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**OHIO FOOT AND ANKLE MEDICAL ASSOCIATION**  
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The Honorable Marilyn Tavenner, RN, MHA  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1612-P

August 25, 2014

Submitted electronically to: <http://www.regulations.gov>

Re: 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

Dear Administrator Tavenner:

On behalf of the members of the Ohio Foot and Ankle Medical Association (OHFAMA), the state association which represents almost 80% of the estimated 1,000 licensed podiatrists in the State of Ohio, we appreciate the opportunity to submit comments on the proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2015 and other matters.

**10- and 90-Day Global Surgical Services**

CMS is proposing to unbundle 10- and 90-day global surgical services, re-value these services as 0-day global services through a yet-to-be-determined methodology, and make these changes effective in CY 2017 (for 10-day global services) and CY 2018 (for 90-day global services). This is a significant and rather alarming policy proposal, especially as CMS moves in other domains to bundle more and more services together, such as under the comprehensive ambulatory payment classification groups (APCs) in the Medicare hospital outpatient prospective payment system and the Bundled Payments for Care Improvement Initiative being tested by the Center for Medicare and Medicaid Innovation. This application would have significant consequences for doctors of podiatric medicine (DPMs), since we estimate that 10- and 90-day global surgical services account for roughly 14 percent of all Medicare revenue for the Podiatry specialty, based on proposed 2015 Medicare payments and 2013 utilization. Furthermore, OHFAMA *strongly* opposes any attempt to finalize an artificial deadline for unbundling global surgical services. It is evident from the proposed rule, that CMS is tentative about how this might be done in a fair and concrete way. We believe that setting enactment deadlines in the absence of more information regarding methodology both impedes adequate public input on the proposal and is unrealistic.

Secondly, any unbundling of the 10- and 90-day global surgical services must guarantee that the values for the base procedures as 0-day globals can be determined accurately and fairly and not end up disadvantaging these services compared to other services paid for under the Medicare physician fee schedule. It is our belief at OHFAMA that the jury is still out on this entire matter. Principally, we believe there is considerable risk that the unbundling process will end up disadvantaging those who provide surgical services by reducing both direct and indirect practice expense payments to these specialties. As it is, CMS understands that direct and indirect practice expense costs are not fully reimbursed under the existing practice expense methodology, and we believe it would be important to demonstrate that any unbundling proposal would not worsen this situation for the affected specialties compared to non-surgical specialties. Unjustified reductions in practice expense payments do not miraculously eliminate real-world practice expense costs.

OHFAMA does see some value in the unbundling proposal in that it would allow more payment for difficult cases, where additional post-procedure visits are needed. This is not a feature of the existing global surgical definition in that the 10- and 90-day global surgical services that are valued-based on the typical patient, as are all other services reimbursed under the Medicare physician fee schedule. Post unbundling of the 10- and 90-day globals is not wise. Physicians furnishing surgical services would face excessive scrutiny and find themselves constantly arguing with Medicare about the medical necessity of every single post-procedure visit. In the context of the current immense backlog in Medicare appeals related to Part B claims, we see this additional potential area of disagreement as an enormous risk for physicians, beneficiaries and even the Medicare program itself. Additionally, we worry that separate billing for each post-procedure service and the separate cost-sharing amounts for each such service might cause some beneficiaries to avoid medically necessary post-procedure care, even if their total cost-sharing obligations might otherwise end up being no different than they are today under the global surgical service policy. This unintended reduction in patient compliance could lead to greater postoperative morbidity and diminished outcomes, and even have professional liability implications.

Likewise, there are other important issues that would need to be addressed if any unbundling initiative were to move forward. For example, it would be absolutely unfair to apply the existing multiple procedure payment reduction policy across all the newly created 0-day global surgical services. That policy was primarily justified by the fact that a single set of post-procedure visits would be furnished following multiple, same-day procedures, rather than the otherwise assumed post-procedure visits associated with each of the individual procedures. However, if and when the unbundling of 10- and 90-day global surgical services occurs, this issue would be addressed Ohio Foot and Ankle Medical Association since physicians would bill separately for each visit.

This multiple procedure payment issue was not addressed in the proposed rule but is a major consideration. If this matter is not addressed properly, it could negatively affect patient care, as physicians would become understandably hesitant to furnish multiple procedures, even if this is clinically appropriate, if they knew that the Medicare payment result would unfairly penalize them. Similarly, there are a number of payment modifiers currently in use in relation to global surgical services and it would be necessary to review all of these and determine which would no longer be needed and which would continue to apply under certain circumstances. OHFAMA cannot rule out the possibility that the unbundling of global surgical services could impact the correct coding initiative. None of this was addressed in the proposed rule.

We would also assert that unbundling of 10- and 90-day global surgical services is likely to increase the volume of claims submitted to Medicare, thereby increasing the Medicare claims submission burden and claims processing costs. Physicians furnishing surgical services would probably end up submitting more than one claim for each procedure. OHFAMA sees this as another area of concern not acknowledged in the proposed rule. Are CMS and the U.S. Congress prepared to increase Medicare contractor budgets to accommodate the increased number of claims that would likely be submitted and processed? Or is CMS planning to force physicians furnishing surgical services to submit only a single claim covering both the 0-day global procedure and all post-operative visits. If so, this would unfairly distinguish between evaluation and management services furnished post-procedure and those furnished during an episode of care for non-surgical problems, or distinctly different conditions. This would be unacceptable. Resulting increases in the number of claims could also affect other contractor costs related to auditing, pre- and post-payment review, and other activities.

The proposed rule raises concerns about the impact of current global surgical service payment policies on alternative payment models. Factually stated, it is true that alternative payment model constructions typically rely on historic Medicare data. It is far from clear to OHFAMA how this historic data would be adjusted going forward in the context of alternative payment models. Any such adjustments to historic data once again risk disadvantaging physicians who furnish surgical services under one or another alternative payment model.

In short, while OHFAMA can appreciate to some extent what CMS is trying to accomplish, and even sees one potential advantage, we are not convinced it is possible to fairly and accurately unbundle the 10- and 90-day global surgical services and we fear that the side effects could be worse than the concerns identified in the proposed rule.

#### **Reports of Payments or Other Transfers of Value to Covered Recipients**

CMS proposes to eliminate the current exclusion for reporting indirect payments made to covered recipient physician speakers at certain accredited and certified continuing education Ohio Foot and Ankle Medical Association events, in part because this exclusion has the unintended consequence of appearing to endorse or

support specific sponsors of continuing education. CMS seeks to correct this unintended consequence by deleting 42 CFR § 403.904(g) to correct this unintended consequence and also because it believes that the current exclusion is redundant with § 403.904(i)(1).

OHFAMA appreciates CMS' consideration of our feedback regarding the reporting of speaker payments associated with certain continuing education events. As we have previously communicated, OHFAMA strongly disagrees with the decision of CMS to omit arbitrarily the accrediting entity for sponsors of continuing education in podiatric medicine, the Council on Podiatric Medical Education (CPME) as an accrediting or certifying entity under the current exclusion. OHFAMA takes issue with the original rulemaking process in this particular case and questions whether CMS provided proper notice to comment on the current exclusion. The proposed rule, published by CMS on December 19, 2011, solicited comments on its proposals regarding categorization of compensation made to speakers. 76 Fed. Reg. 78750. CMS stated that it was considering and welcomed comments on how to categorize CME-accredited speaking engagements and other speaking engagements. The proposed rule did not address, provide notice of, or solicit comment on exempting accredited and certified speaking engagements from reporting requirements, nor did it propose *any list of accrediting and certifying entities* that would be recognized for this purpose. As such, our national affiliate, the American Podiatric Medical Association (APMA), was not able to provide information to CMS on CPME and its standards of approval for sponsors of continuing education in podiatric medicine and explain why they should be exempted in their comment letter, which was submitted on February 17, 2012.

Under 1861(r) of the Social Security Act, Congress defined doctors of medicine, doctors of osteopathic medicine, and doctors of podiatric medicine (as well as doctors of dental surgery and dental medicine, doctors of optometry, and chiropractors) as physicians; however, the current exclusion provides separate and not equal standards without consideration of legislative intent. Additionally, state laws and regulations require continuing medical education for podiatric physicians in order to maintain their licensure to practice, which is required of all physicians. To ensure the credibility of these programs and uniformity in standards, state law and regulations frequently require that podiatric physicians attend continuing medical education programs offered by CPME- approved sponsors. OHFAMA is the sole entity of approval for the state Medical Board's CMEs for podiatric in-state educational programming and OHFAMA is also a CPME approved sponsor for podiatric education. Because CPME was arbitrarily omitted from this list, covered recipients who lecture at continuing education in podiatric medicine programs run by CPME-approved sponsors will be treated differently than covered recipients who lecture at continuing medical and dental education programs run by sponsors accredited or certified by the listed entities.

As the APMA has previously informed the CMS Center for Program Integrity's Data Sharing and Partnership Group and the Department of Health and Human Services Office of the General Counsel, CPME has adopted substantively the same standards and requirements as ACCME and the other entities listed. CPME approves sponsors of continuing education that demonstrate and maintain compliance with the standards and requirements stated in CPME publication 720, *Standards, Requirements, and Guidelines for Approval of Sponsors of Continuing Education in Podiatric Medicine*. The CPME approval standards are comparable to and seek to accomplish the same objectives outlined in the *ACCME Accreditation Criteria*, specifically the criteria for full accreditation or re-accreditation for a 4-year term (criteria 1 through 15), as well as the *ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities*. CPME and its Continuing Education Committee base approval on programmatic evaluation and periodic review. Like the accrediting and certifying entities listed under the current exclusion, CPME approves the sponsor itself rather than each of the sponsor's continuing education activities, but reserves the right to review any or all of a sponsor's activities, educational, or otherwise. Despite these parallels in the continuing medical education approval processes, CMS still chose to arbitrarily include ACCME, AAFP, ADA CERP, AMA and AOA, and not CPME on its list of accrediting or certifying entities.

OHFAMA as well as APMA applauds CMS for proposing changes to resolve the inequity created by the current exclusion. The changes ultimately finalized by CMS should create an equal playing field for accredited or certified sponsors of continuing education who adhere to standards preventing improper industry influence. The current exclusion will result in adverse unintended consequences on the podiatric medicine community and the patients requiring foot and ankle care by podiatric physicians, especially Medicare beneficiaries. The current exclusion can serve as a deterrent for providing grants to sponsors of continuing education due to the additional and arbitrarily added burden to track transfers of value made to covered recipient/ speakers at these programs relative to exempted programs.

CMS proposes to exempt indirect payments made to speakers at certain accredited and certified continuing education events under § 403.904(i)(1), which excludes indirect payments or other transfers of value where the applicable manufacturer is "unaware" of, that is "does not know," the identity of the covered recipient during the reporting year or by the second quarter of the following reporting year. The awareness standard under § 403.904(i)(1) is improper and unworkable in the context of continuing education as applicable manufacturers become aware during the time period specified of the identities of speakers at continuing education events through various avenues, including event attendance and electronic and print publications stating speaker information. Therefore, OHFAMA respectfully requests that CMS finalize distinct regulatory language exempting indirect payments made to speakers at continuing education events as these indirect payments are unlike other indirect payments and transfers of value exempt from reporting requirements under § 403.904(i)(1). CMS should

add the following regulatory text § 403.904(i)(1) to eliminate confusion regarding the awareness standard and prevent the need for subregulatory guidance:

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*The awareness standard shall not apply to covered recipient speakers, faculty, or attendees at a continuing education program if an applicable manufacturer or the (name of entity) provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program.*

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CMS notes that it considered two alternatives, expanding the list of accrediting organizations for which an exclusion would apply or articulating accreditation or certification standards that would allow a continuing education program. Should CMS expand the list of organizations in 403.904(g)(1) by name, APMA has respectfully requested that the accrediting organizations for all physicians, defined 1861(r) of the Social Security Act and adopted by § 403.902 of the Open Payments regulations, be included, including CPME. CMS has previously stated its concern regarding the administrative burden associated with expanding the list of organizations in 403.904(g)(1)(i) by articulating accreditation or certification standards that would allow a CME program to qualify for the exclusion. If CMS pursues this option further, the end result should ensure that all accrediting bodies meeting comparable standards are treated the same. Otherwise, the biased created by the existing CME exclusion would remain unaddressed.

Again, OHFAMA thanks you for allowing our comments to be read for consideration. Additionally, we will be glad to address any area of concern or questions that you may have regarding this communicate.

Sincerely,



Jimelle Rumberg, PhD, CAE  
Executive Director  
Ohio Foot and Ankle Medical Association