Provider Newsflash
July 2025

FDA Recall – SunMed Adult Manual Resuscitator Devices

Purpose of this communication:

- We are writing to inform you that SunMed Holdings, LLC is recalling Adult Manual Resuscitator devices due to incorrect assembly of the B/V filter. The use of affected product may cause serious adverse health consequences, including lack of oxygen to the body (hypoxia), build-up of carbon dioxide in the blood (hypercapnia), organ failure, and death. There have been no reported injuries. There have been no reports of death.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/manual-resuscitator-recall-sunmed-holdings-llc-removes-adult-manual-resuscitator-devices-due?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the replacement, 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.