

Background on FDA's Home Use Medical Device Initiative

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Objectives

- **Understand current home care trends**
- **Describe why the Agency is interested in home use devices**
- **Explain risks with medical devices used in the home environment**
- **Understand the FDA Home Use Device Initiative**
- **Identify Agency actions with the Home Use Device Initiative**

Home Care Trends

- 17,000 home care organizations (9284 Medicare certified)
- 7.6 million individuals in home care
- \$57.6 billion per year
- Growing 20% per year
- 75% receive skilled nursing
- 69% > 65 years old
- 44 million are caregivers of someone >18
- 2/3 are women
- By 2030, 71.5 million over 65
- 1/5 US adults report a disability (47.5 million)



Cost of Inpatient Care Compared to Home Care (Per Patient Month)

Conditions show where devices play a major role

Conditions	Hospital Cost	Home Care Cost	Savings
Ventilator dependent adults	\$21,570	\$7,050	\$14,250
Oxygen dependent children	\$12,090	\$5,250	\$6,840
Chemotherapy for children	\$68,870	\$55,950	\$13,920
Congestive heart failure in adults	\$1,758	\$1,605	\$153
IV antibiotic therapy	\$12,510	\$4,650	\$7,860

(NAHC 2008)



Impact of Healthcare Trends on Home Care

- **Economic Forces**
 - Patients being sent home sicker, quicker, and with technology
- **Caregivers**
 - Vary from clinicians to family to the care recipient
- **Medical Technology**
 - Devices are more complex, smaller, and portable
 - Devices used in the clinical setting are migrating to the home
- **Patient (Care Recipient)**
 - More knowledge about healthcare options
 - More empowered and active in the decisions related to care
- **Setting**
 - Hospital directly to home

Why is the Agency Interested in Home Use Devices?

- Untrained and inexperienced users
- Economic forces
- Advanced medical devices are in the home
- The home is an uncontrolled environment with additional hazards.

Medical Devices Migrating Into the Home – New Risks

■ Environment

- Children
- Electromagnetic Interference (EMI)
- Location
- Noise
- Pets and vermin
- Power outages and sources
- Public emergencies
- Safety
- Sanitation
- Space
- Temperature, air quality, humidity
- Waste
- Water

Medical Devices Migrating Into the Home – New Risks (cont).

■ Use

- Compatible with lifestyle and usefulness
- Instructions for use are poor or non-existent
- Interface and ease of use
- Off label use
- Ruggedness of the device
- Selling Rx devices on the internet
- User's educational level
- User's cognitive abilities
- User's physical abilities
- User's emotional stability

Home Use Medical Device Initiative

FDA launched the

Home Use Medical Device Initiative

to address the safe use of medical devices in the home.

Home Use Medical Device Initiative

1. Establish guidelines for manufacturers of home use devices
2. Develop a home use device labeling repository
3. Partner with home health accrediting bodies to support safe use
4. Enhance postmarket oversight
5. Increase public awareness and education

Establish Guidelines for Manufacturers

- Develop Guidance
- Public workshop held May 24, 2010 to collect information for Guidance document
 - Also to address the definition of a home use device
- Guidance currently being drafted

Develop a Home Use Device Labeling Repository

- Medical devices labeled for home use
- 10 month pilot
- Manufacturers submit their labeling electronically
- Public Workshop April 7, 2011
 - Pros and cons surrounding posting labels and package inserts on one website
 - Identify informational needs

Partner With Home Health Accrediting Bodies to Support Safe Home Use

- Working with 3 main accrediting bodies
- Will work to incorporate medical devices into their accreditation standards
- Encouraged the development of education and CME to include medical device reporting to FDA

Enhance Postmarket Oversight

- Difficult to ascertain adverse events with marketed devices used in the home
- We received over 10,000 reports where the term “home” was used in the narrative
- Challenging to obtain information about event in the home setting
 - Self-blame
 - Fear of reporting
- Work with MedSun to encourage reporting by home health care agencies

Increase Public Awareness and Education

- Partnerships
- Social Media
- Presentations and webinars
- Training modules
- Standards

Educate all stakeholders about medical devices and the responsibilities everyone has to assure their safe use in the home

Summary

- **Home Care Trends**
- **Agency's interest in home use medical device safety**
- **Risks associated with home use**
- **FDA's Home Use Initiative**
- **FDA's Actions**





