

## FDA Beefs Up Home Healthcare Focus

The U.S. Food and Drug Administration (FDA) has stepped up efforts to ensure that devices used in patients' homes are safe and effective.

The new initiative aims to offer guidance to manufacturers who intend to market a device for home use. In addition, the FDA intends to create measures to encourage safe use of these devices and develop educational materials for home use of devices. The FDA initiative complements recent efforts

by AAMI to tackle home healthcare issues, including the creation of a new AAMI standards committee called Medical Devices and Systems in Home Care Applications, and the publication of *Home Healthcare Horizons*, a special magazine that

will be published this month.

An aging U.S. population and the fact that more patients receive at-home care prompted the FDA to take action. According to the FDA, about 7.6 million individuals in the United States currently receive home healthcare from roughly 17,000 paid providers.

Home healthcare, however, creates certain challenges as many medical devices "are still too complex for a lay person to use safely and effectively without proper training," the FDA white paper notes. "In many cases, home care recipients may use devices that were designed for use by trained healthcare professionals in an acute care facility, not by lay caregivers in a non-clinical setting."

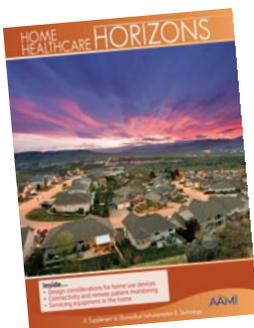
Environmental factors—children, pets, and poor air quality—also present challenges. To address these issues, FDA plans to take the following steps:

- **Establish guidelines for manufacturers of home-use devices.** FDA will develop a guidance document with actions that manufacturers should take to receive FDA approval or clearance of home devices, including usability testing with lay users in a non-clinical setting.
- **Develop a home-use device labeling repository.** This will provide caregivers information about the proper use of the device. FDA will conduct a pilot program in summer 2010 where manufacturers voluntarily submit their labeling to the agency for this repository.



- **Partner with home health accrediting bodies to support safe use.** The FDA will partner with The Joint Commission and the Community Health Accreditation Program to strengthen accreditation criteria for the safe use of in-home devices.
- **Enhance postmarket oversight.** FDA will strengthen the HomeNet arm of its Medical Product Surveillance Network (MedSun) to help identify situations where devices not intended to be used outside a healthcare facility are used in the home.
- **Increase public awareness and education.** FDA is launching a new website, brochures and educational videos.

FDA also held a public workshop recently to solicit feedback from manufacturers and users about the issue. For more information about FDA's home healthcare initiative, visit [www.fda.gov/homeusedevices](http://www.fda.gov/homeusedevices). ■



## AAMI Tackles Home Healthcare Challenges

AAMI has created a new home healthcare committee called Medical Devices and Systems in Home Care Applications to tackle home healthcare issues, which complements the U.S. Food and Drug Administration's (FDA) initiative.

The committee will discuss what specific projects to undertake at its first meeting this month, but potential projects include contributing to the upcoming standard IEC 60601-1-11, which focuses on homecare applications of medical equipment. "The standard will raise the bar for healthcare devices specifically intended to be used in the home environment in terms of safety of construction and installation, electromagnetic isolation, and safety when in use," says committee co-chair Denny Treu, vice president of research for NxStage Medical, a Lawrence, MA, based manufacturer of

the only FDA-cleared home dialysis system marketed today. "I think a major focus of the committee's work will be in the area of human factors and risk management."

Treu says the FDA initiative will augment the committee's efforts. "There is a good long history of the FDA and AAMI working well together and making sure that patient safety is taken into account, while addressing the needs of the manufacturers as well," he says.

Committee member Steve Wilcox, PhD, founder and principal of Design Science Consulting in Philadelphia says AAMI's new healthcare committee can provide "in-depth information to help device manufacturers meet FDA's requirements in the home healthcare arena."

Other committee members say the FDA initiative will help to draw

much-needed attention to the issue.

"In the past, efforts for assuring the safe use of home medical equipment have been overseen by home health companies' accrediting bodies. It is very appropriate for the FDA to create better guidelines, and education from the manufacturer's perspective," says Byron L. Jacobs, CBET, a biomedical equipment technician with Sanford USD Medical Center in South Dakota. "This initiative will need to be clear cut, definitive, and enforceable if it is to have any true effect on things."

Home healthcare is also the focus of the latest edition of AAMI's award-winning *Horizons* series. *Home Healthcare Horizons* will be available at the 2010 AAMI Annual Conference & Expo, which runs June 26–28 in Tampa, FL, and will be mailed to all AAMI members with the July / August issue of *Biomedical Instrumentation & Technology (BI&T)*. ■