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November 17, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3321-NC
Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models
(80 FR 59102-59113 and 80 FR 63484-63485)

Dear Acting Administrator Slavitt:

Thank you for the opportunity to provide input to CMS as it develops its rulemaking and designs its administrative processes for implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). We will focus our comments on the portions of MACRA related to Alternative Payment Models and Physician-Focused Payment Models in Section 101(e) titled "Promoting Alternative Payment Models."

We urge that CMS adopt four principles to guide its rulemaking and implementation processes for Alternative Payment Models (APMs) under MACRA:

- Minimize administrative burdens in implementing alternative payment models
- Create a bottoms-up process for designing alternative payment models
- Reduce barriers to innovation in selecting and implementing alternative payment models
- Implement alternative payment models that improve care and payment for as many types of physicians and patients as possible

Minimize Administrative Burdens in Implementing Alternative Payment Models

MACRA contains only a small number of requirements for Alternative Payment Models, each of which is defined in simple, broad language. If Congress had wished to create detailed requirements for the structure of APMs, it could have done so, since it created extremely detailed specifications for how the Merit-Based Incentive Payment System (MIPS) should be structured.

We believe this was as an intentional effort by Congress to encourage as much innovation as possible in the development and use of APMs and to minimize the administrative burden on physicians in implementing them. Consequently, the small number of requirements for APMs in MACRA and the flexible language used to describe those requirements should not be seen as a void to be filled with extensive CMS regulations.

We urge that all regulations be designed to enable physicians to focus their time and Medicare's funds on improving care for beneficiaries, not on complying with burdensome administrative requirements. In Attachment 1, we recommend specific ways that the legislative requirements for APMs should be implemented. We urge that CMS avoid establishing any additional requirements for APMs that are not absolutely necessary for the protection of Medicare beneficiaries or the prevention of fraud and abuse.

We also urge that CMS avoid requiring burdensome amounts of information to accompany proposals for APMs. The 19 factors that the Center for Medicare and Medicaid Innovation currently uses to select models go far beyond what is required in statute, and requiring submission of information relevant to all of these criteria would make it extremely difficult for small physician practices or medical societies to propose alternative payment models.

Create a Bottoms-Up Process for Physician-Focused Alternative Payment Models

In virtually all of its payment reform efforts to date, CMS has used a "top-down" approach to payment reform, i.e., CMS defines the payment models and it decides which providers will be able to participate. This has resulted in only a few different types of alternative payment models, and the results to date of those models have been generally disappointing in terms of the breadth of participation, the impact on spending, and the speed of implementation. Many physician groups and medical specialty societies have proposed other APMs that could provide greater savings and improve care for a wider range of Medicare beneficiaries, but CMS has been unwilling to implement them.

It is time to create a bottoms-up process through which physicians and the organizations that represent them can develop APMs and have them rapidly implemented by CMS. MACRA specifically authorizes and encourages the development of "physician-focused payment models" through this kind of bottoms-up approach. We provide detailed recommendations on how CMS should solicit and respond to proposed physician-focused APMs in Attachment 2.

We recommend that a physician-focused payment model (PFPM) be defined as either (1) an eligible alternative payment model meeting the requirements of Section 1833(z)(3) of the Social Security Act, or (2) a mechanism for compensating a physician for the physician's services as an integral component of an APM being managed by an alternative payment entity as defined in Section 1833(z)(3). For example, many alternative payment models, such as the payment models used by CMS in its Accountable Care Organization (ACO) and Bundled Payments for Care Improvement (BPCI) programs have been implemented using a "retrospective reconciliation" approach, i.e., the physicians and other providers delivering services as part of the ACO or the BPCI episode continue to be paid under existing CMS fee for service systems, and then the total spending relevant to the payment model is compared to a budget and reconciliation payments are made. However, the individual physicians may not be able to change care in ways that will make the ACO or BPCI episode team successful if there is no fee-

for-service payment (or inadequate payment) for one or more high-value services. A physician-focused payment model could involve making adequate Medicare payments for the currently unpaid or underpaid services in order to support the success of the overall ACO or BPCI episode team.

We urge that the processes HHS and CMS develop for soliciting and reviewing proposals for physician-focused payment models under MACRA be an integral part of the processes that are used to develop, review, and implement alternative payment models, rather than creating separate, disconnected processes for each. In particular, we urge that any payment model recommended by the Physician-Focused Payment Model Technical Advisory Committee should be implemented by CMS unless CMS can clearly demonstrate that the payment model would harm Medicare beneficiaries or increase Medicare spending after the initial years of implementation.

We strongly oppose some of the criteria that the RFI indicates CMS is considering using to determine which physician-focused payment models (PFPMs) should be recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) or implemented by CMS:

- We disagree that proposed payment models should be required to be "primarily focused on the inclusion of participants … 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." Although it should be a *priority* for CMS to ensure that there is at *least one* alternative payment model in which *every* specialist can participate, the fact that CMS has designed one model that it believes includes that specialty does not mean that model will work for every physician in that specialty or that a new APM proposed by physicians in that specialty would not achieve better results.
- We disagree that recommended models should "aim to directly solve a current issue in payment policy that CMS is not already addressing in another model or program." The fact that CMS is attempting to address a payment issue in an existing model or program does not mean that it is doing so as successfully as possible, and a new APM proposed by physicians may well be able to achieve far better results.

Reduce Barriers to Innovation in Selecting and Implementing Alternative Payment Models

Under MACRA, any model under Section 1115A (other than a health care innovation award) can be considered an APM. Section 1115A(b)(2) describes 24 different payment models, but indicates that CMS is not limited to implementing only these models. The only requirement governing which payment models CMS can select to implement is that "there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." While Section 1115A requires CMS to *focus* on models "expected to reduce program costs … while preserving or enhancing the quality of care received by individuals receiving benefits…", CMS is not prohibited from implementing models which will improve quality without increasing spending.

Importantly, Section 1115A(b)(3) states that CMS shall ***not*** require that a model be budget neutral initially. It further states that CMS can continue implementation of a model as long as the model is ***expected*** to either (a) improve the quality of care without increasing spending, (b)

reduce spending without reducing the quality of care, or (c) improve the quality of care and reduce spending. If a payment model is not expected to achieve one of these goals, CMS is authorized to *modify* it as well as terminate it. There is no deadline for how long a payment model may be continued or how many times it may be modified before a final determination is made that it cannot achieve the statutory goals and that it must be terminated.

We urge that CMS follow both the letter and spirit of Section 1115A by:

(1) approving and implementing any proposal from physicians for an alternative payment model that is designed to improve outcomes or reduce potentially avoidable expenditures, without requiring that the payment model be budget neutral initially;

(2) allowing a reasonable period of time for the alternative payment model to demonstrate that it is either (a) improving quality without increasing spending or (b) reducing spending without harming quality; and

(3) if a model is not successfully improving quality without increasing spending or reducing spending without harming quality, allowing physicians to make modifications to the model to address weaknesses before making a decision to terminate it.

Implement Alternative Payment Models That Improve Care and Payment for As Many Types of Physicians and Patients as Possible

There is no single Alternative Payment Model that will work for all physicians or their patients. Different medical specialties treat different kinds of health problems, and the opportunities to improve quality and reduce costs will differ for the different types of health problems addressed by physicians within each specialty and subspecialty. Moreover, the care delivery changes that are needed to address these opportunities will also differ by specialty, as will the barriers in the current payment system that need to be overcome for physicians to redesign care delivery for their patients.

This means there will need to be multiple types of APMs in order for physicians in all specialties to participate and in order for all patients to benefit. A good APM will overcome the *specific* payment system barriers a physician practice faces in pursuing the *specific* kinds of improvement opportunities available for the types of patient conditions the physicians in that practice treat. There is no need for complex and expensive changes in payment structures if simple changes will address the barriers. If paying for a new service code could enable a physician practice to deliver significantly better care at lower overall cost, there is no need to force the practice to find ways to manage a complex bundled payment.

We recommend that CMS be prepared to implement seven different types of physician-focused APMs that can be used to address the most common types of opportunities and barriers across all physician specialties:

1. **Payment for a High-Value Service.** Under this APM, a physician practice could be paid for delivering one or more desirable services that are not currently billable, and the physician would take accountability for controlling the use of other, avoidable services for their patients.

2. **Condition-Based Payment for Physician Services.** Under this APM, a physician practice would have the flexibility to use the diagnostic or treatment options that address a patient's condition most efficiently and effectively without concern that using lower-cost options would harm the operating margins of the physician's practice.
3. **Multi-Physician Bundled Payment.** Under this APM, two or more physician practices that are providing complementary diagnostic or treatment services to a patient would have the flexibility to redesign those services in ways that would enable high-quality care to be delivered as efficiently as possible.
4. **Physician-Facility Procedure Bundle.** This APM would allow a physician who delivers a procedure at a hospital or other facility to choose the most appropriate facility for the treatment and to give the physician and facility the flexibility to deliver the procedure in the most efficient and high-quality way.
5. **Warrantied Payment for Physician Services.** This APM would give a physician the flexibility and accountability to deliver care with as low a rate of complications as possible.
6. **Episode Payment for a Procedure.** This APM would enable a physician who is delivering a particular procedure to work collaboratively with the other providers delivering services related to the procedure (e.g., the facility where the procedure is performed, other physicians who are involved in the procedure, physicians and facilities who are involved in the patient's recovery or in treating complications of the procedure, etc.) in order to improve outcomes and control the total spending associated with the procedure.
7. **Condition-Based Payment.** Under this APM, a physician practice would have the flexibility to use the diagnosis or treatment options that address a particular health condition (or combination of conditions) most efficiently and effectively and to work collaboratively with other providers who deliver services for the patient's condition in order to improve outcomes and control the total spending associated with care for the condition.

More detail on each of these physician-focused Alternative Payment Models and examples of how they could be used to improve care for a wide range of patient conditions is available in a report developed by CHQPR and the American Medical Association entitled *A Guide to Physician-Focused Alternative Payment Models*, which can be downloaded at http://www.chqpr.org/downloads/Physician-FocusedAlternativePaymentModels.pdf.

Thank you again for the opportunity to offer these recommendations. We would be happy to answer any questions you may have about our recommendations or to provide any additional information or assistance that would be helpful to you in implementing them.

Sincerely,

Harold D. Miller
President and CEO

cc: HHS Secretary Sylvia Mathews Burwell
Assistant Secretary for Planning and Evaluation Richard Frank
CMS Deputy Administrator Patrick Conway, MD
CMMI Deputy Director Rahul Rajkumar, MD
Director of the Division of Health Care Quality and Outcomes Scott Smith
Members of the Physician-Focused Payment Model Technical Advisory Committee

ATTACHMENT 1
REGULATIONS NEEDED TO IMPLEMENT MACRA REQUIREMENTS FOR ALTERNATIVE PAYMENT MODELS

Under MACRA, there are three sets of interrelated requirements which must be met in order for a physician to be considered as a qualified APM participant:

1. **Requirements for the physician.** In order to be considered a qualifying APM participant, a physician must either:
   a. receive a minimum proportion of their total Medicare payments, or a minimum proportion of their total payments from all payers, for covered professional services furnished through an alternative payment entity, or
   b. (in situations permitted by the Secretary of HHS) deliver services supported through an alternative payment entity to a minimum proportion of the physician's patients.
2. **Requirements for the alternative payment entity.** An alternative payment entity must:
   a. be participating in an eligible alternative payment model; and
   b. bear financial risk for monetary losses under the alternative payment model in excess of a nominal amount, unless the entity is a medical home expanded under section 1115A(c).
3. **Requirements for the alternative payment model.** An eligible alternative payment model must:
   a. be one of the models defined in Section 1115A of the Social Security Act, or be part of either the shared savings program in section 1899, a demonstration under section 1866C, or a demonstration required by federal law;
   b. require participants to use certified EHR technology; and
   c. provide for payment for covered professional services based on quality measures comparable to the quality measures in MIPS.

We recommend that these criteria in MACRA be interpreted and implemented by CMS in the following ways:

Calculating a Physician's Revenues/Patients in Alternative Payment Models

We recommend that all physicians be given the option as to whether their participation in APMs should be measured through the percentage of their revenue that is coming from APMs or the percentage of their patients being cared for through APMs. In general, Medicare payments that are made directly to physicians represent only a small proportion of the total Medicare spending on the physicians' patients. In some cases, the biggest opportunity for savings to Medicare may be associated with patients who represent only a small proportion of a physician practice's revenues, and so it would be inappropriate to discourage a physician from participating in an APM for those patients simply because it affects only a small proportion of the physician's own revenue.

We recommend that the percentage thresholds be implemented in the following way in order to make the process as simple as possible for physicians:

For the threshold based on percentage of revenue:

- Any payment that the physician practice receives from an alternative payment entity that is related to the care of a Medicare beneficiary (or a patient of another payer, when calculating percentages of total spending) should be counted toward the threshold. This includes any payment the physician practice receives for which it is serving directly as an alternative payment entity.
- Any payment or portion of payment that the physician practice receives from Medicare under traditional fee-for-service payment systems (or from another payer, when calculating percentages of total spending) should also be counted toward the threshold if (a) that payment, or the service for which that payment was made, is considered to be part of an alternative payment model managed by an alternative payment entity; (b) the physician practice is eligible to receive a separate payment from the alternative payment entity, or the physician practice can be required to make a separate payment to the alternative payment entity based on the physician's performance; and (c) the maximum amount of the payments to or from the alternative payment entity meets the threshold for "more than nominal financial risk" established for alternative payment entities. The alternative payment entity should be responsible for documenting that the financial arrangement with the physician practice under the APM would meet the "more than nominal financial risk" standard in MACRA for APMs.

  For example, if the physician practice is part of a Medicare Shared Savings Program ACO or a retrospectively reconciled episode payment model as part of the Bundled Payments for Care Improvement (BPCI) demonstration, the physician practice would be paid directly by CMS for its services, not by the ACO or BPCI episode initiator. However, if the physician practice shares financially in the reconciliation of any gains or losses under the payment model and if the combination of the physician's costs and revenues under the model would meet the financial risk standard for an alternative payment entity, then the Medicare payments received by the physician practice that are assigned to the ACO or BPCI episode should be counted as payments from an alternative payment model.
- The sum of all of the payments received during a period of time that count toward the threshold should then be divided by the total payments the physician practice received during that same period of time to determine whether the practice meets the threshold defined in the law. The physician practice should have the option of computing the payment thresholds on a cash or accrual basis, whichever is simpler for them.

For the threshold based on patient counts:

- If all of the services a physician delivers to a particular patient are compensated through an alternative payment entity (including the physician practice itself if it is serving as an alternative payment entity), that patient should be counted 100% toward the threshold.

- If only a portion of the services the physician delivers to the patient are compensated through an alternative payment entity, then the physician should be able to partially count that patient toward the threshold. The fraction of the patient to be counted should be defined using a methodology established and approved as part of the alternative payment model.
- The sum of all of these "total patient equivalents" should then be compared to the total number of unique patients served by the physician practice during the relevant period of time to determine whether the practice meets the threshold established in the law.

Defining "More Than Nominal Financial Risk"

MACRA requires that an eligible alternative payment entity bear "financial risk for monetary losses" under an alternative payment model that is "in excess of a nominal amount."

Defining "Financial Risk"

The term "financial risk for monetary losses" in MACRA clearly refers to *losses in the operations of the alternative payment entity*, not to losses or increased spending in the Medicare program. The gains or losses of the alternative payment entity are a function of both the *costs that the alternative payment entity incurs* to implement the model and the *revenues it receives under the model*. If the alternative payment entity hires or pays for new staff to deliver services to patients under the alternative payment model, if it acquires new or different equipment to deliver services, or if it incurs other kinds of expenses to implement the alternative payment model, and if those expenses are not automatically or directly reimbursed by Medicare, then the alternative payment entity is accepting financial risk for monetary losses. For example, physician practices incur financial risk for monetary losses today under the fee for service payment system because the costs they incur for office space, equipment, and staff are not directly reimbursed by Medicare, and if the practice does not deliver enough services to generate fee-for-service payment revenues in excess of those costs, it could be forced to declare bankruptcy.

Financial risk cannot be defined simply in terms of the potential reduction in revenues the alternative payment entity could receive from Medicare. The alternative payment entity could easily incur monetary losses under an alternative payment model even if the Medicare program is experiencing savings under the model or even if the entity has no obligation to repay losses that the Medicare program has incurred, as long as the entity could incur costs that exceed its payments. For example, under an "upside only" shared savings model, a physician practice or other provider incurs financial risk if it incurs costs to implement programs that are designed to reduce Medicare spending, since the provider could fail to qualify for the shared savings payment it needs to pay for those costs.

Consequently, an alternative payment entity's "financial risk for monetary losses" under an alternative payment model should be defined as the potential difference between the amount of costs the entity incurs or is obligated to pay as part of the alternative payment model and the amount of revenues that it could receive under the APM. The greater the costs it incurs or the lower the revenue it could potentially receive, the greater the financial risk.

Defining "More than Nominal" Financial Risk

If Congress had wanted alternative payment entities to accept substantial financial risk, it could easily have explicitly required that, so it is clear that in using the term "more than nominal financial risk," Congress did not mean "substantial" financial risk. Logically, "more than nominal" risk would also be significantly less than what would be considered "substantial" risk.

For 20 years, CMS has defined "substantial financial risk" for physician practices receiving payments from Medicare Advantage plans. Section 422.208 of the Code of Federal Regulations define "substantial financial risk" as a situation in which more than 25% of a physician practice's payment is at risk based on services that the physician practice does not deliver itself, or a situation in which capitation payments could vary by more than 25%. Consequently, the threshold for "more than nominal" risk in MACRA would need to be set well below a 25% variation in an alternative payment entity's revenues relative to its costs.

In MACRA, Congress has placed all physicians' payments "at risk" through the Merit-Based Incentive Payment System (MIPS). In the initial year of the program (2019), payments could be reduced by 4%, and the maximum reduction increases to 9% in 2022. These amounts are presumably "more than nominal" if Congress expected them to influence physician performance on the measures defined in MIPS, which includes resource measures.

Consequently, we would recommend that "more than nominal" risk for APMs be defined using the maximum reduction amounts that are used in MIPS, i.e., in 2019, since a physician's payments could be reduced by 4% under MIPS even with no change in the physician's costs, an alternative payment entity should be viewed as being at "more than nominal financial risk" if the amount of costs that it incurs under an alternative payment model could exceed the amount of revenue it receives under the model by at least 4%. That threshold would then increase to 9% in the year 2022 and beyond.

Eligible Payment Models Under Section 1115A

As a result of MACRA, Section 1833(z)(3)(C) of the Social Security Act states that "a model under Section 1115A (other than a health care innovation award)" can be considered an alternative payment model. We urge that CMS approve and implement any payment model proposed by a physician practice that meets the requirements of Section 1115A.

MACRA did not require that a payment model described in Section 1115A had to have been evaluated by the Center for Medicare and Medicaid Innovation (CMMI) or expanded nationally in order to qualify as an alternative payment model. If Congress had wished to limit APMs to models that CMMI had evaluated or the Secretary had expanded, it could easily have done so. Indeed, in the very next subsection of MACRA (Section 1833(z)(3)(D) which defines an alternative payment entity, Congress specified that the entity must either bear financial risk or be a "medical home expanded under section 1115A(c)."

The only requirement in Section 1115A limiting which payment models CMS can select to implement is that "there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." Conversely, Section 1115A(b)(3) states that CMS shall ***not*** require that a model be budget

neutral initially. CMS should not impose more restrictive requirements than these in approving APMs.

Use of EHR Technology

MACRA requires that participants in an alternative payment model must be required to "use" certified EHR technology. We urge that CMS regulations implementing this provision require only that clinical data about the patients receiving care as part of the alternative payment model be stored in a certified electronic health record system. It is impossible to prescribe how a physician or other provider should "use" the technology beyond this without potentially interfering with the provider's flexibility to deliver services in the most effective way or imposing unnecessary costs and administrative burdens on the provider. A physician practice participating in the APM will have a strong incentive to use the EHR if it has capabilities that will improve their success, regardless of any specific requirements imposed by CMS. Any requirements for "use" of EHRs that are imposed in regulations should be counted by CMS as a cost that increases the financial risk for a physician practice to participate in the APM.

Use of Quality Measures

MACRA requires that payments under an APM be based on quality measures "comparable" to the quality measures in the MIPS program. Since MACRA permits a physician practice to choose which quality measures are most appropriate to assess the practice's performance under MIPS, physician practices and alternative payment entities should also have the flexibility to choose which quality measures are most appropriate to use as part of an APM. These measures should be specified as part of the proposal for an APM.

CMS should only require more or different quality measures than what is included in the APM proposal if (a) there is an aspect of patient care where quality could potentially be significantly harmed through a redesign in care under the APM, and (b) there is an endorsed quality measure that specifically measures that aspect of quality. If there are not endorsed measures that are directly relevant to the aspect of quality that is of concern, CMS should not attempt to substitute for this by requiring multiple *irrelevant* quality measures, since this could jeopardize the success of the model. Any quality measures that are required as part of an APM should be counted by CMS as a cost that increases the financial risk for a physician practice to participate in the APM.

ATTACHMENT 2
RECOMMENDED PROCESS FOR RECEIVING AND EVALUATING PROPOSALS FOR ALTERNATIVE PAYMENT MODELS

We urge that CMS implement the following process in order to encourage physician practices and medical societies to develop proposals for physician-focused Alternative Payment Models and to ensure they are promptly reviewed, approved, and implemented.

- CMS should define and publicize the information it needs in order to determine whether a proposal meets the statutory requirements of MACRA for APMs and physician-focused payment models.
- CMS should accept proposals for APMs no less often than quarterly.
- Each proposal that is submitted with the required information should be immediately forwarded to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) so that it can make a recommendation to CMS within 60 days as to whether to implement the model.
- CMS should review each proposal for an APM along with the recommendation it receives from the PTAC and either approve or reject the proposal within 90 days. CMS should approve any proposal recommended by the PTAC unless CMS can show that the proposal would be expected to harm Medicare beneficiaries or to increase total Medicare spending after the proposed payment model had been in place for at least a year.
- If a proposal for an APM is rejected, CMS should provide a detailed explanation of the reasons for rejection and recommendations for the types of revisions which could be made that would enable it to be approved.

  No proposal for an APM should be rejected solely because it does not require physicians to control or reduce the total cost of care for their patients. If the proposed APM gives the involved physicians accountability for controlling key aspects of the costs of care that they can reasonably expect to influence, but exempts them from accountability for costs that they have little or no ability to influence, then the proposal should be approved unless CMS can demonstrate that the proposed APM would result in an increase in Medicare costs or that it would harm the quality of care for beneficiaries.
- If a rejected proposal is revised and resubmitted, CMS should re-review it within 30 days and either approve it or reject it with specific recommendations for the changes needed to obtain approval.
- Once an APM is approved, applications from physician practices and alternative payment entities to participate in an approved APM should be made available within 90 days of the APM's approval by CMS, and physicians and alternative payment entities should be permitted to apply to participate in an approved APM no less frequently than twice per year.

- Applications to participate in an APM should be reviewed and approved or rejected within 60 days; if an application is rejected, CMS should provide information on the reasons for rejection and methods of correction. Applications should only be rejected if an applicant cannot demonstrate that it has the ability to implement the model. If a rejected application is revised and resubmitted, CMS should re-review it, and approve or reject it within 30 days. If it is rejected, CMS should provide recommendations for changes needed to obtain approval.
- CMS should implement an approved APM with the approved physician applicants no later than 90 days after the applications by physician practices to participate have been approved.
- Once a physician begins to participate in an APM, they should be permitted to continue doing so as long as they wish to, unless CMS can demonstrate that Medicare spending under the payment model is higher than it would be under the standard physician fee schedule or that the quality of care for beneficiaries is being harmed.