carecentrix

Provider Newsflash February 10, 2021

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a Class I Recall by Smiths Medical of specific software versions of their Medfusion 3500 and 4000 Syringe Pumps due to a software error that may lead to over-delivery or under-delivery of fluids or medication. Use of the affected syringe pumps may cause serious adverse health consequences including death.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-recalls-medfusion-3500-and-4000-syringe-pumps-due-risk-medication-delivery-error?utm_medium=email&utm_source=govdeliver
- 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.