Alliance of Specialty Medicine

Sound Policy. Quality Care.

November 20, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted electronically via CMMI_NewDirection@cms.hhs.gov

RE: Innovation Center New Direction – Request for Information

Dear Ms. Verma,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy. On behalf of the undersigned members, we are pleased to respond to your request for information on the agency's planned new direction for the Innovation Center.

Guiding Principles

The Alliance is encouraged about the prospect of a new direction for the Innovation Center. While we agree that CMS' existing partnerships with healthcare providers, clinicians, states, payers, and stakeholders have generated important value and knowledge, specialty physicians have faced ongoing difficulty in fostering alternative payment and delivery models in conjunction with agency partners. Without such models, specialists have no other option but to engage in CMS' Quality Payment Program (QPP) via the Merit-Based Incentive Payment System (MIPS) track, as alternative payment models (APMs) – let alone Advanced APMs – are largely unavailable or do not fairly measure the quality and costs of specialists compared to their primary care colleagues.

Where innovative models did address specialty care, they considered only a few select conditions or services, leaving many specialists and subspecialty providers behind. Other models touted as specialty-focused, including the now-withdrawn Part B Drug Payment Model, did not consider the input of specialists during initial development, lacked metrics for quality and outcomes, and mandated participation by the vast majority of prescribers, resulting in a model that constituted a payment policy change instead of a demonstration. More importantly, the model was poised to harm beneficiaries, severely limiting their access to important pharmacotherapy for cancer, rheumatoid arthritis, and other life-altering and debilitating diseases. For these reasons, we are pleased that CMS is considering guiding principles for the Innovation Center and hope the agency will consider the following feedback.

As the agency revamps the Innovation Center, the Alliance urges CMS to adhere to the following guiding principles:

- ***Protect beneficiary access to specialty medicine.*** Innovative payment and delivery models should aim to increase beneficiary access to high-value specialty medical care and treatment, resulting in improved overall outcomes and quality of life. Under the Part B Drug Payment Model, beneficiary access to life-saving and life-changing medications would have been reduced. In fact, the model failed to consider the impact on beneficiary access to specialty physicians administering Part B drugs and quality of care, as metrics to account for these issues were altogether absent. As the agency moves forward with new models, it must collaborate with affected stakeholders to incorporate appropriate metrics that consider beneficiary access to specialists and the care and services they deliver. Models that seek only to reduce Medicare spending to the detriment of beneficiary health and well-being should never advance.
- ***Preserve fee-for-service as a viable payment model.*** There is significant promise in value-driven health care, and several disease states and procedures are prime for quality and resource use improvements. While many specialists are making significant strides to engage in activities that deliver on that promise, some have already refined key conditions and procedures through medical advancement and technological innovation. For example, some specialists have moved services and procedures from expensive inpatient settings to lower-cost outpatient settings, and reduced clinical gaps in care through long-term performance improvement. In some cases, these specialists have eliminated variation in cost and clinical quality across geographic regions, which is documented in the literature. For these specialists, fee-for-service remains the most appropriate reimbursement structure. Their performance can and should be measured to maintain excellence in care and treatment delivery, and most will continue to engage in federally-sponsored quality improvement programs, including the Merit-Based Incentive Payment System (MIPS) under the Quality Payment Program (QPP), to demonstrate their commitment to delivering high-value care to beneficiaries.
- ***Meaningfully engage stakeholders at all phases of model development.*** The Alliance strongly encourages the Innovation Center to engage stakeholders, particularly specialty physicians, during all phases of model development, using transparent, subregulatory processes, such as requests for comment and information. For example, in the development of the Comprehensive Care for Joint Replacement (CJR) and now-cancelled Advancing Care Coordination through Episode Payment Models (EPMs) and the Cardiac Rehabilitation (CR) Incentive Payment Model, specialists were not meaningfully engaged at the outset and in advance of rulemaking. While the models may have stemmed from the Innovation Center's experience through working with providers participating in the Bundled Payments for Care Improvement (BPCI) initiative, the enhancement and broad expansion necessitated robust engagement from the various specialty physicians providing clinical care and treatment inherent to the model, prior to rulemaking. Similarly, specialty physicians were not included in any dialogue during the initial stages of development for the Part B Drug Payment Model. The agency first released the model

for public consumption through notice-and-comment rulemaking, leaving little opportunity for substantive modifications which would have failed the "logical outgrowth" test. While the model as a whole was unworkable, several problem areas could have been addressed at the outset with meaningful stakeholder engagement and in advance of the rulemaking process.

- ***Appropriately test models in advance of expansion.*** As new payment and delivery models are developed, they must be adequately pilot-tested prior to wide-spread expansion. There is no question that health care is local; what may work well in one geographic area, may not be appropriate in other areas. Models should be tested in a variety of environments, properly adjusted for risk based on clinical and sociodemographic factors, and scaled where most applicable. Feedback from stakeholders, particularly specialty physicians, should be sought throughout the process.
- ***Emphasize the use of specialty-developed quality measures and clinical data registries.*** MACRA specifically emphasized the development and prioritization of specialty-focused quality measures. As such, CMS has implemented a Measures Development Plan (MDP) that operationalizes this work, which will significantly enhance the agency's measure portfolio.[1] Members of the Alliance are heavily invested in this work, producing quality measures that improve clinical care, patient experience, and ultimately, beneficiary understanding of the care they can expect to receive by qualified providers. As alternative models of care and delivery are considered, these measures should be inherent to the assessment of the impact on quality of care. In addition, MACRA emphasized the use of qualified clinical data registries (QCDRs). QCDRs are especially important for specialty physicians looking to deepen their understanding of quality and performance for relevant episodes of care, particularly when they identify a gap in care and seek ways to address it. As with quality measure development, specialty societies have invested significant resources to establish QCDRs with the goal of raising the bar in specialty medical care, as well as assist specialists with quality reporting activities. The data collected, and resultant information, has fueled important improvements in quality and resource use across many specialties, not to mention assisted some specialty societies with improving the content of their scientific conferences through the use of aggregate back-end data, benefiting their respective professions at the broadest level. The Innovation Center should harness the power of these registries, incorporating QCDR in specialty-focused models, when relevant.
- ***Incentivize–not mandate–participation.*** Alternative models of payment and delivery should not be forced on physicians, particularly those that lack the requisite infrastructure, data and analytical capabilities, staffing, and capital to assume downside-risk. Instead, the agency should provide appropriate incentives that would allow practices to ready themselves for new value-based models. As new models are implemented, the agency should provide participants, particularly small practices, with ongoing technical assistance and data and analytics support. Similarly, beneficiaries should be given the opportunity to proactively choose participation in a demonstration.

[1] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf

Where an active opt-in is not possible, beneficiaries should at a minimum be given the opportunity to opt out of a demonstration project that they do not feel comfortable participating in.

Proposed Models

Expanded Opportunities for Participation in Advanced APMs

According to a new report issued by Leavitt Partners, not every provider has a path forward under the APM track of the QPP.[2] In fact, some specialists have no opportunities to participate in Advanced APMs at all. According to CMS, between 70,000 to 120,000 eligible clinicians are estimated to be qualifying participants (QPs) for payment year 2019 based on Advanced APM participation in performance year 2017. CMS estimates that approximately 180,000 to 245,000 eligible clinicians may become QPs for payment year 2020 based on Advanced APM participation in performance year 2018, as new Advanced APMs have been infused into the program. Finally, a review of CMS' MIPS exclusion tables in its 2017 QPP final rule show that family medicine, internal medicine, obstetrics/gynecology, and nurse practitioners are the primary specialties that will make up the vast majority of QPs based on 2017 data.

As noted above, specialty physicians have faced ongoing difficulty in fostering alternative payment and delivery models through existing agency channels. Despite a multitude of meetings with Innovation Center leadership and staff, both as the Alliance and as individual societies, many of our proposed models were dismissed – even those that addressed services representing a high proportion of Medicare expenditures and had been successfully tested in the private insurance market. Candidly, Innovation Center officials told many of our organizations that models centered on primary care were the agency's priority. Specialists are eager to contribute to responsible stewardship of federal health programs. It is frustrating to be viewed as a costly part of the Medicare program, while simultaneously being turned away when we present proactive, innovative solutions and proposals.

As we have explained in multiple letters to the agency, other federally-sponsored APMs, such as the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), present participation challenges for specialists. While CMS addressed previous exclusivity requirements that limited specialty physicians' ability to participate in more than one Medicare ACO, other challenges remain. Similar to health insurers, Medicare ACOs have seemingly adopted "narrow networks" as a strategy to control costs, limiting the participation of specialists. Other models that have been identified as Advanced APMs, such as Patient Centered Medical Homes, are also difficult for specialty care physicians to engage, as these models are designed for primary care physicians.

For many specialists, particularly subspecialists, the MIPS track will remain the most appropriate pathway for engagement under the QPP. However, for those specialists where improved quality and resource use can be demonstrated in alternative ways, the option must be made available through the APM Incentive track. **The Alliance would be interested in**

[2] https://leavittpartners.com/wp-content/uploads/2017/09/CMS-Initiatives-White-Paper-9.7.2017-1.pdf

meeting with the Innovation Center's new leadership to discuss ideas for how to improve access to Advanced APMs for specialty medicine physicians.

Consumer-Directed Care & Market-Based Innovation Models

The Alliance appreciates that CMS is considering models that would allow beneficiaries to contract directly with healthcare providers. Under current law, Medicare beneficiaries that choose to see physicians who do not accept Medicare are required to pay the physician's charge entirely out of personal funds; Medicare does not pay any part of the charge. In addition, physicians who choose to provide covered services to Medicare beneficiaries under private contracts must "opt out" of the Medicare program for two years, during which time Medicare does not pay the physician for any covered services provided to Medicare beneficiaries. The Alliance has consistently maintained that these discriminating policies are inappropriate and an impediment to Medicare beneficiaries' freedom of choice. **We urge the agency to allow physicians and Medicare beneficiaries to enter into private contracts on a case-by-case basis.** Medicare beneficiaries should not be prevented from using their Medicare benefits if they choose to see a physician that does not accept Medicare, and physicians should not face penalties or be forced to "opt-out" of the Medicare program in order to privately contract with Medicare beneficiaries.

Nevertheless, we recognize that not every Medicare beneficiary will choose to exercise their right to privately contract, and in some cases, private contracting may be inappropriate. For private contracting models to be successful, **we encourage the inclusion of appropriate protections for low-income and dual-eligible beneficiaries, as well as beneficiaries with emergency or urgent conditions, or those who do not have a choice of physicians.**

Physician-Specialty Models

As discussed above, some specialists, particularly subspecialists, will remain in the MIPS track, given APMs and related population-based measurement strategies are not conducive to care and treatment they deliver. For others, innovative payment and delivery models made available through the APM Incentive track will ensure specialists have more than one way to participate in the Quality Payment Program.

Specialty physicians are poised to address a great number of challenges that plague our health care system. As an example, rheumatologists have the requisite expertise to accurately and appropriately diagnosis, treat, and provide long-term management of serious, complex health conditions, including rheumatoid arthritis, systemic lupus erythematosus, and other debilitating inflammatory diseases. When primary care physicians misdiagnose these conditions, or refer these patients for specialty medical intervention too late, disease progression is heightened and more difficult to control; costs to the Medicare program and beneficiaries are increased; and, beneficiary outcomes and quality of life are diminished until control is regained, if at all.

Individual members of the Alliance, through partnerships and as specialty organizations, are developing specialty-focused models to assist their members with robust participation in the

QPP. **The Alliance and its individual members developing models are eager to meet with the Innovation Center's new leadership to discuss ideas for how to improve access to Advanced APMs for specialty medicine physicians.**

Prescription Drug Models

We appreciate that CMS wants to test new models for prescription drug payment, in ***both*** Medicare Part B and Part D. In recent months, individual organizations within the Alliance met with Innovation Center leadership and staff to discuss models that would address key conditions that rely on pharmaceuticals and biologics reimbursed though both Medicare's medical and pharmacy benefit, but were told that limitations on the Secretary's authority would prevent most of the novel arrangements under discussion. If a new interpretation of relevant statute has resulted in an expansion of the Innovation Center's ability to test models that would address drug spending across the medical and pharmacy benefit, **organizations within the Alliance that prescribe medications under Medicare Part B and D are eager to meet with the agency to discuss their value-driven concepts to address escalating drug prices and access to medicines.**

Program Integrity

Last year, CMS announced an 18-month pilot program to reduce medical record review for certain physicians while continuing to protect program integrity. Under the program, providers practicing within certain Advanced APMs would be relieved of additional scrutiny under certain Medicare medical review programs. **We encourage CMS to expand this to program to *all* Advanced APMs.**

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society