VGM & Associates is the nation's largest and most comprehensive Member Service Organization (MSO) for post-acute healthcare including DME (Durable Medical Equipment)/HME (Home Medical Equipment), Respiratory, Sleep, Wound Care, Complex Rehab, Women's Health, Home Modifications and Orthotics & Prosthetics providers. Over 2,500 providers with nearly 7,000 locations nationwide, including several throughout Maryland, Virginia, and D.C., rely on VGM to connect them to valuable resources every single day so that they can serve their patients, your members, better and more efficiently.

We are writing to you today on behalf of those DME/HME providers who currently serve your members. Your company currently has a CPAP compliance policy in place that requires DME providers or patients to prove they are using their CPAP device for a certain amount of time per night and/or a certain number of nights per week. Historically, there have been an adequate number of CPAP devices on the market which include features that make it easy for providers to remotely track how often the patient is using the device. We as a provider have not had issues with, nor any problems meeting the requirements of, your CPAP compliance policy up to this point. However, current market conditions are making it extremely difficult for us to continue to meet those guidelines.

The CPAP market has been dominated by 2 major manufacturers, namely Philips Respironics (PRI) and ResMed. Both of those major manufacturers routinely offer CPAP machines that make tracking patient compliance easy to do. However, in June of 2021, the FDA announced a major recall impacting Philips Respironics CPAP devices. Because PRI is required to either repair or replace approximately 5 million CPAP devices before any new devices can be allocated for newly diagnosed patients, there is currently a shortage of CPAP devices in the United States as well as other countries. ResMed alone has not been able to demonstrate the manufacturing capacity to fill the void left by the absence of PRI devices. Other manufacturers have stepped up to try to help fill that void (3B, Resvent, RespPlus for example), but a shortage remains.

DME providers who offer CPAP devices as part of their product portfolio are faced with a dilemma; wait until they can procure enough devices through their regular channels (which could be another 6-12 months) or turn elsewhere to get enough devices to meet the current demand. Many providers have been forced to turn to overseas manufacturers to help offset the shortage of CPAP devices. Many of these devices from overseas do not have full FDA clearance but are currently able to be sold in the U.S. under an Emergency Use Authorization (EUA). While the devices do provide CPAP therapy, many of them lack the compliance capabilities that are featured in the PRI and ResMed devices discussed above. Providers can still track compliance, but it is a much more manual, labor-intensive, and therefore costly process.

The global chip shortage further exacerbates this issue. Even if the manufacturers want these compliance features built into their machines, that is difficult to accomplish right now. ResMed, a major manufacturer of CPAP devices who routinely incorporates easy-to-use compliance features into their devices, recently announced they will ship CPAP devices without chips in them, simply because they cannot get their hands on enough chips for the devices they manufacture (https://www.hmenews.com/article/resmed-this-is-a-humanitarian-emergency).

Because of the reasons outlined above, we are asking that you temporarily waive your compliance requirements until the availability of devices with built-in, remote compliance capabilities returns to normal. We will be happy to communicate regular updates on this matter

to you, so that we can mutually agree on when it is appropriate to reinstate the compliance requirements.

More information regarding the recall from both PRI as well as the FDA can be found by clicking the links below.

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update and https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf; https://www.fda.gov/medical-devices/safety-communications/philips-respironics-cpap-bipap-and-ventilator-recalls-frequently-asked-questions