carecentrix

Provider Newsflash
October 2023

FDA Recall – Exela Pharma Sciences, LLC

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has published notice of a voluntary nationwide recall by Exela Pharma Sciences, LLC (Exela) of their 8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL, Midazolam in 0.8% Sodium Chloride Injection 100 mg/100 mL and ELCYS (cysteine hydrochloride injection) USP 500 mg/10 mL due to the presence of particulate matter identified as silicone observed during routine inspection of retained samples.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-50?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the 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 in advance for your cooperation and continued partnership.