HealthTech Activator

Health IT – Disease Management App

Diabetologic TM is a new subscription-based smartphone app that helps diabetic (and pre-diabetic) patients control their lifestyle and improves diabetic (glycaemic) control. Its tagline is: "*Diabetologic™ supports you to live well while keeping a lid on your diabetes*."

Functions of the app include:

- Automatically uploads glucose measurement from wifi-enabled glucose meter
- Food diary (both manual entry and barcode scanning capability)
- Activity tracker using existing smartphone app (e.g. Samsung Health)
- Drug reminders
- Scan drug barcode when taking meds to register compliance
- Insulin dosage calculator (utilising proprietary algorithm)
- Communicates with your doctor to update them on your progress
- Emergency response alarm (lets family member and/or ambulance know if you're hypoglycaemic).

The Diabetologic™ team has developed the app and supporting cloud-based data storage and analytics platform in NZ, using commercial cloud servers in Australia, and are rolling the service out to patients in the US.

The CEO of the company is a doctor with extensive experience in diabetes management and is confident the algorithms provide accurate data on which to adjust insulin dosing. The algorithms were developed in-house and have been tested against large databases of patient data, but not in live patients.

The development team has strong banking experience and integration expertise in linking legacy systems to apps. They are confident about getting the security settings correct but have questions about any data privacy requirements, as part of the app aims to collect data on dietary patterns and over-the-counter medication use that may be valuable to medication and health food advertisers.

The integration of the app into electronic health records (for GPs and specialists), ambulance alert systems and third party apps (e.g. barcode data and Samsung Health) is in testing, but have yet to go live. Some integration using

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RESTful APIs is intended, but the original programming did not consider this approach, so the change is scheduled for subsequent release.

QUESTIONS:

1. Does the Diabetologic™ app need regulatory approval in the US?
2. What elements of the app would most interest regulators?
3. Does the app collect 'sensitive' data about the user (patient)?
4. What privacy legislation defines the privacy requirements for the app in the US?
5. Are there regulations and development standards that would have any impact on the ability to achieve regulatory approval?

ANSWERS:

1. The Diabetologic™ app would need FDA approval/ market clearance due to being considered a 'mobile medical app' under its definition.

   Broadly, an app will be regulated only if:

   a. the app fits the FDA definition of a medical device (below); and if

   b. the app's functionality could pose a risk to a patient's safety if the mobile app were not to function as intended.

   The FDA can use its discretion not to regulate an app if it does not meet both criteria.

   The intended use of a mobile app determines whether it meets the definition of a 'device' and the range of intended uses is very broad: *'intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ...'* or *'... intended to affect the structure or any function of the body...'*.

   The Diabetologic™ app would pose a risk to a patient if it provided an incorrect insulin dose recommendation through its proprietary algorithm. Where apps simply remind patients to take medicine according to a previously prescribed regimen, they do not require FDA approval.

2. Regulators would want the company to provide evidence that the proprietary algorithm provides accurate, reliable dosage recommendations and such evidence would need to have been generated under regulated clinical trial conditions. If, however, the app developer used a standard clinically accepted algorithm, this would avoid the need for development of new evidence for this capability in the app.

   The paired glucose meter (whether it is off the shelf or developed by the DiabetologicTM team) would need regulatory approval via the medical device pathway.

   Where an app only provides the ability to accurately receive, store, transfer, display or convert the format of

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medical device data (from a separate, approved device) this function is now regulated as a low-risk (Class I) category, called Medical Device Data Systems (MDDSs).

3. The Diabetologic™ app would need to collect multiple data components that would be considered sensitive in many jurisdictions (including the US, EU and NZ).

   Data such as patient name, any other identifying data, details of their disease and prescriptions would all need to be collected, stored, used (including use by DiabetologicTM staff members), and shared in a way that meets data privacy legislation for health data. The jurisdiction for such protection is complex and includes where the patient is based, where the company is based and the physical locations of the servers that store the data (including for cloud-based applications).

4. The legislation that controls data privacy in the US is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A summary of the requirements for the US HIPAA can be seen here:
   www.hhs.gov/hipaa/for-professionals/index.html

   The US Department of Health and Human Services, Office for Civil Rights (OCR) is responsible for administering and enforcing Standards for Privacy of Individually Identifiable Health Information (the privacy rule) and there are criminal and financial penalties for not complying. HIPAA compliance is self-determined in practice, with external agencies available to help developers ensure they are compliant, but the responsibility remains with the company/developer to ensure the legislation is followed. The HealthIT.gov website provides extensive material on how to interpret and comply with the HIPAA:

   www.healthit.gov/topic/privacy-security-and-hipaa/health-it-privacy-and-securityresources-providers

5. The FDA recommends that companies develop apps and other software systems according to their Quality System Regulation (QSR – USFDA 21 CFR Part 820), which will support a more streamlined approval process for the manufacturer:

   www.ecfr.gov/cgi-bintextidx?SID=247523cf41b8ab512f6871586d973ea9&mc=true&tpl=/ecfrbrowse/Title21/21cfr820 _main_02.tpl

   Additionally, relevant standards will depend on the regulatory product code classification under which this product is categorised.

   There are some specific guidance that should be considered, including:

   www.fda.gov/MedicalDevices/DigitalHealth/ucm562577.htm

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