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November 20, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted via email to email to CMMI_NewDirection@cms.hhs.gov

RE: CMS Innovation Center Request for Information

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to respond to the Centers for Medicare and Medicaid's (CMS) Request for Information (RFI) on the future direction of the CMS Innovation Center.

The ASGE was founded in 1941 and since that time has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 14,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established under the Medicare Access and CHIP Reauthorization Act (MACRA). When enacted, the physician stakeholder community believed the PTAC and its process for reviewing and commenting on proposed physician-focused payment models (PFPs) proposed by individuals and other stakeholder entities offered promise for creating greater alternative payment model (APM) opportunities for specialty physicians.

At a hearing on APMs held by the House Energy and Commerce Health Subcommittee on November 8, 2017, Jeffrey Bailet, MD, and Elizabeth Mitchell, chair and vice chair of the PTAC, respectively, offered their views on the PTAC, the greatest barriers to APM development, and the priority criteria for reviewing PFPs. Dr. Bailet stated that there has been "tremendous" interest by the physician specialty community in the PTAC process and that the PTAC is reviewing a number of specialty PFPs. Dr. Bailet's comments are encouraging, however, many specialty societies, especially those with fewer resources, are unconvinced at this time that the investment necessary for developing PFPs will actually translate into greater APM participation opportunities for their physicians in Medicare.

In the CY 2018 Medicare Physician Fee Schedule (PFS) Final Rule, CMS decided against any changes to the process or timeline for review of PFPs recommended to

the Agency by the PTAC. CMS also decided it would not change the definition of PFPM to include Medicaid and CHIP as payers, and rejected any changes to PFPM criteria. There is merit to re-examining the Innovation Center's future role by identifying new guiding principles and focus areas for APM development and testing. However, we are concerned the PTAC will become a lost opportunity if the top barriers to development of PFPMs, as identified by Dr. Bailet and Ms. Mitchell, are not addressed by CMS. They are: 1) lack of access to data; 2) lack of opportunity for small-scale testing; and 3) lack of technical assistance. In fact, the need for technical assistance was emphasized in the PTAC's report to the Secretary on the Project Sonar proposal. In that report PTAC stated:

“PTAC also believes that some concerns could likely be resolved through technical assistance. Because PTAC has been advised that it may not provide technical assistance, the Committee is hopeful that the Secretary would consider options for providing technical assistance to this and other submitters.”

ASGE agrees with PTAC in this regard. Many PFPM proposals, particularly, their payment methodologies, could be improved through technical assistance, which many in the stakeholder community have requested. CMS has responded by developing an APM Design Toolkit. We suggest this is inadequate. The PTAC has recommended individualized technical assistance to PFPM submitters, and in an August 2017 letter to the Department, Dr. Bailet stated, “Some of the proposals submitted by practicing physicians provide a clear description for the care delivery model that would be supported by a change in payment, but the detailed description of the actual payment model that would support the new approach to care delivery is underdeveloped.”

Access to data is also of critical importance to stakeholders wanting to develop PFPMs. Among the priority criteria that PTAC uses in its evaluations is whether the proposal will improve health care quality without increasing spending, reduce spending while maintaining quality, or reduce spending and improve quality. As the PTAC has pointed out to CMS, evaluating a proposal against this criterion usually requires analysis of Medicare claims data that has been disaggregated into the types of conditions and procedures being addressed by the PFPM. This task is a significant limiting factor for smaller organizations like ASGE that lack access to data and its analysis. Without this analysis, PTAC cannot adequately review many of the proposals it receives. When asked during the Energy and Commerce Subcommittee hearing whether the PTAC understands the cost implications of the proposals it is reviewing, Dr. Bailet responded quite simply, “no we don't.”

ASGE finds it necessary to comment on the PTAC in the context of this RFI because among the proposed Innovation Center focus areas is increasing the availability of specialty physician models. For this to occur, we ask that the Innovation Center demonstrate its commitment to the PTAC process by addressing the opportunities for improvement identified by the PTAC which require the support of and assistance from CMS.

Guiding Principles for New Model Design

ASGE has reviewed the Innovation Center's proposed guiding principles for evaluating new payment and delivery designs. There is nothing in the guiding principles to which ASGE objects. These guiding principles, however, should be flexible to respond to emerging needs and ideas.

ASGE offers the following general comments with regard to the guiding principles:

- We agree the Innovation Center should focus on voluntary models for the immediate future, with a focus on minimization of regulatory and administrative burdens. However, voluntary models need to include adequate incentives (i.e., no downside risk) to encourage participation so adequate testing can occur.
- Health care providers are more likely to embrace innovative payment and delivery designs if their development occurs in an open and transparent manner with input from affected stakeholder entities.
- The current lack of small-scale testing is a barrier to the widespread adoption and implementation of new models. ASGE suggests that the Innovation Center should re-focus its attention on what's working in the marketplace and work toward replication and widespread adoption of those models.
- A report from the Urban Institute in collaboration with Catalyst for Payment Reform examined how payment methods and benefit design options work in tandem. The report's authors appropriately noted that supply-side incentives can be changed by paying a coordinated risk-based payment to all providers in an episode of care. But incentives for consumers to seek care from providers with the greatest expertise, to ensure that they are receiving excellent, cost-effective care must also be changed. To this end, benefit design and price transparency should not stand in isolation as a guiding principle, but in tandem with innovative payment methods.

Potential Models for Testing

Most Medicare providers are disadvantaged by the lack of choice within the Quality Payment Program by not having Advanced APMs available to them. Another limitation is the high threshold for eligible clinicians to earn the status of Qualifying APM Participant. ASGE strongly supports expanding opportunities for participation in Advanced APMs including by recognizing Medicare Advantage APMs as Other Payer Advanced APMs. CMS states in the CY 2018 Medicare PFS final rule that commercial and other private payers can request a determination of whether their APM arrangements qualify as Other Payer Advanced APMs for the 2020 Performance Period and each year thereafter. CMS should move expeditiously and as early as the 2019 performance year to allow these payers to request a determination of whether their arrangements qualify as Other Payer Advanced APMs. Medical groups, which are capitated for care, are already taking very large financial risks and have operationalized the range of principals in the RFI. Physicians participating in such programs should receive Advanced APM credit for these populations.

With the development of all value-based designs, the Innovation Center should consider the out-of-pocket medication costs for patients with chronic serious diseases. Benefit designs, such as tiered formularies and varied copay levels can create patient compliance problems, which, in turn, have an effect on physician performance and patient outcomes.

In addition to the limited opportunities for most physicians to participate in Advanced APMs, minimal opportunities exist as well for most physician specialist participation in MIPS APMs.

The Innovation Center should also consider recognizing retrospective shared payment models with no downside financial risk as MIPS APMs. And, if they can achieve savings consistent with other qualified Advanced APMs, they should be reclassified accordingly.

As ASGE has commented to CMS in the past, a cost-effective route to the development of APMs is the creation of episodes of care through a multi-specialty and transparent process, such as that currently being led by Acumen. ASGE suggests that voluntary participation in bundled payment models built upon these episodes of care, with nominal downside financial risk and shared savings should be developed and recognized as Advanced APMs.

Lastly, ASGE offers the following two suggestions regarding program integrity:

- Evaluation and management (E/M) services provided within APMs of any type should not be subjected to audits related to history or physical exam. Instead, CMS should focus on documented service times, nature of presenting problems and medical decision-making. Particularly when episodes of care cover periods of time with a single reimbursement and clinical notes from any caregiver should be streamlined to the essential clinical information commonly reflecting the input of a team of caregivers, departing from the traditional E/M chart note structure.
- Reforms to the Stark law are needed so that the formation of and clinician participation in APMs are uninhibited. Physician-led APMs should be granted the same self-referral and anti-kickback waivers that have been granted for Accountable Care Organizations, allowing rewards for value. Incentives to self-refer are often essential to coherent in-network care for the beneficiary, and the payment structure of the APM inherently disincentivizes over-utilization.

ASGE appreciates the opportunity to provide comment on the RFI, and looks forward to continued discussions with CMS on how to expand opportunities for physician specialty participation in innovative payment and delivery models. Should you have questions or require additional information, please contact Lakitia Mayo, Senior Director of Health Policy, Quality and Practice Operations at lmayo@asge.org or (630) 570-5641.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Woods', with a stylized flourish extending to the right.

Karen L. Woods, MD, FASGE
President
American Society for Gastrointestinal Endoscopy