American Academy of
Allergy Asthma & Immunology

October 5, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted online via regulations.gov

RE: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)

Dear Administrator Verma:

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 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 appreciate the opportunity to provide comments on the aforementioned proposed rule and the impact on A/I patients and providers.

Impact of E/M Changes on the Medicare Physician Fee Schedule

AAAAI applauds CMS for reaffirming its commitment to increase payment levels for office and outpatient E/M services and implement a new complexity "add-on" code. While we recognize the significant impact these policies will have on the Medicare Physician Fee Schedule (PFS) – which are the result of CMS' statutory budget neutrality requirements – it is essential for the Medicare program to appropriately recognize the importance of the cognitive process in providing high quality medical care. For several years, Medicare payment rates have not adequately reimbursed physicians for the delivery of primary and

cognitive care; this inequity will be corrected under CMS' aforementioned policies.

However, we also understand that a -10.61 percent reduction in the Medicare conversion factor is not sustainable for our colleagues in many other specialties. The Medicare conversion factor, anticipated at $32.26 beginning January 1, 2021, will be the lowest it has been since the implementation of the current Resource-Based Relative Value Scale (RBRVS) payment system. To that end, ***we urge CMS to work with Congress to eliminate the negative impact, concurrent with prompt implementation of the aforementioned E/M policies.***

Complexity Add-on GPC1X

We are pleased that CMS intends to implement a new complexity add-on code that would "*provide payment for visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious or complex chronic condition*." As a cognitive specialty, A/I physicians lead in the diagnosis, treatment and ongoing management of many complex chronic conditions, including asthma, allergic disorders and primary immune deficiencies. By itself, asthma affects more than 25 million Americans at a total cost of $56 billion per year; causes 14.2 million missed days of work; and, results in 479,300 hospitalizations, 1.9 million emergency department visits, and 8.9 million doctor visits.[1] Primary immune deficiency disease (PIDD) is a group of more than 400 rare, chronic disorders in which part of the body's immune system is missing or functions improperly. PIDD patients are more susceptible to infections--enduring recurrent health problems and often developing serious and debilitating illnesses

We agree with CMS that "*the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.*" Moreover, and in the context of specialty care, we support CMS' sentiment that the new code, "*could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals*."

Nevertheless, we are concerned with rampant and inappropriate use of this code. To mitigate that, and to ensure A/I physicians are not subject to unwanted audits, we urge CMS to work with primary care and cognitive specialties to establish appropriate reporting and documentation requirements. Finally, as the utilization is likely to be considerably lower when the aforementioned guardrails are in place, we urge CMS to revise its utilization assumptions, which should also help reduce the negative impact on the conversion factor.

With that, we urge CMS to proceed with implementation of the complexity add-on code, GPC1X.

Telehealth and Virtual Care Services

As we've expressed in multiple letters to CMS and the Department of Health and Human Services (HHS), AAAAI greatly appreciates the flexibilities provided through CMS' COVID-19 blanket waivers and interim

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

final rules with comment (IFCs). These policies have significantly improved access to care for beneficiaries during the public health emergency. The A/I community experience with delivering virtual care and telehealth services has been overwhelmingly positive, and ***we urge CMS to make these flexibilities permanent.***

Audio-Only Visits

As part of its COVID-19 flexibilities, CMS activated the telephone-only E/M services (i.e., CPT codes 98966-98968 and 99441-99443) and made payment equivalent to that of office/outpatient E/M visits with established patients. Access to these audio-only visits has been essential for beneficiaries, particularly those who face challenges accessing health care due to a variety of social determinants, which is not uncommon in the A/I population. ***We urge CMS to make audio-only E/M visits a permanent fixture in Medicare's growing set of virtual care services codes, maintaining equal payment with in-person E/M visits.***

Direct Supervision Via A/V Technology

CMS proposes to temporarily extend its policy (established under its initial COVID-19 IFC) that allows direct supervision by audio-visual communications technology. CMS clarifies that, to the extent the policy allows direct supervision through virtual presence, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

As noted in our comments of the IFC, we appreciate CMS' goal of ensuring continued access to key services during the pandemic – including the administration of physician-administered drugs. However, we have concerns about certain drugs being administered in the home – particularly products with serious safety warnings or products with the potential for adverse reactions, which would be difficult to appropriately manage in the home by the physician's clinical staff or their contractor. Not only could this create serious risks for patients, it significantly increases liability to the physician's practice, especially when the standard of care does not normally contemplate administration of certain products outside the controlled setting of a medical facility. For our patients with severe asthma, we advise against at-home administration of drug therapies typically provided in the office setting.

To the extent CMS finalizes this "virtual presence" policy, CMS should establish parameters based on specialty society recommendations and guidelines, which emphasize patient safety. We would be happy to work with CMS to develop these guardrails.

Updates to the Quality Payment Program

MIPS Value Pathways (MVPs)

We continue to have significant concerns with the MVP framework, as it does not address many of the issues inherent to the MIPS program, the foundation on which MVPs are built. As such, the MVPs will not meaningfully reform MIPS participation for A/I physicians. We refer you to our CY 2020 MPFS proposed rule comments for a detailed discussion on the MVP framework in the context of A/I, which continue to reflect our sentiments. We urge CMS to delay implementation of the MVPs until these issues are resolved.

A/I Specialty Measure Set

CMS proposes to add multiple measures to the A/I Specialty Set for 2021. Those are:

- Measure #331: Antibiotic Prescribed for Acute Viral Sinusitis
- Measure #332: Adult Sinusitis: Appropriate Choice of Antibiotic
- Measure #398: Optimal Asthma Control
- Measure #444: Medication Management for People with Asthma

We are pleased that CMS has proposed the inclusion of these measures in the A/I specialty set, which we requested in our prior year comments. ***We encourage CMS to finalize this proposal.***

MIPS Performance Category Measures and Activities

AAAAI opposes shifting additional weight from the Quality category to the Cost category. Notwithstanding our long-held objection to the use of administrative, claims-based cost measures in MIPS, this shift comes at a time when A/I physicians are facing significant practice disruptions due to the ongoing COVID-19 pandemic.

As we have explained before, these measures are not appropriate for assessing performance under a clinician-level value-based purchasing program, and it remains unclear how A/I physicians can meaningfully influence outcomes for those measures. Moreover, the National Quality Forum's (NQF) Cost and Efficiency Technical Expert Panel (TEP) reviewed the Medicare Spending Per Beneficiary (MSPB) measure and voted to *not support* the measure. The TEP could not reach consensus on the Total Per Capita Costs (TPCC) measure.

MIPS Final Score Methodology

Similar to the above, AAAAI ***opposes increasing the overall MIPS performance threshold in 2021.*** A/I practices have been distracted by the COVID-19 pandemic, making MIPS engagement a significant challenge. Moving the "goal posts" when A/I physicians were barely able to adjust to the changes at the beginning of the 2020 performance year is inappropriate. CMS should maintain the current threshold for the 2020 performance year.

QCDRs

Like many other specialty societies, AAAAI has invested tremendous resources into establishing and maintaining a clinical data registry for A/I physicians with the underlying goal of continuously improving the quality of A/I care and treatment. To assist with A/I member engagement in CMS' quality programs – namely MIPS – we work tirelessly to remain "qualified." However, the volume of overwhelming and ever-changing requirements forces us to question the investment. For example, while we appreciate that CMS postponed its measure testing requirements for one year in the Medicare and Medicaid Interim Final Rule with Comment (IFC) published in May 2020, and proposes to further modify its QCDR measure testing policies in this rule, we have concerns that these modified testing requirements will still impose too great of a burden on QCDRs in the future. In this rule, CMS proposes to modify the QCDR measure requirement for new and existing measures to be a two-step process that first requires face validity testing (prior to a measure being self-nominated for 2022) and eventually full measure testing (prior to being self-nominated for 2023 and beyond). We are concerned that validity testing beyond face validity is not feasible for most quality measures, including A/I measures. Full measure testing fails to account for the significant investments that QCDRs already make when developing measures to ensure the accuracy of their measures, including vetting by clinical subject matter experts and reliance on clinical practice guidelines, the medical literature, and preliminary data. It is also unreasonable to impose this requirement on QCDR measures when there is no requirement for traditional MIPS measures to be tested prior to being approved for the program. The unreasonable cost and burden this

requirement will impose on QCDRs will cause many registries, including our own, to no longer invest in measure development and potentially leave the program.

We also request that CMS reconsider the proposed requirement that testing data for new QCDR measures must be submitted by the next self-nomination period. Many QCDR's rely on prospective data collection to generate the data needed for testing. As such, most QCDRs will not have twelve months of data available and analyzed by the next self-nomination deadline (September 1). QCDRs need at least two nomination cycles to produce the required testing data.

In addition, we agree that QCDR data should be true, accurate and complete and that data validation audits are important. However, the specific requirements proposed for routine and targeted audits by performance category, mechanism, and submitter type, including the sampling thresholds, will place a significant burden on the AAAAI QCDR and its participants. The cost associated with many of these requirements alone, such as requiring physicians to submit clinical documentation and for registry staff to review and verify data, represents an extraordinary burden. We recognize the value of audits, but request that CMS adopt more flexible QCDR auditing policies that are not overly prescriptive and take into account the unique nature of each registry.

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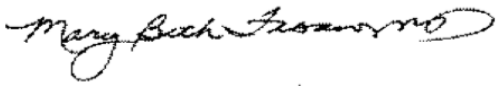
We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@AAAAI.org or (414) 272-6071.

Sincerely,



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