HOME HEALTHCARE EQUIPMENT: AN OVERVIEW

EXECUTIVE SUMMARY

The market for home healthcare equipment is expected to grow exponentially over the coming years, as the delivery of healthcare services shifts from clinical settings to the home. But manufacturers face a series of unique challenges in supplying home healthcare equipment that is both effective and safe. This white paper looks at the current and anticipated regulatory landscape for home healthcare equipment.

The shift to home healthcare is one of several strategies being deployed to reduce the inexorable growth in the cost of delivering healthcare services. As a result, some types of medical devices and home healthcare equipment originally designed for exclusive use in hospitals and clinical settings by trained professionals are being redesigned to be used by patients and lay caregivers in home environments. This dramatic shift in the delivery of healthcare is creating new opportunities for manufacturers of home healthcare equipment.

But placing healthcare equipment in the home also introduces a number of challenges. 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 increased attention on the development, marketing, regulation and surveillance of home healthcare equipment to ensure that the equipment performs as intended, and is safe to use by both patients and caregivers.

This white paper offers an overview of the current and future market for home healthcare equipment, and discusses some of the key issues manufacturers might face when developing products for use in the home environment. The paper then provides a review of applicable standards, a summary of the 2014 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. The paper concludes with a preview of future considerations for manufacturers of home healthcare equipment.

The Home Healthcare Market

The Centers for Medicare and Medicaid Services (CMS) estimates that the U.S. spent $3.2 trillion (USD) in 2015 on healthcare services, an amount representing nearly 18 percent of the country's gross domestic product[1]. The CMS also estimates that spending on healthcare services will grow to faster than the rate of increase in the U.S. gross domestic product (GDP), representing nearly 20 percent of GDP by the year 2025[2].

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 speed this shift.

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 in mind, 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. And, 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. A CMS analysis of healthcare spending by type of service or product estimates that spending for freestanding home healthcare agencies reached nearly $89 billion in 2015[3].

A separate industry report on the global market for home healthcare equipment, supplies and services puts total expenditures at nearly **$230 billion in 2015** and projects expenditures of nearly **$400 billion by 2021**[4].

But 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. However, those opportunities will be tempered by increased oversight by government and insurance regulators, industry accreditation groups, and independent standards organizations. As such, manufacturers of home healthcare equipment must be mindful of the changing regulatory landscape and industry standards development efforts to ensure that their products gain market access and acceptance.

What is Home Healthcare Equipment?

The term “home healthcare equipment” is generally applied to a wide range of devices intended for use in the home or other non-medical facility by nonprofessional caregivers, family members, or patients themselves. The scope typically includes medical electric 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.

The term home healthcare equipment is also frequently applied to products such as drug delivery devices, nebulizers, breast pumps, artificial limbs and other prosthetic devices. Sometimes, the use of 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 a type of home healthcare equipment.

This broad application of the term home healthcare equipment can lead to confusion, particularly when it comes to the application of regulations and industry standards. The confusion is compounded by the frequent use of similar terms, like “home medical equipment” or “medical devices,” since 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 United States.

Ultimately, the defining factor in determining what is, and what is not, home healthcare equipment is the “manufacturer’s intended use.” That is, what is the expected treatment setting (hospital or clinic, or home) in which the equipment will be used, and what is the expected clinical experience level of the user (a trained medical professional, or the patient or 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.

But, with that decision comes the responsibility to design a product that is actually appropriate for its intended use and 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.

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. As noted above, manufacturers must account for these considerations when designing healthcare equipment for use in the home environment.

The sections below discuss some of 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 and 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 would be 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 that have not been designed for operation in active radio frequency environments.

Finally, 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 safe operation of home healthcare equipment.

User Technical Knowledge and Ability
Common knowledge of even seemingly complex technologies is more widespread than ever. But, even as manufacturers strive to make their products more user friendly, many types of home healthcare equipment are often still too complex for safe and accurate use by most patients and caregivers, even those who are not beset by the environmental circumstances noted above.

Beyond operating knowledge, basic maintenance information is often essential to ensure trouble-free performance of certain types of home healthcare equipment. However, due to their lack of experience, patients and caregivers may be unaware of the routine maintenance procedures, e.g., device calibration or cleaning, required to ensure the accurate operation of a device over time.

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

In addressing issues of patient and caregiver knowledge and ability, manufacturers should consider all types of training and labeling required to ensure the effective and safe operation of home healthcare equipment. Equally important, the manufacturer should consider a range of training delivery methods, for example, printed instructions and user manuals, on-line information, device-provided voice-activated prompts, and/or instructional video, to account for varying degrees of patient and caregiver ability and engagement.

Device Usability
As noted above, the degree to which any type of home healthcare equipment can be easily and effectively used by home-based 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 instructions and 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 that they are using. In such cases, they may find themselves using a home healthcare device that does not wholly 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 either circumstance, 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, and quality and safety may be compromised.

Table 2: 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	Operating manuals, Safety features anticipating misuse

IEC 60601-1-11 and Home Healthcare Equipment

In the past, many manufacturers of healthcare equipment intended for use in the home have been 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 medical electrical 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 design effectively mitigated the risks associated with use in the home by patients or caregivers.

However, as the delivery of healthcare services shifted from the hospital and clinical settings 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 publication in 2010 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, and is now used in conjunction with IEC 60601-1 for the certification of home healthcare equipment.

Most recently revised in 2015, IEC 60601-1-11 deals specifically with the requirements applicable to medical electrical equipment intended for use in the home environment. Under its provisions, manufacturers must identify the 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, and compliance with the specifications in these standards can be used in support of 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, *Standard for Personal Hygiene and Health Care Appliances,* covers household electric products for hygiene or other healthcare applications rated at 250 volts or less. Products covered under this standard include hydromassage units, nebulizers, breast pumps, toothbrushes and contact lens disinfectors. The standard does not cover professional medical and dental equipment.

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 a number of important steps in recent years to provide closer oversight of home healthcare equipment in the U.S., under the framework of its 2010 Medical Device Home Use Initiative[5]. 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[6]."

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[7]." 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 as a result of operating such equipment in the home. Finally, the Guidance provides device labeling recommendations.

In February 2016, FDA released three Guidance documents related to the application of human factors engineering (HFE) principles during medical device development: "Applying Human Factors and Usability Engineering to Medical Devices" (final)[8], "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development" (draft)[9], and "List of Highest Priority Devices for Human Factors Review" (draft)[10]. The three Guidance documents provide information regarding how to apply HFE to all medical devices, and provide specific suggestions and provisions addressing home-use products.

The last-named Guidance document specifically calls out the need to include HFE data in premarket submissions for medical devices that have been modified for use in a "new use environment (e.g., in the home or a moving vehicle)," as well as those with "clear potential for serious harm resulting from use error." Notably, the other two Guidance documents indicate additional reasons that HFE data should be included for home-use various devices[11].

In addition to the publication of these Guidance documents, the FDA has been working to develop a publicly-accessible online labeling repository for those devices that have been approved or cleared for home use. The goal of such an online repository would be to provide consumers with direct access to information about the proper use of marketed home healthcare devices. Toward that end, the FDA conducted two separate pilot repository programs, the latest of which was in 2015, to evaluate the submissions process and systems.

These pilot programs resulted in the October 2016 publication of a proposed rule that would require the electronic submission of the device label and package insert for Class II and Class III home-use devices listed with the FDA[12]. Comments on the proposed rule were due to be submitted by mid-January 2017, and the FDA is reportedly reviewing those comments prior to publishing a final rule. However, as of this writing, no firm date has been set for the rule's publication.

What's Ahead for Manufacturers?

The publication of IEC 60601-1-11 covering medical equipment used in home care applications and the release of 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 thoughts on the likely consequences ahead for manufacturers.

A Clearer Path to Compliance

IEC 60601-1-11 provides manufacturers of home healthcare equipment 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 home healthcare equipment offerings brought to market. Competition will increase, as more companies enter the market and as larger players look to capture increased market share. But product ease-of-use, along with advanced technology, will help determine the winners.

More Opportunities to Differentiate Product Offerings

Certification of compliance with the requirements of IEC 60601-1-11 can provide a potential competitive advantage over similar devices. Certification to IEC 60601-1-11 will be viewed by distributors, retailers and consumers as evidence of a manufacturer's commitment to producing quality home healthcare equipment that meets the most rigorous product safety requirements.

Increased Market Oversight

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

Greater Consumer Knowledge

The FDA is expected to launch its home use device label repository as early as 2018, 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 better meets their personal needs.

SUMMARY + 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 important 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 safe and reliable home healthcare products have the potential for significant gains as better educated consumers take greater responsibility for their choices in home healthcare equipment.

UL technical subject matter experts have extensive experience in assessing medical devices to the applicable standards for safety, EMC, wireless and more, including IEC 60601-1-11. In addition, UL has a large team of experienced Human Factors Engineering (HFE) experts who can conduct usability tests with representative users to help identify any potential risks for use error for home healthcare equipment.

To learn more, go to www.ul.com/medical or contact us at Medical.Inquiry@ul.com.

END NOTES

[1] "NHE Fact Sheet," Centers for Medicare and Medicaid Services, June 14, 2017. Web. 31 August 2017.

[2] "National Health Expenditure Projections 2015-2025: Forecast Summary," Centers for Medicare and Medicaid Services. Web. 31 August 2017.

[3] "National Health Expenditures 2015 Highlights," Centers for Medicare and Medicaid Services. Web. 31 August 2017.

[4] "Home Healthcare Market Growth to exceed $391.41 Bn by 2021," press release from Zion Market Research, January 2, 2017. Web. 31 August 2017.

[5] "Medical Device Home Use Initiative," Center for Devices and Radiological Health, U.S. Food and Drug Administration, April 2010.

[6] "Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff," Center for Devices and Radiological Health, U.S. Food and Drug Administration, November 24, 2016. Web. 31 August 2017.

[7] "Home Use Devices Initiative," U.S. FDA, updated January 26, 2017. Web. 31 August 2017.

[8] "Applying Human Factors and Usability Engineering to Medical Devices," Center for Devices and Radiological Health, U.S. Food and Drug Administration, February 3, 2016. Web. 31 August 2017.

[9] "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development," Center for Devices and Radiological Health, U.S. Food and Drug Administration, February 2016. Web. 31 August 2017.

[10] "List of Highest Priority Devices for Human Factors Review," Center for Devices and Radiological Health, U.S. Food and Drug Administration, February 3, 2016. Web. 31 August 2017.

[11] 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.

[12] "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, October 17, 2016. Web. 31 August 2017.