CareSource | NETWORK Notification

Notice Date: September 13, 2021
To: Ohio Providers
From: CareSource
Subject: Notice of Philips Respironics Voluntary Medical Device Recall
Effective Date: June 14, 2021

Summary

As part of CareSource's commitment to continuous improvement, we are focused on ensuring quality care for all our members through active provider engagement. On June 14, 2021, Philips Respironics ("Philips") announced a voluntary recall pertaining to certain ventilators and devices used to treat obstructive sleep apnea, including continuous positive airway pressure ("CPAP") devices and bi-level positive airway pressure ("BiPAP") devices (collectively referred to as "Devices").

The Devices are being recalled due to two issues related to the polyester-based polyurethane ("PE-PUR") sound abatement foam used in the Devices:

- PE-PUR foam may degrade into particles that may enter the Device's air pathway and be ingested or inhaled by the user; and
- The PE-PUR foam may off-gas certain chemicals.

Impact

The FDA issued a Safety Communication on June 30, 2021 regarding Philips' voluntary recall which summarizes major issues and considerations related to the recall.

Please visit https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks for additional information.

Questions?

For additional questions please refer to https://www.usa.philips.com/healthcare/resources/landing/experience-catalog/respironics.

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