFPM models should primarily be focused on the inclusion of participants who have not had the opportunity to participate in another PFPM.

22. **Should proposals be required to include a framework for the proposed payment methodology, how it differs from the current Medicare payment methodology, and how it promotes delivery system reforms?**

It is reasonable that proposals should include at least a basic framework for the proposed payment methodology and how it differs from the current Medicare payment methodology. It should not necessarily be required that all the details are completely worked out and specified because some details will require refinement as the model is developed.

23. **If a similar model has been tested or researched previously, either by CMS or in the private sector, should the stakeholder be required to include background information and assessments on the performance of the similar model?**

This is reasonable to a certain extent. It should be possible for entities to develop PFPM proposals without posing an undue burden on the applicants. The application should not be so restrictive due to the resource requirements (cost, time, availability of data and background information) that potential PFPM entities are not able to complete the application in a reasonable timeframe.

24. **Should proposed models be required to aim to directly solve a current issue in payment policy that CMS is not already addressing in another model or program?**

No. Please see #20, above.

25. **Should CMS require that proposals include the same information that would be required for any model tested through CMMI?**

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**(http://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf). CMS seeks input 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).**

Overall, we consider the CMMI model design factors as a helpful guide for information that CMS could suggest for inclusion in APM model proposals. Although we believe these are important, many seem outside the capacity of most physician specialty societies. As such, we do not believe that CMS should require that the proposal applications address all 19 of these design factors. Instead, we urge CMS to provide resources for applicants to provide some relevant information related to these design factors. We respond to some of the comments below.

CMMI Model Design Factors

**(1) Extent of clinical transformation in model design – Do we expect the magnitude and types of changes in care delivery in the model to be significant improvements over current practice?**

Judging whether there are significant improvements over current practice will also need to include an assessment from the beneficiary standpoint. A model could appear to be neutral on quality or cost but could lead to increased patient engagement or satisfaction and this could be very significant and worthwhile as judged by beneficiaries. As such, the impact on beneficiaries should also be considered when evaluating the extent of clinical transformation in model design.

**(2) Strength of evidence base – What data or prior experience (of CMS or other payers) supports the intervention proposed in the model?**

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If data or prior experience regarding a model are available, they should be included; however, this information should not be a required component of the application. The requirement of this information could inhibit innovative ideas which, almost by definition, may not have readily available data or prior experience.

**(3) Number and/or percentage of beneficiaries and practitioners included in the model – what is the scale of the model?**

The number and/or percentage of beneficiaries and practitioners included in the model could be helpful information, but we do not believe CMS should necessarily give models impacting a greater number/percentage of beneficiaries greater importance.

**(4) Demographic, clinical and geographic diversity – Does the model target key diverse patient and practitioner populations that CMS has yet to engage in other models, or geographic regions with previously low participation in CMS models?**

Although Medicare patients are demographically, clinically, and geographically diverse, it should not be a requirement that PFPMs target key diverse patient and practitioner populations that CMS has yet to engage in other models.

**(5) Alignment with other payers and CMS programs – To what extent can the model leverage investments that:**
- ➔ **other health care payers are making in payment and delivery system reform**
- ➔ **CMS has made in its other programs?**

Providing information on alignment with other payers and CMS programs can help strengthen an application, but should not be required.

**(6) Evaluative feasibility– Will CMS be able to design an appropriate study, collect data, and analyze results to make reasonable conclusions about the model's performance?**

An evaluation of whether CMS will be able to design an appropriate study, collect data, and analyze results to make reasonable conclusions about the

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model's performance is something that will be very difficult, if not impossible, for PFPM applicants to determine.

**(7) Operational feasibility – How feasible will it be for model participants to prepare and build the infrastructure they need to do what is expected? How feasible will it be for CMS to prepare and build the systems, processes, and other infrastructure necessary to test the model within existing time and resource constraints? Will CMS be able to appropriately monitor the model and the activities of its participants to ensure program integrity?**

With respect to operational feasibility, information on how feasible it will be for model participants to prepare and build the infrastructure they need to do what is expected is information that would help strengthen an application, but should not be required. On the other hand, similar to question 6, it will be very difficult for PFPM applicants to thoughtfully comment on how feasible it will be for CMS to prepare and build the systems, processes, and other infrastructure necessary to test the model within existing time and resource constraints and whether CMS will be able to appropriately monitor the model and the activities of its participants to ensure program integrity.

**(8) Waiver authority–Could the model be implemented under existing law, and if not, is CMS authorized to waive any laws or regulations for purposes of testing the model?**

With respect to CMS' waiver authority, it could be difficult for most PFPM applicants to do a comprehensive analysis of CMS' existing law and whether CMS is authorized to waive any laws or regulations in order to test the model. If applicants are able to comment on how the proposed model fits into CMS waiver authority that would be helpful, but this information should not be required.

**(9) Ability of other payers to test the model – Are there other government or private entities that could test the model as effectively as CMS?**

For most groups proposing PFPM models, it will be too speculative for them to comment on the ability of other payers to test the model and whether there are other government or private entities that could test the model as effectively as

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CMS. We do not believe this should be a required component of the application for a PFPM.

**(10) Scalability – Will CMS have appropriate legal authority to scale the model if it proves successful? Are there concrete policies and/or processes that CMS could change or create to scale the model if successful?**

Similar to questions 6, 7, and 9, it will prove very challenging for most PFPM applicants to comment knowledgeably on whether CMS will have appropriate legal authority to scale the model if it proves successful and what concrete policies and/or processes that CMS could change or create to scale the model if successful. It might be more effective to pose this question after a model is shown to be successful.

26. **Should CMS require submission of information in the following areas:**

Similar to question 25, above, we consider much of the information described in this question to be important information for an application; however, also considered some information to be useful, if available, but not necessarily required for a PFPM application. We urge CMS to consider the resources available to potential PFPM applicants when setting forth application criteria. For example, we do not believe that the information required should be so detailed that an extensive literature search or the hiring of a healthcare consulting firm should be required for the development and submission of PFPM applications. We offer more detailed comments below:

**(1) Definition of a 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.**

This is important information for a PFPM application. An application should be able to clearly define a target population and describe how that population differs from the non-target population.

**(2) Ways in which the model would impact the quality and efficiency of care for Medicare beneficiaries.**

The ways in which a model would impact the quality and efficiency of care for Medicare beneficiaries might not be fully known at the time of submission of a

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PFPM proposal, but an application should include an estimate of the impacts. The application should at least address the impacts at a high level.

**(3) 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.**

PFPMs must include some aspect of payment that is linked to quality, so this is information that the PFPM applications should address.

**(4) 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.**

PFPM applications should address what quality measures will be included in the model and how they would further the model's goals.

**(5) How the model would affect access to care for Medicare and Medicaid beneficiaries.**

It is critical that new PFPMs models do not negatively impact access to care. It is important that PFPMs address how the new model will preserve access to care.

**(6) How the model would 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.**

PFPM applications can include this information if known, but it will likely not be known at the time of submission, so should not be required. It is most likely too difficult for the typical PFPM applicant to know a potential model will affect these factors.

**(7) Proposed geographic locations of the model**

The proposed geographic locations should be included in the model application.

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**(8) Scope of EP participants for the model, including information about what specialty or specialties EP participants would fall under the model.**

The scope of EP participants and information about what specialty or specialty EP participants would fall under the model should be included in the model application.

**(9) 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.**

A precise number of EPs expected to participate in the model will likely not be known, but an estimate is important for the model application to show that there will be participation in the model.

**(10) To what extent participants in the model would be required to use certified EHR technology.**

To what extent participants will be required to use certified EHR technology should be included in the model application.

**(11) An assessment of financial opportunities for model participants including a business case for their participation.**

A high level description of financial opportunities for model participants is helpful information, but should not be required. Detailed information or an in-depth assessment should not be required.

**(12) Mechanism for how the model fits into current Medicare payment systems, or replaces them in part or in whole and would interact with or complement existing alternative payment models.**

Describing how the proposed model fits into the current Medicare payment system and how it interacts with existing APMs is a complicated question to answer because it requires a working knowledge of APMs, and there are currently so many models. Perhaps a better response would include how the proposed model links to the strategic plan to have more APMs.

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**(13) What payment mechanisms would be used in the model, such as incentive payments, performance-based payments, shared savings, or other forms of payment.**

It is important that an application describe what payment mechanisms would be used in the model.

**(14) 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.**

Model applications should describe whether the model would include financial risk and how the risk changes over time.

**(15) Method for attributing beneficiaries to participants.**

The application should describe patient attribution. It is important to provide predictability for APM participants with respect to patient attribution.

**(16) Estimated percentage of Medicare spending impacted by the model and expected amount of any new Medicare/Medicaid payments to model participants.**

The estimated percentage of Medicare spending impacted by the model can be included in the application, if known, but does not need to be a point of emphasis. It will not be possible for applicants to provide this information, however, unless CMS provides access to the data needed to calculate these amounts.

**(17) 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.**

The estimated amount of anticipated savings to Medicare can be included, if known, but should not be required.

**(18) 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**

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**include additional payers other than Medicare, including Medicaid.**

Information about any similar models used by private payers can be included, if known, but should not be a requirement.

**(19) 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?**

Whether the model engages payers other than Medicare should be included in the model application.

**(20) Potential approaches for CMS to evaluate the proposed model (study design, comparison groups, and key outcome measures).**

Potential approaches for CMS to evaluate the proposed model should be included in the model application.

**(21) Opportunities for potential model expansion, if successful.**

Opportunities for potential model expansion should be included in the model application.

***C. Technical Assistance to Small Practices and Practices in Health Professional Shortage Areas***

The inclusion of technical assistance funding for small and rural practices was an important safeguard designed to help physicians in these practices thrive under the new payment system. When the MIPS criteria are first established, there needs to be a level playing field for solo practitioners and the smallest practices. These physicians already face additional challenges and often lack the resources present in larger practices particularly in staffing and the area of HIT.

The new payment system, which streamlines and combines the PQRS, EHR-MU and the VBM into a single MIPS program, while intended to reduce duplicative reporting requirements and administrative burden, will also put these practices in direct competition with all other physicians throughout the

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Medicare program for annual updates. For this reason it is vital not only to ensure that there are applicable and minimally burdensome measures and CPIAs for small practices, but also that resources are available to help them compete with larger systems.

Additional financial disincentives experienced by rural practitioners in Medicare could have the unintended consequence of driving more doctors from rural areas, increasing shortages, and failing to meet the goal of improving quality.

**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?**

Given that measures and activities in several MIPS categories, (particularly quality measures and CPIAs) will vary greatly by specialty, we feel that in addition to quality improvement organizations, regional extension centers, or regional health collaboratives, CMS should offer to partner with specialty societies and state medical societies in providing technical assistance. Such a partnership between specialty societies and CMS (potentially with CMS participating through the Medicare Administrative Contractors), would allow for combined ongoing assistance to small practices developed with both administrative and clinical expertise and tailored to the needs of those being assisted.

Specialty societies will in many cases be working to develop the quality measures and CPIAs upon which their composite scores will be based. Specialty societies have also in many cases developed and maintain QCDRs which are a reporting method of growing importance in the new law. Automatic data extraction and the repurposing of data so that it can be used for multiple reporting and quality improvement purposes will be a key tool in reducing the administrative burden on small practices, helping them to succeed.

CMS will be responsible for developing and administering the details of the new payment system and should from the outset recognize the great heterogeneity in American medicine and ensure that measures and requirements are scalable down to the smallest rural practices. If this is done correctly and these practices have applicable measures and clinical practice

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improvement activities available, technical assistance will be that much simpler.

**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?**

Feedback from surgeons indicates that small and rural practices would welcome additional help in complying with CMS requirements but feel that support from the federal government has been lacking. Those who have sought help from the Regional Extension Centers often report that the assistance has been of limited value in achieving MU, with some noting that the program is not tailored to the unique needs of different specialties. As mentioned above, a combination of a hotline and web portal along with direct on-site assistance will be needed to ensure these practices have all the tools necessary to succeed.

**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?**

One of the major challenges faced by physicians, particularly those in small practices and rural areas, is the growing administrative burden associated with participation in Medicare. Rural practices frequently have smaller staffs and therefore face higher data entry and other burdens. As requirements have increased from year to year and physicians must do more and more to avoid penalties, many small offices simply have been unable to keep up without the tools available to larger, highly sophisticated urban and academic systems.

One potential method of alleviating some of this burden is the new virtual group reporting method. Funds should be available for facilitating creation of virtual groups in rural areas, including resources for obtaining the necessary infrastructure and training. If the virtual group option is well implemented and rural practices supported, it could be a powerful tool to reduce such burdens.

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Implementation of EHRs also poses a major financial burden on smaller practices, as do the lack of interoperability and continuously changing technology standards and MU requirements. More substantive support in this area could go a long way to helping these practices.

**What kind of support should CMS offer in helping providers understand the requirements of MIPS?**

It is difficult to know how best to advise and support small practices until we have a better understanding of how the existing programs will change, what new measures will be developed, what clinical practice improvement activities will be included, and many other factors.

Many of the targeted practices may not be successfully participating in PQRS or the VM, and small practices are least likely to successfully achieve meaningful use requirements. CMS should consider providing direct technical assistance by partnering with specialty societies and others to organize site visits in some of these small rural towns. In addition to improving performance and helping physicians and administrators to use their existing resources to develop the desired practice models, this could provide CMS employees with valuable firsthand experience of the unique challenges faced by rural practices. Such visits might be most valuable in 2016, the first year of technical assistance funding, and could help to identify barriers to success in the current PQRS, EHR Incentive Program and VM and shape future assistance efforts to increase small and rural practices ability to succeed in MIPS.

Beyond initial site visits, we would also suggest that future technical assistance come directly from CMS through the MACs who currently have the responsibility to enroll health care providers in the Medicare program and educate providers on Medicare billing requirements, in addition to answering provider and beneficiary inquiries. Since MIPS is a new payment system this may already be partially under their responsibilities. Allowing partnerships between MACs and state medical societies, specialty societies and others to provide assistance more specific to various types of physicians and targeted toward overcoming regional barriers could help put practices on a pathway to successful participation.

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More traditional technical assistance tools should also be made available, such as a hotline with extended hours and a web portal with tools to help these practices understand the various reporting methods and requirements of the program as well as the various approved alternative payment models and the risks and potential rewards of participation in these models.

**Should such assistance require multi---year provider technical assistance commitment, or should it be provided on a one---time basis?**

Technical assistance will need to be a multi-year ongoing effort if rural practices are to succeed in MIPS. Ideally certain resources should be made available to providers at any time, including evenings and weekends which may be the only times available for some.

MIPS is a new program and will evolve over time as new measures, risk adjustment techniques and other requirements are developed. Technology also evolves rapidly and rural areas may not have as large of a pool of IT talent available, meaning that compliance and success in MIPS will be a continuous effort on the part of busy providers themselves.

Not only will each practice progress at a different pace in MIPS, the transition to APMs will also be a decision undertaken at different times by different physicians and practices.

**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?**

For physicians who meet the requirements of MACRA (i.e. MIPS eligible professionals in practices of 15 or fewer with priority given to rural areas, HPSAs and shortages areas, or those with low composite scores) there should be no additional conditions of participation other than those in the law. There should also be no exclusions. This assistance should be easily available to these providers without having any additional requirements.

Participation in reform initiatives such as the Transforming Clinical Practice Initiative do not guarantee success in MIPS nor would it provide the

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knowledge needed for successful transition to APMs, especially those that develop as a result of the new law. The very practices most in need of assistance to succeed under the new law may be some of those least likely to have participated in TCPI or other initiatives due to lack of resources or access. Participation in the TCPI might better serve as a means of earning credit in the CPIA category of MIPS.

Uniformity of design is crucial and the conditions should be transparent and fair across all practices and venues. The intent of a technical assistance program is to level the playing field, not to increase confusion through additional requirements.

We appreciate the opportunity to comment on this RFI. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager in the ACS Division of Advocacy and Health Policy at vollapally@facs.org or Jill Sage, Quality Affairs Manager in the ACS Division of Advocacy and Health Policy at jsage@facs.org.

Sincerely,

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