

**SEPTEMBER 2025** 



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# Latest Philips Recall Reinforces Need for Policy Change to Protect Patients

A new recall affects 65 Dream Station Auto CPAP and Auto BiPap devices in the U.S. due to programming errors that can cause serious injuries. Though smaller than the 2021 Philips recall that affected 5 million U.S. devices, the latest recall reinforces the need for policies that protect sleep apnea patients.





A limited number of Philips Respironics DreamStation Auto CPAP and Auto BiPAP machines are being recalled because of software programming errors that could put patients at risk, the U.S. Food and Drug Administration (FDA) has <u>announced</u>.

A list of recalled devices is here.

#### What's the issue?

The affected devices may deliver the wrong pressure levels due to programming errors. This can cause patients to miss needed therapy—or in some cases, receive pressures that could cause serious health problems. The FDA has identified this recall as the most serious type and notes "This device may cause serious injury or death if you continue to

use it."

So far, the FDA has received three reports of injures and no reports of death. The agency notes: "Use of the affected devices may cause serious health consequences including hypoventilation, disrupted sleep, skin or airway burns, and ineffective treatment of sleep apnea, which could worsen comorbidities."

### What should patients do?

- Check your device: Use your device serial number to see if it's affected. Philips and your equipment provider can help.
- Talk to your doctor before stopping use: Untreated sleep apnea also carries risks.
- Contact Philips at 1-877-387-3311 or <u>PatientSupport@philips.com</u> if you received the company's Urgent Medical Device Recall Letter mailed June 6 but have not been contacted since.

According to the FDA, Philips is calling affected patients and suppliers and sending replacement devices and instructions for returning recalled devices.

### Why this matters

This recall is smaller than the <u>2021 Philips recall</u>, which affected more than 5 million CPAP and BiPAP devices across the U.S. That recall stretched over years and left many patients without safe treatment or facing huge out-of-pocket costs. <u>Read more</u> about that recall and ASAP's related push for policy change.

Alliance of Sleep Apnea Partners is pushing for reforms that put patients first:

- 1. A national respiratory device registry to quickly notify patients and providers of recalls
- 2. Automatic insurance claim subrogation so patients aren't forced to pay out of pocket for replacement devices.

### Stay informed

For details on this recall, visit the <u>FDA's recall notice</u>.

For background on the 2021 recall and our policy priorities, read our **Fast Facts**.

Read the FDA's New Recall Notice

Learn More About ASAP's Call for Change

# Patients Want Innovation and More Treatment Options for Their OSA

Recalls like the ones that have affected patients using Philips Respironics CPAP and BiPAP devices point out the need not only for policy change, but also for innovative sleep apnea therapies that reduce dependence on one treatment and help patients find what works best for them. The good news: treatment options for

obstructive sleep apnea (OSA) are expanding.

In a new blog post, ASAP board Secretary and sleep consultant Lori Schulman highlights a variety of therapies now available to patients and calls on the sleep industry to "embrace a culture of continuous improvement and innovation. We must challenge the status quo and recognize that what worked for patients 20 years ago may not be the best option for patients today.

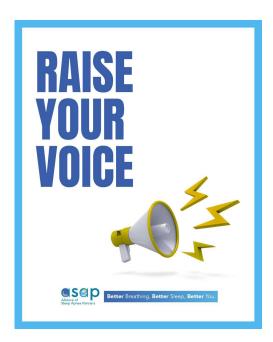


"This is not about replacing standard care, but rather about enhancing it with a broader, more patient-centric approach."

"This shift in mindset" she

writes, "is about offering **better care—sooner**. Instead of waiting for a patient to fail CPAP therapy before exploring alternatives, clinicians should be educating them on all options from the outset. This empowers patients to make informed decisions and increases the likelihood that they will find a treatment they can stick with long-term."

Read the Blog Post



# Tell Us: Your Experience With the Philips Recall

As part of our ongoing <u>advocacy and policy</u> <u>efforts</u>, the Alliance of Sleep Apnea Partners is collecting patients' personal experiences with the recall of Philips Respironics positive airway pressure devices.

Personal stories are compelling to highlight the real-world effects of policy on patients. They also help ensure that the patient voice remains at the center of policymaking.

How and when did you first become aware of the recall? Were you able to replace your recalled PAP machine—and, if so, how long did that take? Did you have to pay to replace your

machine? How were your sleep apnea treatment and health affected by the recall? Let us know.

Raise your voice as part of ASAP's work to shape policy for better patient outcomes.

Share Your Story

## **CMS Testing New Payment Model on Prior Authorizations, Including OSA Service**

The Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) will test its new WISeR Model insurance review and prior authorization in six states next year as part of a plan to streamline insurance companies' review processes for some services, procedures, and devices, including hypoglossal nerve stimulation for obstructive sleep apnea.

The WISeR (Wasteful and Inappropriate Service Reduction) alternative payment model will test artificial intelligence (AI) and machine learning (ML) for prior authorization and prepayment review processes for the selected services starting Jan. 1 in Arizona, New Jersey, Ohio, Oklahoma, Texas, and Washington. Companies whose technologies are selected to participate will receive a percentage of the savings attributed to their review processes.

A recent National Law Review article called WISeR "unique because, unlike CMMI's other payment models where participants are accountable care organizations and health care providers, participants in WISeR will be technology companies with AI/ML solutions and experience managing the prior authorization process for payers, including Medicare Advantage plans. WISeR participants will conduct prior authorization and pre-payment reviews, supported by AI/ML tools that are expected to streamline those processes."

Read the Dept. of Health and Human Services Press Release

## **ASAP NEWS**

### ASAP Unveils New Pediatric OSA Resource

Children also can suffer from obstructive sleep apnea. While some pediatric OSA symptoms—such as snoring or gasping during sleep—echo typical adult OSA signs, some are more subtle and can be overlooked. A child with OSA can appear hyperactive rather than sleepy. Growth problems also can signal OSA.

ASAP has developed new pediatric OSA resources to help parents identify potential OSA in their children and to guide a discussion with their pediatric primary care providers.

ASAP's new <u>pediatric OSA page</u> includes

- common (and often overlooked) symptoms
- fast facts about OSA in children
- risk factors
- tools for parents
- a downloadable resource



- Kids with OSA may not look sleepy. In children, symptoms of OSA can mimic (or even worsen!) ADHD symptoms such as hyperactivity, poor focus, or behavioral issues. Disrupted sleep can also cau problems with learning, memory, and mood.
- Growth problems could signal OSA. Children may show poor weight gain, failure to thrive, or worsening obesity. Overweight children, especially those over >8 years, have a significantly higher risk of moderate to severe OSA.
- 4. An OSA evaluation differs in kids vs. adults. Kids deserve to have an age-specific sleep evaluation. Diagnostic scoring criteria for OSA in children are more strict due to the importance of healthy sleep in brain development.
- 5. **Pediatric OSA is treatable!** Options are tailored to each individual and may include tonsillectomy (if tonsils are enlarged), CPAP, weight management, dental approaches, and allergy treatment.

Find the new resources at apneapartners.org by hovering your cursor over the Education tab in the top menu, then clicking on Children and Sleep Apnea.

### News You Can Use on the ASAP Blog

Right now on the <u>ASAP blog</u>, guest contributors Dr. Muhammad Usama and Dr. Audrey Wells weigh in on three important topics for the patient community:

## Can Wearable Tech Diagnose OSA?

Wearable tech is popular, and companies who make it say it can detect or monitor some conditions, including sleep apnea. Dr. Usama shares six things sleep apnea patients should know about this much-hyped tech, including how it can help in your care.

### Why You Need a Sleep Specialist, Not Only a Primary Care Doctor

Many people who suspect they have sleep apnea start with their primary care doctors—a logical first step. But when it comes to sleep apnea, Dr. Audrey Wells <u>explains</u> why asking your primary care provider for a referral to a sleep specialist, who is

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trained to look deeper, is important. She also covers how to choose a sleep specialist and how to prepare for your first visit.

### Women's OSA Signs You Might Have Missed

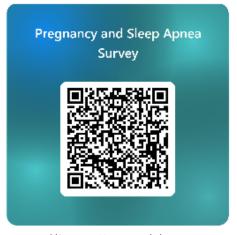
If you're female, your sleep apnea experience might not involve snoring, the classic symptom most associate with obstructive sleep apnea. The differences in how OSA presents in women versus in men is a critical health issue—and understanding those differing signs can help ensure women get the diagnosis and treatment they need. Dr. Audrey Wells reveals the subtle signs of OSA in women and discusses when to seek help.

**Explore Our Blog** 

Take or Share the Survey: Pregnancy and OSA



Your input is needed! The Alliance of Sleep Apnea Partners is partnering with a team at Magee-Womens Hospital at the University of Pittsburgh to help better plan future studies on sleep apnea in pregnancy. Below is a link to a survey to get valuable input from pregnant women and women with sleep problems. Please help us by completing this quick survey (should take no more than 5 minutes).



https://forms.office.com/r/wmbWdKiiyS

Take or Share the Survey

### **ASAP Joins Obesity Action Care Advocacy Network**

In September, the Alliance of Sleep Apnea Partners joined the <u>Obesity Care Advocacy</u> <u>Network</u>, a diverse group of stakeholders that have come together to change how obesity is perceived and treated in the United States.

OCAN focuses on treating obesity as a complex chronic disease so that individuals impacted have access to the evidence-based screening, care, and treatment on par with other chronic diseases. Obesity and obstructive sleep apnea often are linked.

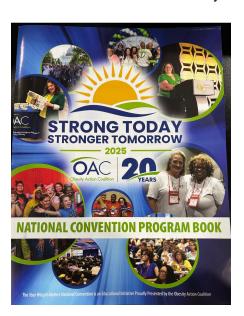
"At ASAP we are elevating the conversation around OSA and its connection to conditions like obesity at the national level by engaging with our alliance partners such as Obesity Care Action Network to ensure that sleep apnea is a national priority," ASAP President and CEO Dr. Monica Mallampalli said. "We are thrilled to be part of OCAN and hope to contribute our efforts to OCAN's ongoing work on the problem of obesity while independently putting a focus on OSA as part of the complex chronic disease epidemic."

## ASAP and Obesity Action Coalition: Synergy at OAC Your Weight Matters National Conference

Dr. Monica Mallampalli, President and CEO of the Alliance of Sleep Apnea Partners, represented the organization and sleep apnea patients' perspectives July 24-26 at the Obesity Action Coalition's national conference, Your Weight Matters, in Washington, D.C..



Dr. Mallampalli at the ASAP booth at the Obesity Action Coalition's "Your Weight Matters" National Conference in July.



The OAC's Your Weight Matters is billed as "the nation's leading gathering for science-based insights on weight management, nutrition, mental health, treatment options, and more." Like ASAP, Obesity Action Coalition offers education, advocacy, awareness, and support.

OAC is an <u>Alliance Partner</u> of the Alliance of Sleep Apnea Partners.

There is a natural synergy between the two nonprofit organizations, as the conditions they focus on often are intertwined.

Excess weight makes obstructive sleep apnea worse, and OSA can contribute to weight gain, which can establish a vicious cycle for patients. OSA and obesity also can increase risks of type 2 diabetes, hypertension, osteoarthritis, and cardiovascular conditions.

Learn more about the OSA-obesity connection in ASAP's <u>Fast Facts: Sleep</u> Apnea & Obesity.

In November, Dr. Mallampalli will represent ASAP at the Women and Sleep Summit in Chicago and the Maryland Sleep Society conference.

## ASAP Presents SHINE Survey Results Showing OSA's Negative Effect on Work Productivity

ASAP, which previously partnered with Apnimed, Inc., on a patient survey to understand the psychosocial impact of obstructive sleep apnea in men and women, is presenting the results at conferences in the U.S. and abroad this summer and fall.

The <u>SHINE</u> online survey of 1,500 OSA patients found that work productivity "is significantly negatively impacted by OSA symptoms and negative feelings." Of 934 patients employed full-time, 75% reported that OSA negatively impacted their work moderately to extremely. It also found that the likelihood of work being affected by OSA increased 1.42 times for each additional OSA symptom and 1.21 times for each additional reported negative feelings, such as anxiety, embarrassment, or depression.

ASAP President and CEO Dr. Monica Mallampalli is the survey's presenting author.

Following the poster presentation of these results at the SLEEP 2025 conference, they were also presented Sept. 5-10 at the World Sleep Congress 2025 in Singapore. We are now looking forward to presenting part of the SHINE survey results at the CHEST Annual Meeting 2025 in Chicago, III., on Oct. 21 from 1:45-2:30 p.m.

### ASAP's Mallampalli, Bishop Share Perspectives on

### Research Collaboration in AASM Foundation Webinar

Alliance of Sleep Apnea Partners President and CEO Dr. Monica Mallampalli joined a webinar as part of the series "Partnering for Progress: Community Collaboration in Research," hosted by the American Academy of Sleep Medicine's AASM Foundation, on Sept. 24.

The series explores how to engage community leaders and partners to drive meaningful research. Dr. Mallampalli's presentation focused on the topic of "Patients as Partners: Championing Patient Voices in Sleep Apnea Research and Care."

The panel also included a presentation by David Bishop, CEO of Sleep Equity Project and member of ASAP Community Leadership Council.



# Help ASAP's Patient Advocacy Mission

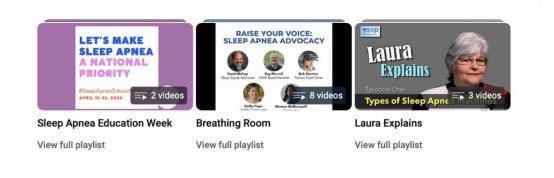
The Alliance of Sleep Apnea Partners is a patient-centered 501(c)(3) nonprofit working to ensure not only that patient voices are heard, but that health care policies benefit patients and improve their health outcomes.

We're dedicated to serving those living with sleep-disordered breathing or who have been diagnosed with obstructive sleep apnea. We strive to represent diverse patient voices at the local, regional, and national levels through education, advocacy, and support to eliminate gaps in patient care.

Your donation helps ASAP carry out this work to create a brighter future for everyone living with sleep apnea.

**DONATE TO ASAP** 

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Stay up to date with Alliance of Sleep Apnea Partners news, webinars, and social media on all of ASAP's online channels. Bookmark our website and follow us on social!

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### We Want to Hear From You!



Do you have questions or concerns about sleep apnea? Do you have a sleep apnea story to share? Email ASAP and let us know!













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