haynesboone

HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

NOVEMBER 2017

QUICK SHOTS

THA coordinates assistance for hospitals affected by Harvey.

Read more.

Congress introduces alternative sanctions bill for technical noncompliance with Stark rule.

Read more.

Texas Department of Insurance proposes rule amendments on out-of-network claim dispute resolution

Read more.

UPCOMING EVENTS

Dallas Bar Association - Health Law Section

The Stark Law and Certain Trending Arrangements: What to Know When Analyzing Lithotripsy, Neuromonitoring, and Pathology Arrangements

Lisa Prather and **Jennifer Kreick**

November 15, 2017
Dallas, TX

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

Kenya S. Woodruff and **Neil Issar**

Kenya Woodruff

Neil Issar

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.

While regenerative medicine offers significant medical promise, it lacks a comprehensive or consistent regulatory framework. To address this issue, the Food and Drug Administration ("FDA") has announced that it is working to increase regulatory oversight and enforcement activity over regenerative medicine products to better identify fraud and provide a more efficient approval pathway for responsible product developers.[1]

Specifically, the FDA will "advance a comprehensive policy framework that will more clearly describe the rules of the road for this new field."[2] As part of this framework, the agency proposed adding to the list of products eligible for expedited FDA review under the **Regenerative Medicine Advanced Therapy ("RMAT")** designation. The agency also promised to give product developers "a very reasonable period of time to interact with the FDA in order to determine if they need to submit an application for marketing authorization and to come into the agency and work on a path toward approval."[3]

At the same time, the FDA is stepping up enforcement against developers and manufacturers subject to and attempting to sidestep more stringent regulations. For example, the FDA recently issued a warning letter to a Florida clinic for marketing stem cell products derived from patients' body fat without FDA approval and for significant deviations from current good manufacturing practice (or CGMP) requirements, including some that could impact the sterility of their products and

put patients at risk.[4] The agency rejected the clinic's argument that its products qualified as human cells, tissues, and cellular and tissue-based products (or HCT/Ps) and could be manufactured and sold without pre-market approval. Similarly, the FDA seized vials of a rare smallpox vaccine being used by a California clinic to create unapproved stem cell treatments for cancer patients.[5] The agency has said these actions are just the beginning of its increased focus on entities that pose a danger to patients and/or overstep regulatory lines.

The FDA's announcement may present an opportunity for unprecedented agency-stakeholder collaboration in shaping a new regulatory framework for regenerative medicine products. This may be especially timely given the recent approval of Tisagenlecleucel (marketed by Novartis as Kymriah)—the first ever gene therapy to be approved in the United States. Kymriah genetically modifies patients' own T-cells to treat and potentially cure their cancer.[6] It is approved for children and young adults with relapsed or refractory acute B-cell lymphoblastic leukemia—a leading cause of childhood cancer deaths. The drug's price tag comes in at a whopping $475,000, but the manufacturer has reportedly agreed with The Centers for Medicare and Medicaid Services (or CMS) to only accept payment if a patient successfully responds to treatment within the first month of infusion.

Companies conducting research on potentially transformative gene therapies are likely to follow in Novartis's footsteps and seek FDA approval, so an improved regulatory framework, streamlined and cost-effective approval processes, and consistent enforcement activity to weed out bad actors will be more important than ever before.

[1] **Press Release**, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D. on the FDA's new policy steps and enforcement efforts to ensure proper oversight of stem cell therapies and regenerative medicine (Aug. 28, 2017).

[2] *Id.*

[3] *Id.*

[4] **Press Release**, U.S. Food & Drug Admin., FDA warns US Stem Cell Clinic of significant deviations (Aug. 28, 2017).

[5] **Press Release**, U.S. Food & Drug Admin., FDA acts to remove unproven, potentially harmful treatment used in 'stem cell' centers targeting vulnerable patients (Aug. 28, 2017).

[6] **Press Release**, U.S. Food & Drug Admin., FDA approval brings first gene therapy to the United States (Aug. 30, 2017).

FDA's Health Software Precertification Program Aims to Foster Innovation, Reduce Time/Cost of Market Entry

Kenya S. Woodruff and **Neil Issar**

Kenya Woodruff

Neil Issar

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.[1]

The action plan lays out the agency's vision for fostering digital health innovation while continuing to protect and promote the public health with an appropriate level of regulation. Specifically, the plan is the first step towards creating a regulatory framework that accommodates the clinical promise and unique user interfaces of digital health technologies, as well as the industry's compressed timelines for new product introductions. Towards this end, it will involve:

- Issuing new and revised guidance to provide clarity on the medical software provisions of the 21st Century Cures Act, including policies pertaining to clinical decision support software, mobile medical applications, medical image storage and

communications devices, and low-risk general wellness products[2]

- Developing a new approach to digital health technology oversight, including a pilot precertification program that will give software developers that meet certain criteria access to streamlined approval processes[3]
- Augmenting the FDA's staff and expertise of the CDRH's digital health unit[4]

The plan's Digital Health Software Precertification ("PreCert") Program is a voluntary, risk-based pilot program in which the FDA will focus on the developers of Software-as-a-Medical Device ("SaMD"),[5] rather than primarily on their products, to reduce their time and cost of market entry. The PreCert program was conceived after the FDA recognized that its "traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software products."[6]

After receiving more than 100 applications for participation in the first phase of the program, the FDA recently announced the selection of nine participants, including Apple, Johnson & Johnson and Roche, to name a few.[7]

As participants, these companies will provide access to measures they currently use to develop, test, and maintain their software products, including ways they collect post-market data. Participants also agreed to be available for site visits from FDA staff and to provide information about their quality management systems. The FDA will use the information to explore whether and how precertified companies—which will have demonstrated a culture of quality, patient safety, and organizational excellence—can bring certain types of digital health products to market without FDA premarket review or through a more streamlined FDA premarket review. The streamlined review may include reduced submission content, faster review of that content by CDRH staff, or both.

To support and help develop the PreCert program, the FDA also launched a Digital Health Entrepreneurs-in-Residence ("EIR") Program, which brings together world-class entrepreneurs and innovators to work with the CDRH digital health unit staff for a minimum of six months to iteratively develop and test key conceptual elements of the program. The FDA just completed accepting applications for EIR Program participation, and will share public updates about it and the PreCert pilot program **online** as well as through stakeholder meetings, including a January 2018 workshop.

---

[1] U.S. Food & Drug Admin., **Digital Health Innovation Action Plan** (July 27, 2017).

[2] *Id.*

[3] *See* 32 Fed. Reg. 35,216 (July 28, 2017).

[4] U.S. Food & Drug Admin., *supra* note 1.

[5] For the PreCert program, the FDA will initially use the SaMD definition and framework outlined by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The IMDRF defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." Examples of SaMD include smartphone apps used for diagnosis of medical conditions, medical image-processing software intended to run on a computer, and in-vitro diagnostic software.

[6] 32 Fed. Reg. at 35,216.

[7] **Press Release**, U.S. Food & Drug Admin., FDA selects participants for new digital health software precertification pilot program (Sept. 26, 2017).

Navigating the Texas Telemedicine Rulemaking

Michelle "Missy" D. Apodaca

Michelle "Missy" D. Apodaca

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 five, six and seven addressing changes to Chapter 1455 of the Texas Insurance Code will be effective on January 1, 2018.

The Texas Medical Board ("TMB"), the first of several state agencies impacted by the new law, began its rulemaking process by publishing revised telemedicine rules in the **Texas Register on September 15, 2017**.[1] After the 30-day comment period, the new rules were adopted at the TMB Board meeting on October 20, 2017. Thereafter, the Texas Board of Nursing, Texas State Board of Pharmacy, Texas Physician Assistant Board, Health and Human Services Commission ("HHSC"), and Texas Department of Insurance ("TDI") will develop new rules to comport with the new law. Additionally, the Division of Workers Compensation at the TDI released informal rules in September 2017 and will release formal rules at a later date.

Key issues addressed in the TMB rulemaking include:

- Removing the requirements for "in-person or face-to-face visits" to establish patient-physician relationships, "established medical sites" and "patient-site presenters." These changes remove the significant limitations to providing telemedicine and provide new opportunities to increase access to care regardless of the location of the patient.[2]
- Clarifying standards of care delivered through telemedicine medical services or in an in-person setting must be the same.[3]
- Requiring a notice to privacy practices must be given prior to treatment or evaluation and consistent with federal standards.[4]
- Clarifying standards for valid prescriptions are the same if done through telemedicine or an in-person and setting a limitation on the use of chronic pain treatment through a telemedicine medical service.[5]

Texas Medicaid

While the TMB was quick to release their proposed rules, HHSC, the state Medicaid agency, has indicated that they will release information on their rulemaking in late October or early November 2017. HHSC anticipates an estimated 10-month implementation with the following activities: (i) a State Plan Amendment amending the state definition of telemedicine services will need to be submitted to The Centers for Medicare and Medicaid (or CMS), (ii) amendments to the State's Medicaid managed care agreements with managed care organizations will need to be implemented to strike conflicting language, (iii) amendments to the programmatic administrative rules in 1 Texas Administrative Code Section 354.1430 and Section 354.142 will need to be completed, and (iv) the Texas Medical Policy and Texas Medicaid Provider Procedures Manual will need to be updated.

As HHSC and other state agencies tackle implementing the new law, healthcare providers and stakeholders interested in providing telemedicine services to patients are encouraged to consult their lawyer for clear guidance on permissible activities.

Haynes and Boone lawyers will continue to monitor and provide timely updates on additional telemedicine rulemaking activities.

---

[1] **Proposed Rule Changes**
[2] Amendments to § 174.2
[3] Amendments to § 174.6
[4] New to § 174.4
[5] Amendment to § 174.5

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

KENYA WOODRUFF
PARTNER | CHAIR - HEALTHCARE PRACTICE GROUP
kenya.woodruff@haynesboone.com