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

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