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Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1631-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

***Re: File Code CMS- 3321-NC***

Dear Mr. Slavitt:

We appreciate the opportunity to provide comments to the Request for Information (RFI) regarding implementation of a new Merit Based Incentive Payment System (MIPS), Promotion of Alternative Models, and Incentive Payments for Participation in Eligible Alternative Payment Models. As CMS begins an historic shift from a volume-driven reimbursement system to one based on the value of care provided, bold creative thinking is required to ensure that patients have access to the full spectrum of healthcare from primary care to highly complex specialized care and that payments are tied to services that truly benefit the patient. Mayo Clinic is a not-for-profit health care system dedicated to medical care, research and education. With more than 3,600 physicians and 60,000 employees, Mayo Clinic demonstrates a relentless and unwavering commitment to excellence which has spawned a rich history of health care innovation. Each year, more than one million people from all 50 states and 140 countries come to Mayo Clinic to receive the highest quality care at sites in Minnesota, Arizona and Florida. In addition, Mayo Clinic Health System, a family of clinics, hospitals and health care facilities, serves communities in Iowa, Georgia, Minnesota, and Wisconsin. We respectfully submit the following comments to this RFI.

As CMS contemplates the appropriate regulations to implement the MIPS program and in particular Alternative Payment Models (APMs), it will be important to recognize the tremendous diversity among integrated health care systems. This complexity must be taken into account when designing a new risk based financing system for the future. The patient populations to be covered in these systems are very complex and diverse, in terms of both illness burden and demographic variations. Mayo Clinic recommends that as CMS moves forward with the new MIPS payment system and APMs it considers the breadth of this diversity of health care needs of

Medicare beneficiaries. We therefore appreciate the opportunity to comment on the following four key factors as being critical for consideration in designing a new payment system:

- Reliable risk adjustment mechanisms that distinguish cost between primary care delivery and referral care delivery.
- Equitable payment mechanisms between the historical Medicare Advantage Program and new “alternative payment models” for eligible providers in highly specialized care delivery systems.
- Benchmarking of cost from both a geopolitical perspective and for establishing payment taking into account care delivery to highly complex patients.
- Data feedback to providers.

### Risk Adjustment

Because we have a diverse care system in this country, risk adjustment mechanisms must account for variations on patient illness burden across all levels of care delivery. This will be especially true for adjusting payments to highly diverse specialty care systems that assume care delivery responsibility for complex patients and patients who have developed a need for highly specialized care. Risk adjustment must appropriately account for variations in cost across the care delivery spectrum and appropriately attribute cost to primary care eligible providers and specialty care providers. A referral provider should not be penalized because they care for referral patients from primary care settings. New risk adjustment mechanism need to be developed that fairly assess costs to highly specialized quaternary care and academic care settings.

### Setting the Value of Payment in Alternative Payment Models (APMs)

The metrics and rules used to establish payments in APMs must reflect the same type of risk assumed by integrated care delivery systems and be similar to the rate methodologies used for managed care models. As risk based contracting evolves for care delivery systems, a level playing field must be established that treats risk based contracting the same be it in an insurance setting or a care delivery setting. Historical fee for service costs does not adequately account for cost trends over time. In addition, the metrics and methodology within APMs must be clear and transparent to delivery systems opting to participate in this new program. If transparency in the methodology is not as clear to providers, the model will likely fall short of achieving the ultimate goal to reward providers for value. No provider care system can succeed in an environment where the metrics and methodology are not understandable.

### Benchmarking

Medicare must accomplish an equitable benchmarking system that compares the total cost of care delivered across the country. To be successful, alternative payment models must examine geopolitical factors in how costs are determined and payments are made to providers of care. This will impact the ability of not only providers to succeed but states to succeed in fashioning future payment models that meet the needs of patients and communities. Benchmarking must be established at a federal level that puts all regions of the country on a level playing field.

### Data Feedback to Providers

For providers who have the capability to implement highly specialized data analytic practices, it will be necessary for those providers to receive complete and timely feedback of data relative to the patient population for which a provider is accountable. Anything short of complete and timely data will jeopardize our ability to determine utilization patterns and adjust cost trends and demographic changes in the populations we serve. This is particularly important for highly specialized academic medical centers providing the most complex levels of care for patients. This also means that detailed care claims data must be available for complex patients from the primary care sites from which patients are referred.

Below are comments on specific categories of questions posed in the RFI.

#### Physician-Focused Payment Models (PFPM)

Mayo Clinic supports the overall comment provided by the Society of Thoracic Surgeons. It is critical that the MACRA regulations establish a clear and transparent pathway for models to be proposed to the PTAC and for those models that are recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to be implemented by CMS as qualified APMs. CMS has stated that it has no obligation to test models that are recommended by the PTAC. We disagree and believe that this extremely narrow perspective is not in agreement with the intent of the legislation. For MACRA to succeed in reforming the delivery of care and improving value for patients and the Medicare Trust Funds, CMS must be willing to give serious consideration to proposed PFPMs that are approved by the PTAC and support their implementation, as intended by the law. Within MACRA, establishment of the PTAC is under the title, “Promoting Alternative Payment Models.” The PTAC subsection’s purpose is stated as “increasing transparency of physician-focused payment models.” This legislative language makes it clear that Congress intended for PFPMs to provide an alternative, more transparent avenue for the development of qualified APMs than currently exists.

Since model development is likely to require a substantial investment in time and money, there should also be a process whereby PFPM applicants can find out at certain points during the development process of their model whether they are on the right track or if they need to make changes. At the very least, if a model is not accepted, the PTAC/CMS should be required to give the rationale for rejecting the model and suggestions for improving the model. Otherwise PFPM applicants stand to lose the entire investment.

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

#### Definition of Physician-Focused Payment Models (PFPMs)

The definition of PFPMs should be as broad as possible. As long as a model uses a payment method other than traditional fee for service (FFS), achieves certain agreed-upon quality metrics and reduces spending, it should be considered a candidate for approval. CMS should ask what costs the model participants are likely to incur in order to participate in the model, what savings the model is likely to achieve for Medicare, what accountability measures should be used to

judge whether the model is meeting its targets for costs savings and care quality, and how to hold participants accountable for these measures. A well-designed APM will pay adequately for high-value services and avoid financially penalizing physicians when they reduce avoidable services and prevent complications. Physicians need the flexibility to use payments in various ways in order to improve care and reduce overall spending. A narrow definition will inhibit innovative ideas.

#### MIPS Payments

As CMS defines the new MIPS payment system, it is important that the existing physician quality reporting (PQRS), Value Modifier (VM), and EHR meaningful use reporting efforts be incorporated into MIPS to minimize new reporting requirements. As a result of the complexities involved and extensive resources invested in quality reporting, we recommend CMS provide minimal changes to the current reporting programs. MIPS should encourage physician-hospital collaboration and allow for maximum flexibility. Eligible professionals (EPs) in group practices should be assigned one MIPS score based on all individual EP scores within the group setting. Because the definition of eligible professional is not consistent across the various reporting programs it will be important that CMS clearly define the EP under MIPS.

We seek clarification as to how MIPS adjustments will be applied to nonparticipating physicians with respect to the limiting charge amount. We have three large group practices with thousands of nonparticipating physicians who will be reimbursed under the MIPS adjustment. Currently, we must maintain a single Medicare fee schedule with the limiting charge amount for each payment locality for the entire group practice. If the MIPS adjustment is applied to each individual physician in the group practice instead of a single adjustment for the group practice as a whole, we are concerned we may have to maintain multiple fee schedules to accommodate each potential MIPS adjusted limiting charge amount. This would be a significant burden for large group practices that are nonparticipating providers. Providing clear guidance as to how group practices will be treated under MIPS, how the nonparticipating physician limiting charge will be considered, and impacts to beneficiaries' responsibilities will be extremely helpful for practices to prepare their billing systems for the new payment system. Currently the Value Modifier (VM) is not provided to a nonparticipating practice submitting non-assigned claims. Inclusion and consideration for nonassigned claims in all facets of the MACRA process should be incorporated. No consideration based on the EP status as participating or nonparticipating should be made under MACRA. The MIPS adjustments should apply to all services provided by the EP. Lastly, we seek to understand the impact of shifting from a Physician Fee Schedule to a new MIPS system will have on Medicare Advantage payments and the calculation of cost in the Medicare Advantage Program.

#### Other MIPS Measures

CMS should avoid adopting additional measures such as those used in local markets until such a time when confidence can be established that the new MIPS methodology is working properly. This would include population health measures, which can be quite unique to specific communities. These measures should be developed through local participation between providers and social service agencies. Duplicating costs would be harmful and not beneficial to measurements in the short term.

### Quality & Data Accuracy

Mayo Clinic supports the goal of establishing one set of measurement criteria, rather than several criteria under the various quality reporting programs. CMS should develop a methodology where by providers are not penalized if there is insufficient data in their samples. MIPS need a statistically sound model that supports using the existing structural, process, and outcome measures. Mayo Clinic supports measures that follow the current CMS protocols (i.e. NQF endorsed measures). Measures should be designed for discrete EHR documentation within clinical workflows with few numerator and denominator exclusions/exceptions.

Mayo Clinic supports data accuracy and believes in testing of quality data. Data that is publicly reported should be able to withstand any audit. The current PQRS data auditing process and EHR data auditing process are not well defined. CMS must ensure that accurate data can be achieved through sampling methodology. One sampling option might be to validate data accuracy similar to the current inpatient quality reporting program in which CMS randomly selects number hospitals each year for review. Registries should be required to submit data to CMS using certain standards; however, QRDA may not be the appropriate standard to use. If submissions do not initially meet data integrity standards, there needs to be an opportunity for formal resubmission. The CMS inpatient quality reporting (IQR) has a well-defined audit process, including an appeal process and efficiencies could be gained using a similar audit process under MIPS.

### Development of Performance Standards

Benchmarks should be established so as to not further penalize already high performing providers/regions of the country. It is important that CMS begin using national benchmarks. In addition, target thresholds should be considered so that high performing providers are not penalized if already providing optimal care. MIPS must avoid the use of topped out measures. Unique cost structures of academic health centers and quaternary care centers should be included in measures to accurately reflect comparative cost. In the first few years of this methodology, we request that CMS provide an option for selecting a performance benchmark to be achieved. For example, an absolute score to receive full credit, or improvement year by year. Mayo Clinic supports using information from the previous performance year as a threshold similar to the current Value Modifier threshold. This option provides important information on positive results, as well as highlights areas to focus on for improvements.

### Clinical Practice Improvement Activities

We appreciate the opportunity to aid in the development of activities that contribute to improved patient outcomes and to which provider payment should be linked to improved outcomes. Clinical Practice Improvement Activities (CPIA) are defined as activities that relevant eligible professional organizations and other key relevant stakeholders identify as improving clinical practice or care delivery and are likely to result in improved outcomes. Much of the work currently performed by faculty physicians should qualify as clinical practice improvement activities. The incorporation of this new component will provide credit to professionals working to improve their practices and facilitates future participation in alternative payment models (APMs). We believe clinical practice improvement activities should be clearly defined and should not create additional burden on the provider. Examples of such activities include Maintenance of Certification (MOC) practice improvement projects, practicing in interdisciplinary teams, and education. Measures that document clinical improvement can be better

collated with specialty board certification process such as the MOC where providers are required to demonstrate participation in a quality improvement (QI) project. We support participation in MOC to be considered as an option for the subcategory of patient safety and practice assessment due to the potential it has to reduce burden on physicians. If physicians are already pursuing these activities, they should receive credit. Pairing the clinical process improvement measures with another activity that has already been developed will help decrease burden to the providers.

The initial period of CPIA should require attestation only for providers that meet some measures but not all measures. Group practices should be responsible for handling this process at the group rather than provider level as most process improvement activities are system wide initiatives. Otherwise, it would be resource intensive to do this at the provider level.

Mayo Clinic supports the various subcategories as outlined in the proposed rule and provides the following comments with respect to certain subcategories. Under the subcategory Care Coordination, we have concerns about the feasibility of collecting time-based measures across PQRS providers. Time-based measures are either difficult to collect or unreliable, due to the fast-pace of clinical care delivery and the lag time in medical documentation which results in inaccuracies of computer entry times. With respect to Beneficiary Engagement, the validation, collection, and documentation of measure(s) performance can be burdensome. Beneficiary engagement could be measured by participation rates in care communication, such as usage of health portals or participation in health and wellness programs. This would be more feasible to collect. With respect to Patient Safety and Practice Assessment, the clinical practice improvement activities can be achieved through use of clinical or surgical checklists and practice assessments related to maintaining certification. The use of checklists in the clinical practice, such as a standardized patient rooming process in ambulatory clinics, will promote the systematic engagement of beneficiaries in chronic disease management activities and in preventative care activities (i.e. screening management of blood pressure, glucose, etc.). Employing checklists and registries to ensure that recommended care is delivered, or at least offered to patients, will demonstrate clinical improvement actions and continual improvement efforts.

#### Meaningful Use of CEHRT

Mayo Clinic requests an option for group practices that has no limit to the number of eligible professionals in the Tax Identification Number (TIN). This would be similar to the hospital quality reporting options. This option will alleviate the burden of duplication and patients will only be counted when seen in a group practice setting. Of additional importance is ensuring that the practice only includes providers who are employees of the practice, and not providers who are independent contractors. This would reduce much of the current complexities associated with Meaningful Use attestation and reporting. MU Penalties should be tiered based on the number of CORE and MENU measures/requirements satisfied by the eligible provider. An example would be that if the provider or group practice met half of the MU requirements, they would get half of the available MU points. If a hardship is granted, the provider/group practice would earn full credit for the MU portion of the composite MIPS score. Further, Mayo Clinic urges that CMS create parity for physicians and hospitals in the MU program by also removing the all or nothing construct for hospitals.

### Alternative Payment Model and Eligible APMs

Alternative Payment Models (APMs) offer an opportunity to create workable healthcare delivery models that focus on the value and the quality of care as opposed to cost and quantity of care. The APM process created by MACRA will allow physicians and key stakeholders an important voice in the development and implementation of new reimbursement models. Encouraging physician input from all care settings promotes quality and efficiencies in resource utilization. When developing APMs, the framework needs to provide for solid population risk-adjustment methods for various performance measures and population of patients (i.e. chronically ill, terminally ill) including adjustments for patients opting out of participating in associated care models or seeking care outside of the model. There is also the need for rural and socio-economic exceptions within these models to include patient medication non-adherence, patient inability to access technology for care coordination efforts, family/caregiver disengagement, and transportation issues that often create barriers for patients despite providers' best efforts. The APMs should also follow current standards of care as stipulated by professional specialty boards and societies offering providers the ability to quickly initiate the most appropriate treatment protocols and intervention for their patients, which will ultimately result in cost savings to Medicare.

We believe that the intent of the MACRA legislation is to allow our providers a choice between participating in a revised system of fee-for-service that would reward providing high quality care and improving patient outcomes or design and implement one or more specialty specific payment models that would be appropriate for the patients they treat. We remain concerned with the fact that CMS "has no obligation to implement any APM proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)." Because of differences in care provided in various settings, providers need multiple options and not just one approach for all. We encourage CMS to develop and test multiple models to determine what works best for different providers in different settings. CMS has the opportunity to allow different providers in different settings to demonstrate how to best navigate patient and payment attribution for their individual practices. Only models that should be able to address these RFI questions should be approved by the Secretary and then evaluated through a demonstration program under the Centers for Medicare and Medicaid Innovation (CMMI).

CMS should also make it easy to be an APM provider. Providers should be provided the option of risk based contracting. CMS could allow providers, who want to participate to prospectively enroll patients, analyze the burden of illness, and create an expected spending target with a simple risk calculation. If a provider meets the health outcomes for a total cost of care that is within a given range, the provider would receive a bonus if producing the health outcomes below the corridor of expected spending and a penalty if above the corridor. APMs should be able to demonstrate improved outcomes of Medicare beneficiaries.

### Eligible Alternative Payment Models (EAPM) Entity Requirements

CMS must establish a process whereby proposed PFPMs have a clear and transparent pathway to adoption. In terms of basic criteria for adoption, EAPMs should: assume responsibility for the care (episode- condition- or procedure-based) of a population of patients; meet certain agreed upon quality measures; provide care for the determined services at agreed upon costs. EAPMs should be developed with the intent to improve patient care and patient outcomes and reduce

healthcare costs. If APM entities are not physician-owned, the entity should provide a means for physicians to influence the policies and goals of the organization. CMS should place as few prospective restrictions as possible on new EAPMs proposals. Instead, each proposal should be evaluated on its overall merits. CMS should also resist imposing one-size-fits-all criteria on all possible EAPMs

Technical Assistance to Small Practices and Practices in Health Professional Shortage Area (HPSA)

Assistance to small group practices and practices in an HPSA is critical. As small practices prepare for participation in MIPs or an APM, technical assistance should prioritize smaller, independent practices that will be much less able to bear the administrative burden of the significant reporting requirements and the potential financial burden of participating in APMs.

Thank you for the opportunity to comment on the RFI and for consideration of our comments. If you should have any questions, please contact me at (507) 284-3774.

Very truly yours,

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