Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards for Therapeutic Shoe Inserts
Frequently Asked Questions

1. Q. Why is the Centers for Medicare and Medicaid Services (CMS) proposing to revise the DMEPOS Quality Standards?

A: CMS has learned that due to advancements in computer-aided design/computer-aided manufacturing (CAD/CAM) technology an actual model of a patient's foot may no longer be needed in all cases. The CAD/CAM technology now allows direct milling of a therapeutic shoe insert for individuals with diabetes without molding it to the patient's foot or negative impression of the patient's foot. CMS is proposing revisions to the definitions of custom fabricated and therapeutic inserts which would allow Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) to account for the use of this new item and service when processing claims for therapeutic shoes and inserts.

2. Q. Will Industry representatives be able to comment on the proposed changes to the definitions prior to any change taking place?

A: Yes, the full Revised DMEPOS Quality Standards were posted to the CMS website on Thursday, November 9, 2017, along with an excerpt of the full document containing the Revised Definitions only of Custom Fabricated and Therapeutic Inserts. Comments from interested parties will be accepted until Monday, December 11, 2017. Comments should be submitted to: ReducingProviderBurden@cms.hhs.gov

3. Q. Where can we find the revised *DRAFT* DMEPOS Quality Standards?

A: The full Revised DMEPOS Quality Standards or the excerpt containing the Revised Definitions only of Custom Fabricated and Therapeutic Inserts can be found on the Reducing Provider Burden webpage.

4. Q. When were the DMEPOS Quality standards last updated?

A: The DMEPOS Quality Standards were last updated in October, 2008.

5. Q. Where can we find the current DMEPOS Quality Standards?

A: The current DMEPOS Quality Standards.

6. Q: What is the scope of the proposed revisions to the DMEPOS Quality Standards?

A: The proposed change to the DMEPOS Quality Standards is only on the technological changes related to the creation of therapeutic shoe inserts for individuals with diabetes. Specifically, the proposed revisions would update the definitions of Custom Fabricated and Therapeutic Inserts located in Appendix C of the document. Appendix C begins on page 15 of the full Revised DMEPOS Quality Standards. This change would mean that this new type of therapeutic shoe insert meets the DMEPOS Quality Standards.

7. Q: Are additional changes to the DMEPOS Quality Standards being proposed beyond those related to the creation of therapeutic inserts for diabetes?

A: No.

8. What are the specific changes CMS is proposing to the DMEPOS Quality Standards?

A: CMS is proposing to update two definitions in Appendix C to reflect the technological changes related to the creation of therapeutic shoe inserts for individuals with diabetes. First, CMS proposes to update the definition of *Custom Fabrication* to detail the two methods of creation, 1. "Molded-to-Patient-Model" and 2. "Positive Model of the Patient." Each will detail the various methods through which the models can be created, including the use of CAD-CAM systems software. Second, CMS proposes to update the definition of *Inserts* to account for therapeutic inserts created from a patient-specific, rectified electronic model, in addition to the types already included in the definition.

9. Q: How will the public know if and when the DMEPOS Quality Standards have been changed?

A: Our goal is to finish any changes to the DMEPOS Quality Standards regarding this matter by no later than January 1, 2018. Interested parties should visit the Reducing Provider Burden webpage. This page will be used to communicate updates regarding any revisions to the DMEPOS Quality Standards, including the effective date of the Final version of any revisions.

10. Q: If the proposed changes are finalized, would suppliers still be paid for the other types of therapeutic shoe inserts for individuals with diabetes?

A: Yes, suppliers would continue to be able to use the other types of therapeutic shoe inserts for individuals with diabetes defined in the DMEPOS Quality Standards, including molding it to the patient's foot or a negative impression of the patient's foot. The proposed revisions to the DMEPOS Quality Standards would just add another type of therapeutic shoe insert.

11. Q: Would a new code be added to the Healthcare Common Procedure Coding System (HCPCS) for the new type of therapeutic shoe insert if it is added to the DMEPOS Quality Standards?

A: The need for a unique HCPCS code for Medicare purposes for direct milled inserts would be evaluated once the issues related to the DMEPOS Quality Standards are addressed. Once any changes to the Quality Standards are finalized, contractors would advise suppliers regarding any corresponding changes to coding and billing requirements.

12. Q: What would the fee schedule amount be for the new type of insert for diabetes, if the Quality Standards are updated in a way that allows payment for this type of insert?

A: The 2018 fee schedule amount would be $38.67, based on the requirements of section 1833(o)(2)(A) and 1834(h) of the Social Security Act. This amount is based on the payment limit established in the statute in 1988 for therapeutic shoe inserts, updated by the covered item update factors at section 1834(h)(4) of the Social Security Act.

13. Q: Why would the fee schedule amount for HCPCS code A5513 not apply to this new type of insert?

A: The items and services described by HCPCS codes A5512 (inserts molded to the patient's foot) and A5513 (inserts molded to a model of the patient's foot) are different types of therapeutic shoe inserts. Both use different, specific processes for molding or customizing the multiple density insert for the patient. The new, direct milled type of insert uses a specific process for customizing the multiple density insert for the patient that is different than both A5512 and A5513. The inserts are not molded to the patient's foot and are not molded over a positive model of the patient's foot. So, a separate fee schedule amount is needed for this type of insert.

14. Q: Would this change mean that this new type of inserts falls within the scope of the Medicare Part B benefit for therapeutic shoes and inserts?

A: Yes, if the DMEPOS Quality Standards are updated to recognize this type of inserts as inserts of appropriate quality, then they would fall within the scope of the Part B benefit for therapeutic shoes and inserts. In that event, CMS would need to update the definition of *Inserts* located in §140, *Therapeutic Shoes for Individuals with Diabetes* located in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, *Covered Medical and Other Health Services* to be consistent with any change to the DMEPOS Quality Standards.

15. Q: Why are the definitions and descriptions of inserts in the DMEPOS Quality Standards, Benefit Policy Manual, and HCPCS codes so specific?

A: The descriptor for the original code for therapeutic shoe inserts was "for diabetics only, multiple density insert(s), per shoe." Because this general code and descriptor was the target of fraud and abuse, we used more specific wording and codes to describe the processes of creating

inserts of an appropriate quality to prevent payment for inappropriate inserts. To recognize a new type of insert or process for creating inserts of an appropriate quality, a change to the DMEPOS Quality Standards would be necessary.