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September 10, 2018

Ms. Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P

P.O. Box 8011

Baltimore, MD 21244-1850

Submitted online via regulations.gov

Re: CMS-1693-P – Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator 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 appreciate the opportunity to provide feedback on proposals outlined in the 2019 Medicare Physician Fee Schedule (MPFS) and Year 3 Quality Payment Program (QPP) proposed rule.

Medicare Physician Fee Schedule

Evaluation and Management (E/M) Proposals

In our comments last year, AAAAI urged CMS to fully eliminate the E/M documentation guidelines rather than expend years of effort modifying the current guidelines, which will never fully satisfy all stakeholders. With that in mind, we appreciate CMS' proposal to significantly reduce E/M documentation requirements on clinicians, which would also eliminate the majority of E/M audits. Nevertheless, we are deeply concerned with CMS' proposed collapse of E/M services (Level 2-5) into a single, blended payment rate. We strongly oppose this action, which would devalue the cognitive work of many A/I professionals whose patient population necessitates the use of higher level E/M codes.

(more)

Moreover, the proposed add-on codes aimed at improving payment for those that use higher level E/M services, are funded through an inappropriate multiple procedure payment reduction (MPPR) when certain procedures, including many A/I services, are performed in conjunction with an E/M service. Through efforts of the AMA Relative Value Update Committee (RUC), there are no duplicative costs to recapture and redistribute through such a policy.

Worse yet, the E/M proposals have significantly impacted the relativity of the entire Medicare physician fee schedule. For example, CMS established a new E&M “specialty” which has arbitrarily adjusted the indirect practice cost index (IPCI) for every specialty, including A/I. In fact, the A/I IPCI was reduced so drastically (downward by 36 percent) that services poised to receive increases as a result of improvements in direct practice expenses will now realize steep reductions.

CMS’ well-intended proposals are unsustainable for the A/I specialty, which already faces tremendous challenges due to multiple Medicare payment and quality improvement program requirements. CMS acknowledges the unique challenges to A/I in its proposal; therefore, we encourage the agency to reconsider moving forward with finalizing its E/M proposals. We urge CMS to work with the medical community through the AMA CPT/RUC process over the next year on a solution that achieves reduced administrative burden for both physicians and the agency, which could be first implemented in FY 2020.

Venom Immunotherapy and Antigen Costs (SH009 and SH010)

The cost of venom antigens has risen sharply as a result of consolidation in the market. With one manufacturer left to produce these *life-saving* antigens and as prices are expected to remain at the current increased rates, A/I practices and beneficiaries that depend on venom immunotherapy need CMS to reconsider the direct cost inputs and fully implement new, higher amounts effective January 1, 2019.

According to invoices collected from allergists around the country (included in comments from the American College of Allergy Asthma and Immunology), the current cost of SH009 (single venom antigen) is \$30.93. This represents an average of the per cc cost of honey bee (\$25.38) and wasp (\$36.38) which are the two most commonly used single venom antigens. ¹ The cost of SH010 (3-vespid mix) is \$61.32 per cc, which is an average of the price for a 5cc and a 12 cc vial. ² We urge CMS to adopt these cost inputs and fully implement them effective January 1, 2019. Doing otherwise puts venom sensitive patient lives at risk. We are aware of allergists who are no longer providing venom allergy shots because the cost exceeds their reimbursement for this life-saving therapy.

Inhalant Allergen Immunotherapy Costs

While CMS has proposed a sharp decrease in the cost of inhalant antigens (SH007), which are used in CPT codes 95144 and 95165, we understand that CMS’ contractor, StrategyGen, may be recommending a higher amount following additional analysis. We would agree with StrategyGen that the amount should be higher than the current amount of \$6.70; however, without the benefit of the new

¹ 3-Vespid mix can be purchased in vials of 5ccs and 12 ccs. The price of the 12ccs is slightly less. Our recommendation reflects the average.

² The invoices were collected from allergists around the country. The cost of the vials were divided by the number of ccs to get the per cc cost. The number of ccs in each vial is indicated on the invoice, with the exception of the mixed-wasp venom which was not specified by the manufacturer. To fill in this gap, we obtained the item numbers from the manufacturer’s website (Attachment B) and matched them to the invoices to calculate the cost per cc.

reimbursement level or how it was calculated, it is challenging to provide a robust comment. We are also concerned that StrategyGen has used data from providers from large healthcare institutions that is not representative of the majority of A/I specialists who primarily practice in groups that involve 1-3 physicians, thus, their negotiating and buying power is not the same as a large healthcare institution. If this is where StrategyGen obtained a significant proportion of price data, it will undervalue the cost of allergens for the majority of practicing A/I specialists.

The societies representing A/I are coordinating efforts to understand changes in allergen immunotherapy and the impact on costs, and will submit findings and cost inputs to CMS in future years. However, based on preliminary findings, we ask CMS to implement a higher direct cost input determined by StrategyGen. Alternatively, CMS should maintain the current input.

Part B Drugs

AAAAI opposes CMS' proposed cut to WAC-based drug payment. The proposal would simply cut reimbursement for physicians who have no control over the setting of drug prices, and will do nothing to bring down the underlying prices of these products. We urge CMS not to finalize this policy and instead work with AAAAI and other stakeholders on meaningful reforms to drug pricing.

Quality Payment Program

General Comments

We appreciate that CMS is considering, for future years, to further reduce reporting burden by linking or otherwise bundling performance categories (e.g., creating sets of multi-category measures that would cut across different performance categories; allowing clinicians to report once for credit in all three categories) and/or creating public health priority measure sets. With this in mind, AAAAI would encourage CMS to emphasize the use of qualified clinical data registries, allowing clinicians to fully satisfy Merit-based Incentive Payment System (MIPS) requirements when they participate in a robust clinical data registry. Further, A/I specialists treat a number of conditions that have a significant impact on public health. We would be interested in collaborating with CMS through a technical expert panel on public health priority measure sets that address asthma, allergy and immunology diseases that impact patients in federal health programs.

Quality Performance Category: Allergy/Immunology Specialty Measure Set

We remain concerned and frustrated with the A/I Specialty Measure Set, which continues to include measures that are not pertinent to our specialty. Given A/I specialists do not diagnose, treat or manage HIV/AIDS, measures related to this disease do not belong in the A/I Specialty Measure Set. Therefore, we ask CMS to remove the following measures:

- Measure 160: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
- Measure 338: HIV Viral Load Suppression
- Measure 340: HIV Medical Visit Frequency

However, A/I specialists do diagnose, treat and frequently manage sinusitis and asthma, therefore, we ask that CMS return the following measures to the A/I Specialty Measure Set:

- Measure 331: Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis
- Measure 332: Adult Sinusitis: Appropriate Choice of Antibiotic

- Measure 333: Adult Sinusitis: CT for Acute Sinusitis
- Measure 334: Adult Sinusitis: More than One CT Scan within 90 days for Chronic Sinusitis
- Measure 398 Optimal Asthma Control
- Measure 444: Medication Management for People with Asthma

Promoting Interoperability (PI) Performance Category

As a specialty society that has invested significant resources in a clinical data registry, we have concerns with CMS' intent to remove the Public Health and Clinical Data Exchange objective and measures no later than 2022. While some clinicians may continue to share data with public health entities and report data to clinical data registries, it remains a significant policy lever for those who have yet to engage in this aspect of promoting the exchange of important health information. CMS is aware of the Medicare Access and CHIP Reauthorization Act (MACRA) emphasis on the use of clinical data registries; therefore, we see no reason for CMS to propose removing this objective/measure in a future year. More importantly, we encourage CMS to count meaningful participation in a robust registry as a means for fully satisfying MIPS.

Qualified Clinical Data Registries (QCDR)

We are deeply opposed to CMS' requirement that a QCDR measure owner must enter into a license agreement with CMS to "openly share" all of its "home grown" measures with all other approved QCDRs. In the case of the AAAAI QCDR, these measures were developed specifically for use A/I specialists based on A/I practice patterns and guidelines and would be inappropriate if reported by other specialists or through other registries not specific to A/I. Moreover, the process to review and consider whether modifications would be necessary for a broader audience is not possible in the timeframe between the announcement and the September 15 self-nomination deadline. We oppose this requirement and urge CMS to withdraw it.

In addition, we are concerned with CMS' proposed requirement of 25 participants. For a small specialty, and one that does not have a high volume of Medicare patients, this will be a challenge to meet. CMS should allow QCDRs time to build a base of participants, particularly in the early years. We ask CMS to significantly lower the threshold or to remove it entirely, at least for those QCDRs that have already been in operation and have lost participants when the low volume threshold increased significantly. We would also ask that those practitioners who were eligible to and successfully participated in 2016 and 2017 be allowed to participate again, even if they do not meet the low volume threshold.

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,



Robert A. Wood, MD FAAAAI
President