

## Provider Newsflash October 2024

## FDA Recall - Medtronic

## Purpose of this communication:

• We are writing to inform you that the FDA has posted a Class 1 recall notice issued by Medtronics with an addition to the actions outlined in the Urgent Medical Device Correction letter sent to all users of MiniMed 600 and 700 series insulin pumps on October 4, 2024 due to the potential risk of shorter than expected battery life and less time until shutdown after a battery alert occurs for pumps that have been dropped, bumped, or experienced another physical impact that may have damaged electrical components. Medtronic has now added a statement instructing all users to contact their 24-hour Support Team at 1-800-378-2292 to determine if a replacement pump is needed if their pump experiences any significant reduced battery life whether or not the pump has been dropped, bumped, or experienced other physical impacts. This notice does not involve the removal of all products.

## What do I need to do?

- Please review the following recall notice: <u>Insulin Pump Recall: Medtronic Notifies Users of MiniMed</u>
   600 and 700 Series Pumps of Risk of Shorter than Expected Battery Life | FDA
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, 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.