The Standard Approach Is Becoming the Standard

A new SDO ensures the consistency and quality of the manufacturing process for therapeutic shoe inserts.

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We all use an abundance of different products daily, but how can we be reasonably certain that they are going to do what they purport to do—and perhaps more importantly, that using them will not produce any harmful or untoward effects? Just as relevant is the question of: will using a competitor's product produce inferior, the same, or significantly better results? These are very essential questions, especially as they relate to those recommendations made from a healthcare provider to their patients regarding products or other scenarios that can markedly affect a person's health. Does not the purchaser have a right to know the answers to these questions? It stands to reason, then, that when any product becomes commercially available, the purchaser—whether it be the public or a business selling to another business—has a mandated right to know what the product is, what it's made of, what it's supposed to do and how it compares with other similar products on the market. Therein lies the vital importance of the development and implementation of standards for each particular type of product.

A standard involves a technical document designed to be used as a rule, guideline or definition.[1] These are usually published credentials that establish specifications and procedures intended to ensure the reliability of the materials, products, methods, and/or services people use every day. Standards address a range of issues, including but not limited to: various protocols that help ensure product functionality and compatibility, facilitate interoperability and support consumer safety and public health. Standards are created by bringing together all interested parties, such as manufacturers, consumers and regulators of a particular material, product, process or service, so that various areas of interest in a particular product are addressed. The process of developing a standard is rigorous and strictly controlled. It is typically facilitated by a Standards Development Organization (SDO),[2] which firmly adheres to fair and equitable processes that are designed to bring about the highest quality outcomes as well as support the market relevance of its standards. SDOs function to incorporate time-tested platforms, rules, governance, methodologies and even facilitation services that objectively address the standards development lifecycle (Figure 1), and help facilitate the development, distribution and maintenance of standards.

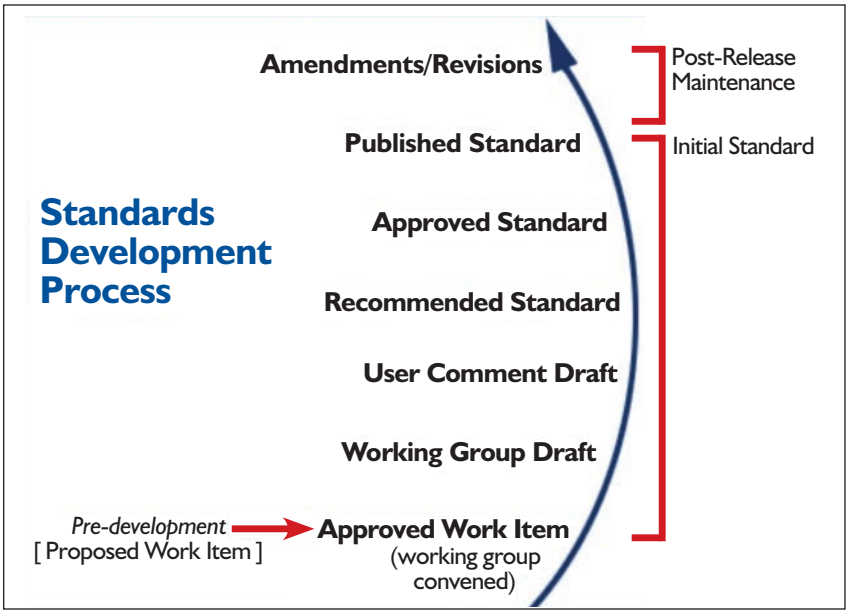

Figure 1: Standards Development Process

While the goals of each SDO are essentially the same, each SDO uniquely applies its own regulations, policies, procedures, guidelines and vocabulary applicable to its own standards development process. Typically, each SDO is comprised of boards, committees and staff who establish and maintain the policies, procedures and guidelines that help ensure the integrity of the standards development process, and the standards that are generated as an out-

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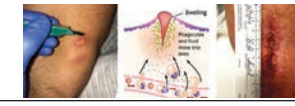

The Standard Approach (from page 109)

come of this process. The development of a new standard is usually initiated by a sponsor who makes a formal request to the SDO for review and evaluation. There is a standards committee formed for the project, which assumes responsibility for the respective area of standards development, including the organization of the standards development team and its activities.

Once the SDO approves the request to develop a new standards development project, a working group, comprised of individuals and/or entities (such as people, companies, organizations, non-profits, government agencies) who volunteer to support the development of standards, is formed. Working cooperatively, these volunteer participants each represent their individual interest in a specific area of development as producers, sellers, buyers, users and/or regulators of a particular material, product, process or service. There are then rules set in place to ensure that no one interest dominates the standards development process. Consensus is built through a democratic process of meetings, draft and review pieces, creation and review of presentations, examination of pertinent data, active discussion and debate to resolve unsettled issues that come up.

These activities fuel the gradual development, definition and crystallization of each standard, which is then compiled into a draft standard that may undergo multiple revisions. Once a draft standard has been finalized, reviewed, and approved by the Working Group, it is submitted first to the Standards Committee and then the Review Committee before being submitted to the Standards Board for approval. After submission, review and acceptance, the approved standard is then published and made available for distribution and purchasing within in a number of outlets, including through the SDO itself.

Standards address various protocols that help ensure product functionality and compatibility, facilitate interoperability and support consumer safety and public health.

Importance of Standards Development

The importance of standards development[3] cannot be understated. Without the development of standards, a product that was developed in a particular field could not be relied upon to operate in a way that these manufactured goods are supposed to. Consistent protocols that can be universally understood and adopted would not have been established. Competing products would not be sufficiently understood or easy to compare. Therefore, it is only through the application of standards that the credibility of new products and new markets can be verified.

It is important to highlight the importance of products relating to the foot in a person with wounds and/or diabetes. Products that are intended to, expected to, and relied upon to help prevent the devastating sequela of a non-healing wound or loss of limb must be intensely scrutinized for integrity and consistency in all the areas of development, from manufacturing to distribution to marketing and then to the ultimate impact it has on the end user.

Therapeutic Shoe Inserts

A key product of critical importance in this category is the therapeutic shoe insert for diabetic patients (TSIDP), These are relied upon to support the prevention of ulcerations and amputations in persons with diabetes. It is interesting to note that such a critical item, so widely used and depended upon, had never been placed under this sort of analysis, until now.

CMS's requirement for shoe inserts was developed more than fifteen years ago[4] without any current updates other than for whether a virtual or physical positive is utilized in the production of custom shoe inserts (A5513 vs. A5514). The specifications are other-

Continued on page 111

The Standard Approach (from page 110)

wise identical to what was originally published and have little cited scientific basis; as the literature search completed prior to the development of this standard minimally supports many of CMS's current specifications for TSIPD. This includes the paucity of peer review literature to support the efficacy of various material(s), durometer (density), and thickness required by the Medicare policy, as well as a myriad of issues created when attempting to properly fit these inserts in appropriate footwear.

Shoe and insert manufacturing processes have dramatically changed, with advances in materials science highlighting the development of resource materials that have dynamic capabilities. Evolving complex digital technology resulted in the advent of 3D and 4D technology, and is currently revolutionizing the manufacturing of inserts, necessitating the advent of new manufacturing specifications and quality assurance of TSIPD. There is also the current Medicare's Quality Standards (specifically Appendix C), whose requirements were originally published 20 years ago. A recent update still is mostly rooted in antiquated manufacturing techniques.

Current thickness and durometer requirements often do not fully address many patient's medical conditions.

The existing CMS reimbursement policies for TSIPD are listed in the various Durable Medical Equipment Administrative Contractors (DME MAC) Local Carrier Decisions (LCD). The specifications as outlined by these policies offer few manufacturing process specifications other than durometer and material thickness, fitting and impression, some molding and some virtual manufacturing requirements. The current Medicare requirements, however, do little to address the quality of the manufacturing process or the needs of patients, and clearly fall behind modern technological paradigms.

These inconsistencies weigh heavily on manufacturing. Manufacturers have to balance the Medicare requirements vs. potential liabilities should patients incur injuries due to providing inserts that meet the technical specifications but are inappropriate for their footwear or condition. There is an Impact on the prescriber and the supplier as well. Product suitability may be inappropriate to address all the variability in patient conditions. This bleeds over to the impact that these inadequacies have on the patient beneficiary. Current thickness and durometer requirements often do not by themselves fully address many patients' medical conditions.[5]

TSIPD has the potential to decisively enhance or detract from the protective potential of diabetic shoes. Given the variability of inserts available, one can see the glaring need for a standard to address these matters.

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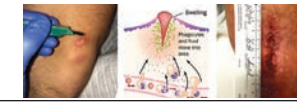

The Standard Approach (from page 111)

ABMSP and the TSIDP SDO

The American Board of Multiple Specialties in Podiatry (ABMSP) understood this deficiency and was the first authority to do something about it.

ABMSP is a nationally recognized professional board of podiatry dedicated to reducing the extensive patient suffering and morbidity caused by diabetes. According to the American Diabetic 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,* published by the 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 1998, ABMSP began providing a professional board certification for podiatrists in diabetic foot wounds. This certification reflects the board's desire to educate and assure best practices by physicians that treat and prevent the debilitating effects of diabetes in the lower extremity. In 2016, recognizing the need to further integrate medical education and knowledge of diabetes into the footwear prescribed to help this disease, ABMSP sponsored the SDO to address the lack of a standard for therapeutic shoe inserts. The initial goal was to develop a voluntary manufacturing standard for TSIDP.

Let's evaluate some numbers. In 2017, according to a report published by Zion Market Research, 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%. With an explosion of the diabetic shoe market and recognition of the importance and value of quality shoe inserts, the Centers for Medicare and Medicaid Services (CMS) is publishing specifications for their manufacture. The standard links these specifications to requirements for quality assurance methods in the manufacturing process, and is the first American National Standard to address the entire TSIPD manufacturing process.[4]

ANSI accreditation of the SDO and the standard's designation as an American National Standard means that this standard meets all published prerequisites stipulated by the *ANSI Essential Requirements: Due process requirements for American National Standards.*[5] Meeting these maxims guarantees that it also meets those of the International Standardization Organization (ISO). This makes the standard eligible for ISO recognition, potentially improving both national and international manufacturing processes and physician outcomes.

This certification reflects the board's desire to educate and assure best practices by physicians that treat and prevent the debilitating effects of diabetes in the lower extremity.

A Working Partnership and a Published Standard

Typical of a standards development organization, The ABMSP SDO membership is a working partnership of stakeholders and stakeholder organizations from both inside and outside the community of interest, in this case podiatry. Meeting ANSI and ISO dictums requires motivated participation and cooperation from the representative community of interest comprised of those individuals, institutions and organizations impacted by the standard. Key contributors to the development of this standard include diplomates of the ABMSP and

Continued on page 113

The Standard Approach (from page 112)

other podiatric professional organizations, participating clinicians, leading research organizations and researchers, manufacturers, universities, schools of podiatric medicine and other medical schools, motion analysis labs and CMS who prescribe the insert specifications, as well as those from industry, federal agencies, and other professionals and their corresponding professional boards. CMS specifications, together with ABMSP SDO authored quality assurance requirements, form the core of the new standard.

The new Standard has the potential for reducing adverse reactions to ill-fitting inserts and therefore reducing further iatrogenic costs.

The ABMSP SDO last year published the first American National Standard for diabetic inserts: *ANSI/ABMSPSDO ASN-001-2018, Inserts for Diabetic Footwear aka Therapeutic Shoe Inserts for Diabetic Patients.* The standard is accredited by the American National Standards Institute (ANSI) and compatible with the requirements of the International Organization for Standardization (ISO). ANSI published this standard for manufacturing of therapeutic shoe inserts for patients with diabetes. The standard affects those shoe inserts with the following HCPCS codes: A5512 (def), A5513 (defn) and A5514 (defn). This achievement is designed to improve the reliability and predictability of clinical outcomes for diabetic shoe inserts.

Credit Due

Credit for this prestigious accomplishment must be given to the following professionals:

Stephen B. Permison, MD, who, working together with the American Board of Multiple Specialties in Podiatry and many exceptional practitioners, manufacturers, university medical schools, motion analysis labs and private orthotic groups, conceived, organized, helped develop and now directs the ABMSP Standards Development Organization (SDO).

The late Dr. Earl Horowitz, who while president of the ABMSP Board of Directors chaired the SDO's Steering Committee that oversaw final aspects of the standard's development and distribution.

Jason Kraus, the former Chief Revenue Officer for Orthotics Holdings International (OHI), led the SDO's National Standards Board responsible for reviewing successive drafts of the standard and assuring that it met industry needs and followed the published policies and procedures.

Dr. Paul Kesselman, DPM and Dr. Josh White, DPM co-chaired the Standards Development Workgroup and its Technical Subcommittee with considerable input and

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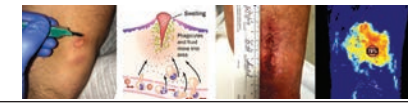

The Standard Approach *(from page 113)*

guidance from Drs. Kenneth Rehm and Dr. Stephen Hill, PhD. Dr. Rehm and Dr. Victor Quijano, DPM, PhD, represented the ABMSP on the SDO's Standards Development Workgroup, National Standards Board and on the Steering Committee. Dr Hill, Assistant Professor and Laboratory Manager of the Motion Analysis Research Center at Samuel Merritt University, was also the team leader for literature review.

These new benchmarks will affect both the prescriber and the supplier.

The Road Ahead

What will this new standard accomplish? First let's consider the impact it will have on the patient beneficiaries. This new American National Standard for the manufacturing of TSIPD will assure production consistency, allowing for superior fit and addressing variable medical conditions associated with diabetic foot pathology. This has the potential for reducing adverse reactions to ill-fitting inserts and therefore reducing further iatrogenic costs.[6]

This standard will also influence the model used for manufacturing, allowing manufacturers to continually adapt their current quality assurance process to new technology. These new benchmarks will affect both the prescriber and the supplier. Linking quality assurance with current technologies provides both the prescriber and supplier with greater expectation of product consistency and therefore superior and more consistent patient outcomes. This also allows the clinician greater latitude in addressing the various complex needs of the diabetic foot. It is hoped that eventually third-party insurance companies as well as Medicare will gravitate from the current policy to an ANSI accredited, standards-based policy.

In conclusion, with new standards development, let us usher in a new wave of consistency, quality, credibility, security and efficiency. Let us all not forget, in this age of medical complexity and uncertainty, the most important cog in this wheel of the healthcare machine is the patient, who is the one that really matters when standards are developed in this critical area of healthful living.

And it's just beginning!

More information about the standard and those responsible for its development is available at www.abmsp-sdo.org. **PM**

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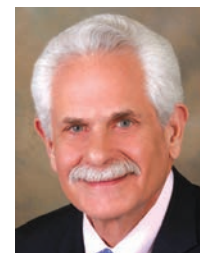

Dr. Rehm is a Diplomate, American Board of Multiple Specialties in Podiatry and Medical Director of Neighborhood Healthcare's Division of Podiatry. He is Assistant Clinical Professor at the California School of Podiatric Medicine and CEO Dr. Rehm Remedies, division of KBR Health Products, Inc.

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. 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. 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.