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

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FDA Improving Regulatory Oversight of Stem Cell Therapies and Regenerative Medicine Products

Regenerative medicine is a burgeoning interdisciplinary research field aiming to offer new therapies that replace or regenerate human cells, tissues, or organs with the goal of restoring or establishing normal function. The field includes treatments using stem cells and tissue engineering, which is the use of biomaterials-based scaffolds, seed cells, and bioactive molecules to build biomimetic tissue-like constructs that can be implanted into the body to repair failing tissues and organs.
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FDA's New Digital Health Software Precertification Program Aims to Foster Innovation Reduce Time/Cost of Market Entry

The American healthcare industry is ripe for technological disruption, but it has been slow to embrace true digital health reform. Certain government agencies, however, finally appear to be embracing digital health technology. Most recently, the FDA's Center for Devices and Radiological Health ("CDRH") announced a Digital Health Innovation Action Plan.
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Navigating the Texas Telemedicine Rulemaking

Texas is on the road to modernizing its telemedicine and telehealth regulations after Governor Greg Abbott signed into law Senate Bill 1107 as previously covered in Health Law Vitals. While most of the provisions of the new law were effective in late May 2017, Sections 5, 6 and 7 addressing changes to Chapter 1455 of the Texas Insurance Code will be effective on January 1, 2018.
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