

AAMI Cautions FDA Against Regulating Medical Device Repair

In advance of the June 3 deadline for the FDA's comment period regarding medical device repair and refurbishment, AAMI submitted its own thoughts to the agency on the controversial matter. The organization's 57-page document, consisting of an 18-page letter and various addenda, is posted on its website. The letter carefully avoids arguing that a particular group take ownership of medical equipment service and repair, and it does not answer the FDA's detailed questions about service. Rather, asserting its role as "a neutral organization that highly values its... 'honest broker reputation,'" AAMI acknowledges the various parties and their concerns, finally advocating for consensus-based standards over regulation. "Decisions made by the FDA, working alone, tend to have unintended consequences. Likewise, decisions made by industry or healthcare delivery organizations while working alone in their own silos tend to have unintended consequences. Standards that are developed through an open consensus-based approach...tend to solve problems without creating new ones and also tend to build the strongest buy-in from all stakeholders because they contributed to the solution rather than being told what they must do." The letter concludes, "...as is often the case with complex issues that involve multiple disciplines, multiple service models, lack of standardization, paucity of reliable data about the industry, uneven lobbying capabilities across the sector, strong opinions, and stories galore, there is a huge risk of unintended consequences from increased regulation involving healthcare technology." Find more information and links at goo.gl/o94UhN.

Almost 1 in 4 Data Breaches Occur in Healthcare, Report Finds

A new report from the Brookings Institute states that while public awareness of and consequences for healthcare data breaches is growing, so is the rate of breaches. The study found that 23% of all data breaches occur in healthcare, and that more than 155 million Americans have been affected by breaches over the last 6 years. The per-record cost of a data breach in healthcare is \$363, higher than in any other industry, the report found. The health sector is being targeted by hackers for a number of reasons, including the value of data retained by healthcare organizations such as Social Security numbers and home addresses, which can be sold at premium prices on the black market. Healthcare organizations also store large volumes of data for long periods of time, both factors that increase the risk of a breach. In addition, the increasing interconnectedness of healthcare means that more personnel now have access to patient data than ever before. Human error is cited as the most common cause of breaches, but several other factors play a role. According to the report, the Health Insurance Portability and Accountability Act's privacy rule is vaguely worded and outdated, and provides no specific direction about how to protect patient information. Organizations that suffer from a security breach also undergo an audit by the Office for Civil Rights, a process many say is unduly punitive and discourages health organizations from sharing details about the breach with other hospitals. Many health organizations are also reluctant to circulate their experiences because of the negative publicity associated with breaches. Find more information and links at goo.gl/jh64hj.



Lucian Leape Institute Releases Patient Safety Compendium

The National Patient Safety Foundation's Lucian Leape Institute has released a compendium of the executive summaries and recommendations from five other reports published by the Institute between 2010 and 2015. *Transforming Health Care*, as it's called, was recently announced at the 18th Annual Patient Safety Congress in Scottsdale, Ariz. "We hope this publication serves as a call to action for healthcare leaders, who can use it to inform discussions, implement recommendations, set work priorities, and make decisions that, though sometimes difficult, are necessary to improve patient safety," said Gary Kaplan, MD, chair of the NPSF Lucian Leape Institute and CEO of Virginia Mason Health System. The document centers around five areas identified by experts as being crucial to enhancing patient safety throughout a health system. Those areas are transparency, care integration, patient/consumer engagement, restoration of joy and meaning in work and workforce safety, and medical education reform. "Leaders of organizations don't necessarily know where or how to begin in approaching these issues," said Tejal K. Gandhi, MD, president and CEO of NPSF and president of the Institute. "We urge healthcare leaders to use this resource to assess where their organizations stand in the journey to safer care and to help map out how they can accelerate their progress." Find more information and links at goo.gl/Rv5Kgj.



HTM Week 2016 Winners Announced

The AAMI Technology Management Council's annual Healthcare Technology Management (HTM) Week, held this year from May 23 to May 27, aims to celebrate the contributions of HTM departments around the country. On the final day of the festivities, the TMC announced the winners of its individual and group contests. Eastern Maine Medical Center in Bangor, Me, won the facility celebration contest for its "outstanding spirit and creativity." Each day of the week was devoted to a special celebration, with baked goods, a catered lunch, and a small gift to team members. Team-building activities with go-kart racing and paintball wrapped up the week. The department will receive a \$500 gift card. The winner of the "My Dream for HTM" short essay contest was Ismael Cordero, biomedical service manager for Gradian Health Systems. His winning entry envisioned "a medical device that's been created and designed with BMETs in mind from its very inception. It's easy to troubleshoot, and all of its modules and components are easily accessible and replaceable." Gradian, a nonprofit based in New York, manufactures a Universal Anaesthesia Machine designed for use by low-resource hospitals in the developing world without access to reliable electricity. The unit comes with extensive customer support from Gradian. Second and third place in the essay contest went to Michael Rakauskas of Baxter Healthcare and J. Patrick Lashway of Oregon Health and Science University, respectively. Find more information and links at goo.gl/vsPF0v.



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