6 MEDICAL DEVICE TRENDS IN 2018

1. UDI REGULATIONS

While manufacturers of Class II and/or III medical devices have been managing unique identifier (UDI) regulations since September 2015, requirements coming in September 2020 will require that nearly all manufacturers be in compliance with UDI law, which includes labeling, GUDID data submissions, data formatting, and direct mark requirements. UDI regulations were created to improve traceability, combat the rising threat of device counterfeiting, and replace a patchwork of state level laws with a set of federal regulations. For those manufacturers unaffected by previous deadlines, a strategy and/or implementation plan should be in place now to meet the 2020 deadline.

2. 3D PRINTING

In the past decade 3D printing has gone from a futurist pipedream to the verge of transforming the medical device industry. Today, many medical devise companies use the technology to create cheap and reliable product prototypes and proof of concepts. In the future, the technology is poised to enable personalized medicine via devices designed around a patient's anatomy, reduced waste, and greater biocompatibility through increased surface area. Governments and companies have already invested hundreds of millions of dollars—a number that will surely rise as ROI becomes established.

3. INCREASED FOCUS ON END-OF-LIFE AND PALLIATIVE CARE

The number of Americans aged 65 or over is predicted to double to 72 million people by 2030. This demographic will account for 20 percent of the population, and it's estimated that two-thirds will have more than one chronic health condition. Medical industry analysts believe advancements in VAD technology and a lack of medical donors have poised the industry to make this phase of life substantially more sustainable and comfortable through advancements in pre-transplant and destination therapy procedures.

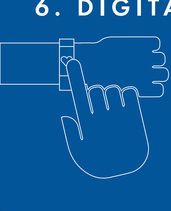
4. VOLUME TO VALUE

The current pay-for-procedure healthcare model has created spiraling costs and medical device companies are transitioning their business models towards value-based reimbursement (VBR). In 2016, nearly 30 percent of healthcare payments were paid based on outcomes rather than unit sales. It is estimated that by 2020, nearly 60 percent of reimbursements will be through VBR programs. Large opportunities exist for medical device companies that can deliver greater outcomes at a lesser cost, integrate into technology systems, and enable preventive monitoring.

5. CYBERSECURITY

Major cyber attacks dominated recent newspaper headlines, but many security experts believe that the medical device companies are also at risk. In 2017, the FDA publicly criticized Abbott after it was discovered that security flaws allowed hackers to shut-down pacemakers and defibrillators its subsidiary produced. Companies must take proactive steps to ensure that products and systems are secure, and future digitally connected innovations are HIPAA compliant.

6. DIGITALIZED DEVICES



The line between digital medical applications and traditional medical devices is constantly eroding. There are currently over 165,000 health related apps across a variety of functions including: Fitbit (wellness), WebMD (information), ZocDoc (booking), and more. The FDA is currently partnering with tech and medical device industries on the Digital Health Innovation Action Plan, which should create clear and accurate guidelines. Digitally-enabled medical devices could create better outcomes through the real-time monitoring and information sharing. Even more promising are the AI and machine learning implications of the large data set created.

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