Unique Device Identification & Implementation

What to Expect?

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IAMERS

IAMERS
INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS & SERVICERS

FDA Law Regarding UDI

September 27, 2007, the FDAAA signed into law:

The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

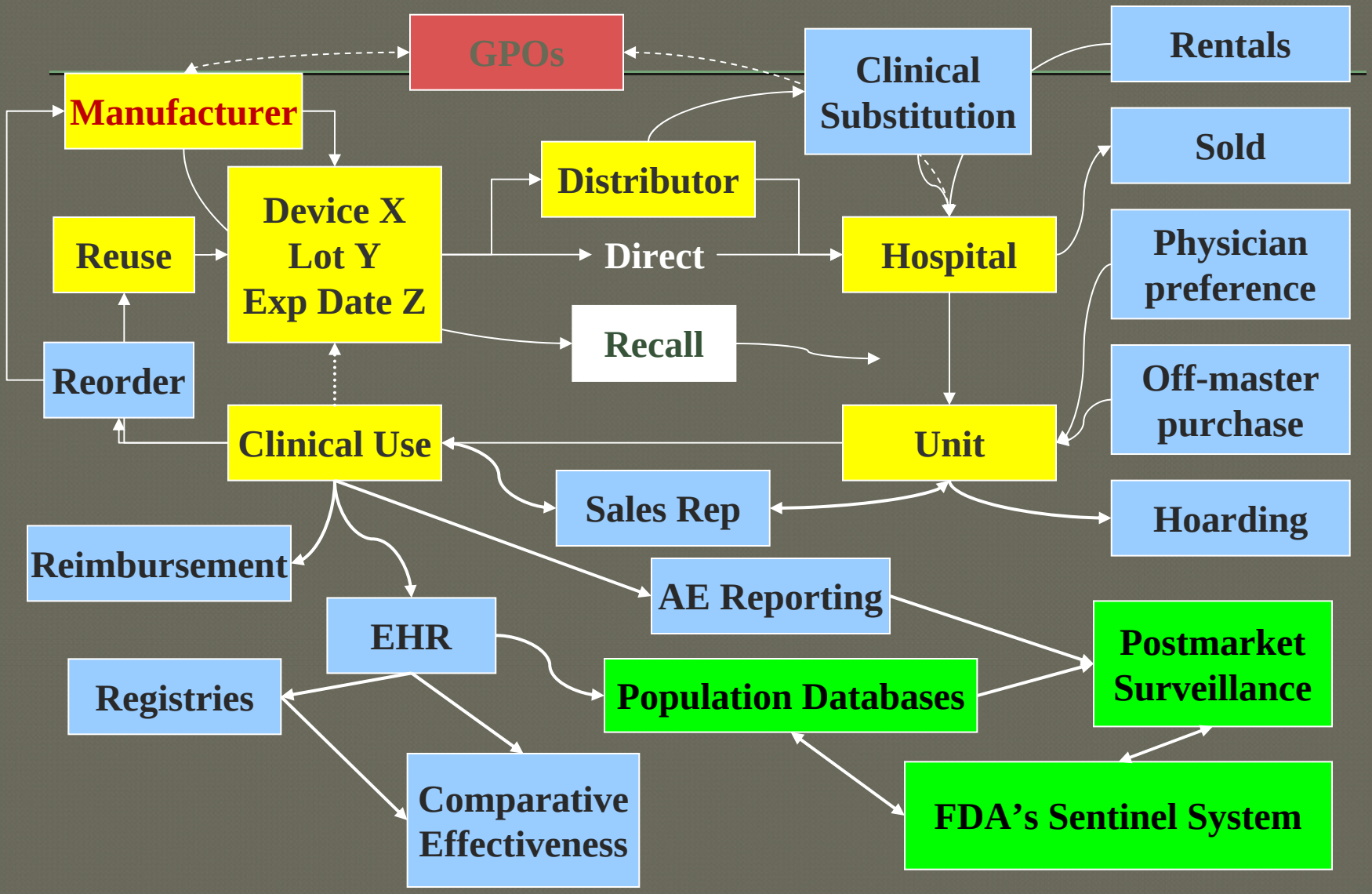
UDI Public Workshops

12 February 09
300 people attended; 4000 webcast

Next workshop:
Post-market Surveillance & Enforcement
Sept 12th (1 – 5 pm) & Sept 13th 2011(9 am – 5 pm)
Bethesda North Marriott Hotel & Conference Ctr
Bethesda, MD

FDA's Device Information Lifecycle

Courtesy of Jay Crowley @ FDA



FDA Believes UDI Can Improve…

- Medical device recalls
- Adverse event reporting and post-market surveillance
- Locating products and medical devices
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

UDI Should Provide

- A single, globally-accepted source for positive identification of medical devices.
  - Reducing medical errors
  - Providing more rapid resolution to device problems such as recalls

Medical Device Identification FDA Perspective

Develop a system to identify medical devices, which is:

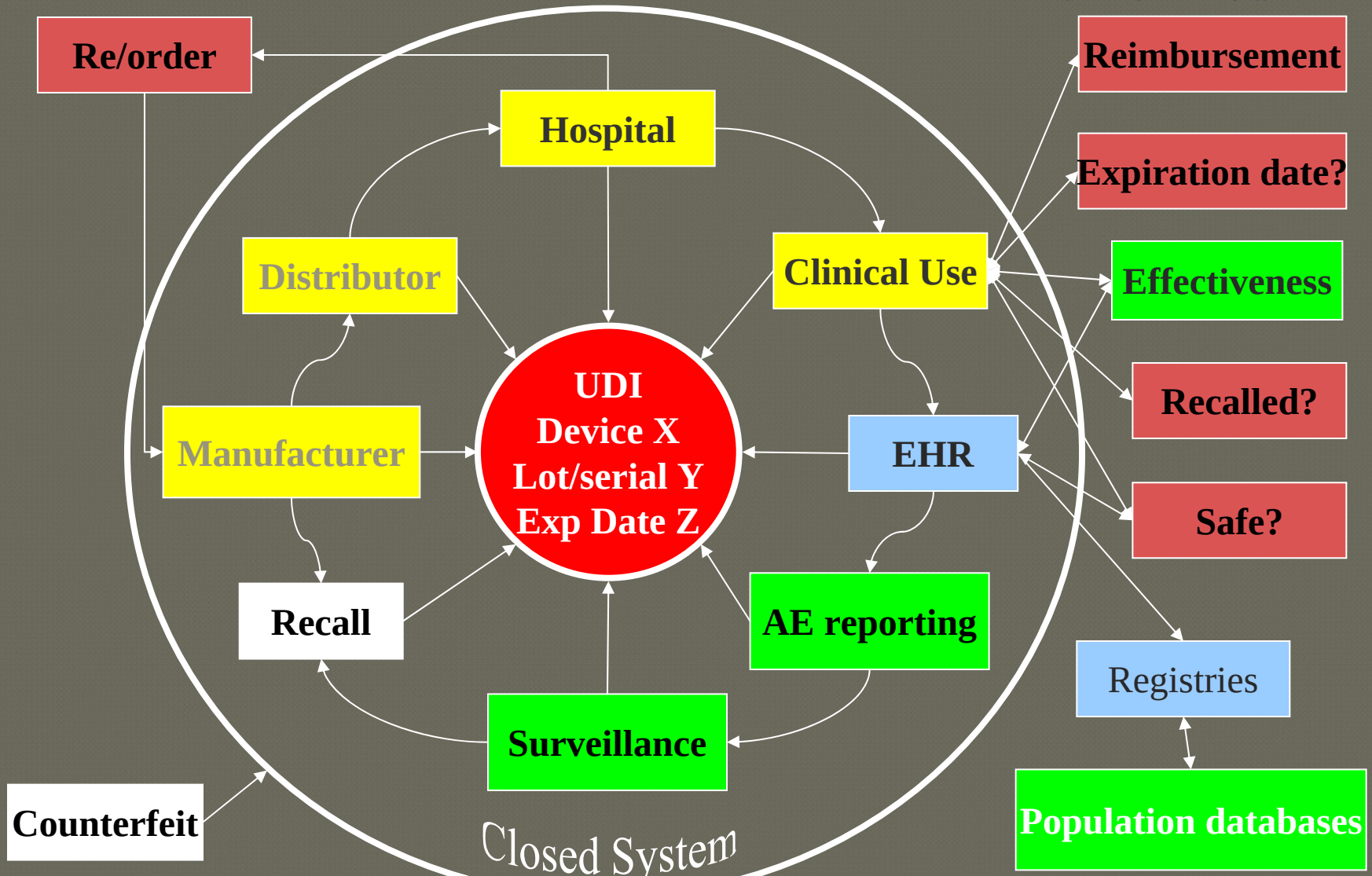
- **Consistent**
- **Unambiguous (differentiates among all dimensions)**
- **Standardized**
- **Unique at all levels of packaging**
- **Harmonized internationally**

And facilitates the:

- **Storage,**
- **Exchange, and**
- **Integration of data and systems**

Future Information Lifecycle

Courtesy of Jay Crowley @FDA



GHTF Recommendations

- The Global Harmonization Task Force (GHTF), in conjunction with FDA, also advocates UDI.
  - To facilitate tracing
  - Enhance identification in case of adverse events
  - To assist in any field safety correction

In addition, GHTF aims to avoid country-specific requirements.

UDI Application Example

Courtesy of Jay Crowley @ FDA

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REF	FMF02

Complications

It’s not the VIN number on your car

Complications

- Where to locate the UDI on a pre-owned MRI when the gantry and the magnet come from two different systems?
- What are the rules for replacing major parts on existing systems?

IAMERS White Paper

- IAMERS believes that standards need to be defined for complicated equipment entering the secondary market.
- IAMERS, at the suggestion of the FDA is working on a White Paper in hopes of making useful suggestions.

Additional Info

FDA News

Unique Device Identifiers:

Best Practices for Regulatory Compliance

&

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

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