ASPEN TECH POLICY HUB

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Improving Diabetes Management Through Device Interoperability Requirements

Updating FDA device interoperability designations to provide more avenues of diabetes management

EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has recognized that interoperability – the ability of a device to use and share information among one or more devices, systems, or platforms – offers several benefits, such as improving patient care, reducing errors, encouraging innovation, and enabling more diverse study datasets. In recognition of these benefits, the FDA should update the guidance for its Breakthrough Devices Program to make it clear that third-party medical devices need to be interoperable in order to be considered for the program. This clarification would incentivize medical device sponsors to create interoperable devices, which would lead to more choices and better outcomes for diabetes patients.

PROBLEM

There is currently no interoperability mandate for insulin devices in the United States. There are 3 separate parts needed to support automated insulin dosing for diabetes management: a continuous glucose monitor (CGM), an insulin pump, and an automated glycemic controller (AGC). Because the FDA has only approved a few interoperable diabetes devices, patients and providers can only choose from limited bundles of these devices. The lack of interoperability makes it harder for patients to manage their diabetes care in a way that is tailored to their individual needs.

The FDA should incentivize interoperability of insulin pump devices by updating its Breakthrough Device Designation in order to better help patients manage their care.

SOLUTION

The FDA has already created a Breakthrough Device Designation program to expedite the regulatory review of medical devices and encourage innovation. The Breakthrough Devices Program lacks an interoperability mandate. To foster innovation and improve patient outcomes across the medical device industry, the FDA should update the Breakthrough Device Designation to clearly indicate that third-party interoperability is a feature that could qualify a device for the designation. Clarifying that third party interoperability qualifies a device as a breakthrough device would create further incentives for device sponsors to build true third-party interoperability into their products. A modest clarification of existing guidance would remove the risk of misinterpretation that contributes to the failure of device sponsors to incorporate interoperability into innovative devices, thereby enabling what the medical community and the FDA have already confirmed is in the best interest of public health.

Mandating interoperability of devices will allow patients and providers to tailor their diabetes management to their individual device preferences and needs, which will lead to better outcomes for those struggling to access the care they need.

For more information, please see:

(1) a policy brief describing this program; and

(2) the redlined FDA designations.

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PROJECT BRIEF

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