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Smitha M. Ballyamanda, M.D., CAQSM
Medical Director
DME MAC Jurisdiction A
Noridian Healthcare Solutions, LLC

Robert Hoover, M.D., MPH, FACP
Medical Director
DME MAC Jurisdiction C
CGS Administrators, LLC

Stacey V. Brennan, M.D., FAAFP
Medical Director
DME MAC Jurisdiction B
CGS Administrators, LLC

Peter J. Gurk, M.D., CPE, CHCQM
Medical Director
DME MAC Jurisdiction D
Noridian Healthcare Solutions, LLC

Re: Philips Respironics Voluntary Medical Device Recall (“Recall”)

Dear Dr. Ballyamanda, Dr. Brennan, Dr. Hoover and Dr. Gurk:

The American Association for Homecare (“AAHomecare”) includes a cross section of durable medical equipment (“DME”) suppliers, manufacturers, and other stakeholders that furnish DME to individuals in their homes. AAHomecare’s members are proud to be part of the continuum of care that assures that individuals receive cost-effective medical equipment and supplies, and related services, in their homes.

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.

The Philips Recall announcement advises CPAP and BiPAP patients to “[d]iscontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.”

The Philips Recall announcement advises ventilator patients as follows:

“Do not stop or alter your prescribed therapy until you have talked to your 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 your physician determines that you must continue using this device, use an inline bacterial filter. Consult your Instructions for Use, for guidance on installation.”

The challenge for patients who use the Devices (“patients”) and for DME suppliers is that it is an impossibility for (i) Philips, in the short term, to replace and/or repair the Devices and (ii) patients, in the short term, to access replacement devices manufactured by companies other than Philips. This impossibility arises from the fact that (i) Philips has a large share of the device market and (ii) competitors of Philips, in the short term, cannot “fill the gap.” The end result is that patients, in consultation with their physicians, have to decide whether to continue their use of the Devices...or to forgo treatment until sometime in the future. **AAHomecare anticipates that while some patients will discontinue treatment until their Device is repaired or replaced, most will continue with treatment using the Device.** For patients who make the decision to continue to use them in the near-term, these Devices are still delivering the benefits of the prescribed therapy.

If a patient informs their DME supplier that the patient will discontinue use of the Device until it is repaired or replaced, the supplier will cease submitting claims for the Device. On the other hand, if a patient does not inform their DME supplier that the patient will discontinue use of the Device, it is important for the supplier to continue to provide the Device and services and supplies related to the Device. It is also important that the supplier continue to be paid for the Device and related supplies. Patient outreach is a priority for DME suppliers. The goal is for patients (i) to be aware of the Recall, (ii) to talk to their physicians, and (iii) to let their DME suppliers know if they will not continue to use their Devices until they are repaired or replaced sometime in the future.

We request that the DME MACs work with the DME industry by continuing to reimburse for Devices and related supplies for patients who elect to continue using their Device. We further request a temporary suspension of time-specific adherence rules to allow patients time to have Devices repaired or replaced. Specifically:

- The PAP devices are subject to the CMS Local Coverage Determination (“LCD”), Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718), that has requirements for continued coverage of a PAP device beyond the first three months of therapy. This requirement states that “no sooner than the 31st day but no later than the 91st day after starting therapy, the treating practitioner must conduct a

clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.” AAHomecare is concerned that the Recall will disrupt treatment for patients with OSA, and many will not meet the adherence requirements before their Devices can be repaired or replaced. **Therefore, we request that CMS temporarily suspend the 90-day adherence rule, to allow patients time to have their Devices repaired or replaced.**

We acknowledge and appreciate the Joint DME MAC Article published June 25, 2021, addressing FAQs related to the Recall. We note that FAQ No. 3 addressed this issue by referencing the availability of the waiver of clinical indications for coverage for respiratory devices during the PHE period. However, it is possible that this PHE waiver will expire prior to Philips’ ability to repair or replace all affected Devices. The response in FAQ No. 4 states that a beneficiary receiving replacement equipment due to the Recall ‘has the option to restart the 90-day adherence trial or they may resume meeting the adherence metric where they left off’ and that the supplier should notate their records if the recall impacted the beneficiary’s adherence timeline. We would like for the DME MACs to make it clear that any period of interruption of use due to the Recall will pause the timeframes to demonstrate compliance and clinical reevaluation. The current requirements are:

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

Adherence to therapy is defined as use of PAP ≥ 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

This will allow patients to meet criteria for continued coverage of their devices once therapy resumes.

- L33718 further states: “If a PAP device is replaced during the 5-year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.” Although these Devices have not been lost, stolen, or damaged due to a specific incident, AAHomecare requests that CMS allow for an exception to the RUL requirements for replacement of these Devices resulting from the Recall. We believe it is reasonable to allow DME suppliers to replace the Devices without requiring documentation of a new clinical evaluation, sleep test or trial period, and do not think that patients should be responsible for the replacement costs.

- We are concerned by the response given in FAQ No. 9 which asks if the supplier inspects beneficiary-owned equipment that is affected by the Recall, is the supplier under any obligation to replace that machine? The response given states that “[i]f the equipment is beneficiary-owned, the supplier is under no obligation to repair or replace the equipment, assuming that they’re not billing for any equipment or supplies.” (emphasis added) We are unclear what is meant by the phrase underlined above. If the equipment is beneficiary-owned, the supplier would not be billing for that equipment; but they may be billing for supplies. Is this a reference to the supplier billing for any other equipment it may be providing to that patient? Billing for a different piece of equipment does not obligate the supplier to replace a different piece of beneficiary-owned equipment. Similarly, providing supplies for beneficiary-owned equipment does not obligate the supplier to replace that beneficiary-owned equipment. We would appreciate a clarification by the DME MACs on this issue.

AAHomecare members and the DME community are committed to supporting the broad cohort of patients who depend on high-quality respiratory equipment and related services, and we look forward to working with you to ensure a high standard of care for these individuals under the current challenging conditions.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Ryan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Tom Ryan, President & CEO
American Association for Homecare