

## Background and Summary of Comments on Proposed Revisions to the DMEPOS Quality Standards

### Background:

Historically, a “molded to patient model” fit for a therapeutic shoe insert for an individual with diabetes was achieved by creating a physical model of the patient’s foot through the use of a negative impression. Computer-aided design/computer-aided manufacturing (CAD/CAM) technology now allows the direct milling of a therapeutic insert without molding it to the patient’s foot or negative impression of the patient’s foot.

In November 2017, the Centers for Medicare & Medicaid Services (CMS) proposed revisions to the definitions of Custom Fabricated and Therapeutic Inserts located in Appendix C of the DMEPOS Quality Standards in order to account for the technology. Subject matter experts discussed the changes during a Special Open Door Forum on November 28, 2017 at 2:00pm EST.

CMS requested suggestions on the proposed revisions be sent to [ReducingProviderBurden@cms.hhs.gov](mailto:ReducingProviderBurden@cms.hhs.gov) by December 11, 2017.

In total, we received approximately 87 responses. Of these 87, 74 generally supported the changes to the Quality Standards. About seven individual comments requested wording changes to the proposed Quality Standards. The remaining comments (approximately 306) concerned the coding and monetary value decisions yet to be made by CMS.

Below is a summary of the comments CMS received regarding the proposed revisions to the DMEPOS Quality Standards.

**Comment:** CMS received approximately seventy-four comments indicating general support for the proposed revisions to the quality standards. Many of these same comments referenced the importance of CMS accounting for technological changes with regard to the manufacturing of inserts.

**Response:** CMS appreciates the support for the proposed revisions to the Quality Standards. CMS strives to ensure its policies are reflective of innovations, which enable the delivery of quality items and services to Medicare beneficiaries.

**Comment:** Two comments requested that the word “practitioner” be deleted from the definition in order to clarify that the practitioner does not have to be the individual who rectifies or modifies the virtual model.

**Response:** Thank you for the comment. While we recognize the possibility that the actual practitioner may not rectify or modify the model, it is still the practitioner who has the responsibility for the final product. The use of “practitioner” is intended to account for this responsibility, and the final DMEPOS Quality Standards retain the use of the word “practitioner.”

**Comment:** Approximately five commenters suggested adding language into the definitions of Custom Fabricated and/or inserts. As examples, the commenters requested that the definition of “Custom Fabricated” be modified to incorporate the use of “foam box impressions” since this method is frequently used to create impressions and the commenters also requested that “Inserts” be modified to include a reference to the use of computerized models.

**Response:** CMS recognizes the importance of establishing clear instructions for suppliers to follow, while also affording suppliers the flexibility to use existing and/or new methods in developing therapeutic shoe inserts. While the Quality Standard language historically has not included every method available for creating impressions, we do believe that incorporating a reference to the use of foam box impression could improve the clarity of the Quality Standards, along with conveying that it is one example of several acceptable methods. The final DMEPOS Quality Standards have been revised accordingly. However, with regard to the incorporation of computerized models into the definition of inserts, we have not made this change. In proposing the revisions to the DMEPOS Quality Standards, we specifically incorporated language related to the use of a “patient-specific, rectified electronic model,” and we believe that this language sufficiently accounts for the use of a computerized model of the foot. As such, no additional changes have been made to the definition of Inserts in response to these comments.

**Comment:** The remaining comments (approximately 306) relate to the establishment of a new code and impact of the payment amount for the new code.

**Response:** The first step CMS must take is to finalize the DMEPOS Quality Standards. Once that step is completed, CMS can assess what needs to be done in order to implement any changes to the quality standards.