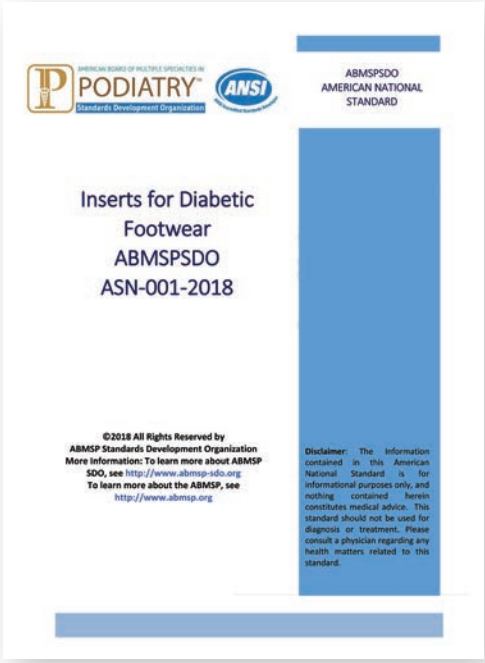
New American National Standard for Therapeutic Shoe Inserts for Diabetic Patients



It's important to understand this landmark standard.

BY PAUL KESSELMAN, DPM, STEPHEN B. PERMISON, MD, KENNETH REHM, DPM AND JOSH WHITE, DPM

Abstract

The American Board of Multiple Specialties in Podiatry (ABMSP)[1] Standards Development Organization (SDO) has announced a new American National Standard (ANS) to improve the reliability and predictability of clinical outcomes for diabetic shoe inserts: ABMSPSDO 001–2018, Inserts for Diabetic Footwear. The standard is accredited by the American National Standards Institute (ANSI). Accreditation, publication, and distribution of this standard heralds a new era of reliability for therapeutic shoe inserts for diabetic patients (TSIDPs).

Background

A standard is a technical document that establishes specifications and procedures to help guarantee the reliability of materials, products, methods, and/or services. Standards help ensure product functionality, consistency, and interoperability, thereby supporting consumer safety and public health. The process of developing an ANS is rigorous and strictly controlled by ANSI and the International Organization for Standardization (ISO) requirements. ANS development requires open, consensus-based, participation of representatives from the community that the standard affects.

Prior to accreditation and publication by ANSI, this ANS underwent multiple cycles of development by ABMSP SDO committees and staff representing manufacturers, researchers, providers, and consumers of diabetic footwear, followed by national review and accreditation. The goal is availability of a voluntary, consensus-based, manufacturing standard, a standard applicable to changing technology. Such standards ensure the consistency and quality of the manufacturing process for TSIDPs prescribed by medical professionals to better protect patients with lower extremity, foot and ankle disease.

Need

Diabetes often leads to lower extremity foot and ankle disease. According to the American Diabetes Association (ADA) 30 million Americans live with diabetes. The National Institutes of Health (NIH) and the Centers for Disease Control (CDC) recognize diabetes as an endemic disease. The World Health Organization (WHO) declares that diabetes is an ongoing pandemic disease. The *Atlas of Diabetes,*[2] published by the

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International Federation of Diabetes (IFD), reports that approximately 382 million people worldwide are diagnosed with diabetes and the incidence of un-diagnosed disease ranges from less than 33% in high-income countries to nearly 90% in sub-Saharan Africa. In 2017, according to a report published by Zion Market Research,[3] the global diabetic shoe market was valued at USD 5.27 billion. It is expected to reach approximately USD 10.40 billion by 2024, an annual increase of more than 10%.

Importance

The importance of standards for products relating to the foot, particularly in a person with diabetes, cannot be over-estimated. Standards ensure that products that are intended to, expected to, and relied upon to help prevent the loss of limb reflect current technology and are manufactured with quality assurance dictums that ensure product integrity and consistency regarding their ultimate impact on the end user. CMS' guidelines for shoe inserts were developed more than twenty years ago with few current updates except for whether a virtual or physical positive is utilized in the production of custom shoe inserts (A5513 vs. A5514). Shoe and insert manufacturing processes have dramatically changed, especially with evolving complex digital 3D and 4D technology and in the material sciences that now provide resource materials with new and improved dynamic capabilities.

Current CMS thickness and durometer requirements often do not fully address a patient's medical conditions and do little to assure the quality of the manufacturing process. They clearly fall behind modern technological and quality assurance paradigms. These inconsistencies weigh heavily on manufacturing. Manufacturers have to balance the Medicare requirements versus potential liabilities should patients incur injuries due to inserts that meet CMS specifications but are inappropriate for patients' footwear or condition. TSIPD has the potential to decisively enhance or detract from the protective potential of diabetic shoes. The variability of inserts currently available underscores the glaring need for industry-wide implementation of a standard to address this situation.

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Conclusion

This standard is the first ANS to address the importance and value of quality shoe inserts, changing TSIDP technology, and the need for quality assurance in the manufacturing process. It acknowledges that the quality and consistency of shoe inserts greatly affect the efficacy of shoes prescribed for patients with lower extremity foot and ankle disease. The standard will help assure that patients prescribed diabetic shoes with inserts receive inserts held to a new and broad standard of consistency, credibility, efficiency, quality, security, and accountability. More information about this standard and those responsible for its development is available at www.abmsp-sdo.org.[4] **PM**

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References

[1] The American Board of Multiple Specialties in Podiatry (ABMSP) is a national board offering certifications in seven podiatric subspecialties. The board is dedicated to reducing the extensive patient suffering and morbidity caused by diabetes. In 2016, ABMSP initiated and supported the establishment of this ANSI accredited SDO in order to develop an American National Standard for TSIDPs.

[2] DF Diabetes Atlas: Global estimates of diabetes prevalence for 2017 and projections for 2045; authored by Cho NH, Shaw JE, Karuranga S, Huang Y, da Rocha Fernandes JD, Ohlrogge AW and Malanda B.

[3] Zion Market Research: "Diabetic Shoes Market by Distribution Channel (Online and Offline) and by End User (Men, Women, and Children): Global Industry Perspective, Comprehensive Analysis, and Forecast, 2017–2024".

[4] If you are interested in serving

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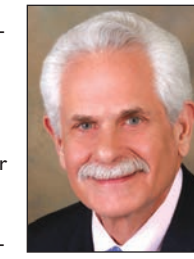
on this standard's International Advisory Board, to advise and promote this American National Standard to the International Organization for Standardization (ISO) for their accreditation and publication, please contact Dr. Steve Permison at sbp@standardsbasedprograms.com.

Dr. Kesselman is in private practice in NY. He is certified by the ABPS and is a founder of the Academy of Physicians in Wound Healing. He is also a member of the Medicare Provider Communications Advisory Committee for several Regional DME MACs (DMERCs). He is a noted expert on durable medical equipment (DME) for the podiatric profession, and an expert panelist for Codingline.com. He is a medical advisor and consultant to many medical manufacturers.

Dr. Permison is the Principal of Standards Based Programs (SBP). He is the founder of the Federal Credentialing Program (FCP) and VetPro, used to credential all healthcare providers by the Department of Veterans Affairs. He is the originator of several national Standards Development Organizations (SDO's) for Fortune 500 companies, the past Chief Medical Officer for the National Practitioner Data Bank (NPDB) and served for many years as the National Director of Clinical Programs for the Indian Health Service. With over 25 years of government service in the Public Health Service, Dr.Permison now works directly with government leaders, professional accreditation organizations, and the private sector to forge strong relationships across government departments and national healthcare organizations. These include the Joint Commission (JC), the National Committee on Quality Assurance (NCQA), the Utilization Review Accreditation Committee (URAC), and the American National Standards Institute (ANSI).



Dr. Rehm is Medical Director of the Diabetic Foot &Wound Treatment Centers in San Marco, CA. He is board certified by the American Board of Multiple Specialties in Podiatry.

Dr. White has long combined interests in healthcare with entrepreneurship. Dr. White became the first podiatrist in NYC to participate in a Medicare program that provided coverage for shoes for people with diabetes. He later created SafeStep, which offered a propriety, web-based program that streamlined shoe ordering and electronic billing combined with guaranteed assurance of Medicare compliance. Dr. White is the principal of HealthyOutcomes EOS, serves in an advisory role to the American Podiatric Medical Association and as a consultant to Orthotic Holdings Inc. on matters relating to durable medical equipment, and is a Codingline expert panelist. He is a council member of the National Coalition of Falls Risk Awareness and Prevention and is a three-time Ironman triathlon finisher.