



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, SW, Mail Stop 314G
Washington, DC 20201

For electronic submission to CMMI_NewDirection@cms.hhs.gov

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), we commend the Centers for Medicare & Medicaid Services (CMS) for recognizing the need for a new direction for the Center for Medicare and Medicaid Innovation (CMMI), and for soliciting input from the AMA and other stakeholders before determining what that direction should be.

Alternative payment models (APMs) can provide significant opportunities for physicians to improve the quality and outcomes of their patients' care in ways that also lower growth in Medicare and Medicaid spending. Many patients develop health problems that could have been prevented, receive tests and procedures that are not needed, are hospitalized because their health problems were not effectively managed, or experience complications and infections that could have been avoided. Other patients could receive different types of treatment than they do today, or be treated in different sites of service, that would be equally effective but cost less. If these avoidable health problems, services, and costs could be eliminated, billions of dollars could be saved and patients' quality of life improved. It is critical that physicians be involved in designing APMs because only physicians can ensure that alternative ways of delivering services will safely and appropriately address patient needs and not produce savings by delivering lower quality care.

The AMA knows of many physicians and medical societies who have developed ways of providing higher quality care to patients while lowering spending by Medicare and other payers. All too often, however, these desirable changes in care delivery cannot be implemented due to barriers in the current payment systems. The two most common barriers are:

- **Lack of payment or inadequate payment for high-value services.** Medicare does not pay physicians for many services that would benefit patients and help reduce avoidable spending, such as: responding to patient phone calls about new symptoms or problems; communicating with other physicians about patients' diagnosis, treatment planning, and care coordination; and proactive outreach to high-risk patients to ensure they get preventive services.

- **Financial losses for improving health and eliminating unnecessary services.** Most of the savings from improved care delivery will come from reducing avoidable utilization of hospitals, tests, medications, and post-acute care. Yet under current Medicare payment systems, if physicians keep patients healthy or successfully prevent disease progression and complications, their fee-for-service revenues will be lower, which may leave them with insufficient resources to continue providing high quality care and cover their practice costs.

The AMA has strongly and consistently supported the creation of APMs that will overcome these barriers. We have conducted numerous education programs about APMs for physicians across the country and provided technical assistance to physician practices and medical specialty societies in developing APMs.

Unfortunately, seven years after the CMMI was launched, most physicians still do not have the opportunity to participate in an APM that can provide them with the resources and flexibility they need to deliver better care to patients at lower costs. The 2017 Quality Payment Program final rule indicated that about five percent of clinicians would be qualified APM participants in 2017, and the forecast for 2018 is similar. The AMA welcomes the new direction for CMMI because we are convinced that it can implement more and better APMs more quickly and effectively than it has to date.

The balance of this letter recommends that 11 strategies be adopted by CMMI to design and implement new APMs consistent with the guiding principles outlined in the Request for Information, and discusses the AMA's perspective on the list of potential models.

Strategies for Design and Successful Implementation of APMs

The AMA supports the list of guiding principles in the Request For Information (RFI). We would welcome development and implementation of new APMs that would help to promote market choice and competition, allow physicians to voluntarily choose to participate in new models, harness ideas from stakeholders, and utilize small scale testing. We recommend that CMMI deploy the following strategies to achieve these objectives:

1. Support Physician-Driven Approaches to Innovation in Patient-Centered Care

To date, CMMI has taken a primarily top-down approach to designing APMs, and most of these APMs are designed for implementation by large provider organizations and health systems, not small and medium size medical practices. We recommend that CMMI shift to a bottom-up approach that welcomes APMs designed by physician organizations and encourages models that are feasible for most physician practices to implement. Since Congress created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to encourage the development of physician-focused APMs, CMMI should make a commitment to test or implement every APM that the PTAC recommends.

2. Provide Adequate Payments to Support High-Quality Care and Limit Accountability to Aspects of Quality and Cost That Physicians Can Control

Too many of the APMs developed by CMMI have failed to provide the resources physicians need to deliver new types of services, and they inappropriately transfer insurance risk to physicians. Physicians tell us that they are willing to take accountability for the aspects of spending and quality they can control

or influence if they have adequate resources and flexibility to deliver high quality care in the most appropriate settings. Physicians are willing to participate in APMs that hold them accountable for decisions on the appropriateness of tests they order, procedures they perform, medications they administer, and whether patients are discharged to their homes or to expensive facilities, but they are not willing nor should CMMI expect them to take risk for things they cannot control, such as the prices of drugs and biologics or the severity mix of their patient population. Most Medicare spending does not go to physician services, so increasing physicians' financial risk for Medicare spending on hospitals and drugs will be a major barrier to increasing their participation in APMs.

3. Eliminate Unnecessary Administrative Burdens in APMs and Waive Regulatory Impediments

We commend CMS for acknowledging the need to reduce burdensome requirements and unnecessary regulations. Many of the concerns that we hear from physicians about the current payment system have more to do with administrative and regulatory burdens than with payment rates. Prior authorization, certification, documentation and reporting requirements, and electronic health record systems that do more to hinder than support patient care are enormously burdensome. In developing APMs, CMS should take maximum advantage of opportunities to lessen these burdens by waiving unnecessary and problematic requirements in existing payment systems. CMMI should not include new administrative requirements in APMs unless it can be shown that they are essential. Before any administrative requirement is imposed, potential participants in the APM should be given the opportunity to suggest less burdensome approaches to achieving the same goal, and then the APM should provide participants with adequate resources to cover the costs of implementing any administrative requirements. If potential participants in a payment model identify regulatory barriers to success, CMS should use its waiver authority to modify or eliminate these barriers. For example, endocrinologists face burdensome certification requirements to allow their patients with diabetes to obtain diabetic shoes. Allergists face numerous prior authorization and step therapy barriers to their patients with asthma receiving appropriate medications. Stark law prohibitions on certain types of referrals prevent linking payments to the volume of certain services, even if participating physicians reduce the volume of avoidable tests and other services. Also, payments cannot be tied to the value of services, such as the value derived from adherence to clinical protocols that shift patients from higher cost, less efficient inpatient rehabilitation facilities into high quality, lower cost outpatient settings.

4. Require Use of CEHRT Only If It Has the Functionality Needed for the APM

Too many physicians have found that instead of helping them to deliver higher-quality, more coordinated care, certified electronic health record technology (CEHRT) is reducing the time they can spend with patients and increasing their administrative costs. CMS should only require physicians and other providers to use CEHRT as part of APMs if CMS has verified that CEHRT can, in fact, deliver the information needed by participants in the APM efficiently, effectively, and at an affordable cost. APMs should be encouraged to leverage technology to support the goals of the APM and help participants improve communication, patient engagement, collaboration, diagnosis, treatment planning, and quality. While CEHRT supports some basic, fundamental functionality to help APMs achieve their goals, it is our experience that CEHRT often needs to be enhanced or supplemented before true usefulness is fully realized. Any CEHRT requirement must also provide sufficient flexibility as to recognize custom functionality that "builds on" CEHRT—a concept taken directly from one of CMS' priorities for new Advancing Care Information measures in the Quality Payment Program (QPP). Often, these additional enhancements are layered on top of CEHRT—creating a new and improved experience for patients and

their care team—and is a greater return on investment than the original purchase of the EHR. The effort and value of refining the EHR experience based on patient and physician need should be rewarded by CMS. Going forward, CMS and the Office of the National Coordinator for Health Information Technology should take greater responsibility for proactively ensuring that CEHRT includes the capabilities physicians need to enter, retrieve, share, and analyze clinical data in APMs.

5. Encourage Multiple Choices for Delivery of Patient-Centered Care

The AMA agrees with CMS that patients and their families and caregivers should be empowered to take ownership of their health and to have the flexibility and information needed to make good choices about the care they receive, but patient choice cannot be successful unless there are multiple good options for care they can choose among. Rather than trying to determine a single “best” approach to care delivery or payment, CMMI should proactively plan to test multiple approaches. It should encourage physicians to propose the types of improvements in care and payment that make sense for the patients they treat in the specific environment where they practice. We also agree that CMMI APMs should be voluntary. Physicians should be given the choice of which APM they would like to participate in or whether they want to participate in an APM at all.

6. Enable Implementation of a Diverse Array of New Models

We were pleased to see the principle on “Small Scale Testing” included in the Request for Information (RFI). When an APM is designed to support significantly different ways of delivering patient care, the payment amounts, risk stratification factors, and performance measures must be based on the new approach to care delivery, not the current approach. However, it is impossible for physicians to accurately determine the costs or outcomes of a new approach to care delivery without actually implementing it, and that requires having a payment model that will support the new approach. Firms in other industries have addressed similar challenges by developing methods for “rapid prototyping” of new products, and we believe CMMI needs a similar process for APMs. CMMI has already demonstrated that it can support an array of small-scale projects through the two rounds of Health Care Innovation Awards, so it should be feasible to implement multiple limited-scale APM tests each year.

7. Refine and Improve Promising APMs Over Time

CMMI has implemented most APMs using a single-step testing and evaluation process, i.e., it decides how an APM should be structured, implements it for several years, and terminates the APM if it has not demonstrated statistically significant savings. Only one model has been expanded under this approach, so it is clear that a different paradigm is needed. Physicians, hospitals, and other health care providers cannot fundamentally change the way they deliver care in response to temporary payment changes. In addition, significant changes in care delivery typically take at least one to two years to implement, so it is not surprising that CMMI has not found sufficient justification in its evaluations of 3-year demonstration projects to expand other APMs and make them available to all physicians and patients. In our view, it is unlikely that either CMMI or stakeholders developing APMs can determine how a successful APM should be designed before it has ever been tried. Instead of trying to assess whether particular APMs “work” after only a few years, CMMI should assume that every APM will need refinement. CMMI should focus, therefore, on rapid-cycle improvement and formative evaluation. Then, if an initial prototype seems to be working on a small scale, the APM can be implemented on a broader scale and a formal, summative evaluation can be conducted. CMMI has statutory authority to modify the design and

implementation of models after testing has begun, so we urge CMMI to use a multi-step process for developing and implementing APMs, beginning with limited-scale testing and then refining and expanding promising APMs over an extended period of time.

8. Establish and Meet Deadlines to Test CMMI and Stakeholder Developed Models

CMMI has imposed aggressive deadlines on applicants for submitting applications and reports, but the agency takes 18-24 months to carry out its complex internal process of deciding whether and how to test a payment model. The entire process should be redesigned to enable limited-scale tests of APMs to be implemented within 6 months following submission of a detailed proposal and broader-scale tests to be implemented within 12 months. We are particularly concerned that there seems to be no pathway or timeline for stakeholder developed APMs to be tested by CMMI, and no integration between the PTAC process and CMMI such that APMs recommended by the PTAC can be tested or implemented. We urge CMMI to develop a transparent process with reasonable deadlines for implementing APMs that are recommended by the PTAC.

9. Help Physicians Obtain the Data and Analytic Support Needed to Design and Implement APMs

CMS needs to create more effective and user-friendly mechanisms through which physicians can access and analyze CMS claims data and provide financial support to physicians to help them gather and analyze relevant clinical data that is not contained within claims data.

One of the greatest barriers physicians face in designing and implementing new approaches to care delivery and payment that will reduce Medicare spending is their inability to obtain data on the full range of services their patients are receiving today. Most of the savings from improved care delivery come from lower spending on services such as hospital admissions and post-acute care that are not delivered directly by physicians, and some of the biggest opportunities for improved care coordination come from avoiding duplication and conflicts with services delivered by other providers. Physicians do not have access to information about the other services their patients are receiving that would enable them to identify and quantify opportunities for savings or take action to achieve these savings.

APM developers also need assistance with technical issues such as risk stratifying patients and risk adjusting payments. The risk adjustment methodologies used in the Medicare and Medicaid programs to date are designed to address differences in patient needs among large populations associated with a health plan or hospital. These methods cannot be appropriately transferred for use in risk adjusting payments associated with medical practices or with a particular condition. Current risk adjustment methods, for example, do not take into account patients' stage of disease, functional status, whether they have a caregiver at home, and social factors. Factors like these can have a significant effect on treatment plans, adherence, patient outcomes, and health care costs, but it is expensive and time-consuming for physician practices to collect these data, particularly given the limitations of current EHR systems.

We recommend that CMMI seek information from specialty societies about the specific types of services where they think savings are possible through an appropriately-designed APM. CMMI should then create mechanisms for providing Medicare claims data and analyses regarding those services to physicians in that specialty who are developing APMs. CMMI should also compensate physician practices that are willing to collect the types of data that would help in the design of better risk adjustment methods that can be used for APMs.

10. Digital Medicine Tools (Telehealth, Remote Patient Monitoring)

The AMA recommends that CMMI seek proposals to test APMs and demonstrations that extensively utilize digital medicine services and tools including telehealth and remote patient monitoring. (CMMI has the authority to waive Medicare telehealth requirements as part of its efforts to implement and test these models but it has only done so on a limited basis to date.) The need to scale patient-centered services by leveraging new technologies that enhance the quality of virtual interactions between patients and the health care team and that organize relevant patient data, including physiologic, to support targeted management of chronic conditions and rapidly manage acute events by the health care team is essential as clinician shortages persist and the size of the Medicare eligible population grows. This technology can also be used for e-consults to help address deepening specialty shortages and geographic mismatches between specialists, patients, and patients' established medical teams which hamper access and undermine efficient and high quality care. As detailed in the Government Accountability Office April 2017 Report to Congressional Committees: *Telehealth and Remote Patient Monitoring Use in Medicare and Selected Federal Programs*,¹ CMS has several models and demonstrations underway that include waivers of primarily two telehealth statutory limitations: the geographic or originating site restrictions. We recommend that CMS seek proposals to test waivers of multiple restrictions including: (1) waiver of both the geographic and originating site restrictions for telehealth services already covered by Medicare; (2) waiver of all telehealth and remote patient monitoring restrictions for dual eligible beneficiaries consistent with telehealth and remote patient monitoring benefits offered in states to their Medicaid-only beneficiaries; and, (3) waiver, at a minimum, of the telehealth geographic and originating site restrictions and any remote patient monitoring restrictions for one-sided risk accountable care models.

Testing these waivers would provide critical information to address both cost reduction and/or improved quality of care. First, larger scale testing of waivers of geographic and originating site restrictions are needed to adequately evaluate whether telehealth services are cost neutral or cost saving. Although the Veterans Health Administration beneficiary population is much smaller than the number of Medicare beneficiaries, VHA has successfully deployed telehealth and remote patient monitoring services to a far larger number of beneficiaries with documented improved health outcomes and lower cost. Congress and CMS continue to limit telehealth services due to the paucity of telehealth claims in the Medicare program even though an array of clinical services have been evaluated by CMS and determined to be clinically appropriate when delivered via telehealth. Second, because dually eligible patients account for a disproportionate share of the expenditures, the AMA agrees with CMMI that a fully integrated, person-centered system of care that ensures that all their needs are met could better serve this population in a high quality, cost-effective manner. Digital medicine tools that focus on a host of integrated technologies that enable virtual care, including two-way audio visual communications in patients' homes, and access to the health care team through virtual communications and specialists, will overcome geographic barriers that could inhibit essential specialty care, facilitate digitization and documentation of encounters that will help patients, medical homes, and caregivers coordinate and ensure follow-up care.

11. Prevention

The one model that was expanded nationwide after being tested by CMMI was a model focused on preventive care, the Diabetes Prevention Program (DPP). The AMA recommends that CMMI build upon

¹ As of April 2017, CMS was supporting eight models and demonstrations that have the potential to expand the use of telehealth in Medicare.

this model by initiating other models focused on improving access to preventive services. CMMI should also implement the online/virtual model of the DPP to bolster the available evidence confirming that virtual program participants reach the outcomes seen in the in-person model. The AMA urges CMMI to proceed expeditiously, as we are concerned that the current access and availability of the in-person DPP is limited and non-existent in certain markets.

Another example of a preventive model that the AMA would encourage CMMI to pursue is a model test of a self-measured blood pressure (SMBP) program. Clinical guidelines recommend utilization of SMBP to confirm the diagnosis of hypertension (in part, to rule out white coat hypertension, which does not require treatment with medication) and for the monitoring of control of diagnosed hypertension. Economic modeling has demonstrated that implementation of a SMBP program in a commercial population results in a net savings of \$33 to \$166 per member in the first year and from \$415 to \$1364 over 10 years.² Currently, Medicare does not cover home blood pressure monitoring devices for patients. AMA recommends a model test of SMBP, including coverage of the home blood pressure device as well as reimbursement for clinical team time to educate patients on proper use of their device, physician time for interpretation of SMBP results, and physician time for adjustment of medication therapy. AMA believes that it is likely that CMS would observe an improvement in blood pressure control rates, an improvement in accurate diagnosis of hypertension, and overall cost savings for Medicare with implementation of such a model.

Focus Areas for APMs

We have a number of comments regarding the eight focus areas proposed in the RFI:

1. Expanded Opportunities for Participation in Advanced APMs

Participation in current Advanced APMs has been limited because of the limited number of such APMs and the problematic designs of the existing Advanced APMs. A primary focus of CMMI should be the development and testing of new, physician-focused APMs using the strategies articulated above. We recommend that CMS modify its regulations to allow a much larger number of the APMs being tested by CMMI to qualify as “Advanced” APMs. Practices that participate in APMs that involve delivering care in new ways with new payment methods are inherently incurring significant financial risk to do so. The current standards for quality measures, CEHRT use, and financial risk criteria to qualify as an Advanced APM set the bar unnecessarily high.

2. Consumer-Directed Care and Market-Based Innovation Models

We support empowering consumers to drive change through the choices they make, but this can only be effective if there are good choices for consumers to make. Encouraging physicians to develop innovative care delivery models and payment models and implementing them quickly will give consumers multiple good choices for care delivery, rather than a choice between the current system and one APM.

In many cases, higher-quality care will be less expensive. However, for some patients, better outcomes can only be achieved with additional services or more intensive services that will involve higher costs, at

² Alejandro Arrieta, John R. Woods, Nan Qiao, Stephen J. Jay. Cost–Benefit Analysis of Home Blood Pressure Monitoring in Hypertension Diagnosis and Treatment: An Insurer Perspective. *Hypertension*. 2014;64(4):891-6.

least in the short run. We support testing of models in which physicians have the ability to deliver more or different services to patients who need them and to be paid more for doing so. Moreover, a portion of this testing could be done through models in which patients' responsibilities for costs are determined differently than they are today. For example:

- Allowing patients to contract directly with physicians and physician-led teams to deliver the care they need, with Medicare contributing what it would have expected to spend under the current payment system and the patient paying the difference.
- Allowing patients to receive care from "direct primary care" practices, where the patient pays the practice and is reimbursed by Medicare.
- Allowing physicians to define a team of providers who will provide all of the treatment needed for an acute condition or management of a chronic condition, and then allowing patients who select the team to receive all of the services related to their condition from the team in return for a single pre-defined cost-sharing amount.

While the AMA supports transparency of cost and quality data, we discourage CMMI from making this an initial primary focus due to the complexities around public reporting of data and the measurement science that supports it. Rather, the focus should first be on adoption, testing, and refinement of APMs. Otherwise, CMMI runs the risk of releasing information about APM entities that is inaccurate and could lead patients to make inaccurate inferences about cost and quality. Once APM models are stable and practices have had at least three years' experience with implementing an APM, then CMMI should focus its attention on releasing cost and quality information to the public about APMs. If CMMI moves forward, we recommend that the following public reporting standards be put in place:

- *Appeals Process and Preview Period:* Prior to publicly releasing cost and quality data, APM entities must have a 90-day preview period to review their data and contest any inaccuracies with the data. And if an entity files an appeal and flags their demographic data or quality information as problematic, CMMI should postpone posting the information until the issues are resolved.
- *Ensure Statistical Reliability and Validity:* We request that CMMI be transparent with what it considers acceptable reliability for public reporting and measuring performance so measure stewards can develop and test their measures appropriately. As CMS states in the Physician Compare section of the 2018 QPP proposed rule, "high reliability for a measure suggests comparisons of relative performance across entities, such as [eligible clinicians] ECs or groups, are likely to be stable and consistent, and that the performance of one entity on the quality measure can be confidently distinguished from another." The AMA strongly agrees with this statement and encourages CMMI to adopt the same standards when it comes to publicly posting data on APMs.
- *Allow APM Entities Three Years to Report on Measures Prior to Public Reporting:* Including measures after one year of reporting does not allow CMMI to adequately evaluate meaningful trends over time or provide APM entities or physicians with an adequate period to fix data collection issues. Allowing physicians three years to report on measures prior to posting measure data on Physician Compare or publicly releasing the information will improve the chances that only robust and meaningful data is included on the web.

3. Physician Specialty Models

CMMI's highest priority should be expanding the availability of APMs in which specialists can successfully participate, including additional and expanded APMs for primary care specialists. Instead of CMMI defining such payment models itself, the agency should commit to implementing condition-specific APMs that have been developed by physicians and medical specialty societies and recommended by the PTAC. There are many specialty societies currently working on physician-focused payment models, including: the American Academy of Family Physicians, American Academy of Hospice and Palliative Medicine, American Academy of Neurology, American Association of Clinical Endocrinologists, American College of Allergy, Asthma, and Immunology, American College of Emergency Physicians, American College of Radiation Oncology, American College of Rheumatology, American College of Surgeons, American Gastroenterological Association, American Society of Clinical Oncology, American Society of Radiation Oncology, and others. CMMI could accelerate these efforts and encourage similar efforts by other specialty societies if it would provide them with access to Medicare claims data and commit to implementing the APMs they develop after they are approved by the PTAC.

4. Prescription Drug Models

High prices and price increases for many prescription drugs are causing serious problems for both patients and the Medicare program, and better ways of controlling prices are needed. However, CMS should not attempt to control the prices of drugs by shifting the risk for spending on drugs to physicians under APMs. Physicians are willing to be accountable for using drugs that are appropriate for their patients and for using lower-cost choices among drugs that are equally effective, but they must not be penalized for prescribing the most effective drugs for their patients simply because of their cost.

5. Medicare Advantage Innovation Models

Despite the fact that Medicare Advantage plans have the flexibility to pay physicians differently, most of them pay physicians and other providers using standard fee-for-service systems. When they do implement APMs, they often use different quality measures, attribution systems, risk adjustment formulas, and other components than other payers do, which increases administrative burdens for physicians. Although CMS has tried to encourage multi-payer participation in some of its APMs by selecting states and regions where payers other than CMS are willing to participate, this makes it impossible for physicians to participate in a CMS APM if they are located in a region with high MA penetration where the MA plans are unwilling to participate. We recommend that CMMI reverse the approach—it should allow willing physicians to participate in an innovative APM even if only Medicare patients participate in it, but then both CMMI and the participating physicians should encourage Medicare patients to choose a health plan (whether it be an MA plan or traditional Medicare) that pays physicians using an APM that supports effective care.

6. State-Based and Local Innovation, Including Medicaid-Focused Models

We recommend that in states or regions where physicians have developed and implemented innovative APMs with their local payers in order to support better approaches to care, CMS should agree to participate in these multi-payer models and align itself with the approach that was agreed to locally. This was done in five states in 2011 for the Multi-Payer Advanced Primary Care Practice initiative. We recommend that CMMI announce its willingness to participate in similar locally-generated multi-payer initiatives in the future. In addition, when the Innovation Center implements an APM, it should automatically grant state Medicaid agencies approval of any State Plan Amendments needed in order for Medicaid payments to be made consistent with the APM.

7. Mental and Behavioral Health Models

Better models for delivery of behavioral health services require APMs that support new approaches to care delivery. Physician practices and specialty societies, such as the American Society of Addiction Medicine (ASAM) and the American Psychiatric Association, are already working on such APMs. As a component of our efforts to help bring an end to the epidemic of opioid overdose deaths, the AMA has been working closely with ASAM to develop a physician-focused APM for managing the treatment of opioid use disorder. As CMS knows, the opioid epidemic is widespread, growing rapidly, and has overtaken many other leading causes of death. The treatment model for opioid use disorder requires interventions that address its medical, psychological and social components, including medication-assisted treatment. The ASAM model aims to broaden coordinated delivery of the full spectrum of services needed for treatment, improve transitions to outpatient care for patients discharged from more intensive levels of care, and reduce the number of avoidable emergency department visits and hospitalizations. Payments under the model would support an evaluation, diagnosis, treatment planning, and treatment induction phase, followed by a maintenance phase. Patient-centered, comprehensive, and collaborative treatment plans would cover care from induction through stabilization, treatment, and long-term recovery. It would also support more intensive management when warranted by special circumstances such as a relapse, comorbidities, or a patient choosing to discontinue the medication. Payments under the model would be adjusted based on performance on outcome measures. The AMA urges CMMI to help advance this model so that it can be tested, and to support similar models for patients that need a range of biopsychosocial services.

8. Program Integrity

The AMA is firmly committed to eliminating fraud, waste, and abuse from health care. However, broad brush requirements that impose burdens on physicians, rather than focusing on those providers who have demonstrated a propensity to commit fraud or abuse, inequitably affect responsible physicians and providers making it more difficult for them to deliver care to their patients and adding unnecessary administrative costs to the health care system.

As it relates to CMMI, the AMA is supportive of the fraud and abuse waivers, and would urge for the continuance of these waivers in current and future models. In developing future waivers, AMA would prefer broad waivers without any technical requirements that require a fact-intensive analysis. Greater flexibility is needed to allow for proper testing of innovative models. Detailed technical requirements can hinder participation in models because physicians will not participate due to concerns about not perfectly adhering to the terms of the waivers and the incorporated participation agreements. CMMI should

consider lesser administrative sanctions for potential violations to allow for the ability to correct issues when they are identified (e.g., failure to post an arrangement on a website).

Additionally, to increase program integrity, CMMI should promote consistency by creating a template or model fraud and abuse waivers that will generally apply to future models. Currently, the waivers' requirements vary by model. This may lead to provider confusion and may make it more difficult to manage a growing portfolio of models. When contemplating template waivers, CMS should consider examining the pre-participation and participation waivers in the Medicare Shared Savings Program.

CMMI may also want to consider creating a new program integrity model based on provider screening to identify more sophisticated physicians and providers who are already in compliance with all program requirements. Once the providers have passed this check and agreed to certain program integrity measures in a participation agreement, the providers operating under the model could be allowed to provide identified health care services with the necessary fraud and abuse waivers to provide innovative and cost-saving care. Similar to the Transportation Security Administration Pre-check program for air transportation, physicians in this model would have more flexibility in their use of waivers than those who have not gone through the pre-screening process. This screening should be focused on how providers are already preventing and monitoring for fraud, waste, and abuse, and corrective actions could include an appropriate compliance program based on the provider's resources and size. As part of the screening, CMMI could also use claims data to identify aberrant claims, cross reference such claims with other data sets to recognize potentially fraudulent or abusive activity by physicians, and work with the Office of Inspector General to develop fraud risk scores. These types of comparisons need to take sub-specialization and patient mix into account. When a provider is identified based on aberrant behavior or if an audit identifies potential errors, CMMI should work with the provider to understand the reasons why the provider was identified, and if there are problems, CMMI should educate the provider or take other appropriate, corrective actions. The goal of this model should not be to punish physicians for billing errors or technical flaws.

CMMI also requests information regarding how program integrity should be layered upon models. The participation agreements already have many program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming. The very design of the waivers is premised on the expectation that the requirements of the Participation Agreement promote program integrity and mitigate risks of fraud and abuse. For example, Participation Agreements generally require participant screening by CMS for program integrity issues prior to and during program participation; certification of completeness, truthfulness, and accuracy of virtually all data generated and submitted to CMS; patient protections including notice and freedom of choice; a compliance program with reporting of any probable violation of fraud; and enhanced CMS monitoring through identification of all participants, site visits, and multi-year maintenance of record provisions. Thus, program integrity is already layered on top of every model and provides greater assurance of program compliance and monitoring capabilities than providers operating outside of the models.

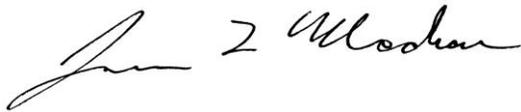
Conclusion

The most successful examples of innovative payment and delivery reforms around the country were generated through a partnership between the purchasers and providers of care. We urge CMMI to find ways to work more collaboratively with physicians and physician organizations, not only to design specific payment models, but to create a more effective process for supporting the design and implementation of such models.

We recommend that CMS publicly post all of the comments it receives in response to this Request for Information and also detail its reactions and responses to those comments. If there are barriers that CMMI faces in implementing ideas that it believes have merit, we would encourage the agency to inform stakeholders about those barriers and to seek help in overcoming them.

Thank you for the opportunity to comment. If you have questions, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, stylized initial "J".

James L. Madara, MD