Kansas City

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Dear Provider Partner:

PHILIPS RESPIRONICS VOLUNTARY RECALL UPDATE

Blue Cross and Blue Shield of Kansas City (Blue KC) has been made aware of a voluntary recall that Philips Respironics has issued on specific brands of their Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines and Ventilators manufactured prior to April 26, 2021.

WHAT YOU NEED TO KNOW

- If your patient currently has a device on the recall list, the patient must register on the Philips website at www.philips.com/src-update. You can also register on behalf of the patient. The website lists all the affected BiLevel PAP and CPAP sleep apnea devices and affected ventilators. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

- Philips needs to know who has the recalled units. Since Philips uses other vendors as their distributors, such as Apria and LinCare, they don't know who has the recalled units.

- If you have patients who are currently registered, Philips will determine how to address the issue by deciding to either replace or repair their machine. Philips is currently drop-shipping new units to registered customers. However, it's a first-in, first-out process, so it is imperative that your patients register with Philips as soon as they can.

- If your patients are sent a new unit, they have 60 days to send the recalled unit back to Philips to ensure there is no cost to them. This information is contained in the materials sent to them with the new equipment.

- This website also includes resources such as news articles, guidance and a link to the Philips website to register machines: www.aahomecare.org. After clicking on Policy & Advocacy at the top, select Philips Respiratory Products Recall-News & Resources.

- Since there is a process with the manufacturer (Philips) to repair or replace the affected devices, Philips will be responsible for covering the total cost of replacement or repair, and no claims should be filed with insurance.

- There will be no customer financial responsibility provided your patients register their machine AND return the old one within the 60-day timeframe.

- Patients should not stop or alter their prescribed therapy until they have talked to their physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

- If a patient's physician determines that the patient must continue using this device, the patient should use an inline bacterial filter. The patient should consult the "Instructions for Use" for guidance on installation.

- Philips Respironics has voluntarily recalled these devices due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators:
    - PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user.
    - PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and off-gassing may occur during operation.
    - These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment

QUESTIONS?

We value and appreciate you as our partner in providing quality care. If you have questions about any of this information, please call the Blue KC Provider Hotline at 816-395-3929 for commercial line of business, 866-508-7140 for Blue Medicare Advantage line of business or 866-859-3822 for the Affordable Care Act Provider Hotline.