Health Services
LOS ANGELES COUNTY

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TO: DHS primary care providers, MHLA community partner providers

FROM: DHS Sleep Medicine Specialty-Primary Care Workgroup

SUBJECT: Philips Respironics recall

On June 14, 2021, Philips Respironics issued a voluntary recall of several home ventilators, CPAPs, BiPAPs, and AVAPs (Trilogy) devices related to degradation of the sound-abating foam used in the device. The risks that we have been made aware of at this time include headache, sinus infections, cough, and bronchospasm related to particulate matter exposure as well as possibly carcinogenic effects from the release of toxic fumes from the polyester-based polyurethane (PE-PUR) material in the foam itself.

The overall risk is reported to be very low and to date there have been no reports of life-threatening injury or death due to this issue. PAP devices should be stored in areas to avoid high humidity and heat exposure and patients should be advised to use only products recommended by the manufacturer to clean their device as well. The popular commercial based products such as ozone and harsh chemicals have been associated with a higher risk of this foam breaking down. **At this time, DME companies have informed us that there may be significant delays in getting PAP devices out for new prescriptions.**

The American Academy of Sleep Medicine, American College of Chest Physicians, and several other societies that are impacted by this recall have recommended that patients with significant sleep disordered breathing, symptoms related to this sleep disorder, or comorbidities remain on their device as the risk of stopping the device is much greater than the risk of adverse events related to this recall. However, this is a risk-benefit discussion provides should have with their patients.

If this patient is on any type of recalled device, the following recommendations should be followed:

1. Talk to your patient about the risks and benefits of remaining on PAP therapy given their underlying sleep-disordered breathing and comorbidities. For patients who are very symptomatic, have severe underlying sleep disordered breathing, or significant co-morbidities they should be encouraged to remain on their current devices as the risk of stopping this important therapeutic intervention far outweighs the small risk of adverse events related to the sound abatement foam in their devices.

2. Should your patient decide to remain on the device, **please alert patient they must register their device with Philips Respironics to be contacted for either a replacement device or to fix the existing device they have in their possession.** If they do not get their device registered, they will not be contacted once Philips Respironics has a resolution for this recall. Philips Respironics can be contacted at (877) 907-7508 or at *https://www.philipssrcupdate.expertinquiry.com/* and register their device.

3. Advise your patient to avoid high humidity and heat exposure to their PAP device and to use only products recommended by the manufacturer to clean their device. Ozone containing agents should be avoided as well as harsh chemicals that may contribute to the foam breakdown.

4. Should your patient decide that they do not want to remain on this device, non-device interventions should be reviewed with them including sleeping more upright or in a lateral decubitus position, weight loss, and avoiding alcohol/tobacco/respiratory depressants while awaiting a device replacement.

Patients may be referred to their local dental clinic (if available) to be fitted for an oral advancement device if covered by their insurance carrier. It should be discussed with the patient that these interventions, unfortunately, are less effective than their PAP device but are the only option until your patient is able to get a new device or their current device is fixed.

Please note that most insurance companies may not cover the cost for providing your patient with a new PAP device as they have already paid for the recalled one in their possession and in general patients are only eligible to get a new device every 5 years or when the machine malfunctions and cannot be repaired. The availability of ResMed PAP devices and non-recalled Philips Respironics devices such as the DreamStation2 are extremely limited.

* For new diagnosed OSA patients, the **prioritization criteria** that you can use to identify who should receive PAP machine sooner or later are as follows:

High priority	Low priority
Severe OSA (AHI ≥ 30 per hour) and Moderate OSA (AHI ≥ 15, but < 30 per hour)	Mild OSA (AHI ≥ 5, but < 15 per hour)
Mild OSA with comorbidity (stroke, diabetes, heart diseases, etc.)	
Mild OSA with severe excessive daytime sleepiness and have high risk of occupational accident (e.g. truck driver, etc.)	

For further information on managing your patient during this time please contact your facility sleep medicine department or MHLA liaison.

DHS Sleep Medicine Specialty-Primary Care Workgroup