Provider Newsflash April 30, 2021

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately, the FDA has issued notice of a Class 1 recall by Pacific Medical Group (Avante Health Solutions) of their Alaris Infusion Pump Module, Model 8100 Front Bezel distributed from 7/10/2020 to 2/18/2021. This recall was issued because the front bezel components may crack or separate, leading to inaccurate delivery of fluids to patients. The separation of one or more bezel posts may result in free flow of fluids to patient, over delivery or under delivery of fluids delivered to a patient, or interruption of fluids delivered to a patient.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/pacific-medical-group-dba-avante-health-solutions-recalls-alaris-infusion-pump-module-8100-bezel-due?utm_medium=email&utm_source=govdelivery
- 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.