August 27, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop 314G
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1612-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule; 79 FR 40318 (July 11, 2014)

Dear Administrator Tavenner:

On behalf of the nearly 13,000 U.S.-based members of the American Academy of Dermatology Association (AADA), I am responding to the Centers for Medicare and Medicaid Services' (CMS') CY 2015 Physician Fee Schedule (PFS) proposed rule published in the *Federal Register* on July 11, 2014. The AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. We appreciate the opportunity to provide comments to CMS on this proposed rule and hope CMS will take the AADA's concerns and recommendations into consideration when crafting the final rule and formulating future policy.

Using OPPS and ASC Rates in Developing PE RVUs

The AADA is pleased that CMS has decided not to use the hospital outpatient department or ambulatory surgical center (ASC) payment amount as the basis for establishing PFS payments. While we are sympathetic to concerns about the methodology for reviewing and updating PFS physician expense (PE) amounts, the way that the Ambulatory Payment Classification (APC) fee schedule calculates those payment amounts is inappropriate for the PFS.

American Academy of Dermatology Association
Excellence in Dermatology™

1445 New York Ave., NW,
Suite 800
Washington, DC 20005-2134

Main: 202.842.3555
Fax: 202.842.4355
Website: www.aad.org

We are aware that CMS is seeking alternate ways to evaluate PE inputs, including the possible use of hospital outpatient cost reports that are used to establish and update the APC fee schedule. However, we are not familiar with the details of what is included in those reports and how those data are collected. The process used to establish PE for the PFS must include the individual direct expense components.

Improving the Valuation and Coding of the Global Package

CMS proposes to refine bundles by transitioning all 10- and 90-day global codes to 0-day global codes. Several concerns with the global packages were identified and, while none of them alone are sufficient, CMS believes that taken together they justify the change. Medically reasonable and necessary visits would be billed separately during the pre- and post-operative periods outside the day of the surgical procedure. CMS proposes to make this transition for current 10-day global codes in CY 2017 and for the current 90-day global codes in CY 2018, pending the availability of data on which to base updated values for the global codes.

The AADA supports efforts to assign appropriate relative values to physician services. However, the proposal to eliminate the 10- and 90-day global periods is misguided. Those global periods were established in part to simplify payments from Medicare and patients, and to remove incentives for over treatment that CMS and MedPAC continue to insist are inherent in fee-for-service payments. The proposed rule does not address either of these rationales, or why they are no longer relevant.

This proposal will increase out-of-pocket costs for many patients. Patients who are sicker will need additional and more complex visits than typical patients. Medicare Advantage plans often require standard out-of-pocket amounts every visit, so costs for those patients will also increase. Even if the total patient costs would be about the same under this proposal, some patients may choose not to return for needed post-operative visits to save the expense of those visits.

The 10- and 90-day global periods were established as bundled services to ensure that physicians shared some of the risk for services provided during the post-operative period. Though CMS makes some attempt to address the issue, this is clearly a move away from that concept. CMS indicates that valuing each service provided during the current 10- and 90-day windows will help with development of appropriate payments in new payment models, but the fact is that most services are not provided using those payment models. Most payments

continue to be fee-for-service, and this change may encourage higher utilization of services by paying for each visit and service. This change will result in millions of additional claims – an administrative expense for CMS and for providers.

It has taken over 20 years to establish the relative values of the over 4,200 codes that CMS is proposing to review. If CMS chooses to move forward with this proposal, the Relative Value Scale Update Committee (RUC) and CMS are not capable of revaluing these codes in the short amount of time that CMS proposes. CMS must first identify the best methodology to appropriately re-value these codes and vet that methodology through the rulemaking process. The complexities of the valuations make it impossible to simply back out the values of post-procedure visits. Once the methodology is understood, CMS must allow sufficient time to ensure that the codes are fairly valued. The schedule can be developed only after the methodology is finalized.

Valuing New, Revised and Potentially Misvalued Codes

In the proposed rule, CMS describes the current process of valuing codes and identifies some of the concerns with that process. CMS states that an assessment of the process is warranted.

After examining alternatives, CMS proposed to modify the process to make all changes in the work and malpractice (MP) relative value units (RVUs) and the direct PE inputs for new, revised and potentially misvalued services under the PFS by proposing the changes in the proposed rule, beginning with the PFS proposed rule for CY 2016. CMS proposes to include proposed values for all new, revised and potentially misvalued codes for which RUC recommendations are received by January 15th of the preceding year. For the CY 2016 rulemaking process, CMS would include in the proposed rule proposed values for all services for which we have RUC recommendations by January 15, 2015.

For those codes for which CMS does not receive the RUC recommendations by January 15th of a year, CMS would delay revaluing the code for one year (or until they receive RUC recommendations for the code before January 15th of a year) and include proposed values in the following year's rule.

The AADA believes that the CMS should use the proposed Medicare fee schedule rule to publish interim values of codes that have been reviewed as potentially misvalued. We have

some concerns about the timeline that CMS proposes. We recommend revising the proposal to reflect the following:

- It would be inappropriate for CMS to implement this proposal in the November 1, 2014 Final Rule for the 2016 cycle because the current procedural terminology (CPT) Editorial process for the 2016 cycle will already be nearly complete by that date and requiring publication in a proposed rule next summer will delay implementation of new CPT codes in Medicare by an additional year. We therefore recommend that CMS begin implementing the new timeline and procedures for the CPT 2017 cycle and the 2017 Medicare Physician Payment Schedule.
- Retain the current meeting infrastructure for both CPT and the RUC, while shifting the workflow to accommodate the review of commonly performed services to the May CPT/October RUC and October CPT/January RUC meetings. CMS would use the recommendations from each January RUC meeting for inclusion in the proposed rule for the following year.

CY 2014 Interim Final Work RVUs and PE RVUs

In 2013 the RUC reviewed and recommended work and PE RVUs for the actinic keratosis (AK) destruction codes, 17000, 17003, and 17004. In our comments on the 2014 final Medicare physician fee schedule rule, we noted that the AADA and the RUC made an error in the PE inputs in recommending 3 units (grams) of LMX 4% anesthetic cream (SH092) for each additional AK destruction, CPT 17003. The correct quantity is 1 gram. We ask that CMS correct the practice expense inputs for CPT 17003 (destruction of premalignant lesions, 2-14) in the final 2015 PFS.

Electronic Health Record (EHR) Incentive Program

In the proposed rule, CMS addresses feedback from stakeholders regarding the difficulty and expense of having to test and recertify certified EHR technology (CEHRT) products to the most recent version of the electronic specifications for the clinical quality measures (CQMs). To eliminate this added burden CMS proposes that beginning in CY 2015 eligible professionals (EPs) would not be required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for CQMs.

The AADA supports this proposed change to not require providers to use EHRs that have to be re-certified to the year's most up-to-date electronic specifications for CQMs.

Substitute Physicians (Locum Tenens)

In the proposed rule, CMS suggests it is contemplating changes to its substitute physicians (locum tenens) policy. CMS expresses concern about operational and program integrity issues that it believes result from the use of substitute physicians to fill staffing needs or to replace a physician that has permanently left a group. The agency seeks comments about h*ow* physicians and other entities are currently utilizing the services of substitute physicians and billing for such services, and whether there should be limitations on the use of substitute physicians or on substitute physician billing arrangements.

The AADA urges CMS to look at locum tenens policy in the broader context of evolving healthcare workforce dynamics. Medical practice models are in a period of rapid change, and the use of locum tenens has been growing as the healthcare industry continues to shift toward larger practices and the employed physician model. More physicians are opting to work as locum tenens. We believe the use of locum tenens is largely driven by the physician shortage, particularly in rural and already underserved geographic areas.

Locum tenens physicians are held to the same high standards as staff physicians, and often have the same or even higher credentials or experience. They provide services while staff physicians are on vacation, absent due to a health reason, or to meet emergent patient need for a specialist. They also fill unfilled slots in rotations and maintain services offered by practices while those practices seek hard-to-find permanent staff.

The AADA believes that locum tenens physicians are important to providing continuity of care because they treat patients who might otherwise not have the option of seeking treatment from a provider other than their regular provider. Accordingly, we urge caution in imposing restrictions or limitations on the use of locum tenens and recommend that CMS ensure that locum tenens policy retains the necessary flexibility to maintain patient access to care, particularly dermatologic care.

Open Payments

The AADA is concerned with CMS' flawed implementation of the Physician Payments Sunshine Act (Sunshine Act). We are particularly concerned with the way the roll-out has disadvantaged physicians in almost every respect. While we generally support efforts to increase transparency in the interactions between physicians and industry, we are concerned about the accuracy of

the data and the abbreviated timeframe for physicians to register and review data. Accordingly, we request an expanded timeframe of at least an additional six months to allow physicians to register, review, and dispute their data in the Open Payments System before publication.

Revocation of Exclusion for Continuing Medical Education (CME)

The AADA protests CMS' proposal to eliminate the continuing medical education (CME) exemption in the Open Payments Program. In the proposed rule, CMS proposes revoking the existing Sunshine Act reporting exclusion for CME-certified activities. Under the proposal, CMS would exempt third party transfers to accredited CME providers only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. The AADA questions CMS' reasoning in changing its policy regarding the exemption for reporting indirect payments or transfers of value related to CME-certified events before the Physician Payments Sunshine Act has even been fully implemented. Accredited CME providers have relied on the existing exemption in planning, offering, and documenting CME activities over the past eighteen months since the final rule was published. We believe that this mid-stream reversal of policy is outrageous and undermines the educational viability of accredited CME providers and their programs.

In the existing CME exemption, CMS specified five accrediting organizations that have proven track records for adherence to stringent standards that ensure integrity and independence from inappropriate industry control in providing certified CME. We believe CMS' proposal to delete the section identifying CME accreditors and their standards is misguided. That section lists the accreditors and standards which accredited CME providers have used to self-regulate successfully for a decade. The AADA urges CMS to retain the current exemption, which provides a list of accreditors. If CMS cannot retain the current list, then it should endorse the key standards by which any accreditor should be judged, which are the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support (SCS).

Educational Materials

In addition, The AADA urges CMS to reconsider its decision not to cover medical textbooks, journal article supplements, and reprints within the existing statutory exclusion for educational materials that directly benefit patients. We believe these materials have a direct benefit to patients and their medical care. Accordingly, we believe CMS' decision to not cover these

materials under the educational materials exclusion is inconsistent with the statutory language on its face, as well as congressional intent.

Physician Registration and Data Review

The AADA is concerned about the myriad problems with CMS' roll-out of the physician registration and data review processes. Most recently, in early August, CMS closed down the online provider review version of the database in response to reports that a physician could access information on payments reported to another physician. We are concerned that the implementation of this new system for data collection is not ready for implementation and it will likely lead to the release of inaccurate, misleading, and false information. Accordingly, the AADA recommends a minimum six-month period to upload the data, process registrations, generate aggregated individualized reports, and manage the dispute communications and updates.

Throughout this roll-out, CMS has not provided effective notification to physicians and it has not provided a reasonable amount of time for professional organizations to engage and educate physicians on the registration and dispute process. The AADA urges CMS to restructure its communication strategy with impacted physicians. We recommend that CMS notify all physicians who are named in the reports from manufacturers prior to those reports being made public—even where the physician has not previously registered. We believe CMS should proactively alert all affected physicians and provide them with the link to the website where they can review their data before it is made public.

Moreover, we believe the registration process is substantially more complex than CMS has suggested. Our physician members are expressing frustration at an overly complex registration process which, combined with the pre-registration step of verifying identity in Medicare's Enterprise Identity Management (EIDM) System, and the condensed timeframe is unduly burdensome. The AADA urges CMS to streamline these processes and allow physicians adequate time to review and dispute their reports. The AADA requests that CMS afford physicians additional time to register into the system before the data is posted. Additional time would allow for greater physician engagement that will contribute to the success of Open Payments. Accordingly, the AADA urges CMS to delay for six months, until March 31, 2015, the publication of the information collected in the Open Payments System.

Dispute Resolution

We believe the recent problems resulting in the system being taken offline underscore the need for more time for dispute resolution. The AADA urges CMS to ensure that all parties are given ample opportunity to correct any inaccuracies prior to the information becoming public.

The AADA is concerned that very few manufacturers have implemented a process for managing physician inquiries. There is no obligation under the Sunshine Act for a manufacturer to provide a process for physicians to review and/or dispute potentially reportable transfers. There has been little attention given to how the physician inquiry process will unfold. We believe that researching and reviewing a disputed transaction is a labor intensive endeavor. It would likely entail reviewing the original transaction and supporting documentation and then executing numerous communications between manufacturers and physician offices. The AADA believes that even a small number of physician disputes could disrupt and delay the process. If the majority of inaccurate reports cannot be resolved before publication, then the pre-publication review period is of no meaningful use.

The AADA requests that CMS provide guidance to physicians and other stakeholders clarifying that disputes must be resolved between physicians and manufacturers and that manufacturers do not have the power to unilaterally dismiss disputes that are initiated by physicians. The AADA advocates for CMS to limit administrative burden on stakeholders and ensure a uniform and efficient method of resolving discrepancies. At present, CMS has no arbitration process in place to ensure resolution If the manufacturer and physician cannot reach agreement on their own. The AADA strongly urges CMS to establish a neutral arbiter to resolve these lingering disputes.

The AADA recommends that CMS ensure physicians fundamental due process by allowing physicians an opportunity to provide commentary about all reported transfers of value and ownership issues. In addition, the AADA urges CMS to implement a protocol that provides that any disputed data will be immediately removed from the physician's report until a resolution is reached and that any dispute that is left unanswered or fails to be resolved in the allotted time will not be made public.

We believe that CMS' roll-out of the Open Payments Program has not been well thought-out, and we urge CMS to provide adequate time for providers to review and correct information included in the database. Accordingly, the AADA requests CMS to implement a six-month delay in publishing the information over concerns that disclosing incorrect information about financial relationships might negatively impact physicians.

Medicare Telehealth Services

The AADA recommends that CMS explore reimbursement for "store-and-forward" telehealth encounters. The AADA is disappointed that CMS did not address adding dermatology services to the telehealth list because the request of the American Telehealth Association (ATA) did not cite specific codes pertaining to urgent dermatologic problems and wound care. The AADA would like to continue our dialogue with CMS on the value and importance of expanding the role and reimbursement of telehealth with the use of store-and-forward dermatology. With comprehensive patient information and clear images, the dermatologist can often make a diagnosis at a distance and advise the local physician how to care for the patient, keeping patients out of high-cost care sites and allowing patients access to care that may have otherwise seemed unattainable. CMS has, at various times, expressed its interest in expanding the use of store-and-forward teledermatology. The AADA would like to again invite CMS to call on the AADA as a partner in developing and implementing this expansion to provide access and cost savings to the Medicare program.

Physician Quality Reporting System (PQRS) Measures

The AADA opposes the proposed increase in the number of PQRS measures that eligible providers (EPs) must report to avoid penalty in 2017. The AADA remains committed to providing high quality dermatology services and has devoted significant resources to a long-term effort to develop, test and seek National Quality Forum (NQF) endorsement of performance measures for dermatology services. The AADA also supports CMS' efforts to align the various reporting programs, such as PQRS and Meaningful Use, so that measures meaningful for patient care can be reported without undue burden.

However, the jump from the 2014 requirement to report at least three measures to avoid a payment reduction to the proposed 2015 requirement to report nine measures does not reflect the pace of measure development for the majority of specialties. In addition, the lengthy NQF endorsement process slows the pace of moving new measures into PQRS. Considering these

bottlenecks, the AADA supports a phased approach to increasing the measure reporting threshold and urges CMS to require five measures rather than the proposed nine. A more manageable phased approach is consistent with CMS' principle of gradual implementation and will provide time for the development of more measures relevant to specialty services. Five measures is a more feasible benchmark for EPs to reach given the currently available PQRS Measures.

The AADA appreciates that CMS is proposing to continue to include five measures in 2015 PQRS which are particularly important to dermatology services: #137 Melanoma: Continuity of Care Recall System; #138 Melanoma: Coordination of Care; #224 Melanoma: Overutilization of Imaging Studies; #265 Biopsy Follow-Up; and #337 Tuberculosis Prevention for Psoriasis and Psoriatic Arthritis Patients on a Biological Immune Response Modifier. These measures help ensure quality care for patients with skin cancer and skin diseases, are crucial to quality improvement initiatives within dermatology and provide meaningful metrics for dermatologists to participate in PQRS.

The AADA also supports the CMS proposed goal of including measures in 2015 PQRS that represent the full spectrum of patient care -- measures that focus on condition-specific care, as well as those that focus on key aspects of quality medical care. We support the proposal to group some existing measures on key aspects of care into a set of crosscutting measures. However, consistent with a staged approach to increasing the number of measures required for PQRS reporting, we strongly encourage CMS to require one, not two, crosscutting measures for 2015.

In addition, the AADA remains concerned about the requirement to report Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey data. Although we support the proposal that reporting CAHPS for PQRS would be optional for groups of 2–99 EPs, we continue to be concerned that the expense involved with CAHPS will limit participation. We urge CMS to consider ways to fund CAHPS.

New Measure: Melanoma Reporting

The AADA strongly supports the acceptance of the proposed measure, Melanoma Reporting, developed by the College of American Pathologists (CAP). This measure improves patient care by encouraging the reporting of pathology information critical to diagnosis and treatment. Including this measure would increase the number of relevant PQRS measures that can be reported by EPs caring for people with skin disorders, such as pathologists and

dermatopathologists. In particular, it will provide an opportunity to report to some pathology-focused physicians who currently have few or no applicable measures in the PQRS program.

Submission of Data through Qualified Registry

The AADA is pleased that CMS will extend the deadline for qualified registries to submit PQRS quality measure data to March 31 following the end of the applicable reporting period (March 31, 2016 for reporting period ending in 2015). We also welcome the *option* of more frequent submissions of data rather than a single time period.

PQRS Qualified Clinical Data Registries

The AADA continues to support the Qualified Clinical Data Registry (QCDR) option that permits EPs to report quality and outcome measures used in a clinical data registry beyond those on the PQRS measures list. However, we are concerned that CMS proposes to increase the requirement for outcomes measures from one to three. Few validated outcome measures exist for many specialty services, including dermatology. Thus this increase could be burdensome for outcome metric development or force the use of less applicable outcome measures. As QCDRs are still in their first year of reporting, we urge CMS to maintain the current requirement of one outcome measure and to review QCDR experience before considering any increased requirements. In addition, we encourage CMS to delay the public reporting of specialty-specific measures from QCDRs. Registries often serve several functions, including collecting observational data on the course of disease, the variations in treatments and outcomes, care patterns, and factors that influence prognosis and the quality of life. These data can be useful in developing performance measures and for quality improvement, but may not be ready for public reporting. Specifically, additional experience with the QCDR data could provide guidance on trends and improvements in metrics that could inform discussions about public reporting of these data. We encourage CMS to delay the public reporting of specialty-specific measures until specialty societies have tested them for validity, reliability and feasibility for performance reporting. In addition to the continuation of the QCDR option, we encourage CMS to allow for traditional registries to continue as an alternative method of PQRS reporting while outcome metrics are developed. Following the completion of the first year of QCDR reporting, it would be useful to gather feedback from current QCDR stewards that could inform future requirements and clarify instructions for others interested in QCDRs.

Physician Compare Website

CMS proposes to significantly expand the quality measures posted on Physician Compare. For 2015 reporting, in addition to the 20 PQRS measures submitted by individual EPs in 2014, CMS proposes to publish those same measures with data submitted in 2013. For 2016 reporting, CMS proposes further expansion. In particular, CMS proposes to publish all 2015 PQRS GPRO measures submitted for group practices of 2 or more EPs and all 2015 PQRS measures submitted for individual EPs, with a minimum sample size of 20 patients. The AADA continues to support the use of physician data for programs designed to improve or maintain the quality of and access to medical care and where the data provides accurate physician performance assessments. We urge caution as CMS moves to post the performance data of individual physicians, as smaller patient populations will affect the representativeness and accuracy of data. We urge transparency and opportunity for feedback on the methods CMS will use to determine which measures to post on Physician Compare. In particular, we encourage CMS to publish the results of validity and reliability studies as well as the methodology for choosing measures *prior* to posting on Physician Compare. In addition, we continue to encourage CMS to provide a longer period for physicians to review their data. Thirty days is not enough time for ensuring an adequate review. It does not allow sufficient time for revision of the data and a final review by the physician prior to posting.

Value-Based Payment Modifier

The AADA urges CMS to reconsider its planned implementation of the physician value-based payment modifier (VM) by applying the 2017 modifier to solo practitioners and groups of two or more EPs and requiring them to assume risk through the quality-tiering component of the program. The proposed rule would significantly expand the number of physicians subjected to the VM and would also increase payment reductions under the program from a maximum of 2% to a maximum of 4%. Not only is there a doubling of the penalty, but physicians who do not participate in PQRS are subject to an additional 2% payment reduction, putting them at risk for a 6% payment reduction overall. While we appreciate that groups with 2 -9 EPs and solo practitioners receive only the upward or neutral VM adjustment (no downward adjustment) to the 2017 payment, we continue to be concerned that CMS is moving ahead with VM implementation with solo practitioners and small group practices without evaluating data from the implementation with large group practices. The AADA urges CMS to provide more information and transparency on how the agency plans to develop the value- based payment

modifier. It is unclear how cost and quality measures will be weighted to form composites for quality tiering. In addition, the AADA urges CMS to publicly share the methodology as well as the results of the reliability and validity testing of these measures and composites. We request a period of public commenting for the results and the methodologies, which would allow the AADA, as well as other specialty societies, to review and provide relevant comments/feedback to CMS. Accordingly, we ask CMS to delay implementation to allow time to analyze the data from the 2013 performance/2015 payment cycle to determine if methodology adjustments are needed for the approach to be valid, reliable and feasible for small practices and solo practitioners.

Quality and Resource Use Reports (QRURs)

The AADA supports CMS' goal to provide feedback reports to physicians in all groups and solo practices by fall of 2014 and to provide the ability to drill down to additional data. We do not support, however, the proposed shortening of the informal review period from the current 90 days to 30 days as this would not be adequate time to analyze the reports and to request the correction of any identified errors. Shortening the time for review would be burdensome on EPs and may impact the ability to assure the accuracy of data.

Conclusion

The AADA appreciates the opportunity to provide comments on the CY 2015 Physician Fee Schedule proposed rule. We look forward to additional opportunities to comment on these issues and to provide feedback that may help guide reimbursement and policy development.

Please contact Richard Martin, JD, Assistant Director, Regulatory Policy, at (202) 842-3555 or RMartin@aad.org if you require clarification on any of the points or would like more information.

Sincerely,

Brett. M. Coldiron, MD, FAAD
President, American Academy of Dermatology Association

CC:

Elise A. Olsen, MD, FAAD, Vice President
Mark Lebwohl, MD, FAAD, President-Elect
Suzanne Olbricht, MD, FAAD, Secretary-Treasurer
Marta Jane VanBeek, MD, MPH, FAAD, Chair, Council on Government Affairs, Health Policy, and Practice
Elaine Weiss, JD, Executive Director and CEO