

Home Use Medical Devices: New Risks

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Objectives

- **Understand Regulatory Definitions**
- **Provide Examples of Common Home Use Devices and Emerging Technologies**
- **Reiterate Emerging Trends in Home Care**
- **Identify Risks in the Home Environment**
- **Describe device design considerations**

Medical Device

■ Definition

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory

- **Intended for use in the diagnosis of disease, conditions, cure, mitigation, treatment, or prevention of disease**
- **Intended to affect the structure or any function of the body of man or other animals**



U.S. Food and Drug Administration. Food, Drug and Cosmetic Act. Section 201(h) definition of device. Available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterslandIIShortTitleandDefinitions/ucm086297.htm>.

Home Use Device

■ Definition

- Intended for users in any environment, apart from the professional healthcare facility or emergency medical services
- May require training for the user by a qualified healthcare professional to assure safe and effective use.



Home Device User

■ Definition

- A care recipient or patient, and caregiver or family member
- A qualified healthcare professional, licensed or non-licensed healthcare professional





Common Home Use Devices

- **Capital Equipment and Assistive Technology**
 - Medical beds, bedrails, wheelchairs, walkers, patient lifts, shower chairs
- **Home Therapeutics**
 - hemodialysis, infusion pumps
- **Instruments**
 - glucose meters, pulse oximeters, insulin pumps



Common Home Use Devices

- **Monitoring Systems**
 - patient call systems
- **Disposables & Accessories**
 - ventilator breathing circuits, filters, needles, syringes, IV catheters, IV tubing, gloves
- **Implantables**
 - defibrillators, hip/knee implants, drug-eluting stents
- **Computerized Medical Systems**
 - Hardware and Software
- **Reagents**
 - Fecal occult blood tests

Examples of Emerging Technologies for the Home

- **Health Informatics**
- **Nanotechnology**
- **Smart Homes and Interoperable Technology**
- **Telehealth**
- **Wireless Technology**

Emerging Home Care Trends

- **By 2030, 71.5 million over 65**
- **69% > 65 years old**
- **1/5 US adults report a disability (47.5 million)**



Emerging Home Care Trends (cont.)

- **7.6 million individuals in home care**
- **20,000 home care organizations (13,000 Medicare certified)**
- **44 million are caregivers of someone >18**

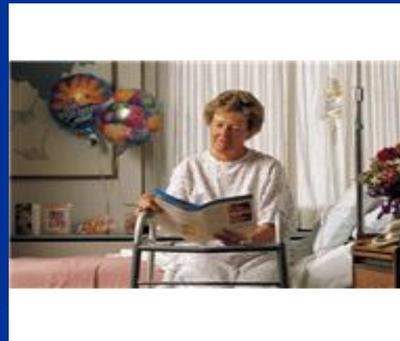
Impact of Healthcare Trends on Home Care

- **Setting**

- Hospital to home

- **Caregiving responsibility**

- Clinicians to family to care recipients



Impact of Healthcare Trends on Home Care cont.

- **Medical Technology**
 - Device size
- **Health Information**
 - Patient empowered



Medical Devices Migrating Into the Home – New Risks

- **Environmental considerations**

- **Location**



- **Housing structure, Space, Sanitation, Temperature, Air Quality, Humidity, Water,**

- **Power Outages and sources**

- **Electromagnetic Interference (EMI)**



Medical Devices Migrating Into the Home – New Risks

- **Environmental considerations**
 - **Children, Pets, Dust and vermin**
 - **Safety, Noise**
 - **Public emergencies**



Medical Devices Migrating Into the Home – New Risks

Use considerations:

- Emotional Stability
- Physical Capability
- Education
- Cognitive Abilities



Medical Devices Migrating Into the Home – New Risks

- Use considerations
 - Educational variances
 - Skilled Users
 - Training
 - Labeling



Design of Home Use Devices .

User Considerations

- Calibration and Operation
- Device maintenance
- Troubleshooting
- Device replacement parts



Design of Home Use Device

Device Considerations

- Language
- Print
- Format
- Display
 - Ambient lighting



Design of Home Use Device

Device Considerations

- Labeling Instructions
 - Information and instructions for use
 - Packaging



Home Use Devices Should be...

- Useful
- Usable
- Iterative



Home Use Devices Should be...

- **Intentional**
- **Intuitive**
- **Integratable**



Home Use Devices Should be...

- Informative
- Address the risks unique to the home

Summary

- **Regulatory Definitions**
- **Examples of common home use devices and emerging technologies**
- **Emerging home care trends**
- **Identified risks unique to home setting**
- **Device design considerations**