Frequently Asked Questions - Philips Respironics Respiratory Products Recall

Joint DME MAC (Durable Medical Equipment Medicare Administrative Contractor) Article

On June 14, 2021 Philips Respironics announced the voluntary, global recall of an estimated 4 million continuous positive airway pressure (CPAP) devices, bilevel respiratory assist devices (RADs), and ventilators. The situation is quite fluid; consequently, impacted beneficiaries and DME (Durable Medical Equipment) suppliers should check the Philips Respironics website for the most up-to-date information.

Based on questions received by the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s, we have developed the following FAQ (Frequently Asked Question)s:

1. **What should DME (Durable Medical Equipment) suppliers and beneficiaries do if they have devices impacted by the voluntary recall?**
   Response:
   - For beneficiaries using bilevel RAD (Respiratory Assist Device) and CPAP (Continuous Positive Airway Pressure) devices, Philips Respironics recommends discontinuing use of the device and working with the physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.
   - For beneficiaries using life-sustaining mechanical ventilator devices, Philips Respironics recommends not stopping or altering prescribed therapy until talking to the treating practitioner. Philips notes 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 the treating practitioner determines that use of a life-sustaining ventilator should continue, use of an inline bacterial filter is recommended. Beneficiaries should consult with the device's Instructions for Use for guidance on installation of the inline filter.
2. **What actions should DME (Durable Medical Equipment) suppliers take, based on the recall information?**
   Response: Suppliers of impacted devices should work with their Philips Respironics sales representative to obtain replacement PAP (Positive Airway Pressure), RAD (Respiratory Assist Device), or ventilator products for their Medicare beneficiaries. Philips Respironics has a plan in place for DME (Durable Medical Equipment) suppliers to register and receive additional information on the Philips Respironics website.
3. **How should DME (Durable Medical Equipment) suppliers address the situation with Medicare beneficiaries who are in the first 90-days adherence metric in the PAP (Positive Airway Pressure) and RAD (Respiratory Assist Device) Local Coverage Determinations (LCDs)?**
   Response: During the Public Health Emergency (PHE), CMS (Centers for Medicare & Medicaid Services) has instructed the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s to not enforce clinical indications of coverage for the types of respiratory devices involved in the voluntary recall. Services must still be reasonable and necessary. Additional information on the PHE waivers and flexibilities is available in the June 29, 2020 article on the DME MAC (Durable Medical Equipment Medicare Administrative Contractor) websites titled "CMS (Centers for Medicare & Medicaid Services) Issues Interim Final Rules with Comment (CMS (Centers for Medicare & Medicaid Services)-1744-IFC (Interim Final Rule with Comment) & CMS (Centers for Medicare & Medicaid Services)-5531-IFC (Interim Final Rule with Comment)) – COVID-19 Public Health Emergency – Revised."
4. **Once a beneficiary gets the new replacement equipment, do they have to restart the 90-day adherence trial? Or do they just pick it up where they left off?**
   Response: The beneficiary has the option to restart the 90-day adherence trial or they may resume meeting the adherence metric where they left off. The supplier should notate their records if the recall impacted the beneficiary's adherence timeline.
5. **What should DME (Durable Medical Equipment) suppliers do if a beneficiary wishes to return their Philips Respironics product that is impacted by the voluntary recall?**
   Response: Suppliers are reminded that the CMS (Centers for Medicare & Medicaid Services) Supplier Standards (42 CFR (Code of Federal Regulations) 424.57) apply to this situation, specifically Standard #15 – [Suppliers] Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold).
6. **If beneficiaries choose not to continue PAP (Positive Airway Pressure), RAD (Respiratory Assist Device) or ventilator use until their equipment has been replaced, how does that affect the supplier as far as Medicare standards? Are they required to provide temporary replacement equipment?**
   Response: If a DME (Durable Medical Equipment) supplier continues to bill for PAP (Positive Airway Pressure), RAD (Respiratory Assist Device), or ventilators, they are required to provide the equipment for which they're billing.
7. **If a beneficiary chooses to wait for new equipment, does the DME (Durable Medical Equipment) supplier stop billing for rental? Is it a break in service that they simply pickup when the new equipment is provided?**
   Response: Yes, the DME (Durable Medical Equipment) supplier must stop billing, and resumption of billing would occur with the next unbilled rental month. There is no break in service because the requirements for a new capped rental billing are not met. CMS (Centers for Medicare & Medicaid Services) defines a 60-plus consecutive day interruption as a period including two full rental months plus whatever days are remaining in the rental month during which the need ends. In addition to the timing requirement, there must also be a change in medical necessity, defined as a resolution of the condition that created the first period of medical necessity and the subsequent development of a second event that creates a new period of medical necessity. In the voluntary recall situation, there is no change in medical necessity as a result of the recall; therefore, there is no break in service and no new capped rental.
8. **Is Medicare Customer Service (1-800-Medicare) aware of the voluntary recall?**
   Response: Yes, the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s have made CMS (Centers for Medicare & Medicaid Services) aware of the recall.
9. **What impact does the voluntary recall have on New to Medicare patients? Specifically, if the supplier inspects beneficiary-owned equipment that is affected by the recall, is the supplier under any obligation to replace that machine?**
   Response: According to the information published by Philips Respironics, beneficiaries are instructed to contact their DME (Durable Medical Equipment) supplier and their treating practitioner. DME (Durable Medical Equipment) suppliers are instructed to work with Philips Respironics directly. If 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.
10. **What guidance, if any, are clinical societies providing to beneficiaries?**
    Response: The American Academy of Sleep Medicine (AASM) has published information on the AASM (American Academy of Sleep Medicine) web site providing information for beneficiaries and treating practitioners. In addition, the American Thoracic Society (ATS) has published "Recommendations for Sleep and Critical Care Medicine Professionals Regarding Philips Recall Notice."

Philips Respironics notes that they are treating this matter with the highest possible seriousness and are dedicating significant time and resources to address this issue. Due to the evolving nature of the voluntary recall and the potential remedies for the situation, the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s strongly encourage DME (Durable Medical Equipment) suppliers and beneficiaries to consult the Philips Respironics website for the most up-to-date information.

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