Health Law Vitals - A Healthcare Newsletter from Haynes and Boone, February 2017

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View the February 2017 Health Law Vitals Newsletter PDF.

Final Guidance Sheds Light on Medical Device Reporting Requirements

In November 2016, the U.S. Food and Drug Administration issued a final guidance on medical device reporting for manufacturers ("Final MDR Guidance"). The Final MDR Guidance addresses: (1) manufacturers' reporting requirements; (2) written procedures, recordkeeping, and public disclosures; and (3) questions posed by industry and needed clarifications for manufacturers.
Read more.

An Update on Telemedicine in Texas and Beyond

The holding pattern for the telemedicine/telehealth industry (referred to generally in this article as "telemedicine") appears to be lifted with a stay in the Texas Medical Board vs. Teladoc litigation and the convening of the Texas Legislature in January. As published in the September *Health Law Vitals*, regulatory and legislative changes were on the horizon, and the next six months will be critical for telemedicine supporters to convince the Texas Legislature that further utilization of telemedicine will positively impact access to care and workforce shortage issues.
Read more.

FDA Issues Guidance on Lead in Lipsticks and Other Cosmetics

The U.S. Food and Drug Administration has issued Guidance recommending a maximum level of 10 parts per million of lead in certain cosmetic products. The guidance is for lip products–lipstick, lip gloss, and lip liners–as well as externally applied cosmetics like eye shadows, blushes, shampoos, and body lotions.
Read more.

Applying Blockchain Tech to Medical Records for Improved Security and Access

The technology that forms the foundation for digital currencies like Bitcoin could be the technology that provides unprecedented security for and access to medical records.

The Blockchain

For years, online communities sought increased freedom and autonomy by shielding their economic activities from the government and corporate intermediaries.
Read more.

2016 FDA Year in Review: Food Edition

As the food industry prepares for a new year, we take a look back at the major developments of the past year. The U.S. Food and Drug Administration ("FDA") released three final rules related to the implementation of the Food Safety Modernization Act of 2011, completing the list of the seven foundational rules (other than registration amendments) initially proposed in 2013 and 2014. The FDA also published much-anticipated final rules on changes in serving size and nutrition facts and on supplements labeling, as well as guidance on menu labeling.
Read more.

OIG Advisory Opinions – CY 2016

The U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG") issues advisory opinions to provide guidance on the application of the Anti-Kickback Statute and other OIG sanction statutes to existing or proposed business arrangements. An OIG advisory opinion is legally binding on the HHS and the requesting party or parties; it is not binding on any other governmental department or agency.
Read more.