



July 9, 2021

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

To: All Health Plans

The American Association for Homecare (“AAHomecare”) includes a cross section of durable medical equipment (“DME”) suppliers, manufacturers, and other stakeholders that furnish DME to acute patients and chronically ill individuals. 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 FDA issued a [Safety Communication](#) on June 30, 2021 regarding Philips’ voluntary recall which summarizes major issues and considerations related to the recall, and encourages patients using BiPAP and CPAP machines to discuss treatment options and alternatives with their healthcare providers, including “Continuing to use your affected device, if your health care provider determines that the benefits outweigh the risks identified in the recall notification.” The notice also advises people who use affected ventilators to “not stop or change ventilator use until you have talked to your health care provider.” This guidance goes in line with the clinical community recommendations issued in a [joint letter](#) issued on June 22, 2021. AAHomecare also agrees with the request made in this letter for payers to temporarily suspend any time-specified adherence rules, to allow patients to have existing equipment repaired or receive new equipment from DME suppliers. It is also important to note that the FDA communication also states they do not have evidence at this time that any other CPAP machines, BiPAP machines, or ventilators, from Philips or other manufacturers are affected.

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The challenge for patients who use the Devices (“patients”) and for DME suppliers is that it is an improbability in the short term for (i) Philips to replace and/or repair the Devices and (ii) DME suppliers or patients to access replacement devices manufactured by companies other than Philips. This improbability arises from the fact that (i) Philips has a large share of the device market and (ii) other manufactures, cannot “fill the gap” because they simply do not have sufficient inventory to replace the large number of Philips devices in use by patients. This situation is exacerbated by the COVID-19 public health emergency which has caused significant shortages in many components used to manufacture these types of devices.

The DME supplier community has conveyed to us that they will continue to provide the Device, services and supplies as prescribed, with expectation for ongoing reimbursement.

AAHomecare is working closely with Philips and our goal is to partner with you to continue to provide you with the most up to date information as it becomes available to ensure that patients continue to receive the best possible care. In the meantime, we strongly encourage you to direct your members to visit the [Philips website](#) to evaluate if they are impacted by this Philips voluntary recall and if so to register their Device.

Sincerely,

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

Tom Ryan
President & CEO
American Association for Homecare