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Forward-Looking Device Makers Should Embrace FDA's Unique Device Identifier System

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FDA instituted the UDI to improve adverse event reporting and device tracking, but it also enables price transparency and improve innovation in an increasingly consumer-centric world, writes Tim Durst with PwC Health Industries.

In today's world – whether at work or at home – I'd be lost without the smartphone that helps me do so much more than just communicate. It knows where I am now and how to get where I want to be next. It can help me order takeout, access my daughter's soccer team schedule, and link to my social media platforms. And the main reason it can do those things – which drove my product selection – is that it is a unique device – and uniquely identifiable.

Unique device identification is at the core of our consumer driven high-tech world. Whether we're talking about the cash card in my wallet, the subscription TV system in my living room, or the new wearables everyone was eyeing at the Consumer Electronics Show. Now, thanks to the FDA, the medical device industry is confronting its own new world of Unique Device Identification.

UDI from FDA

As the FDA tells it, "A unique device identifier system has the potential to improve the quality of information in medical device adverse event reports, which will help the FDA identify product problems more quickly, better target recalls, and improve patient safety."

That effort to improve device safety comes in response to concerns about outdated methods to monitor increasingly complicated devices once they reach patients. In promulgating the rules, the FDA has focused on four new areas to strengthen postmarket surveillance:

- Create a Unique Device Identification (UDI) system and promote incorporation into electronic health information.
- Promote the development of national and international registries for select products.
- Modernize adverse event reporting and analysis.
- Adopt new methods for evidence generation, synthesis and appraisal.

Industry implications

From our work at PwC, we think that in some quarters of the industry, the implications have

been understated, and the cost and complexity of implementation underestimated. This is not just a supply chain or regulatory operations issue. It will affect multiple functions, including product development, operations, quality, order management, and inventory. Our experience indicates that transition investment will be significant, requiring companies to develop a well-thought-out approach to achieve compliance in the most productive manner.

For device manufacturers, challenges range from new labeling and label standards, through quality system and business practice changes on to product data management and new technology. Since most medical device companies have multiple product types, varied quality systems, and multiple IT applications in ERP, Product Lifecycle management, RA/QA, and master data management, the complexity is compounded. Finally, many companies are adding scope to their programs to go beyond achieving UDI requirements and also accommodate new labeling standards, the addition of more capable data management systems, and harmonizing quality systems. Although this level of change can make sense from an investment perspective, it does add additional risk, particularly in meeting compliance deadlines.

Now that the rules were clarified to make clear that every needle being shipped in bulk to a hospital would not require its own UDI compliant label and that stents would not need to be imprinted, the industry can see a clear path toward compliance, while the path toward additional operational benefits is becoming visible. These include:

- Supply-chain cost reduction
- Product configuration control
- Surveillance productivity
- Enhanced Product security
- Deeper channel sales and service visibility
- Reduced product liability risk

Look ahead, not back

I think the long-term implications are even more important. UDI has the potential to facilitate enhanced data for product performance and value, competitive use, and improved innovation. Further down the road, UDI can enhance product control and selection at providers, improve linkage to outcomes, reduce medical errors, improve the thoroughness of product recalls, aid in addressing shortages, and reduce counterfeiting and diversion.

And yet – I remain convinced that manufacturers need to focus on the bigger picture in a new health environment that is increasingly consumer centric. The FDA's focus on speeding tracking and recall after adverse incidents– driven by appropriate patient safety concerns --is really a move to improve the rear view mirror, whereas the device industry as a business really needs to ask itself how to see around the next corner. Manufacturers who want to thrive in the future should be focused less on retrospective benefits – and more on the forward-looking hunt for new possibilities.

Forward-looking device companies will embrace UDI as an aid to price transparency, a path toward greater and more informed customer choice, and a tool to understand how their products affect patient outcomes. Tracking product use and results more accurately, they can use this data to improve pricing and pay-for-performance negotiations.

The consumer is the future

A vision of that future can be found in the article Kerry O'Connell, a senior project manager at a Denver construction company and a dedicated patient-safety advocate, authored in August 2012 for the journal Health Affairs. He detailed his long and painful history of multiple surgeries following an elbow injury. Drawing on his own efforts to research procedures and devices involved in his treatment, he argued that

"Shared decision making must include accurate, detailed outcome information and physician outcome history to be successful."

Regarding the FDA's actions on UDI, and the establishment of the GUDID database, O'Connell wrote: "I often wonder why, in a country that spends nearly $3 trillion a year on health care, there aren't even more systematic efforts like this to track what works best for patients and what doesn't, and to inform everybody so that patients can make better choices and the health system itself can improve..."

And he concluded "Patient safety and protections should be a given. I believe that if I'd been given all the information I needed, including...better information on the risks and benefits of the medical devices my doctors were proposing, even I could have made health care decisions that wouldn't have resulted in my having to type this essay with one hand."

That's the kind of plea for a more patient-centric approach that is going to carry increasing weight in the new health economy – as the weight of changing reimbursement policies and money flows that follow outcomes become the rule. Forward looking device manufacturers have the opportunity today to position themselves out in front of that wave. To start looking at their products through the eyes of their end users –patients who are increasingly thinking about their health as discerning consumers.

The smartphone manufacturers who dominate telecommunications today are those who dropped a B2B focus on manufacturing product to the specifications of the telecom network middlemen, and concentrated instead on delivering devices that exceeded the perceived needs of consumers. Thanks in large measure to the ability of these new devices to be uniquely identified objects, they began to open up whole new worlds of applications and advantages that have leapfrogged previous generations of mobile equipment. These products in turn have been embraced by consumers – and vaulted their makers ahead of companies that a few short years ago were the giants in the field.

That's the kind of innovation and future that medical device manufacturers should be looking to create – perhaps even opening another door to more customized and personalized disease management and treatment – all with the help of UDI.

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