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September 8, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence, Ave., S.W.
Washington, D.C. 20201

Re: CMS-1631-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

Established in 1943, the 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 comment on proposed policies outlined in the CY 2016 Medicare Physician Fee Schedule. In the sections below, we provide both general and detailed comments on specific proposals in the rule.

Potentially Misvalued Codes Under the Physician Fee Schedule
AAAAI disagrees with CMS that CPT codes 94010 (Breathing capacity test), 95004 (Percutaneous allergy skin tests), and 95165 (allergen immunotherapy) are potentially misvalued despite increased utilization of these services.

Spirometry (CPT 94010) is an important tool used to diagnose, treat, and manage patients with asthma and chronic obstructive pulmonary disease (COPD). In fact, in its *Guidelines for the Diagnosis and Management of Asthma*, an Expert Panel convened by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), stated the following:

> *"The Expert Panel recommends the following frequencies for spirometry measurements: (1) at the time of initial assessment (Evidence C); (2) after treatment is initiated and symptoms and PEF have stabilized, to document attainment of (near) "normal" airway function; (3) during a period of progressive or prolonged loss of asthma control; and (4) at least every 1–2 years to assess the maintenance of airway function (Evidence B, extrapolation from clinical trials). Spirometry may be indicated more often than every 1– 2 years, depending on the clinical severity and response to management (Evidence D). These spirometry measures should be followed over the patient's lifetime to detect potential for decline and rate of decline of pulmonary function over time (Evidence C)."* [1]

In adults, the use of spirometry has become more frequent, consistent with the Centers for Disease Control and Prevention (CDC) publication, *Public Health Strategic Framework for COPD Prevention*, which emphasizes the use of spirometry in COPD identification, treatment, and management. In fact, authors of the CDC

[1] "Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma–Summary Report 2007." *Journal of Allergy and Clinical Immunology* 120.5 (2007): n. pag. Web. http://www.nhlbi.nih.gov/files/docs/guidelines/asthsumm.pdf.

report call for collaboration with professional health organizations to communicate current evidence-based standards of diagnosis, including spirometry use, and treatment options for COPD. The authors identify assessing current educational activities and initiatives using evidence-based standards as a strategy for achieving its broad goal to heighten awareness of COPD with multiple stakeholders, including policy makers.[2]

Furthermore, the values associated with spriometry were reviewed by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) at its February 2011 meeting, and CMS agreed with the RUC recommendation to maintain the work RVU for this service.

Allergen immunotherapy (CPT 95165) in an important therapeutic option to treat patients with allergic rhinitis, allergic conjunctivitis and asthma whose disease is triggered by allergens. In fact, in its *Guidelines for the Diagnosis and Management of Asthma*, an Expert Panel convened by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), stated the following:

> "*The Expert Panel recommends that allergen immunotherapy be considered for patients who have persistent asthma if evidence is clear of a relationship between symptoms and exposure to an allergen to which the patient is sensitive (Evidence B)"* [3]

Numerous studies of allergen immunotherapy have demonstrated its efficacy in reductions of asthma symptoms caused by exposure to grass, cat, house-dust mite, ragweed, *Cladosporium,* and *Alternaria.*[4,5,6,7,8,9] Importantly, 2003 meta-analysis[10] of 75 randomized, placebo-controlled studies has confirmed the effectiveness of immunotherapy in asthma, with a significant reduction in asthma symptoms and medication and with improvement in bronchial hyperreactivity.

In addition, it has been demonstrated that: immunotherapy can prevent the development of new sensitivities in monosensitized children and adults[11, 12,13]; immunotherapy with birch and timothy pollen

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[2] Centers for Disease Control and Prevention. Public Health Strategic Framework for COPD Prevention. Atlanta, GA: Centers for Disease Control and Prevention; 2011. Available at http://www.cdc.gov/copd.

[3] "Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma–Summary Report 2007." *Journal of Allergy and Clinical Immunology* 120.5 (2007): n. pag. Web. http://www.nhlbi.nih.gov/files/docs/guidelines/asthsumm.pdf.

[4] Creticos PS, Reed CE, Norman PS, Khoury J, Adkinson NF Jr, Buncher CR, Busse WW, Bush RK, Gadde J, Li JT, et al. Ragweed immunotherapy in adult asthma. *N Engl J Med* 1996;334(8):501–6.

[5] Horst M, Hejjaoui A, Horst V, Michel FB, Bousquet J. Double-blind, placebo-controlled rush immunotherapy with a standardized *Alternaria* extract. *J Allergy Clin Immunol* 1990;85(2):460–72.

[6] Malling HJ, Dreborg S, Weeke B. Diagnosis and immunotherapy of mould allergy. V. Clinical efficacy and side effects of immunotherapy with *Cladosporium herbarum*. *Allergy* 1986;41(7):507–19.

[7] Olsen OT, Larsen KR, Jacobsan L, Svendsen UG. A 1-year, placebo-controlled, double-blind house-dust-mite immunotherapy study in asthmatic adults. *Allergy* 1997;52(8):853–9.

[8] Reid MJ, Moss RB, Hsu YP, Kwasnicki JM, Commerford TM, Nelson BL. Seasonal asthma in northern California: allergic causes and efficacy of immunotherapy. *J Allergy Clin Immunol* 1986;78(4 Pt 1):590–600.

[9] Varney VA, Edwards J, Tabbah K, Brewster H, Mavroleon G, Frew AJ. Clinical efficacy of specific immunotherapy to cat dander: a double-blind placebo-controlled trial. *Clin Exp Allergy* 1997;27(8):860–7.

[10] *(Abramson MJ, Puy RM, Weiner JM. Allergen immunotherapy for asthma. Cochrane Database Syst Rev 2003;(4):CD001186.*

[11] Des Roches A, Paradis L, Menardo JL, Bouges S, Daures JP, Bousquet J. Immunotherapy with a standardized *Dermatophagoides pteronyssinus* extract. VI. Specific immunotherapy prevents the onset of new sensitizations in children. *J Allergy Clin Immunol* 1997;99(4):450–3.

[12] Pajno GB, Barberio G, De Luca F, Morabito L, Parmiani S. Prevention of new sensitizations in asthmatic children monosensitized to house dust mite by specific immunotherapy. A six-year follow-up study. *Clin Exp Allergy* 2001;31(9):1392–7.

extracts can prevent the development of asthma in children who have allergic rhinitis; and, that allergen immunotherapy has efficacy persisting for years after discontinuation[14].

Finally, a more recent pharmacoeconomic study has demonstrated that adult and pediatric patients started on immunotherapy can significantly reduce health care costs.[15] Thus, the body of evidence that exists to date suggests that immunotherapy is an efficacious, cost effective, disease modifying treatment that improves the care of patient with certain allergic diseases.

Regarding allergy skin tests (CPT 95004), this service was last reviewed more than 8 years ago, however it has a work RVU of 0.01, which is nominal, and not worth the time and resources to conduct a robust survey and re-review the service.

Finally, we continue to believe that increased utilization is not an accurate indicator of whether a service is potentially misvalued. In many instances, increased levels of utilization can be attributed to a specialty's response to evolving practice guidelines and current medical literature, as well as the sharp increases in the number of beneficiaries becoming eligible for Medicare each year.

We urge CMS to remove the aforementioned services from its list of potentially misvalued codes.

Refinement Panel
Last year, CMS finalized its process for valuing new, revised, and potentially misvalued services. In light of this new process and given expanded opportunities for comment on proposed relative values for new, revised, and potentially misvalued services, CMS proposes to eliminate its Refinement Panel process. AAAAI understands CMS' rationale for this proposal, yet we are concerned that societies will have limited opportunities to engage with the agency without the Refinement Panel, particularly in cases where the specialty disagrees with a CMS' final RVU decision.

Absent the Refinement Panel, the process by which societies may "appeal" an RVU determination is unclear. Should CMS finalize its proposal to eliminate the Refinement panel, we urge the agency to provide detailed guidance on how to seek a change in previously finalized RVUs, including the process to initiate a meeting with CMS staff to share and discuss new information or clarify previously shared information, as well as any key timelines or dates that may impact CMS' ability to initiate a change in previously finalized RVUs.

Improving Payment Accuracy for Primary Care and Care Management Services
AAAAI supports efforts to improve payment accuracy for primary care and care management services, which are a critical element to the work of A/I specialists in managing asthma, allergy, primary immune, and other A/I conditions. The options CMS has offered for consideration, including evaluation and management (E/M) "add-on" codes, codes for collaborative care and professional-to-professional communication, and refinements to existing care management code requirements, may be useful to the A/I community; however, we believe that other pathways for improving payment for these services, particularly in the realm of cognitive medicine, are needed.

As we stated in our comments to the CY 2015 MPFS Proposed Rule, we continue to urge CMS to adopt and implement codes for chronic disease management (CDM) services and provide a fair and appropriate payment amount for the work involved coordinating care for beneficiaries with one significant chronic condition, such a primary immune deficiency disease (PIDD), asthma, or COPD.

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[13] Purello-D'Ambrosio F, Gangemi S, Merendino RA, Isola S, Puccinelli P, Parmiani S, Ricciardi L. Prevention of new sensitizations in monosensitized subjects submitted to specific immunotherapy or not. A retrospective study. *Clin Exp Allergy* 2001;31(8):1295–302.

[14] *Durham SR, Walker SM, Varga EM, Jacobson MR, O'Brien F, Noble W, Till SJ, Hamid QA, Nouri-Aria KT. Long-term clinical efficacy of grass-pollen immunotherapy. N Engl J Med 1999;341(7):468–75.*

[15] Hankin et al J Allergy Clin Immunol. 2013 Apr;131(4):1084-91.

We urge CMS to consider allowing organizations additional opportunities to respond to the agency's proposals and offer their own ideas for improving payment accuracy for primary care and care management, perhaps through an additional Request for Information (RFI) process or via CMS-hosted listening sessions and town halls.

Target for Relative Value Adjustments for Misvalued Services and Phase-in of Significant RVU Reductions

CMS proposes a methodology to implement provisions from the Protecting Access to Medicare Act (PAMA) and the Achieving a Better Life Experience (ABLE) Act, which established an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. PAMA applied a 0.5 percent target for reductions for 2017 through 2020, however, these target amounts were subsequently revised by ABLE to 1 percent for 2016 and 0.5 percent for 2017 and 2018.

We are deeply concerned about CMS proposed methodology for achieving the target amount. For one, we are concerned that CMS has considered in its calculation of the target the values for codes newly proposed for payment in CY 2016, the Advance Care Planning service codes. We urge CMS to exclude these codes from its calculation of the target as these codes are not and have never been, identified as potentially misvalued.

Regarding the phase-in of significant RVU reductions, we urge CMS to reconsider its proposal to adopt a 19% reduction as the maximum 1-year reduction and to phase-in any remaining reduction in the second year of the phase-in, and instead adopt a 50 percent phase-in approach, which will be much cleaner and understandable to those paid under the MPFS.

Advance Care Planning Services

While it may be unlikely for many A/I professionals to engage in end-of-life discussions with their patients, AAAAI supports CMS' proposal to make separate payment for advance care planning (ACP) services. We urge CMS to finalize this proposal in the final rule.

Incident-To Proposals: Billing Physician as the Supervising Physician

CMS proposes to change its current "incident-to" regulation by adding language that requires "*the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service*." To align with the new requirement, CMS also proposes to remove the current regulatory language allowing a physician or other practitioner to directly supervise (and bill for the service) that is not the physician or other practitioner who provided the services related to the "incident to" service being billed.

This proposal could be particularly problematic for A/I practices that provide immunotherapy and/or intravenous immunoglobulin (IVIG) therapy, which may be administered to a patient over the course of several hours, days, weeks, months, or years depending on the treatment plan established for the patients.

If AAAAI interprets this change literally, it would mean that the same physician would have to examine the patient, order the immunotherapy or IVIG therapy, and be physically present in the office at all times when one of his or her patients is receiving therapy by a non-physician practitioner or auxiliary personnel, in order to bill for the service as "incident-to."

If an A/I practice has multiple locations and/or multiple physicians, it would be wholly impractical to have the same physician physically present for treatments that occur over the aforementioned timeframes.

We urge CMS to clarify whether it is now requiring that the physician upon whose professional services the incident-to service is based must always supervise the services, or if it would consider physicians in the same A/I practice to be considered the same physician for purposes of applying the clarified incident-to supervision requirement. If the former, we strongly oppose the proposed change.

Furthermore, we are concerned that this proposal would unduly impact A/I practices with regard to CPT code 95165, *Professional services for the supervision or preparation and provision of antigens for allergen immunotherapy; single or multiple antigens.* Because this code is not a direct, patient care service, and is performed when the patient is not in the office, CMS should exclude it from its incident-to proposal, if finalized as proposed.

Physician Self-Referral Updates
CMS is proposing to add a new, limited exception for hospitals, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to provide remuneration to an individual physician to assist with the employment of a nonphysician practitioners to provide primary care services to patients of the physician practice. CMS is accepting comments on whether it should consider other, more, or fewer types of services to be "primary care services" or whether the exception should be broadened beyond "primary care services."

As a cognitive specialty, A/I physicians provide enhanced primary care and care coordination services to many of its patients with conditions such as asthma, COPD and PIDD. To that end, we urge CMS to broaden its definition of primary care services to include those services provided by our specialty.

Physician Compare
We are increasingly concerned about the potential for unintended consequences as result of CMS' public reporting of quality data. Specifically, we are concerned about CMS' ambitious proposal to report by late 2016 on 2015 performance data for potentially all physicians reporting via any PQRS mechanism given the inadequacy of current measures and methodologies. While we appreciate CMS' planned steps for ensuring it selects appropriate information for which to publicly report, we encourage the agency to adopt a higher minimum case threshold for publicly reported measures, as the proposed 20 patient minimum is insufficient to ensure the validity of the data. In addition, we urge CMS to carefully consider whether it is appropriate to make data available through a downloadable raw data file if it has already been deemed unsuitable for physician profile pages, as the likelihood for misuse and misinterpretation by consumers and public "watchdogs" is exceedingly high. Finally, where insufficient performance data exists, we urge CMS to provide clear disclaimers explaining why certain physicians lack relevant measure data and that this must not be interpreted as poor performance.

Regarding benchmarking, we are concerned that CMS' proposed methodology would not ensure apples-to-apples comparisons. We urge CMS to either calculate separate benchmarks for each specialty (and in some cases, each sub-specialty) or otherwise adjust performance calculations to ensure fair comparisons among similar physicians. In addition, we are concerned with CMS plans for a star rating system, particularly if the underlying data is not adjusted or benchmarked properly. CMS must be very cautious and thoughtful if it moves forward with star ratings for physicians, as these ratings can result in arbitrary distinctions between physicians whose performance is not statistically different. Furthermore, and similar to the above, we are concerned with including a "green check mark" for those practices that received an upward adjustment in the value modifier. The value modifier continues to be fraught with problems, particularly for A/I physicians, and we oppose CMS' proposed addition of a "green check mark" which will lead the public to believe that physicians who do not have a green checkmark are low quality and/or inefficient providers.

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System (PQRS)
AAAAI is concerned about CMS' proposal to move up the deadline by which an entity must submit all documents to CMS for purposes of being considered for QCDR status to January 31 of the reporting year. We urge CMS to preserve the current March 31 deadline, which would give entities more time to fine-tune their validation strategies, measures specifications, audit plans, and other safeguards to ensure that they are able to collect and report data accurately and meaningfully. If preserving the existing deadline is impossible, CMS should at least allow submissions through the end of February.

In addition, we continue to be concerned with CMS' requirement that QCDRs report each quality measure for 50% of ALL applicable patients (i.e., Medicare and non-Medicare), as a sample this large is not always

necessary to ensure the validity and reliability of reported data. As the agency is aware, this requirement is significant more burdensome than the requirement under traditional PQRS, which only requires reporting on 50% of Medicare Part B patients.

Finally, and while we recognize there is a formal process for submitting new measures for inclusion in CMS' quality improvement programs, we urge CMS to support the development and adoption of quality measures, Conditions of Participation (CoPs), and other federal health and safety standards that target a variety of settings to encourage correct identification of penicillin allergies as part of existing infection control requirements or newly proposed antimicrobial stewardship requirements. Our request is aligned with other federal stakeholder activities, including a March 2015 report, National Action Plan for Combating Antibiotic-Resistant Bacteria, issued by the White House.

Value-Based Payment Modifier (VM)
We continue to be concerned about the implementation of the VM, and oppose the measures and methodologies on which CMS relies to make "value" determinations, most of which are irrelevant and not applicable to A/I practices. Nonetheless, we appreciate that CMS is proposing to increase the minimum number of attributed episodes needed for CMS to include the Medicare Spending Per Beneficiary measure in a cost composite to 100 cases, but urge CMS to increase this to 200 cases, which is consistent with the All-Cause Readmission measure that CMS uses to calculate the quality composite of the VM.

We appreciate that CMS is seeking feedback on potential future approaches to addressing the medical community's concerns that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. We urge CMS to apply socioeconomic status (SES) adjustments to cost measures under the VM, which has been shown to have a significant impact on patient outcomes. In fact, CMS has noted in rulemaking for other Medicare payment systems the impact that social and other detriments impacts quality and outcomes of healthcare.

We also urge CMS to consider making additional opportunities available for the medical community to provide feedback on this issue, perhaps in the form of a separate comment opportunity or Request for Information (RFI).

Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
We appreciate the opportunity to provide feedback to CMS as it implements provisions outlined in MACRA related to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).

Regarding MIPS, and in addition to the potential clinical practice improvement activities described in the statute, we urge CMS to consider the following additional activities for A/I physicians:

- Physician attendance and participation in ACGME-accredited events, such as the AAAAI Annual Meeting
- Fellowship or other advanced clinical training completed during a performance year
- Physician practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NQCA), Accreditation Association for Ambulatory Health Care (AAAHC), or other recognized accreditation organizations
- Engagement in private quality improvement initiatives, such as those sponsored by health plans and health insurers

In addition, a universal low volume threshold might not be sufficient for all physicians, and CMS might need to adopt multiple distinct thresholds to accommodate a wide range of specialties and practice types. Regardless, physicians who fall under any adopted threshold should be provided with the option to participate in MIPS if they believe they can provide CMS with meaningful data to qualify for an incentive.

We look forward to providing more detail on the issue of clinical practice improvement activities and low-volume thresholds during a future community opportunity.

Regarding APMs, we urge CMS to adopt a set of fundamental elements that would be core to any model "deemed" by the agency. This would provide the needed flexibility for physicians to develop APMs that make the most sense for their specialty and/or practices. At a minimum, these fundamental elements should include:

- **Quality Measurement** – Measures of clinical quality that meet minimum standards and are developed by relevant clinical experts should be a fundamental component of any APM.
- **Continuous Data Collection** –APMs should require continuous clinical data collection through the use of a qualified registry, database, or other health information technology, as appropriate.
- **Shared Decision-Making (SDM)** – Where appropriate, APMs should encourage engagement in collaborative processes that assist patients with making individualized treatment decisions by taking into account the best scientific evidence, as well as the patient's values and preferences.
- **Care Coordination** – APMs should incentivize seamless transitions of care between providers and care settings, when appropriate, including effective communication during referrals and consultations, systematic processes for tracking follow-up tests and treatments, and patient education and support for self-management.
- **Patient Reported Outcomes (PROs) and Care Experiences** – APMs should collect data on both patient reported care experiences and patient reported health outcomes relevant to the model, using validated instruments.

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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,

Robert F. Lemanske, Jr., MD, FAAAAI
AAAAI President