



NETWORK *Notification*

Notice Date: December 15, 2021
To: Ohio Providers
From: CareSource
Subject: Notice of Philips Respironics Voluntary Medical Device Recall
Effective Date: June 14, 2021

Please Note: This communication is an update from the [network notification](#) dated Sept. 13, 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 note this section is new

CareSource wants to ensure members have necessary tools to improve their overall health. The primary care physician (PCP) and/or treating provider is the lead on how to proceed with the member's treatment plan. Therefore, if a replacement item is needed and the PCP agrees:

- The provider can submit an authorization request as usual but must indicate on the request that the reason is due to recall of the equipment.
- The approval will give permission for the manufacturer to supply the member with replacement equipment
- The provider will then receive outreach from our contracting department to ensure coverage

For additional information, please refer to the FDA article.

Questions?

For additional questions please refer to

<https://www.usa.philips.com/healthcare/resources/landing/experience-catalog/respironics>.

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