UDI Systems

SPECIAL COMMENTARY:
HOW CAN HOSPITALS REACT?

Presented By:
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- *Counsel, Health Care Group, Schenck Price Smith & King, LLP, specializing in health care law and administrative law for regulated professionals*
- *Represents hospitals, group purchasing organizations, physicians, ambulatory surgery centers and regulated professionals in health and non-health industries.*
- *Extensive experience with regulatory and compliance matters, including fraud and abuse, business and operational counseling, mergers and acquisitions and policy reviews*
- *Former Regulatory Analyst and Chief of Regulatory Affairs for the New Jersey State Division of Consumer Affairs, responsible for preparation of regulations and policy statements and regular interaction with the professional boards and the New Jersey Offices of the Attorney General, Administrative Law, Consumer Protection and Weights and Measures and the New Jersey Bureau of Securities*
- *Numerous years of commercial and bankruptcy litigation experience*

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Hospitals Today

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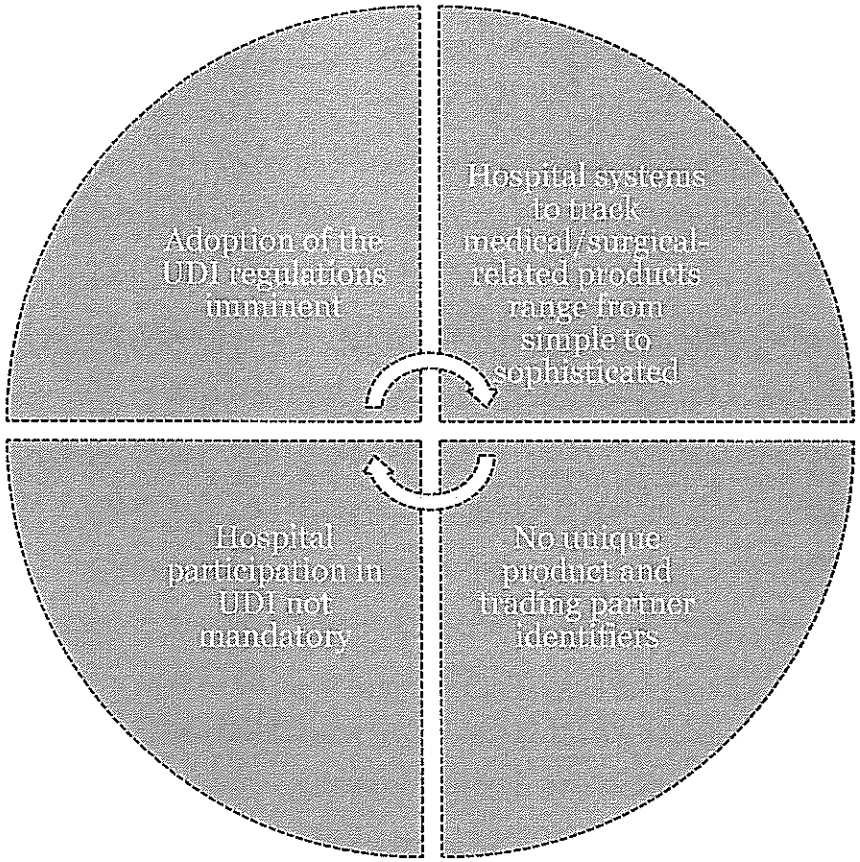

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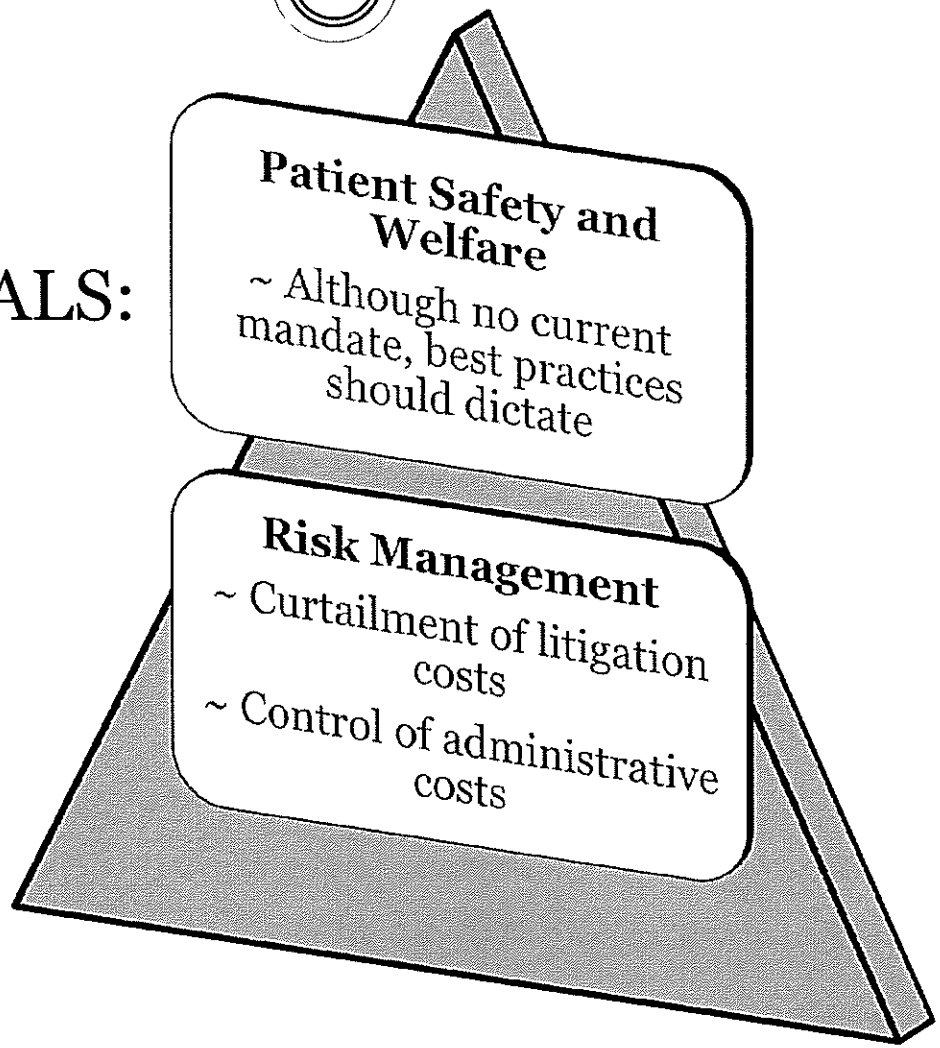
Reasons for the Proactive Stance

TWO MAIN GOALS:



AHA Viewpoint

"We urge the U.S. Food and Drug Administration (FDA) to accelerate the timing of the complete roll-out for the UDI across all medical devices from the proposed seven years to three years . . . we see no compelling reason to wait an additional seven years."

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AHA Commentary

Hospitals are using inefficient systems to track devices

Retail exception removes devices from UDI system and could limit safety benefits of UDI

AHA recommends accelerated roll-out, limitation of exceptions to the regulatory requirements and enhanced information in the GUDID

Benefits

- Delivery of better patient care
- Improved risk management
- Increased control of administrative costs
- More effective inventory management

Plan

Develop a plan with timeline

Consultants evaluate system

- Make recommendations on the most efficient ways to receive, store, manage and use product data from the GUDID and GDSN

Obtain appropriate consultation

- Understand where and how hospitals obtain product data
- Seek to eliminate duplication

UDI offers the first real opportunity to have unique product and trading partner identifiers