Making it Happen: Manufacturer Perspectives on Medical Device Interoperability

Scott Thiel, MBA, MT(ASCP), RAC

Chair Regulatory Working Group Continua Health Alliance

Regulatory Affairs Program Manager; Roche Diagnostic Diabetes Care

Disclaimer

The opinions and conclusions stated in this presentation are those of the presenter and do not represent the official position of either Roche Diagnostic or Continua Health Alliance.

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Goal

Represent manufacturer's needs for development and manufacture of devices to support interoperability.

- Includes both medical devices and non-medical devices.
- Perspective is based upon experience in medical device industry, but believed applicable to nearly any manufacturing industry.

Agenda

- Background
- Manufacturer: Development
- Manufacturer: Pre-launch
- Manufacturer: Post-launch
- Questions & Ambiguities

Where have we been?

FDA historically regulates (including classification) medical devices as a single device / system with a relatively narrowly specified intended use & indication for use associated to a single manufacturer.

Prior to this workshop much has been done to investigate and propose solutions to aspects of interoperable device and their use (e.g. HIMSS, MDPNP, IEEE, IHE, IEC, etc.). Building blocks exist; more may be needed, but assuredly continued effort and perspective is needed to support effective assembly of these blocks.

Where have we been?

We have heard presentations of:

- Why interoperable devices are needed
  - Relationship of medical device interoperability to national HIT infrastructure.
  - Consumer and Patient perspective
- What need these devices answer
  - Setting the stage
- Who the actors are
  - Pieces of the puzzle

We have heard some of the challenges:

- Technical challenges
- Clinical challenges
- Safety and effectiveness challenges

How?

Manufacturers are good at addressing some of the “how.”

Design & develop a product:

- to support an infrastructure,
- to meet a need,
- to monitor a physiological parameter,
- to deliver a therapy,
- to generate a graph or report, etc?

… provided there is a good understanding of key needs.

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Development Activities

General Categories	Specific to Medical Devices
A need / use is determined	Intended use / indication for use
Concept to meet the need / use	Requirements development
Iterative (usually) development process: prototype, test, modify, etc.	Design & verification
Final version reached & tested	Validation
Acceptance process	510(k) / PMA
Monitor feedback after launch	Post-market monitoring
Update product	Lifecycle management

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Pre-launch needs

Understanding of customer needs

- Even to the point of forecasting new needs not yet voiced.

Predictable development and manufacturing environment.

- Clear and consistent rules; understanding how to legally classify and market a device.
- Reliable and consistent methods for confirming that requirements (including rules) are met.

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Post-launch needs

- Reliable and timely information about their product.
- Understanding of what are acceptable failure types and rates.
- Reliable root cause failure analysis methodologies.
- Reliable and cost-effective methods of updating product in the field.

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Questions & Ambiguities

- What are the issues that a manufacturer must address throughout a product's lifecycle (so-called cradle to grave) as a result of interoperable medical devices?

- What solutions are practical for both regulated and non-regulated manufacturers? Can they be the same solutions?

Questions & Ambiguities

Intended use / indications for use:

- How do we write an intended use statement that covers interoperable devices when we are unsure of what other devices it may interface with? What is the intended use of a product that pairs with many?
- How can we assess whether the product is or is not a medical device if there is no clear, final system?

Claims:

- What can (or cannot) manufacturers state in marketing and claims materials? Much will be answered from intended use, but…
- How to guide marketing and sales, especially for co-marketed and / or co-branded product?

Questions & Ambiguities

Collecting field information:

- Who will the customer call with an issue?
- What network will quality issues be communicated on and how much responsibility does the mfg have to monitor / collect this information (especially on social networks)?

Root-cause analysis:

- Who to involve if there is no clear root-cause or discrepant information?
- How to resolve could be challenging if all parties involved in an undefined system don't know each other or are competitors.

Recalls / field notifications:

- Which company reports this? Which is responsible for executing notifications?
- Can regulatory responsibility for reporting and recalls be transferred to.

Questions & Ambiguities

Methods:

- What are the acceptable test methodologies, tools, standards, design guides, etc when all possible use cases are unknown?
- How to support safety and effectiveness without causing validation of an interoperable device / system to be prohibitively time-consuming and expensive? (especially true for software)

Kits containing interoperable devices:

- Can this be done without pre-market clearance of the entire kit as a system?
- Is the seller a re-packager? A kit assembler? Something else?
- What evidence does this company need to confirm that products are interoperable? Could certification serve that purpose?
- How can creation of a new intended use via packaging be avoided?

Questions & Ambiguities

Package containing prescription and non-prescription (OTC) devices:

- Can this be done without impacting the OTC device status?
- Are there special labeling considerations for these devices?
- Who is responsible for managing the distribution of the prescription device?

End users that integrate regulated and non-regulated devices / systems:

- Are the end-user health care providers considered manufacturers in this instance or is this under the practice of medicine?
- If they are manufacturers, are they custom device manufacturers?
- Is this an area for enforcement discretion?

Thank you.