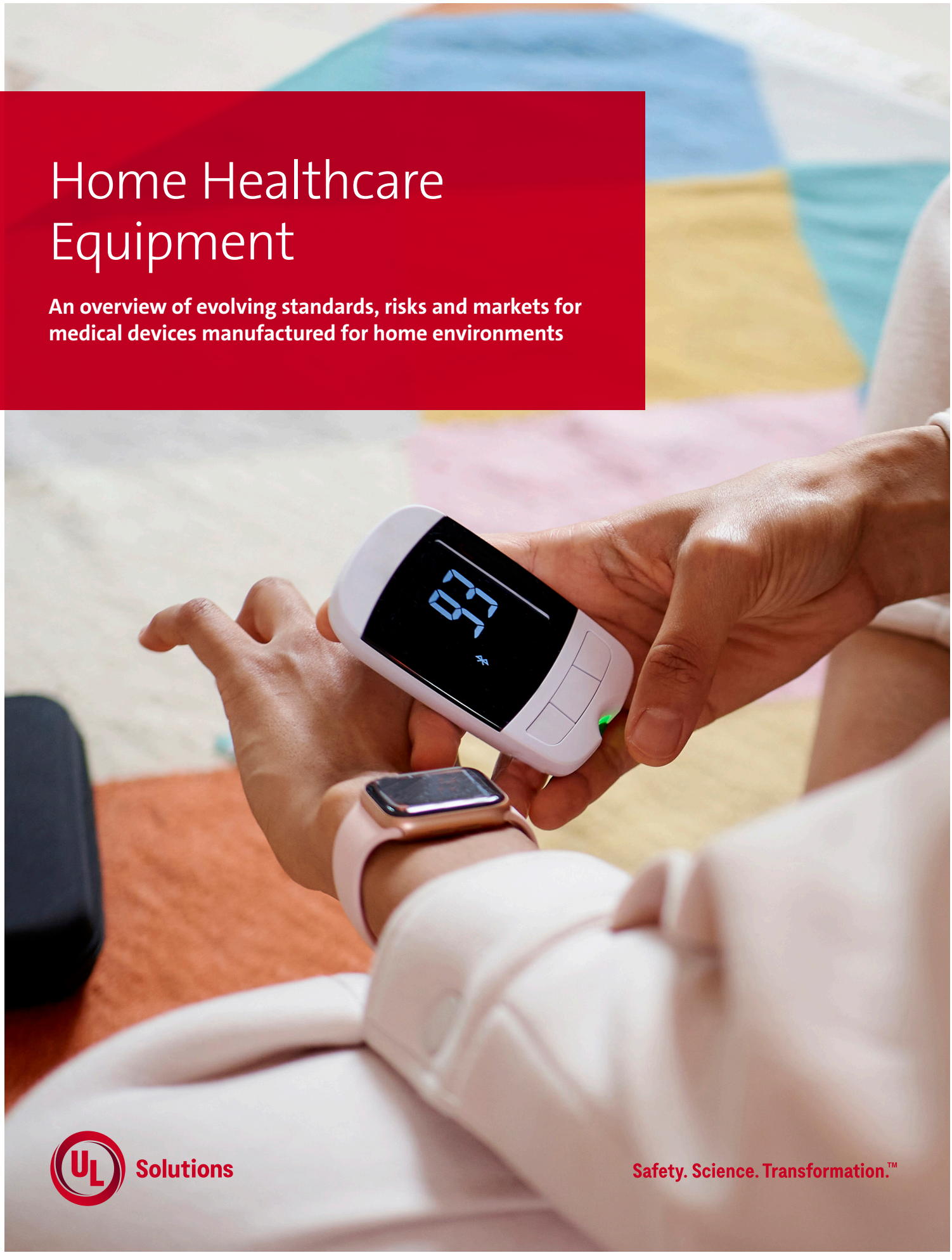
Home Healthcare Equipment

An overview of evolving standards, risks and markets for medical devices manufactured for home environments



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Introduction

As the delivery of healthcare services shifts from clinical settings to the home, the market for home healthcare equipment is expected to grow exponentially over the coming years. However, manufacturers face a series of unique challenges in supplying equipment that is both more effective and safer.

The shift to home healthcare is one of several strategies being deployed to reduce the increasing costs of delivering healthcare services. As a result, manufacturers are redesigning medical devices and healthcare equipment so that they are no longer exclusive for hospital use, allowing patients and lay caregivers to use them in home environments. This dramatic shift in the delivery of medical services is creating new opportunities for manufacturers of home healthcare equipment.

Placing healthcare equipment in the home, however, introduces some complications: Manufacturers are attempting to address the unique issues associated with the use of their equipment by untrained users outside of controlled clinical settings. At the same time, government and insurance regulators, industry groups and independent standards organizations are focusing their attention on the development, marketing, regulation and surveillance of home healthcare equipment to ensure that devices perform as intended and are safer for patients and caregivers to use.

This white paper looks at the current and anticipated regulatory landscape for home healthcare equipment. It offers an overview of the current and future market for this equipment and discusses some of the key issues manufacturers might face when developing products for use in home environments. The paper then provides a review of applicable standards, a summary of the Guidance issued by the U.S. Food and Drug Administration (FDA) on design considerations for medical devices intended for home use and implications of other FDA Guidance documents, specifically those related to human factors engineering (HFE). The paper concludes with a preview of future considerations for manufacturers of home healthcare equipment.

What is home healthcare equipment?

The term “home healthcare equipment” is applied to a wide range of devices intended for use in homes or other non-medical facilities by nonprofessional caregivers, family members or patients themselves. The scope typically includes medical electrical (ME) equipment, such as digital blood-glucose meters, blood pressure monitors and pulse oximeters. In some cases, these devices are available in both hospital and home-use models, with varying features and capabilities differentiating the models.

“Home healthcare equipment” is also applied to products such as drug delivery devices, nebulizers, breast pumps, artificial limbs and other prosthetic devices. At times, the term extends to personal hygiene products, including electric toothbrushes and denture cleaners. Even mechanical assist devices, such as wheelchairs, walkers and seat lifts, can be branded as “home healthcare equipment.”

This broad use of “home healthcare equipment” can lead to confusion, particularly when it comes to the application of regulations and industry standards. Manufacturers must file an application with the FDA for pre-market approval of all medical devices before they can be legally marketed or sold in the U.S., but further misunderstandings arise if they choose similar terms like “home medical equipment” or “medical devices.”

The defining factor in determining what is, and what is not, home healthcare equipment is the manufacturer’s intended use. That references the expected treatment setting (e.g., hospital, clinic, home) in which the equipment will be used and the expected clinical experience level of the user (e.g., trained medical professional, patient, lay caregiver) who will be using the equipment. In the end, it is the manufacturer who determines whether a product is indeed home healthcare equipment by defining the intended use and the intended user.

With that decision, however, comes the responsibility to design a product that is appropriate for its intended use and intended user, and to provide the necessary information to ensure that the product does not pose a safety risk to the intended user. In the case of home healthcare equipment, that task presents its own set of challenges.

The home healthcare market is growing

Precedence Research estimated that the global home healthcare market was valued at $302 billion (USD) in 2022 and is expected to reach around $786.85 billion (USD) by 2032. The market is poised to grow at a compound annual growth rate (CAGR) of 10.1% during the forecast period 2023 to 2032.[1]

Against this backdrop, expanded efforts to reduce the cost of healthcare services and to develop more cost-effective strategies to deliver quality medical care have taken on a new sense of urgency. Driven in large part by more rigorous insurance reimbursement policies, healthcare providers are increasingly focused on lowering costs, in part by shifting limited resources to acute cases and relying on patients and their families to take on a more active role in their own care. Greater investments in new healthcare and telehealth technologies — and the broader adoption and expanded use of existing technologies — is expected to accelerate this shift.

Focusing on comfort and ease-of-use

For many patients, and especially for the growing population of patients over the age of 65, these trends will result in more frequent home delivery of routine healthcare services and self-monitoring of increasingly common chronic medical conditions, such as asthma, diabetes and chronic obstructive pulmonary disease (COPD). With this shift, manufacturers of home healthcare equipment are focusing more attention on comfort and ease-of-use features that make it easier for non-medical professionals to use such devices. In addition, while the growth in the use of home healthcare equipment increases individual responsibility, the shift also promises greater independence by allowing patients to integrate their healthcare monitoring and treatment plans into their existing routines.

Estimates regarding the size of the market for home healthcare equipment, supplies and services vary considerably. However, most estimates agree that consistent and above-average growth from the sale of home healthcare equipment and devices can be expected in the coming years. This anticipated future growth of the home healthcare market presents a significant opportunity for manufacturers of medical devices and home healthcare equipment. Increased oversight by government and insurance regulators, industry accreditation groups and independent standards organizations will temper those opportunities. As such, manufacturers must be mindful of the changing regulatory landscape and industry standards development efforts to ensure that their products gain market access and acceptance.

Key compliance issues related to home healthcare equipment

While the use of medical equipment in clinical settings by trained professionals offers some degree of predictability, the operation of healthcare equipment in the home presents a special set of issues and challenges, including many with potential safety consequences to patients and/or lay caregivers. It is critical manufacturers account for these considerations when designing healthcare equipment for use in home environments. The following considerations clarify the primary challenges associated with the use of home healthcare equipment:

Use environment

Unlike a hospital or other clinical setting, the home presents an array of unique, unpredictable environmental conditions that can adversely impact the performance of home healthcare equipment. One example is the dependence on outside resources for energy and water. Few homes have a reliable alternative supply of electrical power or running water. In the event of a power outage or natural disaster, few patients and caregivers are equipped to handle a medical emergency prompted by the interruption of these vital services.

Within the home itself, outdated or ungrounded electrical wiring systems may fail to protect users of home healthcare equipment from electrical shock. Insufficient ventilation, temperature and humidity control systems may adversely impact the performance of sensitive electronic devices. Electromagnetic interference from common household appliances such as computers, refrigerators and microwaves may interfere with electronic devices not designed for operation in active radio frequency environments. Even seemingly inconsequential environmental conditions resulting from routine activities can have an adverse impact. Basic space considerations, overall household sanitation and cleanliness, the potential for distractions and the presence of children and pets all pose potential risks to the safer operation of home healthcare equipment.

Electromagnetic compatibility for home healthcare equipment
Manufacturers of medical electrical equipment and systems are obliged to demonstrate compliance with electromagnetic compatibility (EMC) requirements, typically against International Electrotechnical Commission/European Standards (IEC/EN) 60601-1-2. This standard forms part of the complete set of elements in the compliance assessment process that every manufacturer of medical electrical equipment (MEE) must consider. ME equipment and systems used in a home healthcare environment, as dictated by IEC 60601-1-11, should be classified as Class B according to International Special Committee on Radio Interference (CISPR) 11:2009.

As home healthcare equipment increasingly evolves towards connectivity, many of these devices are integrating onboard radio connectivity functionalities. In this case, manufacturers are not only required to address EMC requirements but also evaluate and assess specific market access radio regulatory requirements, for example, the Radio Equipment Directive (2014/53/EU) for Europe or FCC and Innovation, Science and Economic Development (ISED) Radio compliance regulations for the U.S. and Canada, respectively.

One important item to consider is that many of these devices are used close to or in direct contact with the human body. This is especially critical when the medical devices have radio technologies on board since electromagnetic waves from wireless technologies are absorbed by the skin, creating potential health concerns. It is important to consider human exposure to electromagnetic fields, which can guide the need for testing against specific absorption rates (SAR). The U.S., Canada and multiple European nations have regulations that introduced limits to mitigate health effects.

Finally, the FDA regulates the use of wireless healthcare devices when present in an environment where they co-exist with other radio devices. Home environments are particularly crowded with wireless traffic, so this is an important consideration. This concept is normally known as wireless co-existence and is typically regulated via American National Standards Institute (ANSI) C63.27 and Association for Advancement of Medical Instrumentation (AAMI) TIR69. It is important that device manufacturers test healthcare equipment accordingly and define the risk of losing wireless functionalities due to crowded wireless environments.

Cybersecurity
The integration of advanced communication technologies in medical devices — or the internet of medical things (IoMT) — has transformed the healthcare industry, resulting in dramatic improvements in the efficiency and effectiveness of patient care. But this integration has fostered the emergence of a new set of challenges for patients, healthcare providers, device manufacturers and system integrators. Today, the healthcare industry is a significant target for threat actors, such as nation-states seeking to compromise sensitive data, including private and confidential healthcare data. These threats place the safety, security and health of patients at risk.

User technical knowledge and ability
As manufacturers strive to make their products more user-friendly, home healthcare equipment can often be too complex for safe and accurate use by most patients and caregivers. Beyond operating knowledge, basic maintenance information is often essential to ensure the trouble-free performance of certain equipment. However, due to their lack of experience, patients and caregivers may be unaware of routine maintenance procedures (e.g., device calibration, cleaning) required to ensure the accuracy of the operation of a device over time.

A factor infrequently accounted for in the operation of home healthcare equipment is the individual physical or emotional state of the patient or caregiver. Patients with compromising physical illnesses or who are suffering from varying degrees of emotional stress will be less capable than “average” users. They may also require additional support.

In addressing issues of patient and caregiver knowledge and ability, manufacturers should consider all types of training and labeling to ensure the effectiveness and safer operation of home healthcare equipment. Equally important, the manufacturer should consider a range of training delivery methods such as printed instructions, user manuals, online information, device-provided voice-activated prompts and instructional videos. These can help account for varying degrees of patient and caregiver abilities and engagement.

Device usability
The degree to which any type of home healthcare equipment can be easily and effectively used by patients and caregivers depends on the amount and type of information and training provided. Often, older equipment comes with little or no labeling or instructions, leaving it to equipment operators to generate their own set of instructions. In instances where they are provided, instructions and user manuals may have been written for medical professionals and include references that are difficult or confusing for users to understand.

Since many types of home healthcare equipment are prescribed by a physician or provided by an equipment supplier, patients and caregivers often do not have a choice in the specific device they are using. In such cases, they may find themselves using a home healthcare device that does not account for their individual needs or which is incompatible with their specific home environment. Even when a patient or caregiver purchases home healthcare equipment from internet-based suppliers, the quality of product information and training available varies from vendor to vendor. In turn, the odds are against ensuring an optimal fit between the features of the home healthcare equipment and the specific needs of the patient and/or caregiver. This can compromise quality and safety.

Key compliance considerations for home healthcare equipment

Issue	Examples
Use environment	Water supply, reliable electricity, cleanliness, temperature control, availability of needed medical supplies, distractions, size
Patient/lay caregiver ability	Training, stress level, cognitive ability, maintenance procedures
Device usability	User interface, markings, operating manuals, safety features anticipating misuse

About standard IEC 60601-1 11:2015/AMD1:2020

In the past, manufacturers of home healthcare equipment were required to demonstrate compliance with the provisions of IEC 60601-1, Medical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance. As originally developed, this standard was intended to apply to ME equipment used in clinical settings by trained medical professionals. To obtain certification for their products, manufacturers of home healthcare equipment were required to comply with the provisions of IEC 60601-1, and to further demonstrate that their product designs effectively mitigated the risks associated with home use by patients or caregivers.

However, as the delivery of healthcare services shifted from the hospital to the home, standards development bodies turned their attention to the special issues related to home healthcare equipment. The result of that effort was the 2010 publication of IEC 60601-1-11, Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in Home Care Applications. IEC 60601-1-11 is a collateral standard, meaning that it directly references provisions in IEC 60601-1. It is now used with IEC 60601-1 for home healthcare equipment certification.

Recent revisions to IEC 60601-1-11

Most recently revised in 2020, IEC 60601-1-11 deals specifically with the requirements applicable to ME equipment intended for use in home environments. Under these provisions, manufacturers must identify specific product safety risks associated with the use of their equipment in uncontrolled environments by untrained users. To achieve certification, manufacturers must mitigate those risks through a combination of appropriate product design, user instructions and training, and maintenance protocols.

In some jurisdictions, evidence of compliance with the technical specifications of IEC 60601-1-11 may be required or may be used to support claims regarding the safety or effectiveness of home healthcare equipment. In the U.S., for example, IEC 60601-1-11 and ANSI/AAMI HA 60601-1-11 (the harmonized equivalent) are FDA-recognized consensus standards. Compliance with these standards' specifications can support a pre-market application.

While IEC 60601-1-11 is intended to cover most home healthcare equipment, it is important to note that some devices may still be subject to the requirements of other standards. For example, UL 1431 3rd Edition, the Standard for Personal Hygiene and Health Care Appliances, covers household electrical products for hygiene or other healthcare applications rated at 250 volts or less. Products covered under this standard include hydromassage units, nebulizers, breast pumps and contact lens disinfectors. The standard does not cover professional medical and dental equipment.

Notable clauses found in IEC 60601-1-11

Clause 7.2 – Additional requirements for marking of IP classification
Clarified requirements for marking of IP classification of a product and its carrying case (if applicable). Manufacturers are urged to read the requirements in clause and familiarize themselves to the revised marking requirements in case their products have an IP classification.

Clause 8.4 – Loss of power
Life-supporting ME equipment shall maintain their essential performance functions during failure of the supply mains. Note, the time or number of procedures remaining shall be visible.

Clause 8.5.3 – Additional requirements for separation of parts
The requirement for type of protection from supply mains was clarified. In the new edition of this standard, there is clear indication that if simultaneous connection of the ME equipment to the patient and the supply mains is possible, then applied parts and parts that are likely to encounter the patient shall comply with two Means Of Patient Protection (MOPP) from the supply mains. This may require that the power supply or charger comply with the MOPP requirements of IEC 60601-1 to achieve two MOPP. However, insulation complying only with two Means Of Operator Protection (MOOP) would be sufficient when patient intentionally handles the ME equipment as the intended operator while the ME equipment is not being used for its intended medical function. As an example, if the ME equipment is constructed such that it can only be connected to an external power source (e.g., a battery charger) while disconnected from the patient. Therefore, during charging the patient is only in contact with accessible parts but not with applied parts and two MOOP is sufficient.

8.3.1 – Ingress of water or particulate matter into medical electrical equipment
The requirement or the IP protection level for the home healthcare medical electrical equipment was not modified. However, it is recommended not only to verify maintaining basic safety and essential performance after IP test, but also to take care of accumulation and drain of water, which may cause interference with basic safety or essential performance. This may also result in deposits on insulation parts or reach live parts which are not designed to operate when wet.

FDA actions applicable to medical devices intended for home use

Historically, the U.S. FDA has regulated medical devices used by consumers similarly to the way it regulates all other medical devices. However, in recognition of the potential safety issues around the use of home healthcare equipment, the FDA has taken several important steps in recent years to provide closer oversight of home healthcare equipment in the U.S., specifically under the framework of its 2010 Medical Device Home Use Initiative.[2] The most important of these actions to date has been the 2014 publication of the FDA's Guidance, Design Considerations for Devices Intended for Home Use.[3]

According to the FDA, the Guidance is: "Intended to improve the design and quality of home use devices to reduce errors that may occur during their use."[4] The Guidance includes recommendations on specific actions that manufacturers can take to receive FDA approval or clearance of devices intended for use in the home. In addition, the Guidance outlines the post-market surveillance activity that the agency expects manufacturers to undertake to identify and address adverse or unsafe events that occur from operating such equipment in the home. Furthermore, the Guidance provides device labeling recommendations.

In February 2016, the FDA released three Guidance documents related to the application of HFE principles during medical device development:

- "Applying Human Factors and Usability Engineering to Medical Devices (final)."[5]
- "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development."[6]
- "List of Highest Priority Devices for Human Factors Review," (draft)[7]

These three documents provide information regarding how to apply HFE to all medical devices. They also provide specific suggestions and provisions addressing home-use products.

"List of Highest Priority Devices for Human Factors Review" specifically calls out the need to include HFE data in premarket submissions for medical devices that have been modified for a "new use environment" (e.g., in the home, moving vehicle), as well as those with "clear potential for serious harm resulting from use error." Notably, the other two documents indicate additional reasons that HFE data should be included for various home-use devices.[8]

Accessing better information for proper use of devices

In addition to the publication of these documents, the FDA has been working to develop a publicly accessible online labeling repository for devices that have been approved or cleared for home use. The goal of this repository would be to provide consumers with direct access to information about the proper use of marketed home healthcare devices.

The FDA conducted two separate pilot repository programs, the latest of which was in 2015, to evaluate the submissions process and systems. These programs resulted in the October 2016 publication of a proposed rule that would require electronic submissions of device labels and package inserts for Class II and Class III home-use devices listed with the FDA. Nine comments on the proposed rule were due to be submitted by mid-January 2017, yet the FDA is reviewing those comments prior to publishing a final rule.

What lies ahead for manufacturers?

The publication of IEC 60601-1-11 covering home healthcare equipment and the FDA's Guidance for healthcare devices intended for home and clinical use are part of the changing compliance landscape for manufacturers of home healthcare equipment. While it is impossible to predict the future, here are some likely outcomes that await manufacturers:

A clearer path to compliance
IEC 60601-1-11 provides home healthcare equipment manufacturers with a more clearly defined path toward certification. With defined product safety requirements that address the specific concerns of the home environment and untrained users, the task of satisfactorily demonstrating compliance with those requirements is more efficient and objective, thereby helping to speed the certification process for new products.

Expanded home healthcare equipment offerings
The overall growth prospects for the home healthcare equipment market — combined with product safety assessment requirements specifically defined for such equipment — will continue to produce a significant increase in the number of offerings brought to market. Competition will increase as more companies enter the market and as larger players look to capture increased market share. However, product ease-of-use, along with advanced technologies, will help determine the winners.

More opportunities to differentiate product offerings
Certification of compliance with IEC 60601-1-11 can provide a potential competitive advantage over similar devices. Distributors, retailers and consumers may view certification to IEC 60601-1-11 as evidence of a manufacturer's commitment to producing quality equipment that meets rigorous product safety requirements.

Increased market oversight
As the FDA steps up its efforts to increase the collection of data regarding unsafe products, the provisions of the Guidance on design considerations for home-use medical devices have increased scrutiny of home healthcare equipment on the market. This increased scrutiny will also bring adverse publicity for manufacturers of unsafe products, as well as the prospect of financial forfeitures, penalties and the recall of unsafe products.

Greater consumer knowledge
The FDA has a home-use device label repository and has stepped up its consumer education activities. These efforts will allow consumers to make more informed choices about the home healthcare equipment they select. In cases where a medical professional has prescribed certain equipment, informed consumers will be empowered to ask questions and to request alternative equipment that can better meet their personal needs.

Why UL Solutions

UL Solutions has extensive experience assessing medical devices to the applicable standards for use in home environments. With locations in many countries and a high degree of technical competence across a wide range of product types and use cases, our experts can help manufacturers address compliance needs for electrical safety, including specific collateral and particular standards for different product types for ME equipment in a home healthcare environment.

Our EMC and wireless test facilities can evaluate whether products meet basic safety and essential performance, as well as wireless performance requirements, and are unaffected by the electromagnetic environment. On top of this, UL Solutions offers nonclinical services, including biocompatibility and package testing, as well as assessing the cybersecurity requirements for medical-connected technologies.

In fact, our full suite of cybersecurity services is designed to help healthcare organizations and medical device manufacturers manage their risks and validate their capabilities in the marketplace. Our services are highly customizable to your specific cybersecurity and organizational needs. They include:

- Private security workshops held under non-disclosure agreements (NDAs) to share best practices and learnings unique to your design and your needs
- Gap analysis services to detect nonconformities and errors early in the product development process
- Custom testing and assessment services throughout the total product life cycle
- Complete evaluation and/or certification services to a variety of international cybersecurity standards including UL 2900, the Standard for Software Cybersecurity for Network-Connectable Products, which has been recognized by the FDA. It is also used globally by the International Medical Device Regulators Forum (IMDRF) and included in many country-specific regulations for geographies including China, France, Canada, Brazil, Australia, Singapore and others.

Finally, we offer a large team of experienced HFE experts who can conduct usability tests with representative users to help identify any potential risks for errors for home healthcare equipment.

Summary and conclusion

The shift in the delivery of many healthcare services, from traditional clinical settings to the home, has spurred significant growth in the home healthcare equipment market, which will continue in the years to come. This shift has also resulted in significant changes in applicable standards and guidelines that are intended to increase the safety of home healthcare equipment for millions of people. By meeting these requirements and regulators' expectations, device manufacturers who are committed to producing safer and more reliable home healthcare equipment have the potential for significant gains as better-educated consumers take greater responsibility for their choices in home healthcare equipment.

To learn more, visit UL Solutions.

If you need further assistance with your medical devices, please contact us.

Endnotes

1. "Healthcare – Home Healthcare," Precedence Research, July 2023.
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5. "Applying Human Factors and Usability Engineering to Medical Devices," Center for Devices and Radiological Health, U.S. FDA, Feb. 3, 2016. Web. Aug. 31, 2017.
6. "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development," Center for Devices and Radiological Health, U.S. FDA, February 2016. Web. Aug. 31, 2017.
7. "List of Highest Priority Devices for Human Factors Review," Center for Devices and Radiological Health, U.S. FDA, Feb. 3, 2016. Web. Aug. 31, 2017.
8. FDA guidance documents are intended to represent only the agency's current view on specific regulatory issues and are not a substitute for applicable regulations and requirements.
9. "Electronic Submission of Labeling for Certain Home-Use Medical Devices," a Proposed Rule by the U.S. Food and Drug Administration, published in the Federal Register, Oct. 17, 2016. Web. Aug. 31, 2017.

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