

Navigating the Waters of Digital Health: Structuring Legal and Operational Considerations

University of Texas Health Law Conference
April 19, 2024

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Case Study Introduction

Lone Star Hospital is technologically advanced hospital in Houston, Texas that offers renowned emergency care, cancer care and nationally ranked hospital for pediatric diabetic care and clinical research.

Lone Star Hospital's affiliated non-profit health organization operates a specialty clinic, Lone Star Specialty Clinic.

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Case Study Introduction

Naomi Wang is a 9 year old who fell ill at school one afternoon.

Naomi went to the school nurse and complained she had blurred vision, felt very tired and thirsty.

The school nurse contacted Naomi's parents and recommended that she be taken to Lone Star Hospital for further assessment.

Naomi presented to Lone Star Hospital's Emergency Department and was admitted to the hospital for three days.

During that time, she underwent multiple tests. Naomi was diagnosed with Type 1 diabetes. At discharge, Naomi was referred to Lone Star Specialty Clinic for further care. Naomi had a follow-up appointment scheduled two days after her discharge.

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Case Study – Specialty Clinic Visit

Upon arrival to the clinic, the medical assistant, Isabella, greeted Naomi and her mom and showed her the hospital's mobile app, DiaBeat, for families to access their health data, speak with members of the healthcare team (physicians, nurse practitioners, dieticians) and for the monitoring of patient's weight, caloric intake, blood sugars, food intake and activity level.

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Case Study – Diabeat App

DiaBeat includes various attachments including blood sugar monitors that transfer blood sugar readings directly into the app.

DiaBeat tracks and monitors relevant health information, and such information is also directly published in the patient's electronic health record so the hospital and healthcare team can have ongoing access to all of the patient's health information for remote patient monitoring.

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FDA Regulation of Mobile Medical Apps

What makes an app subject to FDA regulation as a medical device?

Consideration of attachments such as glucose monitor and connection to the insulin pump.

Policy for Device Software Functions
and Mobile Medical Applications |
FDA

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First appeared as part of the conference materials for the
35th Annual Health Law Conference session

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