



November 20, 2017

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5522-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Centers for Medicare and Medicaid Services: Innovation Center New Direction

Dear Administrator Verma:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS): Innovation Center New Direction Request for Information (RFI).

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to advancing policies that empower patients, ensure that they continue to receive high-quality care that improve outcomes, and are also cost-effective. In the RFI, CMS identified six core guiding principles for consideration of new alternative payment models (APMs) and other Innovation Center models: choice and competition in the market; provider choice and incentives; patient-centered care; benefit design and price transparency; transparent model design and evaluation; and small-scale testing. PAI agrees with these guiding principles, as these are the key elements that should be considered in the development of payment models.

Additionally, PAI has identified five overarching objectives for innovation to be used collectively with the core guiding principles to inform the future development and modification of APMs and Innovation Center models. These five objectives for innovation are payment models should:

- Provide increased flexibilities, incentives, and greater resources for physicians and other clinicians;
- Be patient-centric and include elements that focus on patient needs, as well as encourage and incentivize patient engagement;
- Include pilots and programs with clear guidance and enhanced clarity;
- Rely upon input from, and collaboration with, state medical associations; and
- Reduce the physician burden.

In this letter, we provide comments based on the application of these principles and objectives. Specifically, we provide comments and input on the different potential model categories outlined in the RFI, as well as responses to the specific questions posed in the RFI, including:

- Increased participation in Advanced APMs;
- Consumer-directed care & market-based innovation models;
- Physician specialty models;
- Medicare Advantage models;
- State-based and local innovation, including Medicaid-focused models; and
- Program integrity.

## Increased Participation in Advanced APMs for MACRA's Quality Payment Program (QPP)

CMS is seeking guidance on ways to increase opportunities for providers to participate in Advanced APMs and meet the thresholds for becoming qualifying Advanced APM participants (QPs). The agency is seeking feedback on how the Administration can be more responsive to clinicians and patients, and expedite the process for providers who want to participate in Advanced APMs, and on ways to capture data to drive the design of innovative models and strategies to incentivize participation.

PAI believes that greater resources should be provided to physicians and other clinicians, which provide information and details on Advanced APM opportunities. A key challenge to Advanced APM participation by physicians and other clinicians is the lack of understanding of the different models, what is specifically required of them individually, and how they go about joining and participating in the different models, either directly or through an APM Entity. PAI believes that more detailed, step-by-step guidance and information addressing these questions and better equipping physicians and other clinicians with knowledge about the APMs and APM Entities available in their region and/or specialty, as well as how to join them would be particularly helpful.

Furthermore, greater flexibilities and incentives should be provided for solo practitioners and small practices to encourage their interest in and ability to participate in Advanced APMs. In the CY 2018 QPP Final Rule, CMS finalized several proposals that would help "level the playing field" for small practices and allow them to earn a positive payment adjustment. PAI believes that similar concepts should be adapted for the Advanced APM pathway which provide an "on-ramp" for solo practitioners and small practices. For example, the current nominal risk standard is too high for small group practices and clinicians and often deters them from participating in an APM. To entice small groups, PAI recommends starting with fairly low nominal amount standards and gradually increasing them as small groups become more comfortable taking on more risk.

## Other Payer Advanced APMs

PAI believes that the Other Payer Advanced APM option is valuable and will expand opportunities for physicians and other clinicians to successfully participate in the QPP. Under the Other Payer Advanced APM option, physicians and other clinicians will be able to receive credit for participation in APMs with other, non-Medicare payers that also contribute to increasing the quality and value of care provided to patients. However, PAI has concerns that the requirement that clinicians submit their own payment or patient data for the All Payer Combination QP determination option may be a barrier to successful participation and for clinicians to become QPs. Clinicians will be required to first acquire this data from their payers and then share it with CMS, verifying that it is accurate data. This will be quite burdensome, time consuming, and difficult for clinicians. PAI believes that payers and APM Entities, who have easier and timelier access to this data, and the ability to verify its accuracy, should be the ones who should bear the burden of data submission, but only after clinicians have been offered the opportunity to review their data prior to submission.

PAI reiterates what we noted in our comments in response to the CY 2018 QPP Proposed Rule, that we encourage the agency to have a strong mechanism in place to begin negotiations with APM Entities well in advance of this expected exchange of information. This would ensure that there are appropriate safeguards in place that would protect physicians and other clinicians from issues that may arise from data exchange and communications between the APM Entities and CMS, that could prevent them from receiving credit for participating in Other Payer Advanced APMs.

## QP/Partial QP (PQ) Thresholds

Based on feedback PAI has heard from physicians, there are generally two issues with the QP/PQ thresholds. First, the QP/PQ thresholds are perceived as being too high, especially going forward as they increase each year of the QPP. Second, the attribution methodology varies from model to model and it is often confusing and difficult for physicians and other clinicians to track and predict with some certainty which patients or costs will be attributed to them. The CMS QP Lookup Tool is a positive first step in assisting clinicians already in Advanced APMs, allowing them to see their QP status based on the different snapshot periods. However, there is still a need for a tool or resource that helps physicians understand the attribution methodology to predict in advance whether they will receive QP/PQ status for those already participating in an Advanced APM as well as for those interested in participating in an Advanced APM. PAI recommends that the agency consider decreasing the thresholds for QP/PQ determinations, including those for the All Payer Combination option, and to provide more resources and materials that really help physicians and other clinicians better assess what their attribution would look like under an Advanced APM.

PAI is committed to helping physicians adapt to, and succeed under, the QPP rules, including the Advanced APM pathway. To that end, PAI has launched a comprehensive, free educational initiative to guide physicians at every stage of readiness to succeed under the QPP and other value-based payment programs. These resources are available at [www.physiciansadvocacyinstitute.org](http://www.physiciansadvocacyinstitute.org). PAI welcomes the opportunity to partner with the agency and HHS to help educate physicians to succeed under the program.

## Consumer-Directed Care & Market-Based Innovation Models

CMS is considering developing models that facilitate and encourage price and quality transparency, which would include the compilation, analysis, and release of cost data and quality metrics that inform patients about their choices. Additionally, CMS is interested in building patient incentives into

potential models, such as the ability to share in savings for choosing lower-cost options, or incentivizing patients to achieve better health.

PAI is a strong supporter of developing models and incorporating model designs that not only better inform patients about their choices, but also help them evaluate their options and make an informed decision. PAI encourages the agency to ensure that any price and quality data made available to patients is accurate and presented in a clear and concise way, that is easily understood, so as not to overwhelm patients. We believe that transparency is essential, but also believe it is critical to ensure that the data and information being shared does not unintentionally misguide or misinform patients. Cost information is especially sensitive to these issues because there are several factors that must be taken into consideration when viewing the “dollar sign” associated with a specific clinician or service. For example, costs vary depending on specialty care, geographic issues, diagnoses/conditions, etc. If cost data is made available to patients, through Physician Compare or otherwise, PAI would urge the agency to also focus its efforts on providing resources and assistance to patients to help them understand the different factors that are included in “costs.”

Additionally, PAI supports patient incentives, similar to the Coordinated Care Award available under the Next Generation accountable care organization (ACO) model, for selecting and aligning with “high-quality” physicians and other clinicians who are participating in an APM. These should be built not only into new models, but current models that lack such patient incentives should be modified to reward patients for making high-quality, cost-effective decisions about their health care.

Furthermore, a priority for the development of future models, and modifications of existing models, should be to incorporate elements that focus on the needs of different patient groups who may require translation services, including those who require language assistance or sign interpretation. Currently, lack of Medicare compensation for these services creates a disincentive for some clinicians to be able to offer services for these patients. However, PAI believes that model elements could and should be incorporated, which provide physicians and other clinicians with the right tools and resources to provide care and services to these patients.

## Physician Specialty Models

CMS is seeking input on ways to better engage specialty physicians in APMs. There is currently a lack of specialty specific models, and PAI believes that additional support is required to help develop and implement models that create more opportunities for specialists. The Physician-Focused Payment Model Technical Advisory Committee (P-TAC) was created to accelerate this process, but, to-date, only one model has been recommended for implementation and two for limited-scale testing. This demonstrates the need for the agency to provide additional resources and support to stakeholders who are trying to develop specialty models to ensure that they are successful in their efforts.

PAI also recommends that future specialty (and other) APMs be constructed to most efficiently integrate with existing and future APMs and other value-based payment arrangements, so that all clinicians have an opportunity to participate in an APM without conflict. One potential issue PAI could foresee being raised are conflicts between attribution of patients. Thus, we would encourage the agency to ensure that clear guidance is issued on how the different models align and work-together/support each other, and where they differ.

## Medicare Advantage (MA) Innovation Models

CMS is interested in seeking input on MA innovation models that increase options for patients and increase competition. Many physicians and other clinicians are already actively participating in payment arrangements with MA organizations that are improving quality and lowering costs. PAI believes that it is important to allow additional flexibilities when it comes to benefit designs. Flexibilities in benefit design would help tailor the payment arrangements more to the needs of different patients to meet their needs, similar to as discussed in detail above regarding patient-centered models. Additionally, PAI believes that MA innovation models, like the value-based insurance design demonstration and other future models, should encourage and provide physicians with greater flexibility to better manage the care for their patients.

Additionally, PAI urges the agency to allow physician contracts with MA plans that meet the risk, quality, and certified electronic health records technology (CEHRT) requirements to be included as Medicare Advanced APMs for the QPP. Currently, these arrangements will be able to qualify for the Other Payer Advanced APM option, and the patients and payments will be counted towards the All Payer Combination option. PAI also encourages the agency to implement a policy that would allow the patients seen and payments received through those MA contracts to directly count towards the Medicare Advanced APM QP/PQ thresholds. This would also simplify the prediction for QP/PQ determinations, as discussed above, because it would decrease the analysis from the current multi-level assessment under the All Payer Combination option, to a single level assessment for all Medicare patients and payments.

## State-Based and Local Innovation, including Medicaid-focused Models

CMS seeks to partner with states and providers to develop state-based plans and local initiatives to test new models, which vary based on the needs and goals of each state. PAI encourages CMS to develop these state-based and local innovation models with input from, and in collaboration with, state medical associations as well. State medical associations work closely with physicians across different regions and areas within a state, and understand the needs of physicians and the patient populations, as well as the current gaps in care. As such, state medical associations provide a valuable perspective and insight into the development of these local models.

Medicaid programs provide support to some of the most vulnerable patients and sometimes provides a bridge between other government assistance and healthcare programs. As states gain more autonomy and variability in their execution of Medicaid programs, it will be important for these innovations to efficiently support patients who also participate in APMs, such as dual eligible beneficiaries. For example, dual eligible beneficiaries might require services from multiple APMs to provide a higher probability that the health care needs of that patient will be met. In these situations, the agency should develop policies that ensure and support coordination of care for the patient's totality of care to ensure payment across Medicare and Medicaid programs as appropriate.

## Program Integrity

CMS is seeking feedback on ways to reduce fraud, waste, and abuse, and improve program integrity, taking into consideration the need to find the balance between patient and physician burden and effectiveness of the review. These elements could be tested as part of a new model, or layered on top of other models. PAI believes that program integrity is of utmost importance, however, there must be consideration of the physician burden required to ensure that the time they dedicate to their patients' care is not hindered or decreased by burdensome reporting and compliance requirements.

PAI believes that future model elements aimed towards program integrity should be developed with the following considerations:

- The importance and need to rely on empirical data from the program to support significant changes that could have a substantial impact on physicians' reimbursements.
- The need for clear guidance and specifications on the documentation required in the case of an audit under a specific model.
- The need for adequate time for physicians and other clinicians to respond to requests from the agency, with adequate notice of the issue and information being solicited in the response to an audit or other program integrity-related request.
- The need for a symmetrical review and appeal process.

Furthermore, there needs to be an assurance that the data being posted publicly or supporting any program changes is verified, accurate, and validated. Without transparency and data from the program, it is challenging to affirmatively support changes that could put physicians at risk for greater potential losses.

## Do you have suggestions on the structure, approach, and design of potential models? Please also identify potential challenges or risks associated with any of these suggested models.

PAI believes that a potential design element of a future model which could be challenging for physicians and clinicians, as well as for implementation and adoption, is an element specifying the technology that must be used, for example, CEHRT. There are several issues that are related to this design element that the agency should take into consideration as it develops new models.

First, many physicians and other clinicians in small practices may not have the financial resources to acquire a specific technology or related component, for example, an upgrade for a technical capability for their existing technology. As discussed above, it is important to build new models that provide opportunities, not create obstacles, for participation of solo practitioners and small practices.

Second, physicians and other clinicians should not be penalized under model requirements for actions that are essential or the responsibility of the vendors providing or developing the technology. Physicians are often unjustly penalized for reliance on vendors and trusting that their vendors will become certified, maintain their certification, and appropriately submit their data to CMS on their behalf. Many vendors have delayed their updates and continue charging practices exorbitant fees for these updates, even when they are delayed or not completed. The agency must hold vendors accountable for compliance with program requirements.

Additionally, PAI encourages the agency to consider developing a “Vendor Compare” that would publicly report vendor capabilities, APMs their products can support, and vendor data and error rates, just as physicians and other clinicians participating in the payment models and the QPP are held accountable for their performance on Physician Compare. This would allow physicians and other clinicians who participated or are interested in participating in a specific model to evaluate the vendor that would be most appropriate for them under a specific model. Further, they could select a vendor that is aligned with them on their goal to contribute to improving patient care and experiences through technological advancements and efficiencies.

## Are there any other comments or suggestions related to the future direction of the Innovation Center?

PAI believes that as future models are developed, it is important to remove barriers and ambiguity regarding model participation and opportunity to benefit from optimal payment. PAI specifically supports extending, as appropriate, the application of the Federal Trade Commission (FTC) and Department of Justice (DOJ) Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (MSSP) to the entities under the potential models. This policy statement provides clarity on antitrust issues and guidance on forming procompetitive ACOs. The policy statement applies a rule of reason analysis to determine if an ACO is likely to have anticompetitive effects, and if so, whether its efficiencies are likely to outweigh those effects. PAI believes that entities under potential models will likely incur and have to address similar antitrust issues, and it is important that these be resolved at the beginning rather than mid-year, and create an obstacle to participation.

Furthermore, the agency should also be mindful of other laws and regulations that could be impediments or obstacles participation in potential models, and that appropriate exemptions should be extended and applied, for example, Stark Law exemptions that are similar to those for group practices.

## Conclusion

Overall, PAI supports CMS’s efforts to develop new models that provide greater opportunities and incentives for physicians, other eligible clinicians, and patients, centered around the core guiding principles and the objectives outlined by PAI. PAI and the medical associations represented on the PAI Board of Directors welcome the opportunity to work with the agency to further develop and implement potential payment models in a meaningful and impactful way.

If you have any questions, please contact me at [rseligson@ncmedsoc.org](mailto:rseligson@ncmedsoc.org), or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at [k2strategiesllc@gmail.com](mailto:k2strategiesllc@gmail.com).

Sincerely,



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