carecentrix

Provider Newsflash May 1, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued an update by CME America on 2 previously announced voluntary recalls related to ambulatory infusion pumps and sets. One is related to all models of their BodyGuard Infusion Pumps due to the risk of inaccurate delivery of medication. The second recall is for certain lots of CME America BodyGuard Microset Infusion Set, Catalog A120-003SYVA that was previously issued on September 16, 2019 due to the potential for under-delivery of fluids when used with the BodyGuard infusion pump.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cme-america-provides-update-two-previously-announced-voluntary-recalls-related-ambulatory-infusion?utm_campaign=CME%20America%20Provides%20Update%20on%20Two%20Previously%20Announced%20Voluntary%20Recalls&utm_medium=email&utm_source=Eloqua
- 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

Thank you for your prompt attention and cooperation in this matter.