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ALERT

Full Speed Ahead – FDA's Digital Health Center of Excellence to Host Listening Sessions

October 16, 2020

On September 22, 2020, the U.S. Food and Drug Administration (FDA) announced the establishment of the Digital Health Center of Excellence (DHCE) within FDA's Center for Devices and Radiological Health (CDRH). Bakul Patel will serve as the DHCE's first director. Less than a month after the announcement of its creation, the DHCE is ready to engage stakeholders by hosting two webinars – one on October 19, 2020 and another on November 12, 2020. Here are key takeaways in following the evolution of the DHCE.

What is FDA's Digital Health Center of Excellence (DHCE)?

The DHCE's goal is to "empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation." DHCE is part of FDA's plan to advance digital health and ensure access to high-quality, safe, and effective digital health products for consumers.

While housed in CDRH, the DHCE will align and coordinate digital health work across FDA and many other stakeholders. Dr. Amy Abernethy, Principal Deputy Commissioner and Acting Chief Information Officer of FDA reinforced this purpose when speaking about the DHCE at the recent Food and Drug Law Institute's (FDLI's) Annual Conference in October 2020 – stating that the DHCE is meant to serve as a resource for the entire agency and public. When fully operating, the DHCE will serve as a go to resource for all actors involved in digital health, which includes, but is not limited to, patients, developers, health care providers, researchers, industry, other governmental agencies, and CDRH and other centers within

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Practice Areas

Digital Health
Food & Drug

FDA.

What Services Does DHCE Provide?

The DHCE provides services in the following digital health areas:

- Digital Health Policy and Technology Support and Training
- Medical Device Cybersecurity
- Artificial Intelligence/Machine Learning
- Regulatory Science Advancement
- Regulatory Review Support and Coordination
- Advanced Manufacturing
- Real World Evidence and Advanced Clinical Studies
- Regulatory Innovation
- Strategic Partnerships

You can learn more about the DHCE on its website, which you can find here.

October and November 2020 Listening Sessions

On October 19, 2020 and November 12, 2020, the DHCE plans to host virtual listening sessions for digital health device manufacturers, developers, health care providers, researchers, and other stakeholders to learn about the DHCE. FDA also plans to collect initial feedback about the purpose and function of the DHCE from attendees. Registration is not required for these webinars – you can find information on attending the October 19, 2020 session here and the November 12, 2020 session here.

Industry Points to Consider

There are many points to consider with FDA's establishment of the DHCE – we highlight a few of them here:

- Establishment of the DHCE confirms FDA's recognition that digital health will only continue to grow – and industry has the opportunity to be a part of early discussions addressing complex issues in digital health regulation (e.g., how should FDA regulate artificial intelligence?).
- It is important to remember that the DHCE's purpose is not limited to the medical device industry or assisting only CDRH. Establishment of the DHCE serves as evidence that digital health poses its own unique regulatory issues across a significant number of stakeholders.
- FDA invested heavily in digital health by rolling out the DHCE and its corresponding marketing campaign. On one hand, it is impressive to see FDA put so many resources behind an issue as important as digital health. The agency reports on many initiatives each year and few get the attention or move at the speed we are seeing here. However, significant resources invested in digital health can also be an indicator of significant regulation and/or oversight in the future – with less reliance on

industry self-regulation.

- The DHCE will have to deal with more controversial issues, such as the possibility of industry having to share data streams throughout product lifecycles with FDA (e.g., post-market surveillance), which may raise privacy concerns.
- The DHCE is operational as of September 22, 2020; however, it still needs the right talent to operate. FDA is actively recruiting software engineers, artificial intelligence and machine learning engineers, security researchers, user interface and user experience designers, and product managers to be a part of the DHCE. It may take a while before we see the DHCE operating at its true potential.

Please do not hesitate to contact Ryan Michael Fournier or Ann Begley for more information on any of the issues discussed in this article.