



# HOME HEALTHCARE EQUIPMENT: AN OVERVIEW



# Home Healthcare Equipment: An Overview

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 takes a look at the current and anticipated regulatory landscape for home healthcare equipment, and provides a brief look at what to expect in the future.

## Introduction

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 for use 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 has also introduced 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 caretakers.

This white paper offers an overview of the current and future market for home healthcare equipment, and discusses some of the key issues facing manufacturers in adopting their products for use in the home environment. It then provides a review of applicable standards, and a look forward at prospective actions outlined in the Medical Device Home Use Initiative recently announced by the U.S. Food and Drug Administration (FDA). It 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 United States spent more than \$2.4 trillion in 2009 on healthcare services, an amount representing more than 17% of the country's gross domestic product<sup>1</sup>. The CMS also estimates that spending on healthcare services will grow to \$3.4 trillion by 2015, nearly 18% of GDP. According to the World Health Organization, the United States spends a higher proportion of GDP on healthcare services than any other country in the world, by a margin of more than 4%<sup>2</sup>.

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 investment 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. 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 and supplies vary considerably. Data cited by the U.S. FDA indicates that U.S. expenditures for home care in 2007 were as high as \$57.6 billion dollars<sup>3</sup>. A separate industry report on the global market for home healthcare equipment and supplies puts the total at \$40.5 billion in 2009<sup>4</sup>. This is between 1-2% of the total expenditures on healthcare services in the U.S.

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. The same industry report noted above projects growth of as much as 7.4% each year between now and 2016, to nearly \$67 billion in annual expenditures<sup>5</sup>. A separate study projects that shipments of home use medical devices will increase to over 1.6 million units annually by 2013<sup>6</sup>.

The anticipated future growth of the home healthcare market presents a significant opportunity for manufacturers of medical devices and home healthcare equipment.

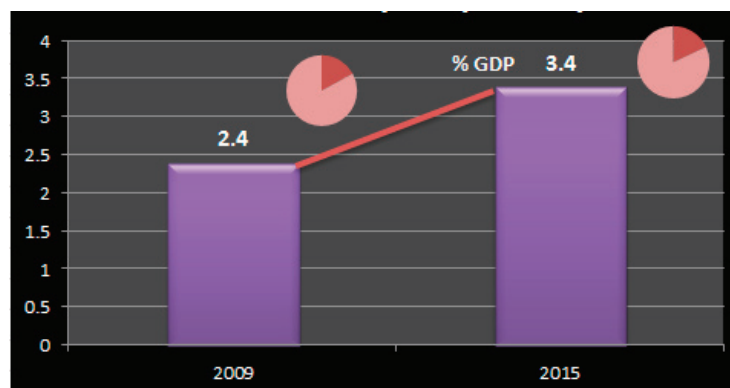


Chart 1: CMS dollars spent (trillion)

However, those opportunities are likely to 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, pulse oximeters and peak flow meters. In some cases, these devices are available in both hospital and home-use models, with varying features and capabilities differentiating the models.

However, the term home healthcare equipment is also frequently applied to products such as nebulizers, breast pumps, and 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.” (Regardless of terminology, 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 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.

However, with that decision comes the responsibility to actually design a product that is appropriate for its intended use, 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 both patients and

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.

#### Operating 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. Perhaps the most obvious example of this 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, and the presence of children and pets can all pose potential risks to the safe operation of home healthcare equipment.

**Caregiver 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 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 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 of the types of training required to ensure the effective and safe operation of home healthcare equipment. Equally important, the manufacturer should consider a range of training delivery methods (printed instructions and user manuals, on-line information, equipment incorporating voice- activated prompts, etc.) 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 the lay reader to understand.

Since many types of home healthcare equipment are prescribed by a physician or provided by an equipment supplier, patients and caregivers often don’t 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 is able to purchase 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 concerns are compromised.

ISSUE	EXAMPLES
Environment	Water / Supply Reliable / Electricity / Cleanliness / Temperature control
Caregiver Ability	Training / Stress levels / Maintenance procedures
Device Usability	Training / Stress levels / Maintenance procedures

Table 1: Key compliance issues for home healthcare Equipment

### IEC 60601-1-11 and Home Healthcare Equipment

Until recently, 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 devices used in clinical settings by trained medical professionals. To obtain certification for their products, manufacturers of home healthcare equipment have been required to comply with the provisions of IEC 60601-1, and to demonstrate that their product design effectively mitigates the risks associated with use in the home by patients or caregivers.

However, as the delivery of healthcare services has increasingly shifted from the hospital and clinical settings to the home, standards development bodies have turned their attention to the special issues related to home healthcare equipment. The most recent result of that effort has been the 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, and is used in conjunction with IEC 60601-1 for the certification of home healthcare equipment.

Published in 2010, IEC 60601-1-11 deals specifically with the requirements applicable to medical devices 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.

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 “Personal Hygiene and Health Care Appliances” covers household electric products for hygiene or other healthcare applications rated at 250 V 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.

### The FDA’s Medical Device Home Use Initiative

The U.S. FDA has regulated medical devices used by consumers in the same way it regulates all other medical devices. However, in recognition of the growing number of potential safety issues around the use of home healthcare equipment, the FDA announced in April 2010 its plan to provide closer oversight of home healthcare equipment in the United States.





According to the agency, the FDA's Medical Device Home Use Initiative will "assure the safety, quality and usability of devices labeled for home use, and...provide more information for home care recipients and caregivers to support safe use<sup>7</sup>."

The FDA's "Medical Device Home Use Initiative" includes five specific actions, as detailed below.

### **Establishing Manufacturers' Guidelines**

The FDA will develop a guidance document that will recommend specific actions that manufacturers should take to receive FDA approval or clearance of devices intended for use in the home. In addition, the guidance document is expected to outline the postmarket surveillance activity that it expects manufacturers to undertake to identify and address adverse and/or unsafe events that occur as a result of operating such equipment in the home. Finally, the guidance document will address device clearance issues and product labeling recommendations.

### **Creation of a Home Use Device Labeling Repository**

The FDA intends to create a publicly-accessible online labeling repository for medical devices that have been approved or cleared for home use, to provide consumers with direct access to information about the proper use of marketed devices. The agency has already launched a pilot repository program in which manufacturers may voluntarily submit their product labeling electronically to the FDA for posting.

### **Partner with Home Health Accrediting Bodies**

The FDA will partner with the Community Health Accreditation Program (CHAP) and the Joint Commission, two major accrediting bodies overseeing agencies that place home healthcare practitioners. The goal of these partnerships will be to strengthen accreditation criteria related to the safe use of medical devices in the home, so that practitioners can properly and safely use these devices.

### **Enhance Post-Market Oversight**

The FDA will take additional steps to strengthen the HomeNet arm of its Medical Product Surveillance Network (MedSun), which collects information from home care agencies on safety issues and concerns related to the operation of home use medical devices. The FDA believes that improved data collection and reporting will create a greater awareness of common home use safety issues, and allow the agency to take appropriate actions to address them.

### **Increase Public Awareness and Education**

Finally, the FDA will step up its education outreach efforts to provide healthcare practitioners, caregivers and patients with information about potential safety concerns and steps to address them. This effort will include the launch of a new Home Use Devices website, which will feature information about the use of medical devices in the home, and strategies to reduce the risk associated with their home use<sup>8</sup>.

### **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 Medical Device Home Use Initiative signal the beginning of long-term changes in the 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**

The publication of IEC 60601-1-11 will provide manufacturers of home healthcare equipment with a more clearly defined path toward certification. With defined product safety requirements in place that address the specific concerns of the home environment and untrained users, the task of satisfactorily demonstrating compliance with those requirements will be more efficient and objective, thereby speeding 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 result in 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. It's likely that product ease-of-use will determine the winner.



### **More Opportunities to Differentiate Product Offerings**

The publication of IEC 60601-1-11 will provide manufacturers with an “early-adopter” opportunity to certify certain types of home healthcare equipment to the new standard, creating a potential competitive advantage over similar devices. Combined with the product’s listing on the FDA’s home use device label repository, certification to IEC 60601-1-11 will be seen as that manufacturer’s commitment to producing quality home healthcare

equipment that meets the most rigorous product safety requirements.

### **Increased Market Oversight**

The provision of the FDA’s Medical Device Home Use Initiative promises 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’s plan to create a home use device label repository, as well as its consumer education 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.





### Conclusion

The shift in the delivery of many healthcare services from traditional clinical settings to the home will spur significant growth in the home healthcare equipment market in the years to come. This shift is also leading to important changes in applicable standards and regulations affecting these products. Adapting to these changes will initially require additional work on the part of manufacturers, and may introduce some short-term uncertainty as these changes fall into place. However, 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.

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<sup>1</sup> Annual figures for 2009, projected by Centers for Medicare and Medicaid Services (as reproduced in "Healthcare Trends in America: A Reference Guide from BCBSA," BlueCross BlueShield Association, 2010 (<http://www.bcbs.com/blueresources/healthcare-trends-report/pdfs/2010-healthcare-trends-in-america.pdf>))

<sup>2</sup> World Health Organization, 2009 (see Endnote 1 above)

<sup>3</sup> National Association for Home Care & Hospice (NAHC), 2008

<sup>4</sup> "The Future of the Home Healthcare Equipment Market to 2016-Market Forecasts, Competitive Landscape and Pipeline Analysis," Global Business Intelligence Research, 2010 ([www.gbiresearch.com](http://www.gbiresearch.com))

<sup>5</sup> "The Future of the Home Healthcare Equipment Market to 2016-Market Forecasts, Competitive Landscape and Pipeline Analysis," Global Business Intelligence Research, 2010 ([www.gbiresearch.com](http://www.gbiresearch.com))

<sup>6</sup> "InMedica Predicts Telehealth Device Shipments Will Top 2 Million by 2013," InMedica, April 28, 2010 ([http://www.in-medica.com/press\\_release\\_details.html&press\\_id=1405](http://www.in-medica.com/press_release_details.html&press_id=1405)).

<sup>7</sup> "Medical Device Home Use Initiative," Center for Devices and Radiological Health, U.S. Food and Drug Administration, April 2010 (<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM209056.pdf>)

<sup>8</sup> <http://www.fda.gov/homeusedevices>