American Podiatric Medical Association

100 YEARS OF ADVANCING PODIATRIC MEDICINE 1912-2012

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September 6, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P

Submitted electronically at http://www.regulations.gov.

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

Dear Ms. Tavenner:

On behalf of the American Podiatric Medical Association (APMA), the national association representing the vast majority of America's foot and ankle physicians and surgeons, I welcome the opportunity to submit comments regarding the proposed rule published July 19, 2013 proposing changes to the Medicare physician fee schedule (PFS) and other Medicare Part B policies for calendar year 2014.

Changes to Direct PE Inputs for Specific Services

Ultrasound Equipment Recommendations

CMS notes that the AMA RUC recommended creating several new equipment inputs in addition to the revision of current equipment inputs for ultrasound services and also forwarded pricing information. However, CMS identified a series of new concerns related to this input and seeks additional public comment prior to proposing to implement any of the recommended changes through future rulemaking.

Ultrasound Equipment Background and Seeps

In the CY 2012 Proposed Rule, CMS asked the RUC to review the ultrasound equipment described in the direct PE input database. This involved reviewing 17 different ultrasound and ultrasound related pieces of equipment associated with 110 CPT codes. CMS requested that the RUC review the clinical necessity of the ultrasound equipment as well as the way the equipment is described for individual codes. The RUC convened a workgroup of the PE Subcommittee and the Ultrasound Equipment Workgroup submitted its recommendation following the January 2012 RUC meeting. Part of the recommendation was a review of the ultrasound equipment rooms, including the *room, ultrasound, general,* EL015 and the *room, ultrasound, vascular,* EL016. The RUC also

recommended creating a new equipment room for cardiovascular studies called *room, ultrasound, cardiovascular*. APMA generally supports the finding and recommendations of the RUC.

CMS states in the CY 2014 Proposed Rule that, "Ordinarily under the PFS, direct PE input packages for 'rooms' include only equipment items that are typically used in furnishing every service in that room". This definition is not consistent with the precedent established by CMS in past rulemaking and APMA disagrees with this definition because not all of the equipment in the room will be used for every service in the room, but if it is used for a typical service furnished in that room it should remain. Although the equipment rooms are packages, including a number of equipment items, they remain direct PE equipment inputs and as such the PE Subcommittee follows the same guidelines as established by CMS to attribute equipment time. These guidelines state that equipment time is comprised of any time that a labor category is using the piece of equipment, plus any additional time the piece of equipment is not available for use with another patient due to its use during the procedure in question. CMS has asked for comment on which of the following three definitions of rooms is appropriate for what should be included in equipment packages called rooms:

- All of the items that might be included in an actual room?
- Just the items typically used for every service in such a room?
- All items typically used in typical services furnished in the room?

APMA supports RUC's determination that based on CMS' own guidelines none of these definitions are appropriate and is proposing that the language read, "Equipment packages called rooms should include all items that are typically in the room and cannot be used for another patient, in order to furnish all typical services performed in that room."

APMA, as a participant in the RUC process, supports the Ultrasound Equipment Workgroup recommendations for the general and vascular ultrasound rooms and the addition of the cardiovascular ultrasound room as submitted, with only a few minor changes as noted in the RUC's submitted comments.

Though it is challenging for specialty societies to obtain paid invoices for equipment and supplies, especially for large equipment items that are bought very infrequently due to the large investment cost, APMA will work with RUC and CMS to develop supporting documentation for the ultrasound room packages and will work with the RUC to provide paid invoices in a reasonable fashion (e.g. paid invoices, rather than quotes, where reasonably available).

CMS is concerned about pricing information. CMS says that a medical specialty society's recommendation to increase the price for an ultrasound system is unsupported. Similarly, CMS argues that certain media articles appear to indicate that the price for "ultrasound unit, portable" (EQ250) is much lower than that currently listed in the PE data base and seeks comment on the appropriate price to use for this item. CMS emphasizes that it is not intending to revise the

equipment items or change the prices of items for "room, ultrasound, general" (EL015, "room, ultrasound, vascular" (EL016), and "ultrasound unit, portable" (EQ250) at this time.
As APMA has reported previously to CMS and RUC, portable unit (EQ250, $ 29,999) pricing is variable based on quality. While less expensive units can be found, they will not necessarily deliver the necessary quality for an accurate survey. We urge CMS not to search for some lowest common denominator but instead to carefully assess the type of equipment that is typically being used in furnishing high quality care.

Ultrasound Equipment Input Recommendations for Particular Services
The RUC made recommendations regarding the typical ultrasound items used in furnishing 110 CPT codes (Table 10, 78 FR 43300). CMS agrees with many of the recommendations of the RUC and we appreciate the agency's thoughtful review. APMA appreciates CMS' review and agreement with the RUC's recommendation to replace the current equipment input of *room, ultrasound, general,* EL015 with the *ultrasound unit, portable,* EQ250 for CPT code 76942 *Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation*. APMA, like the RUC, disagrees that this change in equipment constitutes a change in the typical kinds of procedures reported with this image guidance service. The type of equipment has no bearing on the codes that this service is billed with. Furthermore, CMS states that the CPT code 20610 *Arthrocentesis, aspiration and/or injection; major joint or bursa (e.g., shoulder, hip, knee joint, subacromial bursa)* is the code most frequently reported with 76942. CPT code 20610 is a surgical procedure and 76942 is an imaging supervision and interpretation (S&I) service. For S&I codes, activities occur in addition to the base surgical codes. Many of the clinical staff activities included in the S&I code do not occur with the surgical code and the PE subcommittee is purposeful in separating all clinical staff activities between surgical and S&I codes, so no duplication in PE occurs. Reducing the direct PE inputs for clinical staff and equipment minutes associated with 76942 from 58 to 23 based on an altered intra-service time assumption is not based on sound analysis. In addition, a CPT coding proposal has been prepared by the specialty societies for the October 2013 CPT Editorial Panel meeting to bundle CPT codes 20610 and 76942 and these bundled codes will be reviewed for both work and practice expense at the April 2014 RUC meeting. All aspects of the services, including intra-service time and PE inputs will be reviewed at that time. **APMA supports RUC's request that CMS delay implementation of changes to the work intra service time and PE clinical staff time and equipment time until the RUC has had an opportunity to review the code and account for any efficiencies that have developed since the code was last reviewed and as a result of bundling.**

Using OPPS and ASC Rates in Developing PE RVUs
CMS notes that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in a hospital outpatient department (OPD) or an ambulatory surgical center (ASC). CMS believes this is due to anomalies in the data used under the PFS and in the application of its resource-based PE methodology to the particular services. More specifically, CMS argues that the PFS methodology suffers from incomplete, small sample, potentially biased or inaccurate resource input costs that

can also often be outdated. Consequently, CMS has proposed a new cap on non-facility PE RVUs for certain services furnished in hospital outpatient settings, to ensure that Medicare does not pay more for these services when they are done in the office, when those payments are greater than what is paid when the same service is performed in either the hospital outpatient or ASC facility setting.

APMA opposes the CY 2014 PFS proposal to cap payment rates for 211 physician services at OPPS or ambulatory surgical center ASC rates. This proposal will reduce payments for some services by 50 percent or more, potentially driving them out of physician offices altogether and requiring patients to obtain these services in a more costly, less convenient facility setting. Clearly, this could not have been the intent of the proposed policy. Consider CPT 11760: Repair of Nail Bed. Podiatric physicians and surgeons perform 20 percent of these procedures in the Medicare setting. The proposed policy would reduce payment for CPT 11760 by about 20 percent when done in the office. Based on recent Medicare data, 27% of these are performed in the office setting while 32.5% combined are performed in inpatient or ASC settings. The likely effect of this proposal is to drive these procedures into a more costly inpatient setting which is also likely to inconvenience beneficiaries.

CMS offers two arguments to support the appropriateness of this proposal. First, the proposed policy supposes that there are significantly greater indirect resource costs when a service is performed in a facility compared to the non-facility setting. Second, CMS assumes that the cost data is more reliable in the OPPS and ASC compared to cost data collected under the resource-based relative value scale (RBRVS). Therefore, the agency concludes:

> "We believe that this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting."

APMA disagrees with the reasoning behind this proposal. CMS rationalizes that when a service is more expensive in the non-facility setting it is not because of appropriate payment differentials between the separate provider settings, but rather due to anomalies in the data. This assumption is without basis and leads the agency to conclude wrongly that payment for the affected services must be arbitrarily reduced. While the RUC generally agrees with CMS that the indirect costs for a hospital to provide a service typically should be greater than when the same service is provided in the non-facility setting, we disagree that the correct measurement to identify potentially misvalued services in the nonfacility setting should be to compare the costs generated by two vastly different payment systems. Any comparison of the costs between the OPPS and the RBRVS represents a fundamental misunderstanding of the differences in how resource costs are generated in each payment system. We urge CMS to withdraw this proposal.

Misvalued Codes
Validating RVUs

CMS acknowledges that section 3134(a) of the Affordable Care Act (ACA) specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. CMS reports that it has entered into two contracts. The first is with the RAND Corporation for a 2-year project to use available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. For this project, RAND will use a representative set of CMS-provided codes to test the model.

The second contract is with the Urban Institute. The key focus of this project is collecting data from several practices for services selected by the contractor to develop objective time estimates, which will be compared with current time values used in the PFS. The project team will then convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time. APMA applauds CMS' interest in keeping physicians an active part of this process. We feel strongly that physicians and other relevant health care providers should be a part of the process in evaluating the value of medical procedures. To the extent that these contracts and relationships involve physician interaction, APMA anticipates that this process would involve input from all relevant physician groups, including podiatric physicians and surgeons.

To broaden participation in the process of identifying potentially misvalued codes, CMS sought the input of Medicare contractor medical directors (CMDs). The CMDs have identified approximately one dozen services which CMS is proposing as potentially misvalued (Table 11, 78 FR 43305). The RUC will review specialty society action plans such as those submitted by APMA and discuss these services at the October 2013 meeting. Above, we have already commented regarding one of the codes in Table 11, CPT code 76942 Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation.

CPT Code 11719, Trimming of Nondystrophic Nails
APMA continues to be concerned about practice expense changes made as part of the Medicare Physician Fee Schedule for calendar year 2013, published in the November 16, 2012 Federal Register. In the CY 2013 Final Rule, the non-facility PE RVU was reduced 67% from 0.47 to 0.16. We feel that a reduction of this nature, handled outside of the RUC/ HCPAC process, was excessive and not in line with CMS' intended purpose of bringing this code up to current packages and standard times that are comparable to similar services. At the January 2012 RUC meeting, the Practice Expense Subcommittee reduced clinical staff time from 17 min to 11 min. In the final rule, CMS reduced this amount further to 5 min. APMA, like the RUC, encourages CMS to participate in the RUC meetings and bring up concerns about clinical appropriateness, changes in physician time, equipment minutes, etc. during the PE Subcommittee session and address these

issues in the process available. APMA and the RUC have made our concerns known via detailed comment to the CY 2013 Medicare Fee Schedule Final Rule.

CPT 11719 had a 2011 utilization of 1,520,157 with podiatric physicians accounting for 99% of the total. This procedure was performed in the office 65.5% of the time for Medicare patients. In the CY 2013 Final Rule, Total RVUs were reduced 48% from 0.65 to 0.34, an unprecedented percent reduction. The new value was less than CPT 99441 (Telephone Consultation –Total RVU 0.40).

We also feel that the non-facility PE RVU reduction (67% from 0.47 to 0.16, based on the reduction in time from 11 to 5 min), is unjustified as CPT 11719 includes PE elements for a procedure (trimming nails) and an E/M service. Examples of CMS' PE reductions include:

1. Greet patient (reduced from 3 minutes to 1 minute)
2. Patient education (reduced from 2 minutes to 1 minute)
3. Prepare room and supplies (reduced from 2 minutes to 1 minute)
4. Clean room/equipment (reduced from 3 minutes to 1 minute)
5. In addition, we believe that a standard exam table was considered vs. the more appropriate power podiatry table, which would be typically used in furnishing CPT 11719.

The majority of refined direct PE recommendations for CY 2013 are based on clinical review. APMA agrees with the RUC's concerns in this approach. First, the RUC developed the PE Subcommittee as an expert panel to review the specialty recommendations of the clinical staff time, equipment and supplies necessary to provide a service. Second, in responding to CMS' clinical review, APMA would find it helpful to have detail about the specific rationale used in developing refinements. If there are concerns related to clinical appropriateness at the PE Subcommittee meeting, APMA is happy to support the RUC and the Agency in rectifying these concerns.

APMA appreciates CMS' effort to maintain appropriate relativity among PE and work components of physician fee schedule payment. However, we disagree with these refinements to CPT 11719 and urge CMS to reconsider. APMA has met with CMS to discuss our concerns and we await positive action in adopting more appropriate PE values.

Physician Payment, Efficiency, and Quality Improvement—Physician Quality Reporting System / Electronic Health Record (EHR) Incentive Program

The proposal to increase the number of quality measures for an individual provider to qualify for the incentive payment from 3 measures reported for at least 50% of eligible patients to 9 measures representing at least 3 of the National Quality Strategy domains for at least 50% of eligible patients is too drastic of an increase and will represent a substantial burden for individual providers, particularly those that are in solo practice. For specialty providers, such as podiatrists, there are

already limited quality measures that are reportable. We note, in passing, that the proposed rule was very difficult for stakeholders to assess because it did not include a table containing all of the measures that would be available for CY 2014 reporting. Instead, CMS discussed additions and deletions in Tables 19 and 20 of the proposed rule, respectively, but the wording of the proposed rule made it appear as if only the measures in Table 19 would be available for reporting in CY 2014. We understand that CMS staff subsequently acknowledged the omission of a comprehensive listing of individual measures for CY 2014. In any event, we urge CMS to reconsider its plan to significantly increase PQRS reporting requirements, or at least to postpone the process until the process is clearer and communication to stakeholders more robust.

As APMA understands it, CMS desires to align the PQRS and Meaningful Use programs with regards to reporting of quality measures. However, there is a distinct difference between the two programs that must be considered in any effort to seek efficiencies across both reporting systems. Note that PQRS requires a performance threshold while Meaningful Use is simply a reporting requirement. If eventually all quality measure reporting is to be done through electronic health records, the performance threshold and use for the value modifier will not ultimately be an issue. However, trying to align under these two programs under the current provisions is overly burdensome for most providers and will make achievement of the incentive payment very difficult.

With regards to the penalty adjustment for 2016 based on 2014 PQRS participation/performance, APMA does not believe it is appropriate to adopt the same requirements for both PQRS incentive payments and avoidance of the PQRS payment adjustment. We recommend that CMS require the reporting of three measures for 50% of eligible patients for each measure to avoid the 2016 payment adjustment.

Measures 126 and 127, relating to diabetic foot and ankle care, were developed and are owned by APMA. While these measures were not specifically discussed in the CY 2014 proposed rule, APMA believes they should be retained for CY 2014 and we presume this is CMS' intention. Further, these NQF endorsed measures should remain reportable by both the individual claims method and registry reporting. . In addition, these measures are available in e-reporting format and we would encourage CMS to add these measures to those that can be reported through the EHR method.

Comments on CMS Value Based Payment Modifier Adjustments

In the proposed rule, CMS proposes adding groups of physicians of between 10 and 99 eligible professionals to the value based payment modifier adjustments for CY2016. CMS then describes a complex system utilizing quality measures and costs per beneficiary to determine whether a provider group receives a positive payment adjustment, no payment adjustment or a negative payment adjustment. For CY2016, groups between 10 and 99 are exempt from the negative payment adjustment and we support that concept. However, since much of the value based

payment modifier is based on the PQRS system, we have considerable concerns how this will be applied to groups that are comprised of a single specialty and solo specialty providers beginning in CY2017.

The current PQRS system does not provide sufficient numbers of quality measures for many specialties and for podiatry specifically. The entire PQRS system has a focus on chronic disease states as this is where the majority of costs within the Medicare system are expended. While many specialists, such as podiatrists, treat patients with chronic conditions, they are frequently treating the various complications related to the chronic disease condition. For example in the patient with diabetes, podiatrists frequently treat ulcerations of the foot and ankle related to diabetic neuropathy and loss of protective sensation. These are conditions that are of great risk to the patient, can be very costly to treat and are often the pre-cursor to lower extremity amputations that carry a high cost of comorbidities and impact the quality of life of the person with diabetes. However, the PQRS system does not adequately address the lower extremity needs of the person with diabetes through quality measures. In fact, the PQRS system is focused on the doctor documenting quality measures, when a more proper focus would be on the patient having the appropriate quality measures performed during their visits to health care providers related to their medical condition. To this end, we could see a more effective system if a more comprehensive list of quality measures was developed for a specific disease state, such as diabetes. The care for a specific patient could then be scored on all the quality measures related to their disease state (HbA1c control, blood pressure control, cholesterol control, eye exam, comprehensive diabetic foot exam, etc.) and all of the physicians that provided care for that patient would be graded based on the patient score on achieving all the quality measures being provided to them. Certainly this would seem to be the logical goal with electronic health records and sharing of patient information through health information exchanges. In this scenario, the patient care becomes the focus of quality and all the physicians providing care would make sure the appropriate provider addressed the quality measures that applied to them. This clearly raises some practical issues of physician collaboration and on how to establish real and meaningful incentives for the team to provide the highest quality care. Nevertheless, this proposed system is targeted for success as it makes all the providers responsible for the care of the patient (as in the diabetic patient example and incentives for regular foot exams).

APMA is also concerned that use of the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG CAHPS) may not be feasible for smaller, single-specialty practices; especially if such practices are expected to pay for special vendors to conduct the survey process and report the resulting data to CMS. That could foreclose yet another mechanism for assessing the performance of such practices. In sum, APMA is concerned that the available quality measures under PQRS are not sufficient for fairly assessing the performance of many specialties for purposes of the value modifier.

In light of the above, APMA believes it would make more sense to focus the value based payment modifiers only on primary care providers and not include specialty care providers until such time that there are clearly identified quality measures that are available and applicable to all

physician providers no matter what their specialty. The current proposal for specialty care beginning in CY2017 is vague and confusing and would be very difficult for small groups and solo practitioners to understand and be evaluated in a fair and equitable manner. While we recognize that the current statute requires that the value modifier be applied to all physicians and physician groups beginning in CY 2017, we would encourage CMS to provide special accommodation, especially for small single-specialty practices, until a proper method to evaluate specialty care can be developed. For example, as CMS is proposing to do for physician groups of 10 to 99 eligible professionals in CY 2016, the agency could specify that such small practices would not be subject to negative payment adjustments under the value modifier for some period of time. Or CMS could make quality tiering voluntary for such practices until more experience is gained with the available quality measures and more meaningful measures can be added.

APMA also urges CMS to provide more information to stakeholders regarding the results of the patient attribution methodology for smaller single-specialty practices. We remain concerned, for example, that this attribution methodology will not work or will significantly disadvantage such smaller practices. In fact, patient attribution will obviously be a key determinant of whether the existing cost measures are appropriate for these practices. As it stands, we would find it especially difficult to explain to our members that their performance under the value modifier methodology might, in part, be based on the total per capita costs for beneficiaries with chronic obstructive pulmonary disease, heart failure and coronary artery disease. Similarly, the proposed Medicare Spending Per Beneficiary measure, which focuses on patients with an index admission, is not likely to be of much relevance to small single specialty practices that provide the bulk of their services, including procedural services, in the office. In sum, we are not convinced that the cost side of the value modifier methodology will work for smaller single-specialty practices. We, therefore, urge CMS to convene town hall meetings and use other vehicles for providing more information about the applicability of the value modifier methodology to such smaller practices. We recognize that the statute places considerable pressure on CMS to make the value modifier work for all physicians beginning in CY 2017, which presumably means it must work for a 2015 performance period, but we currently feel as if the process is just blindly moving forward.
In sum, APMA is concerned that the value modifier methodology will not work for or will significantly disadvantage the bulk of our members. We stand ready to assist CMS in any way we can to avoid such an outcome.

Open Payments / Physician Payment Sunshine Act
We would like to take this opportunity to comment on CMS' transparency initiative, the Physician Payment Sunshine Act (OPEN PAYMENTS), specifically the exemption for indirect payments made to speakers at accredited or certified continuing medical education programs from reporting requirements codified at 42 CFR § 403.904(g)(1). Though not specifically requested in this proposed rule, we strongly disagree with the decision of the CMS to omit arbitrarily the Council on Podiatric Medical Education (CPME) as an accrediting or certifying entity under this regulation. Also, we believe that CMS failed to provide proper notice and opportunity to comment on this exemption. We believe that the opportunity to address this inequitable decision still exists and

must be taken. CMS has the authority to and should change its position concerning the inclusion of CPME under this regulation.

APMA takes issue with the rulemaking process and questions whether CMS provided proper notice and opportunity to comment on the exemption for indirect payments made to speakers at accredited or certified continuing medical education programs from reporting requirements. 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 is considering and welcomes 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. As such, 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 our comment letter, which was submitted on February 17, 2012.

Upon review of the final rule, APMA learned that CMS exempted indirect payments made to speakers at accredited or certified continuing medical education programs from reporting requirements and found that CPME was not included on the list of accredited and certifying entities. In an attempt to remedy this oversight, we initiated communication with CMS staff tasked with executing OPEN PAYMENTS. Unfortunately, CMS expressed to APMA directly and through the frequently asked questions (FAQ) section of the OPEN PAYMENTS website that it is unable to add CPME to this list at this time and interpreted the regulation at issue, 42 CFR § 403.904(g)(1), narrowly to only apply to the accrediting and certifying entities listed. The rationale supporting why this regulation cannot apply to CPME is unclear. The CPME standards for approval for sponsors of continuing education in podiatric medicine that apply to continuing education in podiatric medicine programs “meet the accreditation or certification requirements or standards” of the listed entities.

As remedy, APMA requests that (1) CMS interpret the regulation more broadly and as it was written to apply to accrediting and certifying entities who are not listed but whose requirements and standards “meet the requirements and standards” of the listed entities, issue guidance reflecting this interpretation, and issue a proposed rule as described in (1) in the near future.; or (2) CMS issue a proposed rule that solicits comments on this specific exemption and adds accrediting and certifying entities to the list that have standards and requirements that are substantively the same or similar to the accrediting and certifying entities that are already listed It is important that CMS act immediately because manufacturers must started collecting data on August 1, 2013. Though we have sent letters to Administrator Tavenner and calls and emails to the Open Payments department, they have to date failed to set up a meeting with us to discuss our concerns.

We hope the above comments are helpful. If you have any questions regarding our comments or need more information, please contact Scott L. Haag, JD, MSPH, Director of APMA's Center for Professional Advocacy & Health Policy & Practice, at 301-581-9233 or via e-mail at slhaag@apma.org.

Sincerely,

Matthew G. Garoufalis, DPM
President, APMA