carecentrix

**Provider Newsflash** October 10, 2019

# FDA RECALL

## Purpose of this communication:

We are writing to inform you that effective immediately the FDA has published notice of a voluntary recall issued by ICU Medical, Inc. of certain lots of Plum and Sapphire Microbore Infusion Sets with inline filters due to the potential for small amounts of fluid leaking out of the air vents on the inline filters. This may potentially cause delay of infusion, medication under-delivery, contamination of the fluid path which is on the patient side of the filter, exposure to hazardous medications, or fluid path air in the line.

## What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/icu-medical-issues-voluntary-nationwide-recall-certain-lots-plum-and-sapphire-microbore-infusion?utm_campaign=FDA%20MedWatch%20-%20Plum%20and%20Sapphire%20Microbore%20Infusion%20Sets%20with%20Inline%20Filters%20by%20ICU%20Medical&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.