carecentrix

Provider Newsflash July 14, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a voluntary recall by CME America of all BodyGuard Infusion System Administration Sets for use with their BodyGuard Infusion Pumps distributed beginning in May, 2016. This recall announcement is a follow up to their previous voluntary recall of their BodyGuard Infusion Pump Systems issued on April 27, 2020 due to results of additional flow rate accuracy testing identified that some infusion sets do not meet the ± 5% delivery accuracy or the ± 13% accuracy identified in the previous recall. This could cause over-infusion or under-infusion of therapy and result in patient harm.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cme-america-announces-follow-voluntary-recall-bodyguardr-infusion-system-administration-sets?utm_campaign=CME%20America%20Announces%20a%20Follow-Up%20on%20the%20Recall%20of%20BodyGuard%C2%AE%20Infusion%20System%20Administration%20Sets&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.