

March 16, 2015

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

Re: Request for Information on Advanced Primary Care Model Concepts

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to this Request for Information (RFI) from the Center for Medicare and Medicaid Innovation (CMMI) of the Centers for Medicare & Medicaid Services (CMS). The AMA appreciates CMS' efforts to obtain input on the design of the next generation of advanced primary care models, to improve the delivery of patient-centered care and population health.

CMS Background Information, CMS Questions, and AMA Responses

SECTION I: INFORMATION REGARDING ADVANCED PRIMARY CARE MODEL CONCEPTS

The next generation of advanced primary care model(s) could test moving payment for primary care services from encounter-based, or encounter-based with care management fees (as is being tested in the Comprehensive Primary Care Initiative), towards population-based (payment based on a practice's population of beneficiaries). Population-based payments (PBPs) could cover two components:

- (1) Severity-adjusted, non-visit based care management services, and
- (2) A portion or all of the expected, severity-adjusted fee-for-service (FFS) payment for a basket of services provided in primary care. ("rolled-up FFS")

With PBPs, services billed by primary care practices that are not included in the basket would continue to be paid via FFS. Practices that receive only a portion of expected FFS payment for the basket through "rolled-up FFS" would continue to receive traditional FFS payment for billed services in the basket, but at a rate reduced by the amount of the "rolled-up" portion (e.g., if a practice elects to receive 50 percent of expected FFS for the basket in "rolled-up FFS," then traditional FFS payment for billed services in the basket would be reduced by 50 percent). Practices could also be accountable for clinical quality metrics, patient satisfaction, and the total cost of care.

SPECIAL NOTE TO RESPONDENTS: Whenever possible, respondents are asked to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

SECTION II: QUESTIONS

- 1. Please comment on the above description of PBPs [population-based payments] in terms of (a) the impact on the delivery of advanced primary care and (b) primary care practices' readiness to take on such arrangements.**

PBPs could provide support and flexibility for advanced primary care (APC) practices to manage the health of their patient populations and provide services such as care management and consultation with specialist physicians that are not covered in the traditional payment system. To be successful, PBPs should be designed in a way that allows practices to plan and budget ahead of time and does not add to physicians' administrative burdens.

APC practices receiving PBPs should not be asked to take accountability for the total cost of care for their patient population. Instead, the practices should work with payers to identify cost and quality performance metrics that they can reasonably be expected to influence, and then they should be held accountable for achieving these savings and improvements in care. For example, an APC practice should not be held accountable for the occurrence of an epidemic of infectious disease, but they could be held accountable for immunizing their patients, appropriately treating those who get sick, and achieving the cost savings that are linked to high immunization rates. In other words, APC practices can be asked to take responsibility for performance risk but not for insurance risk.

We urge CMS to build upon the work that is already under way to develop new APC models, including the Patient-Centered Primary Care (PCPC) payment system developed by a group of primary care physicians, specialists, employers, unions, and health plans in West Michigan with assistance from the Center for Healthcare Quality and Payment Reform. In this model, a primary care practice could elect to be paid under the PCPC system rather than the current system. The PCPC payment system has two components: a monthly "Core Primary Care Services Payment" for providing preventive services and chronic disease management, as well as "Service-Based Payments" for other services. For any group of patients who are enrolled and paid for under the PCPC payment system, a primary care practice could expect to see at least 50 percent of its revenues coming from the monthly Core Primary Care Services Payment. There are four different levels of the Core Primary Care Services Payment based on whether the patient has one of four chronic diseases (asthma, congestive heart failure, COPD, or diabetes) or significant risk factors. A primary care practice receiving the Core Primary Care Services Payment would commit to deliver high-quality care to patients as cost-effectively as possible, and the payment amount would be increased or decreased based on the practice's performance on quality and resource use measures. A PCPC would be paid additional fees beyond the Core Primary Care Services Payment, and patients would provide some cost-sharing, for office visits for acute issues, tests and procedures performed in the office, and office visits for non-enrolled patients.

Finally, the AMA urges CMS to retain the flexibility to allow appropriate physicians in specialties other than primary care to participate in this and other relevant alternative payment models. For example, the

APC models may be effectively used by practices that manage particular conditions or patient populations but are not in a primary care specialty.

2. What portion of the expected FFS payments for the basket of services would practices be interested in receiving via “rolled up” FFS?

The ability of a practice to move a proportion of its payments into a bundled or “rolled up” payment depends upon numerous factors specific to that practice as well as aspects of the new model. Practices should have the option to move further along a continuum up to 100 percent as they gain more experience with this reform.

3. What services should be included in the basket (e.g., all primary care Evaluation and Management (E&M) services; primary care E&M services based on certain diagnoses; primary care E&M services plus certain procedures; all services in primary care)? Please provide a rationale for the recommendation.

The PBP basket of services could potentially include all E&M and preventive services provided by the practice, identified by CPT® (Current Procedural Terminology®) and Healthcare Common Procedural Coding System (HCPCS) codes. Payment should also cover important services which are not currently payable, such as population health management, patient self-management support, care coordination and compacts with specialists, and quality improvement efforts. Other services should be outside the basket and separately payable. CMS may want to begin with particular conditions and gradually add more of them.

4. To what extent are primary care practices willing to be accountable for total cost of care?

Total cost of care includes both insurance risk and performance risk, where performance risk refers to those aspects of patients’ cost of care that the practice can influence. While physician practices may be equipped to manage performance risk, they should not be expected to manage insurance risk. In addition, currently there is not sufficient price transparency or utilization data available on the additional services that patients receive outside of the advanced payment models (APM). Physicians cannot be accountable for costs of care when those costs are not readily knowable. Practices’ ability and willingness to assume greater accountability for performance risk may be facilitated through the use of a risk corridor approach. The risk corridor could be narrowly defined at the beginning and grow wider over time as the practices gain more experience.

5. Through what mechanism should practices be accountable for total cost of care (e.g., savings paid or losses collected annually; withhold a portion of PBPs and pay/collect the difference between the withhold and savings/losses; modify (increase/decrease) future PBP amounts based on savings/losses; bonus/penalty)?

As noted above, total cost of care includes both insurance risk and performance risk, where performance risk refers to those aspects of patients’ cost of care that the practice can influence. While physician practices may be equipped to manage performance risk, they should not be expected to manage insurance risk. In the West Michigan model discussed above, there would be four levels of monthly core payments

depending on patient severity, i.e., the number of chronic conditions. These monthly payment amounts could be adjusted in subsequent months based on the practice's performance on quality and cost metrics.

6. What key challenges do primary care practices face in assuming financial accountability?

Inherent challenges for individual practices can include:

- Inadequate patient populations to cover their costs;
- Inadequate payment amounts to cover their costs;
- Lack of resources to cover care management and other support services;
- Risk adjustment methods that do not appropriately account for differences in patients' needs;
- Lack of control over the costs of other providers involved in the patient's care;
- Limited financial reserves;
- Narrow margins;
- Insufficient information about their patient population and financial benchmarks to allow proper planning and budgeting;
- Varying levels of ability to incorporate data into care delivery; and
- Varying levels of ability to adapt to changing technology and administrative and regulatory requirements.

Medicare payment, delivery, quality-reporting, and other policies pose additional challenges by failing to provide physician payments that keep up with inflation (and threatening annual cuts under the Sustainable Growth Rate (SGR) formula) and delivering an ever-changing array of quality reporting requirements under the Physician Quality Reporting System (PQRS), Meaningful Use (MU), and the Value-Based Payment Modifier (VBM). Assuming financial accountability also requires access to detailed data currently not available, regarding the costs of services and facility-based care, and utilization of services by each patient (as reflected in all-payer claims data).

a. What supports or mechanisms could assist practices in overcoming those challenges (e.g., limitations on total practice financial benefit or risk during reconciliation; exclusion of specified high cost beneficiaries during reconciliation; allowing pooling of risk among practices)?

As noted above, the use of risk corridors could allow practices to gradually accept greater degrees of accountability. Prospective determination of patient populations in the model and the financial benchmarks, as well as stability in quality measures, would also be helpful. CMS should also create a mechanism to inform the practice when a provider outside the practice checks a patient's Medicare eligibility, which allows the practice to know immediately that their patient is about to do something for which the practice can intervene to coordinate their care. Harmonization of quality measures among payers and programs would also go a long way to help practices meet these challenges. In addition, practices could better coordinate and improve patient care if the following waivers were adopted for APC models:

- The skilled-nursing facility (SNF) three-day stay rule, which requires Medicare beneficiaries to have a prior inpatient stay of at least three consecutive days in order to be eligible for Medicare coverage of inpatient SNF care;

- Medicare requirements for payment of telehealth services, such as limitations on the geographic area and provider setting in which these services may be received; and
- The homebound requirement for home health, which requires that a Medicare beneficiary be confined to the home to receive coverage for home health services.

The AMA also supports waiving the Medicare telehealth geographic restriction and originating site requirement for qualified APC Models. Studies show that certain medical services delivered via telecommunication technologies can be substitutable, cost effective, quality improving, and preferred by beneficiaries. An APC practice's infrastructure and team-based approach provide substantial patient protections. In addition, to ensure the appropriate use of telehealth services, an APC practice should be required to: outline a plan on how it will use telehealth services particularly to improve chronic care management; have a mechanism in place to electronically transmit a record of the telehealth encounter to the patient's primary care provider if the eligible telehealth provider is not the patient's primary care provider; and publicly post their use/approval of the waiver.

7. The move from FFS to PBPs could allow a revision of current medical documentation requirements. What elements of documentation could be revised to be consistent with PBP and not affect patient care negatively?

The successful implementation of APC models requires a fundamental restructuring and scaling back of Medicare's overly burdensome and unnecessary documentation and technical requirements with respect to pre-authorization of durable medical equipment; home health forms; prior authorizations; and other complex documentation that does not directly benefit patient care. In addition, CMS could significantly reduce documentation requirements for services that are included in the "rolled-up" payment as they would not be separately billed. CMS should also revise its documentation rules to allow for a more team-based model of care, so that staff and patients can complete portions of appropriate forms, with a notation confirming that the physician reviewed the information.

8. Practices caring for patients with complex needs—either the practice's full population or a subpopulation of its patients—could receive additional incentives and resources to deliver enhanced services to these patients, including better integration with social and community-based services, behavioral health, and other health care providers and facilities. What are the best methodologies to identify patients with complex needs (e.g., a claims-based comorbidity measurement (Hierarchical Condition Category scores, age, specific conditions, and/or JEN frailty calculation); a claims-based utilization measurement; attribution of a population of local beneficiaries without primary care utilization; and/or practice identification through a risk assessment tool and/or clinical intuition)? Please be specific in your responses and provide examples if possible.

Each practice must have accurate, timely patient-level data to assign patients to risk categories. The attribution process must be transparent, and there must be an avenue available for practices to question potentially missing or extraneous patients attributed to that practice. Under any approach to risk adjustment, information is needed about the characteristics of patients that would require more services or more expensive services to treat. This could potentially include: other diseases or medical conditions (i.e., comorbidities), including things such as tobacco use and obesity; severity of a particular disease or

condition; physical or functional limitations; and language barriers. The practices themselves should be involved in the risk adjustment process.

a. Is there a minimum number of patients with complex needs required for a practice to develop the necessary infrastructure and services to offer these patients?

Yes, but this should be up to the discretion of each APC practice.

c. What would the estimated costs be on a per-patient-per month basis to develop the necessary infrastructure and provide ongoing advanced primary care to these patients? Please provide justification to support these estimates.

These costs would depend on the number and severity of patients in the APC practice. Regarding infrastructure costs, there is growing concern that the cost of the MU program for many physicians far exceeds not only the maximum incentives offered under MU, but also the cost estimated by CMS to purchase and maintain an electronic health record (EHR). Furthermore, physicians have to incur significant expenses to update their EHRs, purchase additional software to share data, or perform other basic functions that many believed were included in the initial price of the system. More concerning is that many physicians are now incurring costs to replace EHRs that do not perform. A 2013 article published in *Health Affairs* found a negative return on investment for the MU program that, on average, amounted to a loss of \$43,743 over five years.¹ Also of note, the study found that the most common ongoing cost was physician time, which was reported by 22 percent of practices. Besides the cost of adopting and maintaining an EHR, there are additional costs associated with data exchange. Today, due to interoperability challenges, only 10 percent of physicians are moving data through a health information exchange (HIE).² Little is known about the cost for physicians to move data on HIEs, which varies by business model. There is also a lack of data available on the cost of using a Health Information Service Provider (HISP), an entity involved in the movement of health data, which can be part of a vendor, HIE, or stand-alone service.

The Government Accountability Office (GAO) found in its March 2014 report on EHRs:

Providers we interviewed reported challenges covering costs associated with health information exchange, including upfront costs associated with purchasing and implementing EHR systems, fees for participation in state or local HIE organizations, and per-transaction fees for exchanging health information charged by some vendors or HIE organizations. Several providers said that they must invest in additional capabilities such as establishing interfaces for exchange with laboratories or other entities such as HIE organizations. For example, many providers told us that the cost of developing, implementing, and maintaining interfaces with others to exchange health information is a significant barrier. One provider and several officials estimated various amounts between \$50,000 and \$80,000 that providers spend to establish data exchange interfaces. Other

¹ Julia Adler-Milstein, et al, "A Survey Analysis Suggests That Electronic Health Records Will Yield Revenue gains for Some Practices and Losses for Many," *Health Affairs*, March 2013.

² Julia Adler-Milstein, et al, "Operational Health Information Exchanges Show Substantial Growth, But Long-Term Funding Remains a Concern," *Health Affairs*, August 2013.

stakeholders we interviewed or who responded to HHS's March 2013 RFI also identified costs associated with participation in HIE organizations and maintaining EHR systems as a challenge for providers.³

d. What performance metrics are the most appropriate and meaningful to assess the quality of care for these patients?

CMS should align the various quality measurement programs that would apply to physicians in these APMs and to the APM as a whole. Physicians who are part of an APM should be able to satisfy their PQRS, MU, and VBM requirements through their affiliation with an APM. This is consistent with the approach of SGR repeal legislation introduced in the 113th Congress (H.R. 4015 / S. 2000), which aligns the reporting requirements of PQRS, MU, and the VBM into one single Merit-Based Incentive Payment System (MIPS), and exempts alternative payment models from its reporting requirements. If the purpose of an APM is to improve quality and care coordination while reducing costs, then physicians who are taking the steps to align themselves with an APM should not have to duplicate quality reporting requirements. CMS should also allow case-by-case changes in the quality measures it requires of individual APMs in order to align with measures required by commercial and Medicaid payers. Additionally, APMs should be allowed to propose quality measures directly related to the aspects of care delivery and cost containment they are focusing on, and avoid reporting on those that are irrelevant. This avoids having the APM spread its care transformation resources too thinly, and ensures that CMS is measuring quality in areas where beneficiaries have the most potential to be harmed by cost reduction efforts. Sociodemographic variables should be considered in risk adjusting any performance metrics, incorporating new data and medical conditions on a rolling basis, to ensure the accuracy of the scoring.

9. What data do practices need from payers to perform well and manage population health in a model that includes PBPs, financial accountability, and specified requirements for primary care delivery? Please be specific in describing helpful feedback or utilization reports in terms of timing, content (e.g., patient characteristics, services used, providers of services), and format.

An APM's success is dependent on the timely transfer of patient information and coordination of patient care. Since Medicare patients have the right to seek care from any provider who accepts Medicare, it can be a challenge for APMs to monitor the services received by their assigned patients. In the December 2014 proposed rule for the Medicare Shared Savings Program, CMS proposed including health status and utilization rates in aggregate data reports to ACOs. It is logical to presume these data would also be beneficial to APC models. In our comments on that proposed rule, we offered suggestions for including the following additional information in the data reports to ACOs, which should also assist APC models:

- Date of the beneficiary's original Medicare eligibility for Part A and Part B;
- Date of change in the beneficiary's eligibility status;
- An indicator identifying the change of an individual beneficiary's Health Insurance Claim Number (HICN), with the date of the change;
- HCC (Hierarchical Condition Category) score for each beneficiary;

³ GAO report (GAO-14-242), "Electronic Health Records HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones" March 2014.

- Opt-out information to the beneficiary attribution file to ensure members are not lost in the data reporting process;
- An indicator of a beneficiary's institutional/hospice status, to help identify domiciled patients; and
- De-identified claims data in the Claims and Claims Line Feed (CCLF), or, as a less preferred alternative, provide aggregated data on substance abuse claims expenditures.

CMS could also make eligibility checks from hospitals, emergency departments, and post-acute providers available to APMs, to offer a point-of-service notification system that would allow them to know when a beneficiary's eligibility is being checked by a provider and a near real-time opportunity to intervene appropriately to coordinate their care, redirect the patient to an appropriate setting, or engage with healthcare providers who may not be participating with the ACO. Daily edits data feeds could be leveraged to improve care processes and CMS could either provide these data directly to the APMs or make the files available to security-approved organizations for dissemination to APMs. CMS should also provide data related to substance use diagnoses and services in the monthly CCLF files, suppressing identifiable elements to protect beneficiary privacy. De-identified cost and claim data for these services could be provided, or at least the aggregate payment amount of these services in the monthly CCLF files.

10. What transformative changes to HIT—including electronic health records and other tools—would allow primary care practices to use data for quality measurement and quality improvement, effectively manage the volume and priority of clinical data, coordinate care across the medical neighborhood, engage patients, and manage population health through team-based care (e.g., transitioning from an encounter-based to a patient-based framework for organizing data; using interoperable electronic care plans; having robust care management tools)?

We appreciate that CMS is acknowledging that there are existing tools beyond EHRs and physicians are eager to take advantage of safe, high-performing technology. These tools could include but are not limited to mobile health applications, clinical data registries, and telehealth. The transformation of medicine is already well under way and driven by the rapid uptake and use of digital health products and the software that supports these devices. Unfortunately, the advancements in technology have outpaced the current regulatory scheme and physicians need to be assured that the technology they are using is indeed safe.

The AMA also supports efforts to increase regulatory flexibilities, especially in the requirements of the MU program, which are essential for innovation to occur.

We share CMS' belief that all patients, their families and their health care providers should have consistent and timely access to their health information in a meaningful format that can be securely exchanged. Health information exchanges are critical to the success of APMs, as it will facilitate the data exchange needed to coordinate care and help facilitate higher quality care. Physicians need highly effective and low cost tools and support to exchange information while protecting patient data in the digital age.

We are concerned, however, that the current data exchange environment largely facilitates the movement of data but lacks the necessary robustness to meet the needs of physicians and clinical staff. Although

there has been an increase in the exchange of patient information, the act of two computers sending and receiving data does not constitute functional interoperability—the ability for information to be exchanged, incorporated, and presented to a physician or other health care provider in a contextual and meaningful manner. It is the exchange, consumption, and use of medical information that is at the heart of interoperability. Additionally, other barriers persist, including cost-effective data exchange.

Interoperability must be a focus for the entire digital health system. EHRs must support and facilitate quality measure alignment between various sources and programs. They must have functional interoperability, beyond moving data from place to place, to exchanging, incorporating, and displaying information in a contextual and meaningful manner. This entails provider directories and patient matching, funding to coordinate standard terms and vocabularies, and identifying priority areas where interoperability achieves the most value.

- a. **In what ways, if any, could CMS encourage advanced primary care practices to implement innovative HIT tools (e.g., facilitate collaboration between HIT vendors and practices)?**

The AMA strongly urges CMS to refrain from tying the use of certified EHR systems to a physician's participation in alternate payment and delivery reform models of care. Given the high costs, lack of flexibility, and poor usability that physicians have experienced in using these certified systems, they need to be free to pursue the use of technology that does not impede their ability to improve care and efficiency. Practices need the flexibility to redesign care in ways that will promote the best care for their patients while achieving quality and shared savings targets. Instead of complying with overly restrictive mandates, they should be given the flexibility to determine how best to deploy technology in a manner that drives efficiency and quality improvement.

- 11. The development of advanced primary care practices within ACOs could potentially yield synergistic improvements in cost and quality outcomes. What resources (financial and/or technical assistance) do ACOs currently provide to primary care practices/providers to enable care delivery redesign, and are they sufficient to deliver advanced primary care as described in this RFI?**

ACOs are able to provide primary care practices with some of the financial operating margin needed to develop a complete basket of advanced services. ACOs can also provide HIT infrastructure, including a clinical and utilization data warehouse to provide organized, actionable data items, and care management support, particularly valuable for patients with complex medical needs. However, few ACOs have the technical and financial resources to support primary care practices participating in APC models, and current ACOs are integrally tied to FFS payments.

- a. **Should primary care practices within ACOs receive PBPs?**

Yes, as there is no guarantee in current ACO initiatives that primary care practices will get back any of the savings they may generate for an ACO. PBPs could serve as a more defined revenue source for those practices ready to take on the risk of the APC model, facilitating the time and investment needed to offer a basket of advanced services at the practice level. Practices should be permitted to participate in CMS, Innovation Center, and private payer initiatives.

12. What potential program integrity issues for CMS are associated with the payment and care delivery concepts discussed in this RFI?

The AMA has been working, along with other stakeholders, to educate and encourage physicians to develop innovative health care payment and delivery models that will lead to improved care coordination and quality while reducing the rate of growth in health care spending. Recognizing concerns outlined by our members, the AMA has sought clarification of existing fraud and abuse laws and broader safe harbors to encourage physician participation in new care models. We believe that appropriate safeguards can prevent quality and efficiency programs from becoming conduits for fraud and abuse, but worry that existing laws remain overly stringent. Currently, fraud and abuse statutes have unreasonably constrained physicians in their efforts to design and implement innovations to improve care.

a. How can these issues be prevented or addressed?

The AMA has supported a number of reforms in this area, including seeking explicit safe harbors to the Anti-Kickback and Stark laws for participants in new delivery and payment models tested through the CMMI (including medical homes, bundled payment arrangements, and other care coordination programs). These programs have built-in safeguards, including monitoring by CMS, which would protect against many of the program integrity concerns and limit unnecessary or low quality care. The AMA also believes that, when implemented appropriately, gainsharing arrangements have the potential to align hospital and physician incentives to provide more cost-effective care. For example, such arrangements can encourage appropriate use of services and more careful choice among available treatments. Additional details regarding the foregoing and other suggested reforms may be found in the AMA's December 1, 2014 letter to the Department of Health and Human Services Office of Inspector General (OIG), regarding its proposed rule on fraud and abuse for Medicare and state health care programs. The letter is available on the AMA website at: <https://download.ama-assn.org/resources/doc/washington/x-pub/fraud-and-abuse-letter-01dec2014.pdf?cb=1426117332&retrieve=yes>).

b. What data elements should CMS collect to detect any fraud, waste or abuse issues? Please be specific in your responses and provide examples if possible.

We believe that that the data elements that CMS currently collects will be sufficient for this purpose. In particular, the OIG and the Department of Justice already have broad access to Medicare data from a variety of sources. We do not believe that participation in new care models should require additional data collection efforts and administrative burdens, which could discourage participation.

13. For stakeholders involved with primary care for Medicaid beneficiaries, please provide comments on any of the concepts discussed in this RFI and any unique considerations to be taken into account for the Medicaid population.

Providing PBPs for Medicaid patients would allow many practices to provide care coordination, nursing, behavioral health, nutrition, health coaching, and other supportive services that Medicaid recipients would otherwise not be able to receive. These services could prevent the utilization of more costly services, including hospitalizations. Establishing round-the-clock patient access to physicians or other health professionals can have an immediate positive impact in a Medicaid patient population. But network

Andrew Slavitt
March 16, 2015
Page 11

inadequacies can pose a challenge in models designed for Medicaid patients, particularly with respect to insufficient providers of mental health, pain management, specialty surgery, and pediatric subspecialty services.

Conclusion

In closing, the AMA appreciates this opportunity to provide our recommendations, and we would be happy to provide additional information and assistance. We look forward to continuing to work with CMMI and CMS to support the successful implementation of Advanced Primary Care Models that can benefit the Medicare program, patients, and physicians. If you should have any questions regarding this letter, please feel free to contact Sandy Marks, Assistant Director, Federal Affairs in our Washington, D.C. office at 202-789-4585 or sandy.marks@ama-assn.org.

Sincerely,

James L. Madara, MD