APMA
American Podiatric Medical Association

9312 Old Georgetown Road
Bethesda, MD 20814-1621
Tel: 301-571-9200
Fax: 301-530-2752
www.apma.org

June 22, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States House Senate
Washington, DC 20510

The Honorable Johnny Isakson
United States Senate
Committee on Finance
Washington, DC 20510

The Honorable Mark Warner
United States Senate
Committee on Finance
Washington, DC 20510

Submitted electronically to chronic_care@finance.senate.gov

Re: Comments on Medicare Chronic Care Management and Solutions

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson and Senator Warner:

On behalf of the members of the American Podiatric Medical Association (APMA), the national organization representing the vast majority of America's podiatrists, also known as podiatric physicians and surgeons, or doctors of podiatric medicine (DPMs), we welcome the opportunity to submit comments regarding ways to improve Medicare patient care for chronic conditions. Podiatrists are qualified through their education, training, and experience to furnish the same services and provide the same care as other physicians and surgeons treating the foot and ankle and related structures of the lower leg. Thus, as in Medicare and other public and private plans, care by podiatrists is covered as a vital component in the continuum of medical care.

APMA greatly appreciates the Committee's leadership, focus and commitment to develop solutions that improve health outcomes for Medicare patients with chronic conditions. Ultimately, comprehensive chronic care delivery system reforms that produce lower costs and better value should be a goal not just for Medicare, but across the entire US health system.

APMA has previously developed, and continues to improve upon, a model targeting diabetes and associated lower extremity complications, designed to identify patients with foot ulcers and the potential to develop foot ulcers and stratify them into varying risk groups for ongoing disease management. According to the CDC, nearly 26 million Americans live with diabetes. Of this population, it is estimated that approximately 25 percent of individuals with diabetes will develop a foot ulcer during their lifetimes. Depending on the study, 6 percent to 22 percent of diabetic patients with ulcers will require amputation; 85 percent of lower-extremity amputations are associated with diabetic complications, and almost all are preceded by foot ulcers. Individuals with diabetes represent a significant subset of patients who clearly demonstrate risk for foot complications such as ulcerations, cellulitis, gangrene, and ultimately, limb loss.

This model would include a **Periodic Comprehensive Diabetic Lower Extremity Evaluation/Examination (CDLEE) Preventive Service Benefit**, which would facilitate access to medically necessary care as well as prevent complications from diabetes, and ultimately result in cost savings to the health-care system. Recognizing the serious medical and economic consequences associated with diabetes, American Diabetes Association has endorsed diabetes care guidelines that include performance of annual (minimal) comprehensive foot examinations.

Foot ulcers and amputation are clearly serious complications in persons with diabetes. The five-year mortality of these conditions is similar to colorectal cancers and is higher than many other cancers.[1] However, with aggressive cardiovascular disease risk factor management, this excess mortality can be cut in half.[2]

Multiple studies have shown that preventive foot care programs for people with diabetes can significantly reduce foot complications including ulcerations and amputations. Recent studies have shown that **evaluation and care by podiatrists** have a significant impact on reducing amputations, hospitalizations and other lower extremity complications both in individual provider care settings and as part of a collaborative care team. Because of our education, training, experience, and specialty, podiatrists are in a unique position to manage cost-effectively high-risk foot care treatment programs and such care can reduce the incidence of and complications resulting from foot ulceration through early intervention and the formulation of treatment protocols.[3]

The cost savings associated with this model would be substantial. In a comprehensive study published in the *Journal of the American Podiatric Medical Association* (Vol 101, No. 2; March/April 2011), among patients with commercial insurance, a savings of $19,686 per patient with diabetes can be realized over a three-year period if the patient visits a podiatrist at least once in the year preceding an ulceration. Coupled with Medicare-eligible patient statistics, conservatively projected, an estimated $10.5 billion could be saved over three years if every patient with diabetes would see a podiatrist for evaluation at least one time in the year preceding an ulceration.

The CDLEE Preventive Service Benefit will lead to reduced expenditures while improving quality of care and outcomes. Direct costs of treatment of diabetes and its complications in the United States exceed $166 billion per year with 30% or more of these costs associated with the

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[1] Armstrong, D.G., J. Wrobel, and J.M. Robbins, *Guest Editorial: are diabetes-related wounds and amputations worse than cancer?* Int Wound J, 2007. 4(4): p. 286-7.
[2] Young, M.J., et al., *Improved survival of diabetic foot ulcer patients 1995-2008: possible impact of aggressive cardiovascular risk management.* Diabetes Care, 2008. 31(11): p. 2143-7.
[3] Boulton, A.J., et al., *Comprehensive foot examination and risk assessment: a report of the task force of the foot care interest group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists.* Diabetes Care, 2008. 31(8): p. 1679-85.

treatment of foot ulcers.[4] With approximately 46 million Medicare beneficiaries and approximately 23% of this population having diabetes, and assuming an annual incidence of 7% of foot ulcerations in this population, approximately 743,820 Medicare beneficiaries are at risk for diabetic foot ulceration. With diabetes described as an epidemic in the United States, the number of beneficiaries at risk will continue to rise. Another recent study utilizing different methodology demonstrated that as few as one visit to a podiatrist in the year preceding a diabetic foot ulceration in a Medicare beneficiary on average saved $4,271 per patient over a three year time period.[5] In a clinical study, the International Working Group on the Diabetic Foot risk classification system was shown to have predictive validity over 2.5 years.[6] Using this approach, as a large prospective cohort study demonstrated a 47% reduction in amputations, 38% reduction in hospital admissions, and 70% reduction in skilled nursing facility admissions observed over a 24 month period.[7]

With the advent of Medicare Part D, medication adherence has increased significantly for patients with diabetes, hypertension, and hyperlipidemia, yet the medication possession ratio remains low.[8] Risk factor management for diabetic patients with peripheral arterial disease (PAD) alone has been poor.[9] Much of this may be due to competing comorbid conditions requiring attention during a typical primary care visit.[10] Recently, podiatrists have been described as increasing medication possession ratios in patients with diabetes.[11] Thus, one of the major goals of offering the CDLEE Preventive Service Benefit is to improve both PAD screening and medication possession ratios for those at risk for a cardiovascular death through greater use of podiatric care.

Would new services be required under this model in order to improve beneficiary care? If so, what are these new services and how should they be paid for under this model?

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[4] Driver, V.R., et al., *The costs of diabetic foot: the economic case for the limb salvage team.* J Vasc Surg. 52(3 Suppl): p. 17S-22S.
[5] Carls, G.S., et al., *The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers.* J Am Podiatr Med Assoc. 101(2): p. 93-115.
[6] Peters, E.J. and L.A. Lavery, *Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot.* Diabetes Care, 2001. 24(8): p. 1442-7.
[7] Lavery, L.A., R.P. Wunderlich, and J.L. Tredwell, *Disease management for the diabetic foot: effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations.* Diabetes Res Clin Pract, 2005. 70(1): p. 31-7.
[8] Zhang, Y., et al., *The impact of Medicare Part D on medication adherence among older adults enrolled in Medicare-Advantage products.* Med Care. 48(5): p. 409-17.
[9] D'Souza, J., et al., *Management of cardiovascular risk factors by primary care physicians in patients with peripheral arterial disease.* Surgeon, 2008. 6(3): p. 144-7.
[10] Abbo, E.D., et al., *The increasing number of clinical items addressed during the time of adult primary care visits.* J Gen Intern Med, 2008. 23(12): p. 2058-65.
[11] Carls, G.S., et al., *The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers.* J Am Podiatr Med Assoc. 101(2): p. 93-115.

The services offered under the CDLEE Preventive Service Benefit include a comprehensive lower extremity examination of all Medicare beneficiaries with a confirmed diagnosis of diabetes mellitus.

Under the CDLEE Preventive Service Benefit, all Medicare beneficiaries having a diabetes diagnosis would be referred to a lower-extremity specialist, such as a podiatrist, for a yearly comprehensive diabetic lower extremity examination. The protocol includes a comprehensive history as well as a comprehensive lower extremity physical examination. This examination will include components of a lower extremity vascular examination, neurological examination, dermatological examination, and a biomechanical examination including notation of significant structural deformities. Based on the comprehensive diabetic lower extremity examination, the patient will be placed in a risk stratification category. Follow-up visit frequency would be dependent on the patient's risk classification.

Risk Classification Based on Comprehensive Diabetic Lower Extremity Examination:

Risk Category	Definition	Treatment Recommendations	Treatment Schedule
0	No LOPS, no PAD, no deformity	• Patient education including advice on appropriate footwear.	Annually
1	LOPS ± deformity	• Consider prescriptive or accommodative footwear. • Consider prophylactic surgery if deformity is not able to be safely accommodated in shoes. • Continue patient education.	Every 3-6 months
2	PAD ± LOPS	• Consider prescriptive or accommodative footwear. • Consider vascular consultation for combined follow-up.	Every 2-3 months
3	History of ulcer or amputation	• Same as Category 1. • Consider vascular consultation for combined follow-up if PAD present.	Every 1-2 months

Loss of protective sensation (LOPS); Peripheral Arterial Disease (PAD).

The CDLEE Preventive Service Benefit is reimbursed through a single "preventive service" code that would include the evaluation and management recommendations in the "Risk Classification" table above. Any palliative foot care performed during the encounter would be included in the single Gxxxx code allowance. PAD screening ABI's, if recommended based on risk, would be reimbursed independently on a yearly basis. Any other treatment or procedures performed on the

foot and/or ankle would be reimbursed independently as they currently are reimbursed based on existing guidelines, standards of care, and medical necessity.

For coding and billing purposes, the comprehensive diabetic lower extremity evaluation/examination would be reported as a "to be established" Gxxxx code. The value also is to be determined, but it should reasonably be comparable to the value of CPT 99213 (given performance of interval history updates as well as lower extremity examinations of vascular, neurological, dermatologic, and musculoskeletal systems). The medical records would be expected to include documentation of the encounter findings as well as any management (e.g., coordination of care, referrals, laboratory/diagnostic testing orders, patient education) commensurate with CDLEE guidelines requirements.

The evaluation guidelines should support the American Diabetes Association's Standards of Medical Care in Diabetes recommendations for all diabetic patients. They include performance of, minimally, an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. That foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold).

Studies have demonstrated that individuals receiving care from a collaborative team including podiatrists and lower extremity care specialists in the year before all stage diagnoses were much less likely to undergo a lower extremity amputation.[12] Risk-based management has demonstrated reductions in amputations, hospitalizations, and skilled nursing facility admissions.[13] Increased use of care by podiatrists has also resulted in lower amputation rates and costs.[14] It is for these reasons that CDLEEs stratified by risk should be expected to prevent foot issues from occurring and/or being ignored until it is too late, and prevention shifts to treatment in order to curtail the chances of progressive complications.

Coding/Billing & Documentation Requirements

The comprehensive "at risk" foot evaluation/examination, in the <u>new</u> patient, would begin with the appropriate level of evaluation and management (E/M) service performed necessary for

[12] Sloan, F.A., M.N. Feinglos, and D.S. Grossman, *Receipt of Care and Reduction of Lower Extremity Amputations in a Nationally Representative Sample of U.S. Elderly.* Health Serv Res.
[13] Lavery, L.A., R.P. Wunderlich, and J.L. Tredwell, *Disease management for the diabetic foot: effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations.* Diabetes Res Clin Pract, 2005. 70(1): p. 31-7.
[14] Carls, G.S., et al., *The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers.* J Am Podiatr Med Assoc. 101(2): p. 93-115; Sloan, F.A., M.N. Feinglos, and D.S. Grossman, *Receipt of Care and Reduction of Lower Extremity Amputations in a Nationally Representative Sample of U.S. Elderly.* Health Serv Res.

establishing/recording the patient's diabetes, history, examination findings, and risk management. Follow-up preventive CDLEE encounters would be coded and billed as a unique Gxxx code that would have the equivalent value to CPT 99213. The medical records of the CDLEE would be expected to include documentation of the findings from a comprehensive examination of the lower extremity. For example:

- Skin (normal, or the presence of any calluses, corns, ulcers, warts, other benign lesions, fissures, cuts/lacerations, scars, dryness, hyperhidrosis, discoloration); status of nails (normal, or findings of long, thick, dystrophic, discolored, brittle, lytic, ingrown nail presence);
- Foot structure, biomechanics, and foot deformities (none, or presence of hammertoe(s), bunion(s), angulation deformities [e.g., hallux abductus, varus or valgus foot rotation] foot type: normal, pes planus, pes cavus, or rocker bottom, any bony prominences present, etc.
- Assessment of vascular status (posterior tibial and dorsalis pedis pulses [0-4 with 2 being normal], elevation-dependency testing, skin temperature, venous filling time, ankle-brachial indices [ABI] if necessary and performed [included], Doppler wave form findings if necessary and performed [included], history of intermittent claudication, rest pain, or leg/foot cramping)
- Assessment of neurological status (normal, or findings of testing for loss of protective sensations, presence of hypesthesia, abnormal reflexes, as well as any history of neurological abnormalities)
- Assessment of footwear

In addition, the encounter should include, and the documentation should confirm performance of:

- A medical history and medication update
- Patient education on prevention, including regular self-examination of the lower extremities, in particular, the feet with specific emphasis on early identification of foot complications.

and include (within the value/allowance of the E/M service):

- The cutting or removal of corns and calluses, as needed;
- The trimming, cutting, clipping, or debriding of nails; as needed; and
- Other hygienic and preventive maintenance care performed in the absence of localized illness, injury, or symptoms involving the foot.

Evaluation and management of localized illness, injury, or symptoms involving the foot, including infections, abscesses, ulcers, and/or wounds, would not be included in this preventive benefit.

How could accountability for drugs prescribed be factored into the payment model?

Part of the benefit of care by the specialist would include proper adherence to all medications prescribed for the patient. However, we would not recommend that the prescription drug costs be part of this program since the need for related drugs could vary considerably from patient to patient and may provide an incentive to prescribe drugs unnecessarily.

What are the important considerations in assigning the responsibility for care (to either the co-managing specialist practitioner or the primary care practitioner) in such a model?

The CDLEE Preventive Service Benefit is a model for coordinating care between primary care providers and specialists as well as among specialists. The foot and ankle specialist would work closely with the Medicare beneficiary's primary care provider. The foot and ankle specialist focuses on lower extremity evaluation and management and communicates information about the Medicare beneficiary's care and status to the primary care provider.

What examples of this model have been tested in the private sector that further the evidence base?

This specific model has not been tested in the private sector. It is analogous to capitation models or delivery systems, such as those offered by Kaiser Permanente or the Veterans Health Administration, where resources are focused on prevention as opposed to treatment of diseases and other complications.

What quality measures should be assessed for this model to ensure safe and effective care?

It is anticipated that this program would result in a decrease in ulcerations, hospitalizations and ultimately amputations. This outcome data should be tracked to evaluate the effective outcome of this treatment model. Secondary outcomes would be related to reinforcement of medication adherence for diabetes, hypertension and hyperlipidemia, through appropriate monitoring of HbA1c, blood pressure and cholesterol level.

What should be the distinctive characteristics between this complex medical management model and the chronic care management model discussed in the 2014 PFS final rule or other primary care initiatives currently operated by CMS?

This treatment model establishes protocol for a CDLEE and risk stratification to guide visits throughout the year. This model could replace current coverage for at risk patients related to foot care and would be easier to administer with enhanced benefits and outcomes.

Further, this model is focused on a specific disease with the goal of prevention of problems or complications in the lower extremities directly or indirectly resulting from diabetes. It represents prevention through risk stratification and reimbursed preventive services.

Which factors would influence a practitioner's decision about whether or not to apply to participate?

Health-care practitioners would welcome an evidence-based treatment strategy for diabetic lower extremity care that offered equitable reimbursement, relatively simple administrative procedures, and logical approach to reducing lower extremity complications in patients with diabetes.

How can CMS encourage the adoption of such a model among other payers?

CMS can encourage the adoption of this model among other payers by explaining the anticipated cost savings related to reduced ulcerations, hospitalization and amputations.

What challenges might be encountered in implementing such a model?

Overcoming the concept that paying for a yearly CDLEE is going to increase costs without understanding the significant cost savings associated with ulcer prevention. The cost savings associated with fewer ulcerations, hospitalizations and amputations far outweigh any costs associated with paying for a yearly CDLEE.

What other factors should the Committee consider in the development of a complex medical management model?

The Committee should consider the intangible benefits of how this treatment model fits into the multidisciplinary team approach of treating a patient with diabetes. This model should result in a reduction in lower extremity complications related to diabetes as well as improvement in the overall health of the patient.

The HELLPP Act (HR 1221 / S 626)

Given the Committee's interest in policy improvements aimed at modernizing and strengthening the Medicare and Medicaid programs, APMA hastens to commend the Committees' attention to the provisions of the common-sense, bipartisan Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act (HR 1221 / S 626) aimed at removing patient access barriers to podiatric physicians and surgeons.

Foot and ankle care provided by podiatrists is essential to any comprehensive national health-care program, especially as the Committee is seeking to modernize health programs to improve outcomes for chronic care. It is important to ensure patient access, especially Medicaid patients, to timely and

early specialty medical and surgical foot and ankle care in order to prevent chronic conditions from becoming an even greater cost burden for our public health programs. Numerous studies underscore that when podiatric physicians and surgeons are providing medically necessary foot and ankle care, patient outcomes are better, hospitalizations are fewer and shorter, and our health system saves billions of dollars annually.[15]

DPMs are on the front line everyday identifying patients at risk for a variety of conditions, including but not limited to diabetes, peripheral arterial disease, and arthritis, as well as treating and preventing complications from these conditions.

Even though foot and ankle care is a covered benefit under the current Medicaid program, access to medical and surgical foot and ankle care *provided by a podiatrist* is considered optional and is not covered by all state plans. As a result, Medicaid patients have limited access to specialized foot and ankle medical and surgical care.

The HELLPP Act would remedy this access barrier by recognizing podiatrists as physicians, just as they are in Medicare, to ensure that Medicaid patients—who disproportionately suffer from chronic conditions—have timely access to the most appropriate and best trained providers of foot and ankle care. The Medicare program has recognized doctors of podiatric medicine as physicians since 1967. Additionally, the HELLPP Act clarifies documentation requirements for Medicare's Therapeutic Shoe Program for persons with diabetes. This provision does not in any way expand the Therapeutic Shoe program. Rather, it would improve coordination of care for beneficiaries with diabetes and result in improved medical care and outcomes, fewer physician office visits and health-care cost savings.

Moreover, the HELLPP Act as introduced contains a budget savings provision which would strengthen Medicaid program integrity. The provision, based on a US Government Accountability Office report and recommendation (GAO-12-857), would allow for improved collection of outstanding tax debts from delinquent Medicaid providers.

The net result of implementing the HELLPP Act's common-sense reforms would be significant improvements to patient access to quality foot and ankle care, and meaningful savings for Medicaid and other parts of our health-care delivery system.

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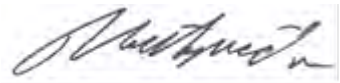
[15] Carls, G.S., et al., *The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers.* J Am Podiatr Med Assoc. 101(2): p. 93-115; Sloan, F.A., M.N. Feinglos, and D.S. Grossman, *Receipt of Care and Reduction of Lower Extremity Amputations in a Nationally Representative Sample of U.S. Elderly*. Health Serv Res.; Skrepnek GH, Mills JL, Armstrong DG, "Foot in Wallet Syndrome: Tripped up by 'Cost-Saving' Reductions", 73rd Scientific Sessions, American Diabetes Association, Chicago, Il, June, 2013. Details of studies accessible at: www.APMA.org/saving; "Fact Sheet: Studies Prove Podiatrists Prevent Complications, Provide Savings"

Conclusion

Thank you for the opportunity to provide input on Medicare chronic care solutions, and we hope the above comments are helpful. If you have any questions regarding our comments or need more information, please contact Scott Haag, JD, MSPH, Director of APMA's Center for Professional Advocacy & Health Policy & Practice, at 301-581-9200 or via e-mail at slhaag@apma.org.

Sincerely,



Phillip E. Ward, DPM
President