Provider Newsflash
May 2024

FDA Recall – OptumHealth Care Solutions, LLC

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class I recall of the Optum Nimbus II Plus (also known as the Nimbus II – Optum Homecare Infusion) ambulatory Infusion System distributed from 8/19/2020 to April 20, 2024. The recall is in direct response to the InfuTronix, LLC recall of these devices on February 21, 2024 due to multiple potential failure modes that may include battery failure, upstream blockage (occlusion), system errors, drug product leakage, high or low flow rate, or damaged housing. The affected pumps could cause infection from microbial contamination after loss of the sterile barrier from leakage, interruption or delays in therapy from unnoticed occlusions or leaks leading to underdosing of vital medications and fluids. Use of these products may lead to serious injury or death.

What do I need to do?

- Please review the following recall notice: OptumHealth Care Solutions Recalls Nimbus II Infusion Pump Systems Under Recall by InfuTronix, LLC | FDA
- 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.