Caution Patients to Not Miss Critical Alerts

The development of diabetes monitoring and treatment devices that utilize smartphone technology has been instrumental in changing the way we help patients monitor and treat their diabetes. As much as we may rely on this technology, it is even more important to our patients who depend on the information to remain safe once they leave their medical provider's office.

Recently, the U.S. Food and Drug Administration (FDA) issued a news release about the possible risk of patients missing critical alerts on their smartphone-compatible diabetes devices. Normally patients can configure how they want to receive alerts from their continuous glucose monitors (CGMs), insulin pumps, and automated insulin dosing systems. Such alerts can include what types of alerts and messages they receive, when they receive them, and how they are sent to patients (ex. via audible, vibration, or text alerts). Recently the FDA identified an increase in reports being filed where patients who were using these monitoring and treatment devices were either not receiving safety alerts or were not hearing them despite having them setup to do so. These missed alerts included those involving severe hypoglycemia, severe hyperglycemia, and diabetic ketoacidosis. Not only did these events occur, they indicated it could have additionally led to death.

The FDA has identified the source of these missed alerts to smartphone hardware and software changes that can occur during normal use and updates. These can include changes the patient may make while operating their phones, or when software updates occur (whether automatic or user-initiated). When these changes occur to phone operating systems, patients may not know how they can interfere with the apps they use for their diabetes monitoring and treatment. In addition, sometimes the phone apps may not be updated quickly enough to continue working in-step with the smartphone. The FDA specifically listed the following issues leading to the noted problems:

- *software configuration issues, such as app notification permissions, using "do not disturb" or "focus mode" or the app entering "deep sleep" after a period of not being used;*
- *connecting new hardware to the smartphone, such as connecting to car audio or using wireless earphones, that can change the default volume of alerts or prevent delivery of alerts; and*
- *smartphone operating system updates that are not supported by the medical device application.*

In addition, the FDA recommended steps that could be taken by patients to hopefully avoid such missed alerts occurring in the first place. They include:

- *Carefully follow the instructions provided by diabetes device manufacturers when installing, setting up or updating mobile medical apps on the smartphone;*
- *turn off automatic operating system (OS) updates to the smartphone and do not update the phone's OS until confirming the diabetes device app is compatible with the new OS version;*

- *after updating the phone's OS or adding a new accessory, such as wireless headphones, confirm alert settings then carefully monitor the medical device app to make sure alerts are received and can be heard as expected;*
- *at least once a month, check that the smartphone alerts are configured as expected;*
- *if alerts are not being received as expected from the mobile medical app, or cannot be heard, call the technical support number for the medical device for assistance; and*
- *report any problems with the diabetes device to the FDA.*

The agency has issued an FDA Safety Communication that provides greater detail to the concerns noted above, The notice also gives recommendations specifically made for patients and caregivers, as well as health care providers. In addition, the FDA notes they are working with medical device manufacturers to try and rectify these issues, as well as working to find ways to prevent them from happening in the first place. If you or a patient become aware of an issue that has happened personally, it is advised that a MedWatch Voluntary Reporting Form be completed.