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:

The American College of Mohs Surgery (the "Mohs College") represents more than 1,200 Mohs micrographic surgeons who have successfully completed extensive fellowship-training in Mohs micrographic surgery following their dermatology residency training. Mohs surgery is the most advanced, precise, and effective treatment for an increasing variety of skin cancers and has been termed the "gold standard" in skin cancer treatment due to the numerous advantages over other treatment options, including the highest success rate of all treatments – up to 99%. Today, we are writing to express concerns about policies outlined in the 2015 Medicare Physician Fee Schedule proposed rule that could affect beneficiary access to skin cancer care and treatment, which is a growing public health concern.

Using OPPS and ASC Rates in Developing PE RVUs

We are increasingly concerned with CMS' intent to use hospital cost reports to revise the Medicare physician fee schedule (MPFS) practice expense (PE) methodology. We strongly disagree with CMS' assertion 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. While CMS is not making any proposal to implement such a policy for CY 2015, we urge CMS against implementing any such measure that would use hospital-level data as the basis for physician office PE RVUs.

In addition, 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, as well as the acquisition of physician offices by hospitals and subsequent redesignation of those offices as hospital outpatient departments (HOPDs), is certainly warranted, 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 do not believe a new HCPCS modifier is the most effective way to collect the needed data, and urge CMS to abandon this proposal.** The administrative burden to practices associated with the proposal, and the likelihood that the modifier would be inappropriately and/or inadequately applied to claims, is significant. In addition, the misapplication of the modifier could create more confusion in the claims data than CMS anticipates. We maintain that CMS' database

already includes the information CMS needs; 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 HOPD and MPFS claims for the same patient, on the same date of service, for a select set of procedure codes of interest to CMS.

In the meantime, and as we noted last year, **CMS should consider revising its regulations that allow hospitals to redesignate physician practices as HOPDs.** Specifically, CMS should create a process that requires CMS approval for such redesignations based on a modified set of criteria. This would provide CMS an opportunity to determine whether a redesignation is appropriate and meets CMS' modified requirements for such a change.

Alternatively, and as proposed last year in the 2014 MPFS, CMS could establish a new place of service (POS) code for off-campus provider-based clinics. CMS could require clinics that use the new POS indicator to meet certain criteria and seek CMS approval for that new designation.

CMS could also place a moratorium on all redesignations until data can be collected and analyzed to inform future policy decisions. CMS should consider further revising its redesignation criteria based on data collected through the aforementioned processes.

Improving the Valuation and Coding of the Global Package

We are deeply concerned with CMS' proposal that would transition all 10-day and 90-day global surgical codes to 0-day global codes. CMS' proposal stems from concerns raised by the Department of Health and Human Services Office of Inspector General (OIG), the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC) about various aspects of the global surgical package, including the number and level of post-operative visits actually furnished compared to the number and level factored into the bundled payment amount. We appreciate CMS' intent to better understand the value of each discrete service independent of the services with which they are packaged, but we are deeply concerned with the impact on patients, how we anticipate CMS implement this policy, and how other payers will respond to a new payment structure for services that were once "bundled."

We are not convinced that CMS and other federal agency partners have fully considered the impact of eliminating the global surgical package on beneficiaries. Anticipated consequences include disruptions in beneficiary care, poor quality outcomes, and increased financial burden.

Beneficiaries, many of whom are on fixed incomes, may be less likely to receive the post-operative care they need if those visits will have a separate co-payment. Even if the total out-of-pocket outlay would be the same (or less), patients may discontinue their follow-up care too soon in order to avoid the additional copayments. This disruption in care could lead to a poor quality outcome, or worse, a failed treatment. This is particularly true for beneficiaries undergoing various forms of skin cancer surgery as the beneficiary may believe that important, medically necessary post-operative follow-up is not required if they "feel fine".

Many Medicare beneficiaries elect to participate in a Medicare Advantage plan, in which they have a substantial co-payment for each visit. Our members report that in many cases the patient co-payment may be $40 or even $50 dollars for each and every visit. In these instances, the beneficiary absorbs a significantly increased cost to themselves. Again, we are concerned that this will compromise the final outcome of the procedure and potentially lead to the need for additional treatments that could have been avoided with more comprehensive follow up care.

In addition, beneficiaries who see a physician that practices in a hospital-owned provider-based clinic, could be subject to additional cost-sharing and co-payments given the addition of a facility fee on top of the physician fee. This would also result in higher spending in an already financially strained Medicare program.

Also, since some patients will require more post-op visits than the "typical patient" scenario used to value the current global RVUs, the net co-payments for patients in some instances will be greater than currently paid under the global payment policy. Not only could this provide a disincentive for follow-up care, but if implemented, CMS will be burdening patients with an additional financial burden.

We are also concerned with the mechanism by which CMS would unbundle and revalue each discrete service. Simply "backing out" the post-operative visits and other discrete services would be inappropriate and could lead to a payment amount that does not reflect the true cost of providing the service, as the values established through the AMA RUC and CMS are based on the "typical patient." The time and effort it would take to revalue each discrete service does not outweigh the benefit to unbundling the global surgical package.

We are very concerned with how other private insurers would respond to CMS' action if finalized. It is not clear whether health plans would follow-suit, and if they did not, the administrative burden to practices and the confusion by patients would be overwhelming.

Another area of concern is the increased administrative burden from the elimination of global period payment methodology. The separate submission, processing and payment of post-operative E/M codes and other miscellaneous post-operative services and supplies will place an additional administrative burden on Medicare providers, Medicare Administrative Contractors and CMS. Beneficiaries, many of whom see multiple providers, will have still more medical claims to review and pay, causing them to devote additional time and resources to managing their medical bills.

For these reasons, we strongly urge CMS to postpone any move to unbundle global surgical codes until further research and analysis has been conducted and all impacted stakeholders have fully weighed in.

Valuing New, Revised and Potentially Misvalued Codes

We appreciate CMS' proposal 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. Regrettably, 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.

While we recognize that CMS needs time to employ its ratesetting methodologies that are part of the physician fee schedule, it is our understanding that CMS has enough time to incorporate revised values for misvalued codes into the proposed rule, given the ratesetting methodologies are mostly automated calculations. 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.

Rather than simply addressing the predominant concern, CMS proposes to disrupt the entire process for establishing RVUs by proposing significant and potentially burdensome modifications that would also affect RVUs

for new codes and technologies. Physicians and other providers that are reimbursed under the MPFS have an expectation of what their payments will be for most established services, whereas with new codes and technologies, there was little (if any) expectation, as reimbursement may or may not have been made previously.

We urge CMS to abandon its proposal and simply begin publishing revised RVU for misvalued services in the proposed rule.

Reports of Payments or Other Transfers of Value to Covered Recipients

The Mohs College appreciates the need for public transparency of industry-physician financial relationships and supports the intent of the Open Payments (Sunshine Act) program. However, we are concerned about CMS' proposal that would eliminate the "bright line" exception for accredited Continuing Medical Education (CME) activities that is currently afforded to physicians through CMS' existing regulations. One of the most challenging aspects of compliance with the Sunshine Act is accounting for "indirect payments" made through third parties, which is with what CMS proposes as a replacement for the current CME exception.

CME is an effective and necessary tool to aid ACMS members in the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes necessary to provide high-quality, patient-centered skin cancer care and treatment. Eliminating the CME exception could have significant, negative ramifications, hindering physicians' ability and willingness to participate in accredited CME events out of concern that a speaking honorarium, travel fees, or any other payment or transfer of value received by physicians for participating in accredited CME events would become subject to public reporting.

As you know, with the promulgation of the Sunshine Act, the acceptance of funds from industry by physicians has come under extreme scrutiny. Consequently, many healthcare organizations, including employers, medical specialty societies, and publishers of medical and scientific literature, have initiated their own rules and requirements related to the acceptance of payments of transfers of value by physicians from manufacturers. For example, some teaching hospitals do not allow their physician employees to accept any funds or transfers of value as a condition of their employment. Many medical professional societies have also revised their by-laws to ban its Board, committee and task force members, and other society leadership from accepting any funds or transfers of value from manufacturers. Also, organizations that publish medical and scientific journals have also implemented rules for their physician medical editors and journal article reviewers that ban them from accepting any funds or transfers of value from manufacturers.

Physicians take their employment and other volunteer commitments very seriously, as these positions are considered a great honor within their professional communities. In fact, many physicians have been elevated into these distinguished roles as a result of their clinical research and participation in accredited CME events, among other things. CMS' proposal, if finalized, would have a negative and detrimental impact on physicians' ability to serve as faculty at many teaching hospitals; serve as volunteers in their professional associations; serve as medical editors and journal article reviewers; and, ultimately, share their knowledge, skills and expertise with their colleagues to improve the quality and cost of healthcare. By eliminating the CME exception, CMS is putting physicians in a position where they will be unsure of which activities will be reportable, and which will not, thus limiting their ability and willingness to participate in accredited CME events.

Again, we recognize that there is some redundancy with the CME exception with other provisions, given the exclusion for certain indirect payments where the manufacturer is "unaware" of (that is, "does not know") the identity of the covered recipient. Nonetheless, it is our sense that the CME exception provides the level of clarity physicians truly appreciate when it comes to CMS' Open Payments program and its impact on their participation and engagement in accredited CME activities. As noted before, accounting for "indirect payments" is already

challenging and the knowingly standard are likely to be more even more problematic for industry if accredited CME events are no longer excluded.

Similarly, CMS' proposal does not provide manufacturers with any assurances that if they decided not to report indirect payments or transfers of value that they become aware of after an accredited CME event, which the manufacturer would not be subject to penalties. Manufacturers with overzealous transparency compliance officers are more likely to report all instances to avoid financial penalties.

In addition, while we understand that CMS would prefer to distance itself from serving as the arbitrator for determining which entities are CME accreditors, and which are not, we note that CMS regularly engages in such activities through its other "deeming" activities. We do not see that maintaining a list of those groups that meet CMS' standards for accrediting CME events as being patently different in that regard. If CMS has concerns about its level of expertise in making decisions about the standards that it should hold CME accreditors, it should use the rulemaking process to gather input from experts and other stakeholders who could assist with this activity. CMS frequently engages in the development of similar standards, and this activity would be no different.

We have carefully considered CMS' proposal and multiple alternatives as part of a thorough review and discussion with ACMS staff, leadership, and relevant committees. **To that end, we have concluded that we do not support the elimination of the CME exception. Instead, we urge CMS to maintain the CME exception and expand the list of CME accreditors.**

Further, this action reverses a decision that CMS had previously reached after reviewing hundreds of stakeholder comments in a comprehensive rulemaking process. This decision, if finalized, would significantly disrupt the practice of CME and the confidence of doctors, educators, and others. **We urge CMS to reconsider its proposal to eliminate this exception, and instead, appropriately expand the list of certified CME accrediting/issuing agencies beyond the five currently cited in regulation.**

Finally, as CMS continues to implement the Open Payments system, 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 (GPOs) 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.

Physician Compare

We applaud CMS for making significant and substantive improvements of its Physician Compare website that will help beneficiaries navigate and better understand the data and information presented. Despite these improvements, we continue to be concerned with accuracy of the data and the resultant value to beneficiaries and their caregivers. CMS must be extremely cautious when moving from reporting physician participation data to performance and quality scores. Any misrepresentations, even by sheer accident, could put beneficiaries and physicians at significant risk and create a sense of distrust between both parties and further denigrate our already fragile healthcare system.

Physician Value-Based Payment Modifier

As a member of the Alliance of Specialty Medicine, ACMS has raised concerns about the value-based modifier (VM) since the release of the first physician feedback reports with which CMS intended to improve physician

understanding of their performance based on quality and cost metrics in advance of implementing any VBM payment adjustment. From the program's inception, CMS has recognized and admitted to the challenges faced with implementation and administration of the VM by the agency, as well as the challenges to physicians, particularly those in smaller, specialty practices, that lack adequate clinical quality measures or a fair and appropriate means for risk-adjustment. We understand that CMS has limited flexibility in certain aspects of the VM to include the timelines by which the program is implemented; however, CMS does have authority in other critical aspects of the VM. Given the challenges both CMS and physicians face with this new program, we are perplexed by CMS' proposal that would double the VM penalty to four percent in 2017, especially given that is the first year of adjustments for the very physicians that face the greatest challenges.

Even more frustrating is that CMS makes significant proposals to modify the Physician Quality Reporting System (PQRS), to include eliminating a host of important clinical quality measures and increasing the reporting burden, when the PQRS is the basis on which CMS calculates quality scores for the VBM.

An increased VM penalty, coupled with other penalties associated with CMS' remaining quality programs, such as the PQRS and Electronic Health Record (EHR) Incentive Program, not to mention the ongoing challenges with the Sustainable Growth Rate (SGR), is too great a burden for practices caring for a high volume of Medicare beneficiaries.

We strongly oppose CMS' proposal to increase the VM penalty in 2017. Instead, CMS should use its authority to make the program as flexible as possible to enhance quality, encourage improved resource use, and strengthen physician practices. In addition, and given CMS' recognition of the fact that many physicians remain unaware of the VM (despite our collective best efforts to create awareness and disseminate education), we urge the agency to step-up its education efforts to improve awareness about the program among physicians. To accomplish this, we urge CMS to consider alternative vehicles for educating providers that may include notices about the VM and links to educational information as part of Medicare Remittance Advice (RA) notices that accompany physician payments.

*****

We appreciate the opportunity to provide comments on the aforementioned issues of importance to Mohs surgeons. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P, at egraham@hhs.com.

Sincerely,

J. Ramsey Mellette, MD
President, ACMS

Brent Moody, MD
Chair, ACMS Public Policy Committee