

#### FDA Recall – Dexcom, Inc.

##### **Purpose of this communication:**

- We are writing to inform you that Dexcom, Inc. is correcting the Dexcom G6 Continuous Glucose Monitoring System's G6 and G6 Pro Android US CGM App version 1.15.0 due to an identified bug that can cause the app to terminate unexpectedly. As a result, the user may not receive estimated glucose values, alarms, or alerts. If a user is unaware that the app has terminated, there is potential for missed detection of a high blood sugar (hyperglycemic) or low blood sugar (hypoglycemic) event. The use of affected product may cause serious adverse health consequences, including hyperglycemia, hypoglycemia and death.

##### **What do I need to do?**

- Please review the following recall notice: [https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/continuous-glucose-monitoring-software-correction-dexcom-issues-correction-dexcom-g6-and-g6-pro?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/continuous-glucose-monitoring-software-correction-dexcom-issues-correction-dexcom-g6-and-g6-pro?utm_medium=email&utm_source=govdelivery)
- Notify impacted patients and facilitate the replacement according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

**Thank you in advance for your cooperation and continued partnership.**