carecentrix

Provider Newsflash March, 30 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has posted a Class 1 recall by CME America of all serial numbers of 5 models of their BodyGuard Infusion Pump Systems manufactured from March 6, 2009 to November 26, 2019 and distributed from March 6, 2009 to November 29, 2019. The reason for the recall is because the pumps may have a slower than expected delivery of medication (under-infusion) and a faster than expected delivery of medication (over-infusion). The cause of the infusion errors is unknown.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/cme-america-recalls-bodyguard-infusion-pump-system-due-risk-over-and-under-infusion?utm_campaign=FDA%20MedWatch%3A%20BodyGuard%20Infusion%20Pump%20System%20by%20CME%20America&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.