American Academy of
Allergy Asthma & Immunology

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,

Established in 1943, the American Academy of Allergy, Asthma, and Immunology (AAAAI) is a professional organization with more than 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

We are pleased to respond to your request for information on the agency's planned new direction for the Innovation Center.

General Sentiments

While CMS' existing partnerships with healthcare providers, clinicians, states, payers, and stakeholders have generated important value and knowledge, engagement with a broader audience, including a wide-range of specialists, will be key to an Innovation Center that advances payment and delivery models for the 21st century.

A/I professionals lead in the diagnosis, treatment and ongoing management of asthma, allergic and immunologic conditions. By itself, asthma – a chronic disease involving the airways in the lungs – affects more than 25 million Americans at a total cost of $56 billion per year. Asthma causes 14.2 million missed days of work and 10.5 million missed days of school, and results in 479,300 hospitalizations, 1.9 million emergency department visits, and 8.9 million doctor visits.[1]

Allergies are among the most common chronic conditions worldwide, with symptoms that range from an itchy nose up to anaphylaxis, a life-threatening reaction. Allergic rhinitis, which affects 17.6 million Americans, can be treated with allergen immunotherapy (AIT), also known as allergy shots. AIT also is

(more)

[1] https://www.cdc.gov/asthma/impacts_nation/asthmafactsheet.pdf

effective in asthma, where it has been shown to reduce symptoms, lower use of asthma medications, and improve patient quality of life. Studies have also shown that AIT is highly cost-effective and severely underutilized[2]. In 2014, six US Senators encouraged the Secretary of Health and Human Services (HHS) to "*develop strategies to promote [AIT] utilization in appropriate patients and encourage provider and patient education and compliance with existing guidelines.*"[3]

Beyond the aforementioned, A/I professionals have expertise in a multitude of other key conditions and disease processes, including preventative and concurrent therapies that would significantly enhance diagnosis, treatment and ongoing management for certain conditions provided by other medical specialists. Examples are outlined below:

- ***Perioperative reactions***: A/I professionals have the requisite expertise to assist in the prevention of perioperative reactions to anesthesia medications. A/I professionals can work with other medical specialties to develop appropriate pre-sedation protocols and include testing for certain allergies, as well as perform such testing to reduce the risk of patient harm during procedures that require anesthetics.
- ***Antibiotic allergies***: A/I professionals lead the way in appropriate diagnosis of antibiotic allergy, which is a key component of antibiotic stewardship efforts. A/I professionals have developed guidelines outlining a standardized approach to penicillin allergy triage and testing. A/I professionals are working with infectious diseases (ID) specialists and other federal agency partners to raise awareness and increase access to penicillin allergy testing, which would drastically improve our nation's response to antibiotic-resistance challenges.
- ***Metal allergies***: Patients are increasingly facing unnecessary surgical procedures due to adverse reactions to metal following joint and other orthopedic replacements. A/I professionals could work with surgical specialties to diagnose metal allergies, ensuring patients are implanted with the most appropriate medical products at the outset. Not only would this reduce spending, it would improve quality, patient experience, and limit risks associated with surgical procedures.
- ***Adverse food reactions***: A/I professionals are the chief professionals addressing food-borne allergies, which are frequently misdiagnosed and/or over-diagnosed by other medical professionals. A/I professionals conduct oral food challenges and other testing that improves patient quality of life and reduces their risk of life-threatening reactions.
- ***Aspirin (ASA) sensitivity***: The prevalence of patents with ASA sensitivity is unknown, yet this is an important consideration for cardiologists treating patients with cardiac and diseases that may require aspirin use. Desensitization by A/I professionals would significantly improve patient access to this cost-effective therapy, thus increasing survival of many patients with heart conditions that would benefit from aspirin use.
- ***Chemotherapy reactions***: Patients undergoing cancer treatment with infused chemotherapy medications may face a serious, allergic reaction; however, A/I professionals can perform appropriate testing in advance of administration and/or prescribe preventative medications to avoid inappropriate exposure or reduce reactions.

[2] https://ahrq-ehc-application.s3.amazonaws.com/media/files/allergy-asthma-immunotherapy-130802.pdf

[3] https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Advocacy/allergy-IT-effectiveness-sebelius-letter-march-2014-final.pdf

A/I can also perform drug desensitization to improve access to a broader range of therapies for patients, particularly where other treatment options may be limited.

- ***Acute and chronic sinus disease:*** Sinus disease can be the result of long standing allergic disease or a manifestation of other immunologic diseases including primary immune deficiency. With their extensive training in allergic and immunologic diseases, A/I professionals are in the position to understand and properly medically manage this debilitating disease.
- ***Primary Immunodeficiency:*** Early onset and/or recurrent infections are often the hallmark of immunodeficiency. With their extensive training in immunology, A/I professionals are the leaders in identifying patients with immunodeficiencies and developing appropriate treatment plans that result in less infectious complications and antibiotic use, consequently playing an important role in overall antibiotic stewardship.

It is critical that CMMI leadership are keenly aware of the scope of A/I expertise and service, which will be essential to the development and advancement of alternative payment and delivery models established internally and presented by external stakeholders.

Guiding Principles

We support the proposed guiding principles; however, we encourage the agency to consider the inclusion of the following:

- ***Improve beneficiary access to care.*** While CMS recently withdrew the Part B Drug Payment Model, it serves as an example of the impact poorly-crafted alternative payment and delivery models may have on beneficiary access to life-saving therapies, such as intravenous immunoglobulin (IVIG). The Part B Drug Payment Model was of significant concern to our constituency and would have negatively impacted A/I professionals' ability to treat beneficiaries with primary immunodeficiency diseases (PIDD), a rare and life-altering cohort of diseases. We also note that the model did not account for the impact on beneficiaries or the quality of care they would receive. In fact, measures of quality were completely absent and CMS stated that it "*may consider a survey…to provide insight on beneficiaries' experience under the model…*" Our specialty was alarmed, believing alternative payment and delivery models should aim to expand and improve access to care, not impose barriers. Moving forward, CMMI must ensure all models, current and future, increase access to important health care services, focusing on quality, beneficiary experience, and improved outcomes, steer away from models that simply aim to reduce spending to the detriment of patient care.
- ***Solicit continuous stakeholder feedback.*** AAAAI maintains that continuous feedback from stakeholders is essential to model development. To accomplish this, CMMI should use a variety of open, public and transparent processes, such as requests for comment and information, to solicit feedback throughout model development. As noted above, the Part B Drug Payment Model, while withdrawn, is a prime example of where appropriate stakeholder engagement failed to occur at the outset. AAAAI and many of its lay-organizations would have appreciated the opportunity to engage in a dialogue in advance of rulemaking, which would have highlighted a number of issues facing A/I and its patients. We look forward to a more collaborative dialogue in the future.
- ***Favor models that incorporate A/I professionals.*** As noted above, A/I professionals have expertise in a multitude of key conditions and disease processes, such as asthma and allergies, as well as preventative and concurrent therapies that would significantly enhance diagnosis, treatment and ongoing management for certain other conditions routinely provided by other medical specialists. A/I expertise is of value to a broad array

of team-based care, which must be reflected in models developed internally and externally. We urge CMMI to favor models that incorporate A/I as an integral component of disease management, where relevant. For the conditions and disease processes listed above, CMMI should ensure A/I professionals have been consulted and incorporated in the model.

- ***Promote inclusion of specialty-focused quality measures, registries.*** AAAAI has developed the only A/I specific clinical data registry, which is recognized by the agency as a qualified clinical data registry (QCDR) under programs established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Given the tremendous investment in developing the registry and associated quality measures, CMMI should capitalize on its value by emphasizing and incorporating it in new and existing APMs, where relevant.
- ***Use incentives, not mandates, to facilitate participation.*** AAAAI has significant concerns with models that mandate participation by A/I professionals and patients. We believe this is inappropriate, particularly for models that are looking to demonstrate whether an alternative payment and delivery concept will increase access, improve quality and potentially reduce costs, through pilot testing. CMMI should use incentives, not mandates, to facilitate A/I professional and beneficiary participation. Incentives should be scaled to assist providers that are new to value-based health care, and lack the necessary infrastructure, data and analytical capabilities, staffing, and capital to assume downside-risk. Moreover, beneficiaries should have the ability to indicate their participation through an opt-in or opt-out mechanism.

Proposed Models

Expanded Opportunities for Participation in Advanced APMs

Engagement with Alternative Payment Models (APMs), particularly Advanced APMs, is a challenge for most A/I professionals. As outlined in CMS' 2017 Quality Payment Program (QPP) Final Rule, only 38 (1.0 percent) out of 3,994 A/I professionals will be a "qualifying participant" (QP) in year one[4].

Given the statistics outlined above and the expertise of the specialty, it is clear that Advanced APMs would benefit from the inclusion of A/I professionals. However, the challenge is that most of these entities are not measured on conditions where A/I professionals play a key role. Moreover, we have found that many Advanced APMs exclude specialists, such as A/I professionals, given concerns that specialty physician engagement will increase overall costs and limit "shared savings" payouts. If metrics were inclusive of diseases and other areas where specialists, such as A/I professionals, could impact quality and resource use, the opportunities for participation would increase. Given the disease burden of conditions managed by A/I professionals, it stands to reason that CMS should consider adopting A/I specific measures into these models.

We look forward to the opportunity to speak with you and the new CMMI leadership in the coming months on ways to engage A/I professionals in existing and future Advanced APMs, including the addition of specific A/I measures to drive improvements in A/I conditions and bring more A/I professionals into the APM track.

[4] https://www.federalregister.gov/d/2016-25240/page-77518

Physician-Specialty Models

Again, A/I professionals are the leaders in the diagnosis, treatment and long-term management of several chronic health conditions. We also play a key role in the diagnosis, treatment and management of conditions and disease processes managed by other specialists. Unfortunately, A/I has not been invited to the discussion on any models established internal to CMMI nor submitted by external stakeholders to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), even those where A/I might play a role. For example, our input would have improved aspects of the Comprehensive Care for Joint Replacement (CJR) model, given our expertise in diagnosing metal allergies, or the Oncology Care Model (OCM), given our expertise in immunotherapy toxicity and drug desensitization.

While A/I professionals have been overlooked as a key player to many APMs in CMS' current inventory, we are raising your awareness to this oversight so that it may be corrected from this point forward. To that end, CMS should favor models that account for A/I expertise where relevant, and particularly in the scenarios listed above. Not only is this important for improving a model's ability to be successful, it would also improve the inventory of APMs that A/I may be able to participate in.

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We appreciate the opportunity to offer these comments. If you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

David B. Peden, MD MS FAAAAI
President