

September 2, 2014

Administrator Marilyn Tavenner
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1612–P
P.O. Box 8013
Baltimore, MD 21244–8013
Submitted electronically via <http://www.regulations.gov>

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and other revisions to Part B for CY 2015

Dear Administrator Tavenner:

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, 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 policies outlined in the 2015 Medicare Physician Fee Schedule proposed rule that could affect beneficiary access to allergy, asthma, and immunology care and treatment.

Using OPPS and ASC Rates in Developing PE RVUs

CMS' intent to use hospital cost reports to revise the Medicare physician fee schedule (MPFS) practice expense (PE) methodology is a growing concern. CMS' claim that hospital cost report data are more reliable than data provided by non-facility providers, particularly when a service is significantly and disproportionately physician office-based, is erroneous. In fact, there are growing concerns with hospital cost reports in light of CMS' transparency efforts, which have shed light on the fact that many hospitals are inflating their costs. We appreciate that CMS is not making any proposal to implement such a policy for CY 2015, however, we caution CMS against implementing any such measure that would use hospital-level data as the basis for physician office PE RVUs in the future.

In addition, we appreciate CMS' desire to better understand the impact of the shift in services from the physician office to the hospital outpatient department, the growing trend in hospital employment of physicians, and the acquisition of physician offices by hospitals and subsequent redesignation of those offices as hospital outpatient departments (HOPDs), given the significantly higher program spending and beneficiary cost sharing (without a notable change in patient care or quality) for the migrating services.

To understand this trend, CMS is proposing to establish a new HCPCS modifier to be reported with every code for physician and hospital services furnished in off-campus facilities of a hospital. We disagree that a new HCPCS modifier will yield the data and information CMS needs to understand and evaluate the impact of this trend. The existing Medicare claims database contains the information needed to address the agency's questions; it is only a matter of working with CMS' software analytics team and programmers in the writing of a query that would

identify and match hospital outpatient and physician claims for the same patient, on the same date of service, for a select set of procedure codes of interest to CMS. We urge CMS to take this approach rather than requiring hospitals and practices to append a modifier, which is more likely to be misapplied and create unnecessary confusion in the datasets.

Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

Without explanation, CMS has proposed reductions in the practice expense relative values for CPT codes 95017 and 95018 of 4.3% and 5.3%, respectively. In 2014, these codes were substantially reduced as a result of significant revisions made to the Medicare Economic Index (MEI). Costs associated with providing these services have not decreased; in fact, costs for some supply items have increased. Should CMS finalize these reductions, the result will be a cumulative cut of 15.3% and 17.1%, respectively, in only two years. These steep reductions in reimbursements force many allergists to discontinue providing these services to Medicare beneficiaries.

Potentially Misvalued Codes

AAAAI disagrees with CMS that CPT codes 94010 (Breathing capacity test), 95004 (Percutaneous allergy skin tests) and 95165 (Antigen therapy services), are potentially misvalued despite increased utilization of these services. The AAAAI is working with other organizations within the A/I specialty to respond through appropriate processes.

Improving the Valuation and Coding of the Global Package

Regarding CMS' proposal to transition all 10-day and 90-day global surgical codes to 0-day global codes, we appreciate CMS' desire to better understand the value of each discrete service independent of the services with which they are packaged. These data may be useful in future payment reform efforts, including bundled and episode based payment models. However, we are concerned that CMS has not provided any detail about the mechanism by which CMS would unbundle and revalue each discrete service. We are also concerned about potential unintended consequences, such as increased financial liability on beneficiaries. We urge CMS to work with the medical specialty societies to ensure the value of discrete services are fair and appropriate, and preserve access to care for medically necessary services.

Valuing New, Revised and Potentially Misvalued Codes

We applaud CMS for proposing to increase transparency in the establishment of relative value units (RVUs) through a revised process that would provide for improved notice and comment. Medical specialty societies and Congressional leaders have urged CMS to take any and all steps necessary to ensure that the rulemaking process for changes in the MPFS under the initiative is transparent and allows for sufficient input by stakeholders well before the new values are implemented. Unfortunately, we believe CMS' proposal is overly complex, potentially burdensome, and goes well beyond the principal request of the medical specialty societies and Congress; that is, for CMS to publish reimbursement changes for misvalued codes in the proposed rule, as opposed to waiting until the final rule.

We note that CMS receives RVU recommendations for misvalued codes from the American Medical Association's Relative Value System Update Committee (AMA RUC) just days after the Spring meeting (typically in April), which is at least two months in advance of the release of the annual MPFS proposed rule. We believe this is enough time for CMS to incorporate revised values for misvalued codes into the proposed rule, and employ its ratesetting methodologies, which mostly automated calculations.

Moreover, we are deeply concerned with the potential negative impact this could have on new codes and technologies. We worry that the proposal could delay bringing new therapies to the Medicare population that could significantly benefit. Given these concerns, we urge CMS to simply begin publishing revised RVU for misvalued services in the proposed rule rather than implement its current proposal.

Chronic Care Management

AAAAI supports the agency's efforts to ensure payment for non-face-to-face work associated with coordinating care for chronically ill beneficiaries. CMS has made a concerted effort to emphasize the value of this important work by finding mechanisms to fund non-face-to-face services. CMS' proposal to eliminate certain restrictions on billing the new chronic care management (CCM) services, to avoid adopting broad practice standards for providing CCM services, and for allowing CCM services to be performed "incident to", are all welcome proposals that we support.

However, we are concerned that CMS' proposed reimbursement would not be adequate to support the patient population for whom the service is intended. Patients that require CCM services are atypically complex; they have multiple chronic healthcare conditions managed by medications with a high risk of interaction and adverse events, and are more likely to have an emergency room visit or hospitalization. The proposed payment amount is more appropriate for "chronic disease management"; that is, care coordination geared toward a patient population that can be managed using standard practice guidelines, which typically call for office visits and lab/diagnostic testing at pre-specified intervals. We believe that patients with persistent and severe asthma do significantly better when an allergy/immunology specialist actively manages their care, resulting in better patient outcomes and lower long term costs. A new CDM code should be designed in such a way as to facilitate this, but to do so must engage specialty care without creating restrictions or disincentives around the structures in which those specialists might be practicing.

In addition, emphasizing the use of EHRs when interoperability standards have not been developed, adopted and incorporated into certification requirements for EHR technology seems inappropriate. CMS is already aware of the current challenges associated with the availability of 2014 Edition certified EHR technology (CEHRT), which has created multiple other challenges for practices. Many Allergy/Immunology practices have experienced significant challenges meeting meaningful use while many systems still do not facilitate the specialty well, even if they have adopted or connected to a system dictated by a hospital or clinical affiliation. Until such issues are resolved, we do not believe CMS should not require practices to be meaningful users of EHRs in order to be reimbursed for care coordination services.

AAAAI supports improved care coordination for **all** Medicare beneficiaries, therefore, we urge CMS to adopt and implement codes for both CCM and chronic disease management (CDM) services, and provide a fair and appropriate payment amount for the work involved coordinating care for both. While doing so, however, we continue to support development of appropriate risk management strategies that recognize that specialties often treat patients with very complicated co-morbidities, and appreciate CMS recognition that many efforts designed to encourage coordination are not equally adaptable among specialties.

Physician Quality Reporting System (PQRS)

Participation in PQRS by Allergist/Immunologists (A/I) has been low despite our considerable efforts over the years. One primary reason for this is that, although population reporting is now facilitated through registry, QCDR or measures groups reporting, the asthma measures themselves do not reach the Medicare population, and PQRS is

recognized as a system based on Medicare reimbursement. This disconnect has plagued the specialty for years, and we believe the incongruity presented in having asthma measures that do not include older patients is a primary reason that (1) AI specialists have not reported and indeed have felt shut out of the system, and (2) the asthma measures feature so prominently in the misapplied codes list recently published for 2012 data. We continue to see significant problems for AI in reporting PQRS, largely on account of this disconnect of having asthma measures that do not include older patients. This is especially disconcerting in light of the PQRS transition to an all-penalty program and CMS' continued reliance on PQRS measures to calculate a Physician Value Payment Modifier that puts physician at an increasingly large risk for penalties.

Reporting options

Quality Clinical Data Registries

These difficulties in relating PQRS to AI specialists were a primary reason why the AAAAI made the tremendous investment necessary to quickly develop and launch a QCDR in 2014. In doing so, we finally had the opportunity to offer our providers a chance to report on measures that better reflect the quality care provided by the specialty, as well as to begin to collect measures data on other measures. We included PQRS asthma measures, but modified them to remove the problematic upper age limit, with the intention of supporting our ongoing advocacy to get CMS to make this change to all PQRS asthma measures. However, making this change made the measures not count as quality measures for purposes of calculating the VBM, as is addressed below.

The AAAAI's commitment is ongoing and we will make changes to the QCDR for 2015, but requiring three outcomes measures to be reported for successful QCDR reporting is asking too much too soon, both of the QCDR sponsors and of the individual users. Even with the allowance for one of the three to be one of a few other options of measure categories, the initial implementation and development of the QCDRs would have been much better followed up with a second year that would allow additional QCDRs to be developed as well as those that launched in the first year to build a broader base of support after a successful initial year. The changes proposed for 2015 just ask too much, too soon. We appreciate the opportunity to add additional non-PQRS measures, and applaud the level of overall reporting having not been raised above last year's monumental jump from 3 to 9, but we ask that you reconsider the requirement of three outcomes measures already for 2015.

In regards to posting of QCDR data, we support posting of measures and who is reporting, but are concerned that CMS is moving too quickly toward reporting measures data; particularly for our smaller practices, which remain the norm in the AI specialty. We believe that the publication of QCDR measures data too soon will significantly impede our ability to development use of the QCDR among these smaller practices. We would support posting QCDR measures data no sooner than 2017, and at that time to have the data posted on the separate website that hosts our QCDR. We would support linking from Physician Compare to the website where the QCDR is hosted, but we will not support posting of individual quality measures data on the specialty society's website.

Claims-based reporting

We are concerned about the ongoing reduction of available measures. However find especially frustrating the limitation of measures available for claims-based reporting, which make it continually more difficult for small practices, many of whom still do not have the expensive technological resources of larger groups or institutions, to participate in these programs. While we acknowledge that CMS is following regulatory requirements to increasingly penalize those not participating and that CMS would like to move the pendulum over to more robust data collection mechanisms, it does not have to simultaneously make reporting nearly impossible for those

practices who still are unable to invest in EHRs or registry reporting. We ask that the needs of the smallest practices, particularly those who may be late in their careers, still be given some consideration and that the claims-based reporting option remain as widely available as other reporting options.

COPD Measures

The Allergy/Immunology specialty is tremendously concerned with the proposal to remove the COPD measures from PQRS reporting. We would ask for an opportunity to work with CMS to engage in the process of seeking a measures steward for these measures.

Asthma Measures

The Allergy/Immunology specialty continues to be challenged in participating in the PQRS program on account of insufficient measures for a number of areas related to specialty care in our patients with allergic and immunologic disease, but we are particularly concerned about the severe problems we continue to experience with asthma measures. We have specific concerns in several areas of the 2015 MPFS proposal regarding its use of asthma measures.

Proposed removal of Asthma Assessment measure

We strongly urge that CMS NOT remove the Asthma Assessment measure from these programs. While CMS intends to replace the measure with the Optimal Asthma Care measure, we do not believe the measures are sufficiently similar for the Asthma Assessment measure to be wholly replaced by the Optimal Asthma Care measure, particularly in the first year for which the Optimal Asthma Care measure is available. These two measures simply do not measure the same thing. With so few asthma measures available, any potential negative implications for having what some might view as similar measures in the same program are far outweighed by the significant repercussions of continuing or exacerbating the lack of sufficient measures to reflect quality care for asthma patients.

The Asthma Assessment measure should be retained, and should have upper age limit removed. As we have previously communicated to CMS, we do not believe there is or ever has been any evidence base supporting the use of an upper age limit in asthma measures. Further, we believe that with this measure extended to finally include asthmatics in the Medicare population, there is additional benefit to be had from maintaining its use in the PQRS program to look for consistency with the use of this measure in older asthma patients, as well as to improve the care of these patients.

Data reports from PQRS have shown that there continues to be room for performance improvement in this measure. We believe this measure continues to have the ability to improve care for asthma patients, particularly with the upper age limit removed.

It is with significant concern that we have noted the prevalence of asthma measures in the PQRS misapplied codes report published earlier this year. We believe that many providers are unsuccessful in reporting these measures because of this age range issue. We strongly encourage CMS to drop the upper age limit for asthma measures, maintain the Asthma Assessment measure, and see what difference that presents in the reporting, before any further consideration is given for dropping this measure.

Proposed Optimal Asthma Care measure

We certainly understand CMS' commitment to embracing measures that reflect patient outcomes, and understand that the Asthma Assessment measure is proposed to be dropped in favor of the Optimal Asthma Care measure. While we are supportive of the intent of the Optimal Asthma Care measure, we have several concerns regarding its use as currently specified and recommendations on how to improve it. We request that modifications be considered to the measure before it is adopted for use in PQRS and other CMS programs, for 2016 at the earliest.

First, the current proposed upper age limit of 50 years of age in the Optimal Asthma Care measure is unacceptable. Again, we have been working for years to include the ever-increasing population of older asthma patients in quality reporting programs through CMS. Incorporating this measure as presented with an unsupported, unjustifiable and arbitrary age limit will result in CMS failing to capture an important population and the very group of patients that the PQRS was initially authorized to target. This is a serious step backwards in extending quality initiatives to cover older asthma patients as the existing age limits have increased to 64 years of age. Our ultimate goal is to see upper age limits eliminated, so going back to 50 is simply unacceptable.

In addition, as allergist/immunologists, we provide care to patients with more severe asthma, and the Optimal Asthma Care measure as currently construed does not allow for risk adjustment for severity. We feel strongly that methods of risk adjustment can and should be applied to adjust for this important factor. We believe that there may be several ways to improve this measure with the inclusion of risk adjustment factors, such as medication use or responsiveness to treatment. The A/I specialty would be pleased to work with CMS and with Minnesota Community Measurement as the measure steward to help develop an appropriate risk adjustment strategy.

Finally, we believe the measure could be improved by being amended to include a substantial improvement in asthma control during the measurement period as being numerator compliant. A substantial change could be defined based on per cent improvement (e.g. 20 %) or based on the minimal important difference (MID) of the instrument (3 for ACT and 0.5 for ACQ). Patients with more severe asthma may improve substantially with appropriate treatment but still not reach the well-controlled level. If the measure were to also capture a meaningful improvement in ACT scores over time, it would still reward appropriate care but also make the measure less severity-dependent.

Again, we are supportive of the concept of the Optimal Asthma Care measure, but we believe that it should not be included in CMS quality programs until significant modifications are given careful consideration.

Spirometry for Asthma Management measure

The specialty has once again submitted a proposal that a measure be added for spirometry for management of asthma, parallel to the equivalent measure for COPD. We realize this is a process measure, but it is guideline based and related to improved outcomes in patients with asthma. We encourage CMS to reconsider moving forward with a spirometry measure for patients with persistent asthma, for whom we believe spirometry to be an extremely important element of care. To disregard its potential simply on account of its classification as a process measure grossly underestimates significant improvement in care that this measure could represent to millions of asthma patients, as well as resource savings to be gained through better medication choices and increased exacerbation prevention.

Asthma Measures Group

With the proposed increase in measures from four to six for reporting via measures groups, and the elimination of the Asthma Assessment measure, we find the asthma measures group to be insufficiently related to quality care for patients with asthma. The proposed composition of this measures group features only one measure, Pharmacologic Therapy for Persistent Asthma, that is uniquely related to asthma. While documentation of current medications, screening for flu vaccine, BMI and intervention in smoking are important elements of care, these measures certainly do not provide an adequate basis for determining and reporting who is and is not providing high quality care to asthma patients.

However, the provision of an Asthma Measures Group remains very important. Therefore we again encourage the reinstatement of the Asthma Assessment measure, with the upper age limit removed, to be included in the 2015 Asthma Measures Group. We would suggest that the increased size of the group from four to six be reconsidered; but especially if the change in size is retained, it is very important that the Asthma Assessment measure be retained for reporting quality care in asthma. We believe the retention of this measure is particularly important for the Asthma Measures Group, but strongly prefer it remain available for all reporting methods for which it was available in 2014.

Further, the meaningfulness of an Asthma Measures Group in particular would be significantly enhanced with the addition of a spirometry measure.

Sinusitis measures

It should be noted in the sinusitis measures set that the recommendation regarding amoxicillin is out of date per Infectious Disease guidelines. We are confident that our colleagues in other specialties will have covered this concern thoroughly, and thus will not belabor the point here.

Physician Value-Based Payment Modifier

The Allergy/Immunology specialty is proud to still include a significant number of very small community practices with just one or two practitioners. The increase of the penalty for not reporting to 4% in such an exceptionally fast timeframe punishes these small practices much more heavily than the penalties to which larger institutions, which were included earlier, were subject in their first years. We ask that, at the very least, these smaller practices be subject to some lower level of penalty or be held harmless from all downward adjustments during their initial year of participation as the Value Based Modifier implementation expands to include them.

Further, the AAAAI is highly concerned about the lack of a connection between the cost and quality measures used to calculate the VBM. Value, by definition, is a combination of both quality and cost. However, the current cost measures used to calculate the VBM have absolutely no connection to the quality measures to which physicians are held accountable under the VBM. The Total Per Capita Cost measures and the Medicare Spending Per Beneficiary (MSPB) measure assess the total amount billed per patient and not the cost of the specific care provided by the individual physician. These general assessments are not appropriate for individual physician accountability since they have little to do with the data captured under the PQRS AND incorrectly assume that physicians have control over the care plan and treatment decisions of other physicians who also treated the patient over the reporting year.

We are encouraged by CMS' ongoing work to define more specific episode-based cost measures and look forward to working with CMS to develop and refine episodes relevant to our members. However, we remain significantly concerned about the interplay between cost mechanisms and the lack of risk adjustment in quality measures as well as in cost measures. We sincerely hope to see episode-based cost measures take this important issue into account.

Further, we oppose CMS' decision to not apply socioeconomic status adjustments to cost measures under the VM. A large and growing body of evidence demonstrates that sociodemographic factors such as income and insurance status affect many patient outcomes, including readmissions and costs. Failing to adjust measures for these factors can lead to substantial unintended consequences, including harm to patients and increased healthcare disparities, by diverting resources away from providers treating large proportions of disadvantaged patients. It also can mislead patients, payers and policymakers by blinding them to important community factors that contribute to worse outcomes. To ignore such factors is to completely misrepresent the realities of care for patients. For example, the significance of addressing the realities of the patients' environments and access to care choices are well documented as being indicators of outcomes in patients with asthma of all ages and across the United States. Until such complicated issues are better addressed, physicians should not be held accountable for a flawed value equation that provides little useful information to both physicians and patients. The unintended consequences truly represent too high of a cost for our patients themselves.

Physician Compare

Under the proposal, physicians reporting via QCDR will be measured for VBM purposes only on the basis of traditional PQRS measures for the VBM, to allow for a year of baseline data to be gathered on non-PQRS measures. This creates an unfortunate and unforeseen disincentive for reporting via QCDRs using only specialty measures. Had we as a QCDR sponsor known that only regular PQRS measures would enable our physicians to show up as better than average on Physician Compare, we would have included PQRS measures, at least to such a level as to be able to report the asthma measures within the current age limits so as to make at least those measures reportable, while still collecting data on the measures in older patients as well. But we had no way of knowing there would be a significant ramification for our users in including only specialty measures, so we moved ahead using a set of measures in the QCDR designed to truly improve quality for all of our patients; and that meant we have no PQRS measures in the QCDR.

We are tremendously bothered by the implications this will have for public reporting. Those who report via QCDR actually report not only more relevant and meaningful data, but more robust data than traditional PQRS reporters since they must report on all patients and not just Medicare patients. Yet, these physicians will be characterized as "average quality" in public reports versus those reporting less meaningful PQRS measures, who may be characterized as "high quality."

Therefore we request that providers reporting via QCDRs using only specialty developed measures at least be listed on Physician Compare in some way that shows that they did fully report according to the requirements of PQRS via QCDR, but that CMS determined after the rules for QCDRs were released that these measures would not be able to qualify them for the highest ranking. Instead of showing these early adopters as "average" we think they should be given some recognition that reflects that they were willing to be early adopters in a new system designed to better identify quality care for their specialty. That would also open a door for creating a way to address any issues that

arise after the first year of reporting for the QCDRs since other issues, such as this need to create baseline data, come up after initial rules are posted.

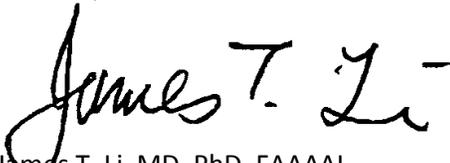
Reports of Payments or Other Transfers of Value to Covered Recipients

CME is an effective and necessary tool to aid AAAAI members in the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes necessary to provide high-quality, patient-centered care. As such, we are concerned with CMS' proposal to completely eliminate the CME exception. Instead, we urge CMS to consider a modification put forward by the American Medical Association (AMA) that calls on the agency to add language that the exemption applies under section 403.904(i)(1) when an applicable manufacturer provides funding to a CE provider, but does not select or pay the covered recipient speaker/faculty directly, or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program.

In addition, as CMS continues to implement the Open Payments program, we urge the agency to review ongoing issues reported by physicians attempting to register and to expand the registration timeframe accordingly to ensure covered recipients have ample opportunity to register, review, and dispute data on the Open Payments System before publication. We also request that CMS provide clarifying guidance that manufacturers and group purchasing organizations are not authorized to unilaterally dismiss disputes by physicians or teaching hospitals. Given the inconsistent interpretations of the Sunshine Act evidenced by manufacturers to date, information collected in the Open Payments system should be flagged as disputed in the public database until resolution is reached between the parties.

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,

A handwritten signature in black ink that reads "James T. Li". The signature is written in a cursive, flowing style.

James T. Li, MD, PhD, FAAAAI
President