CDRH INITIATIVES FOR AGING IN PLACE

NIH Aging in Place Workshop
September 10-11, 2014
Presented by Mary Brady, MSN, RN
Senior Policy Advisor
Center for Devices and Radiological Health
Food and Drug Administration
I WILL ADDRESS:

Final Guidance for Home Use Devices
Final Guidance for Mobile Medical Applications
Research Recommendations to Further Policy
HOME USE FINAL GUIDANCE

Design Considerations for Devices Intended for Home Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on [insert publication date of FR Notice].
The draft of this document was issued on December 13, 2012.

For questions about this document regarding CDRH-regulated devices, contact Mary Brady at 301-796-6089 or by e-mail at mary.brady@fda.hhs.gov; or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Computing Community Consortium
Catalyst

NSF
National Institutes of Health
HOME USE FINAL GUIDANCE

• Provides definitions
  - Home Use device
  - User
  - Lay
  - Qualified health care professional
  - Professional health care facility
HOME USE FINAL GUIDANCE

Leads to useful and usable labeling
DESIGN CONSIDERATIONS

• Risk management
• Software
• Lock-out mechanisms
• Maintenance
• Calibration
• Mechanical
• Electrical issues (supply mains, power sources, permanently installed devices, outlets, adapters, outages, EMC, wireless, alarm systems)
USER CONSIDERATIONS

• Physical
  - Size, mobility, dexterity, strength, stamina
• Sensory/perceptual
  - Vision, hearing, tactile
• Cognitive
  - Literacy, comprehension, learning
• Emotional
  - New diagnosis, treatment, device
ENVIRONMENTAL CONSIDERATIONS

- Location
- Contaminants
- Water supply
- Temperature
- Dampness and humidity
- Atmospheric pressure changes
- Air flow
- Travel
- Fluid exposure
- Storage
OTHER SECTIONS IN THE FINAL GUIDANCE

- Human factors
- User training
- Labeling
- Handling the device in an emergency
- Disposal
- Hygienic maintenance
- Post market considerations
MOBILE MEDICAL APPLICATIONS
FINAL GUIDANCE

Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

The draft of this guidance was issued on July 21, 2011.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul_Patel@fda.hhs.gov. For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Computing Community Consortium
Catalyst
TWO CATEGORIES OF MOBILE APPLICATIONS

• Those that meet the definition of a medical device
  - pose a risk to the patient’s safety
  - referred to as “mobile medical apps”
• Those that do not meet the definition of a medical device
  - not regulated by FDA
MOBILE MEDICAL APPS INTENDED USE

• To be used as an accessory to a regulated medical device

• To transform a mobile platform into a regulated medical device
CRITERIA FOR FDA TO EXERCISE REGULATORY OVERSIGHT

- Connecting to a medical device to control the device
- Displaying, storing, analyzing, or transmitting patient-specific medical device data
- Transforming the mobile platform into a regulated medical device
- Providing patient-specific diagnosis or treatment recommendations.
CRITERIA FOR FDA TO EXERCISE ENFORCEMENT DISCRETION

- Providing supplemental clinical care
- Providing patients the tools to enable easy access, track and organize their health information
- Helping patients document and communicate to providers potential medical conditions
- Performing calculations used in clinical practice
- Enabling individuals to interact with PHR or HER systems
RESEARCH RECOMMENDATIONS

- Readmission rates of people with technology
- Purchasing equipment after a period of reimbursement
QUESTIONS???