

ResMed Secure in CPAP Position Despite Increased Challenges

Companies: AMS:PHIA/PHG, FPH, RMD

October 18, 2012

Research Question:

Are increased competition, lower reimbursements and the CMS competitive bidding program leading to less market share for CPAP industry leader ResMed?

Summary of Findings

- The CMS' [competitive bidding program](#) and declining reimbursements will not reduce market share for CPAP leaders [ResMed Inc.](#) (RMD) and [Philips Respironics](#) (Philips Electronics N.V./AMS:PHIA/PHG).
- Only three of 36 sources said ResMed would lose share as a result of Respironics' lower pricing, better device/patient monitoring software and stronger performance with in-home test devices for [obstructive sleep apnea](#), or OSA.
- ResMed holds 70% share of the sleep apnea [mask](#) market and splits the CPAP machine market with Respironics, each with 40% to 45% share. [Fisher & Paykel Healthcare Corp. Ltd.](#) (FPH) and [DeVilbiss Healthcare LLC](#) are quality CPAP manufacturers but only hold a very small percentage of the CPAP market.
- Pricing pressure stemming from declining [CMS](#) and health insurance reimbursements is leading to an emerging trend of in-home sleep tests. Both ResMed and Respironics have in-home testing devices, but Respironics has an edge in this segment.
- [DME](#) companies that distribute CPAP equipment may be most at risk because they face a declining fee structure while being required to serve patients. Two sources commented on CPAP manufacturers possibly buying DMEs or selling directly to patients.
- All sources expect the diagnosis and treatment of sleep apnea to grow. Expanding markets include [perioperative](#) patients, cardiology patients, and at least 30% of the estimated [11.4 million CDL holders](#) in the United States.

Silo Summaries

1) SLEEP THERAPY CLINIC PROFESSIONALS

Only one of nine sources said Philips Respironics was offering lower prices in bids and taking share from ResMed. Both companies are the dominant providers of CPAP equipment. ResMed holds 70% share of the mask market but splits the CPAP machine market with Respironics. Fisher & Paykel is a competitor but not an overwhelming concern. Sources agreed the landscape for diagnosing and treating sleep disorders is changing and expanding. CMS and insurance company reimbursement cuts are expected to continue, but will have a minimal effect on the CPAP market. Home sleep studies are an emerging trend and are encouraged by the CMS and insurance companies.

2) CORPORATE HOME HEALTH PROVIDERS

Two of these six sources think ResMed will lose share to Philips Respironics. Both ResMed and Respironics are considered the sleep therapy equipment market leaders and are expected to do well despite the continuation of CMS cuts and the new medical device tax. The diagnosis and treatment of sleep apnea are growing. Cost-containment efforts include home testing, competitive bidding in additional markets, and cheaper CPAP devices from China.

3) PHYSICIANS AND DENTISTS

These eight sources, comprising six physicians and two dentists, said the sleep apnea diagnostic and treatment population is growing. ResMed and Respironics are the clear leaders in CPAP device manufacturing. Pricing pressure stemming from competitive bidding and reimbursement cuts from CMS and insurance companies is leading to increased in-home testing and the use of lower-grade equipment.

4) EQUIPMENT SALES PROFESSIONALS

These five sources, representing three CPAP companies and two oral device companies, consider CPAP to be the gold standard for treatment and ResMed and Respironics to be the industry leaders. Competitive bidding and reduced reimbursement will not affect the two companies' market share. Emerging trends include the increase in home testing, the use of oral devices, and growth in sleep apnea treatment for perioperative patients.

5) INDUSTRY SPECIALISTS

These eight sources reported growth in the sleep apnea market and pricing pressure from reduced reimbursements and increased competitive bidding. ResMed and Respironics are the clear market leaders. Fisher & Paykel and DeVilbiss hold niche positions with quality products. In-home sleep studies are on the rise because of third-party payers' cost-containment measures.

	CPAP Market to Grow	ResMed Share at Risk	CMS Cuts to Continue
Sleep Therapy Clinics	↑	↓	↑
Home Health Providers	↑	↓	↑
Physicians and Dentists	↑	↓	↑
Equipment Sales	↑	↓	↑
Industry Specialists	↑	↓	↑

Background

Despite its leading position in the CPAP market, U.S.-based ResMed faces several challenges including increased competitive bidding, reimbursement cuts and greater competition from low-cost vendors. ResMed management [contends](#) that competitive bidding accounts for only 9% of its worldwide business, but bids represent 22% to 25% of the company's U.S. revenue. ResMed is responding by increasing its product selection, improving efficiencies and testing partnerships with customers to improve its bidding success.

CURRENT RESEARCH

To assess whether ResMed is losing market share because of challenging marketing conditions, we employed our pattern mining approach and established sources in six independent silos:

- 1) Sleep therapy clinic professionals (9)
- 2) Corporate home health providers (6)
- 3) Physicians and dentists (8)
- 4) Sleep apnea equipment sales professionals (5)
- 5) Industry specialists (8)
- 6) Secondary sources (3)

We interviewed 36 primary sources and included three of the most relevant secondary sources focused on sleep disorder diagnosis and treatment.

Next Steps

Blueshift will continue to monitor the bidding environment for sleep apnea equipment providers in the United States, including ResMed and Philips Respironics. We will check on the trend toward in-home testing and determine if ResMed can challenge Respironics' apparent lead in this segment. We also will research ResMed's business outside the United States and its growth and expansion in new markets and performance in more mature markets. Next, we will follow the growing market of oral sleep-apnea devices and the dental community's involvement. Finally, we will research ResMed's planned expansion plans, including its own oral treatment device and treatment of other breathing disorders.

Silos

1) SLEEP THERAPY CLINIC PROFESSIONALS

Only one of nine sources said Philips Respironics was offering lower prices in bids and taking share from ResMed. Both companies are the dominant providers of CPAP equipment. ResMed holds 70% share of the mask market but splits the CPAP machine market with Respironics. Fisher & Paykel is a competitor but not an overwhelming concern. Sources agreed the landscape for diagnosing and treating sleep disorders is changing and expanding. CMS and insurance company reimbursement cuts are expected to continue, but will have a minimal effect on the CPAP market. [Home sleep studies](#) are an emerging trend and are encouraged by the CMS and insurance companies. Respironics has an advantage in serving the in-home testing market. Sleep clinics are experiencing increased demand but are feeling the fiscal pinch of lower reimbursements and the shift toward home testing.

➤ Sleep clinic manager for more than 10 years, Texas

This source is very concerned about the CMS' competitive bidding program because it reduces competition and restricts equipment availability. Aided by the financial backing of Philips, Respironics is winning more bids, but the source believes ResMed has superior products. Home sleep studies are increasing, which also benefits Respironics.

- “We’re in the second wave of CMS bidding, and we’re expecting 30% reductions. It means no competition, and it’s a bad thing for patients. There’s limited equipment choice and mask availability; what they get is already decided.”
- “Our volume is declining due to competition.”
- “Philips Respironics can offer cheaper pricing so they’re getting the bid. ... Respironics is getting a little more market share because Philips is behind them financially.”
- “ResMed has the best products. ResMed has an incredible marketing department, and they can keep prices low. Fisher & Paykel [just doesn’t] have the market share.”
- “We prefer the small CMEs [common medical equipment vendors] because they do more for patients than the big companies, but patients have to go to them because of insurance.”
- “The home sleep studies and units are increasing. Philips Respironics has a huge market there. They’re doing a spring cleaning of the other guys.”

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*Sleep Clinic Manager
Over 10 Years of Experience*

➤ **Manager of a midsize sleep center and also a sleep apnea patient, Arizona**

ResMed equipment is superior, and its [nasal pillows](#) are popular. The company will not lose share, but the expected decrease in CMS reimbursements will force DMEs and patients to use less expensive CPAP models, which manufacturers are developing. Insurance companies will follow quickly and reduce their own reimbursements. Insurers are pushing in-home studies, which one-fourth the cost of a lab sleep study. The source said [UnitedHealth Group Inc.](#) (UNH) soon will no longer pay for lab sleep studies in Arizona unless patients have comorbidities. He expects patient compliance to deteriorate. Pediatric cases are driving up his center’s patient volume.

- “DME companies provide compliance tracking and work with the patient. If reimbursement is cut 30%, it will be very difficult to provide that. Compliance training programs helps the patient and helps identify if they’re not compliant. That’s the goal of our DME and our sleep centers.”
- “If reimbursement decreases, [vendors] will get more innovative with the tracking. Now DME companies have teams to call patients and even get them in to see their physicians. There will be more wireless or web-based programs.”
- “If CMS cuts reimbursement 30%, insurers will renegotiate for less. There’s not a lot to reimburse higher when their formulas are based on CMS rates.”
- “I’ve worked in sleep apnea for eight years now, and it’s definitely changing. UnitedHealth on Nov. 1 in our state will no longer cover a lab sleep study unless the patient has comorbidities. A home sleep test is very limited, and is only for obstructive sleep apnea. It’s a dumbing down of sleep medicine, but it is finally decreasing the costs.”
- “I don’t think ResMed will lose market share, but the patient has to suffer with cheaper-built and noisier machines. Both ResMed and Respironics are coming out with economy machines, with no bells and whistles, to meet that demand.”
- “ResMed and Respironics have great products, and both companies are coming out with new designs for better tolerance. I think having two strong competitors is great for the patient. As far as machines, the ResMed is quiet and a nice package. Their masks far exceed others we use here. ResMed’s R&D is the best, and their reps are professional—not to say Respironics’ aren’t.”
- “The new nasal pillow design [Swift FX](#) by ResMed is gaining. We use a lot of ResMed’s [Mirage \[FX\]](#). They’re really, really popular, and the techs find it easy to fit.”
- “Our organization has its own CME company that we work with, but they don’t dictate what we use. We see more patient tolerance and effectiveness with ResMed equipment in our lab.”
- “I haven’t heard about [tighter mask regulations](#), but it sounds terrible. They’re a wear item, and it’s good to have auto shipments, which reduces the chance of infection. People come in to our sleep center with awful masks.”
- “Dentists set up a CPAP or oral device, but who follows up then? Each dentist decides what oral device to use. I attended one talk, and there were 70 to 80 dental devices on the market. ResMed just purchased their own device. One dentist specialist gave a talk and whittled that down to two models.”
- “DME is a big service industry, and not all are good. It’s not just putting CPAPs on the patient. If patients aren’t seeing a sleep specialist, their primary care doc doesn’t always know what is best. They rely on the DME who too often says, ‘Here’s the machine, and good luck.’”

- “This is our best year; we’re up about 7% year to year. We’re seeing our pediatrics volume double the last few years.”

➤ Sleep lab coordinator in Florida

This source had not heard about directed Medicare cuts, but said other insurances will follow suit if the decreased reimbursement occurs. Both This sleep clinic does not have a company preference and views both ResMed and Respirationics as good vendors offering on-time deliveries and quality service. Sleep study numbers have remained the same year to year. Increased awareness and diagnosis of sleep disorders are countered by reductions in health insurance. Clinics will feel the effects of an increase in home sleep studies.

- “I’m not sure what the next Medicare move is; I haven’t heard anything. But whatever they do, the other [insurance] companies probably will follow. However, most of our patients are on Medicare.”
- “Sleep study numbers are staying the same. There is more patient and doctor awareness of the problem, and doctors are diagnosing sleep apnea more often. But with all the insurance changes, such as increasing the home testing, our numbers are even.”
- “If home sleep testing is approved by insurances, then fewer people will be coming to the sleep labs, and our numbers will keep dropping.”
- “We order ResMed and Respirationics equipment on an equal basis. For both companies, the service is good, and all deliveries are on time. There are a few more companies, and I think all companies are OK.”
- “We have had no complaints from our patients, and I can’t say that our patients prefer one company over the other. They try the masks on, then pick the mask and device they prefer.”
- “A good-fitting mask is important to make the CPAP effective, so I can’t imagine they would change the rules on that one.”

➤ Sleep practice manager for a medical center in the central United States

This source has not heard about the CMS-directed reimbursement cuts, but said health insurance companies likely will mirror the decrease. ResMed, Respirationics and Fisher & Paykel products are prescribed and used equally, although some patients prefer Respirationics. Starting in November, home testing will be the norm, but patients with more difficult cases still will be tested in the lab.

- “I haven’t heard of any new CMS cuts. I would imagine that other [insurance] companies would follow.”
- “We prescribe both ResMed and Respirationics. We also prescribe Fisher & Paykel. One is not really used much more than the other. We give our patients choices.”
- “Our patients might prefer Respirationics just a bit more because it is easier to use.”
- “Starting in November, testing will be done in-home. It was driven by insurance companies because it is hundreds of dollars cheaper. Severe apnea cases will still be tested in the hospital.”

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*Sleep Practice Manager
U.S. Medical Center*

➤ Sleep laboratory manager and polysomnography technologist, Ontario Canada

Ontario is unique in Canada as it houses 100 sleep labs. Other provinces typically have one to two sleep labs. Home studies are not performed in Ontario but are common elsewhere in Canada. Cost-containment efforts are likely to mandate home testing over in-clinic sleep studies. CPAP is the default OSA therapy. It is 100% effective but not always viable for an individual patient. ResMed and Respirationics split the machine market, but ResMed leads in masks. Brand recommendation is controlled by the DME.

- “Although Ontario has a unique focus on sleep study clinics historically, eventually the government will almost certainly become more aggressive in pushing home studies due to cost.”
- “The Ontario government pays for about 75% of the blower and mask costs. Anything additional and any upgrades are paid by the patient.”
- “Physicians are not allowed to recommend a specific brand. DMEs typically provide the patient education and make brand recommendations.”

- “ResMed and Respirationics place approximately equivalent numbers of blowers, effectively dominating the entire market between them. ResMed is definitely the mask leader with 70% of the market. Respirationics controls 25% of the mask market, with various other manufacturers making up the remaining 5%.”
- “ResMed has the best mask. It is easier to fit, more comfortable, and has fewer parts.”
- “CPAP is 100% effective but not always individually viable. Newer technologies will fill a niche for [non-CPAP compliant] OSA patients. Oral appliances are not for everyone. Surgery is painful, expensive and provides only short-term results. Other technologies like [‘microwaving’ the palate](#) to tighten it have not demonstrated long-term success.”

➤ Sleep center manager in southern Florida

CMS will continue to reduce reimbursements across the board, and is expected to make further cuts in 2013. Health insurance companies will follow. Sleep studies at this source’s center are up 15% year to year and quarter to quarter. The center has used ResMed masks for years, but relies on Respirationics CPAP devices for sleep studies. ResMed and Respirationics are the only real competitors in the CPAP market. She no longer will meet with the regional ResMed sales rep because of his aggressive sales tactics.

- “We do expect fee changes from CMS next year. There is talk of another 7% cut for baseline studies and 9% for CPAP next year. And they’re going to pay less for home sleep studies, about 2% less.”
- “I’ve heard that some in the industry think CMS reimbursement could be cut as much as 30% through bidding on equipment. I don’t think it’s a good idea. If it happens, insurance companies will only follow.”
- “I don’t see how they could make regulations much tighter. If a little clip falls off a sleep mask, patients have to get a doctor to write that they need a new part for their mask. We have to send more records, handle more phone calls. It’s getting crazy. And all the audits: A lot of the durable medical-equipment companies are getting a lot of audits by insurance companies for their sleep patients to prove the necessity of the machines.”
- “We use Respirationics because we like their equipment better. We notice that patients on Respirationics machines on [C-Flex](#) like that better. The people returning their machines were all ResMed patients.”
- “We prescribe more CPAP flow devices made by Respirationics. It works better.”
- “We do use the ResMed mask all the time and prefer it. Overall, I think ResMed as the best full-face mask on the market. Also, their nasal masks and nasal pillows are by far the best.”
- “Competition for sleep apnea devices is just between ResMed and Respirationics. Fisher & Paykel really isn’t much of a competitor.”
- “I would say ResMed is too aggressive. I personally don’t care for the ResMed sales rep in our area. I don’t even see him anymore. He just leaves samples for us. He was very pushy.”
- “Our procedural study volumes are up 15% from 2011 and up 15% as well this quarter from last quarter. It’s about the same since last month.”
- “I think the dentist oral appliances are picking up some steam. You have to go to a dental office specializing in sleep apnea for these. It’s an alternative to CPAP for patients who cannot tolerate it or won’t wear it, but you must have mild to moderate sleep apnea for it to work.”

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*Sleep Center Manager
Southern Florida*

➤ Sleep center manager in Florida

Reimbursement for sleep studies is decreasing, and competitive bidding may lower reimbursement for sleep apnea equipment. Sleep study procedural volumes are up 10% year to year, but have held at the same level in the last quarter and month to month. The center uses different brands of sleeping masks but primarily ResMed, and only Respirationics’ CPAP equipment. ResMed and Respirationics are the primary competitors for CPAP devices. Both companies are keeping pace with each other in terms of product improvements.

- “The only change we’ve seen in fees is insurance companies are going toward the home studies.”
- “It’s possible that CMS reimbursement could be cut through competitive bidding for sleep apnea devices. Insurance companies always follow.”
- “Our studies are up 10% since last year, but we have not seen an increase from the last quarter or month.”

- “We use ResMed masks but not ResMed equipment. We use Philips Respironics. It’s a physician decision.”
- “ResMed’s masks are better than any other company’s. They have amazing masks for patients. We don’t work with them on other devices like CPAP machines.”

➤ **Nurse manager for a medical center in the Pacific Northwest**

This source had not heard of additional Medicare cuts. Patients are new to the procedure and equipment, and do not appear to have a brand preference. The center stocks equipment from ResMed, Respironics and whatever donations it receives from people who have dropped out of the program. Some insurance companies cover the test but not the equipment. Patients then buy used equipment online via Craigslist for much less. Referrals have increased 15% since the center started checking surgery patients for sleep apnea. Tests are done in-house or in-home, depending on insurance.

- “The patients are new to all of this. They have no idea what to choose, so they come in and try things out. I can’t see that they really have a preference to one brand.”
- “We use ResMed, Respironics and whatever anyone gives us. We keep a fair amount of donated equipment here and just give it to the patients. Some people just try this out for a few weeks and decide it is not for them. I can’t say if ResMed or one of the others is any better.”
- “Our numbers have been increasing, especially in the past year. We are up about 15% because of surgical services.”
- “Patients have a few options for sleep studies. Whether they do the study in-house or in-home depends on their insurance. The in-lab study is more comprehensive.”

➤ **Executive for a sleep clinic/OSA DME service in Southern California**

CPAP is the default OSA therapy. Respironics and ResMed have equivalent machine market share, but ResMed controls the mask market. Payer price pressure is driving the trend toward in-home sleep studies and default [CPAP therapy/auto-titration](#). Regulation will result in a large increase in screening and treatment of commercial drivers and other at-risk occupations. New innovations will fill niche markets.

- “Follow the money. Payers are driving the behavior. Home testing is much less expensive than an in-lab study. The problem is that the people who fought so hard against home studies on the basis they are less sophisticated and, therefore, less clinically valuable effectively drove down the reimbursement rate for home studies. It is now almost impossible for labs to make money.”
- “The total number of sleep tests is probably flat, but there is a definite move toward portable/home testing. Ninety percent of cases are suitable for home testing. There was a time when insurers would not pay for home testing; now it is the default.”
- “There is a push by the [National Sleep Foundation](#) and others to eliminate formal sleep studies altogether. A presumptive OSA patient should go directly to CPAP with auto-titrate. The machine and the patient response will tell the tale. If the industry is really looking to cut costs, it is a sensible approach. Ninety percent of patients with two to three clinical criteria have OSA. Insurers, however, also want to prevent overtreatment.”
- “Tighter regulation on risk-sensitive jobs like commercial drivers is likely to dramatically increase the number of OSA diagnoses and treated patients. There is a precedent for this. For example, mandatory drug screening resulted in an explosion of diagnostic devices, and regulation of medical sharps drove a massive increase in sharps container manufacturing and education.”
- “There is relative equivalence between Respironics and ResMed with each company controlling 40% to 45% of the blower market. ResMed has significant mask advantages, resulting in approximately 70% share of that market. The other, smaller CPAP manufacturers make up the balance. In essence, the CPAP market is a duopoly. The R&D investment of the two leaders far outweighs the total revenues of all the smaller players.”

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*Executive
Sleep Clinic/OSA DME Service
Southern California*

- “There is an expectation that the DOT [Department of Transportation] will mandate OSA screening in the next three to four years. OSA is considered an epidemic among truckers.”
- “New OSA innovations are likely to address only a small percentage of the market. There are concerns about clinical efficacy, reimbursement and total cost to the patient. CPAP is the most effective and reliable solution for sleep apnea patients. Compliance and monitoring are also critical to a CPAP treatment program. These alternatives do not offer clear approaches to ensuring compliance.”

2) CORPORATE HOME HEALTH PROVIDERS

Two of these six sources think ResMed will lose share to Philips Respironics. Both ResMed and Respironics are considered the sleep therapy equipment market leaders and are expected to do well despite the continuation of CMS cuts and the new medical [device tax](#). The diagnosis and treatment of sleep apnea are growing. Cost-containment efforts include home testing, competitive bidding in additional markets, and cheaper CPAP devices from China.

➤ Manager of a home health service center, Southern California

CMS reimbursement cuts are coming and will hurt the bottom line of home health service companies. Although ResMed’s products are excellent, this center’s respiratory therapist and corporate office prefer Respironics, which should continue to gain share through its product line and lower pricing. Corporate is asking centers to consider lower-cost CPAPs from China. Also, insurers are pushing for home studies. About 40% of CPAP prescriptions are for specific manufacturer products. The center’s patient volume has grown 5% to 10% year to year.

- “CMS reimbursement cuts are going to happen, and it’s going to hurt. It’s happening in other areas too—oxygen, DME and CPAP. It’s really going to hurt our margin first. We have to adjust services based on cost, and then it will hit the manufacturers. We’ll have to stray from the higher-end products to meet our bottom line.”
- “Our respiratory therapist prefers ResMed and particularly Respironics. ... Respironics is definitely the go-to company here and with our corporation. We’re leaning toward them.”
- “China is coming out with low-priced CPAPs. No one is sure of the warranty or how long they last. We’re already getting emails saying their cost is two-thirds cheaper [of our CPAPs] and asking us to look at them.”
- “I don’t know about changes in sleep center fees, but there’s a push for at home studies at one-tenth or two-tenths the cost. The cash price for a 10-channel study is \$295 at home versus \$2,000 to \$4,000 at a center.”
- “I hadn’t heard of tighter mask regulations. That would be terrible. Patient masks wear out regularly. ... If replacement every six months is cut back to eight months or a year, that’s bad for the patient. Obviously, it’s a source of revenue for us, but \$75 every six months is not a big revenue driver.”
- “Volume is definitely growing [about 5% to 10%]. The majority of people with sleep apnea aren’t identified. The signs of obstructive sleep apnea is common snoring. Docs are writing lots of prescriptions for CPAPs.”
- “We go with the equipment my respiratory therapist believes is best, with the patient weighing in heavily. They could wear a mask for a month or two and come back saying it’s leaking or it hurts. We only take insurers where patients have some choice.”
- “Not all companies have respiratory therapists on staff. We believe it’s crucial to have licensed practitioners involved to follow up. There are HMOs that have no licensed practitioners involved, and they will send a DVD set to the patient or the sales rep delivers the unit.”

➤ Manager of a midsize DME specializing in sleep apnea, California

Downward pricing because of competitive bidding and stricter insurance coverage will force manufacturers to cut costs. ResMed’s masks and [heated tube product](#) have been good sellers, but Respironics, historically dominant with large contracts, should gain share with its recently launched [heated tube product](#). This source is hopeful about a competitive CMS bid he submitted, saying that small players now will be represented in the larger market. He expects similar reimbursement cuts. Supply sales are going up. Vendors soon will be exhibiting their newest products at [Medtrade](#) in Atlanta.

- “Competitive bidding has been around for several years. In the first 10 markets, reimbursement went down 30% in a poorly designed program. We just placed our bid as part of the top 100 markets. Our chances are fairly good. We worked hard to come in with an intelligent bid. They’re supposed to be making sure small players are represented.”

- “I’m expecting the second-round [CMS] cuts to be about the same. Many small providers don’t really do the math to make sure there’s a viable business in their bid. They desperately want a winning bid, and presume that they can make up for the lower margins with increased volume.”
- “Private insurance companies did follow suit and cut reimbursement in the first round. We’ll be seeing more cuts.”
- “ResMed dominates the mask industry; they’re the proven leaders. Respiroics is desperately trying to make the mask business more competitive, but they haven’t done it yet. ... With CPAPs ... we try to be brand-agnostic. We carry Respiroics, ResMed and Fisher & Paykel.”
- “The docs write the scrip or their staff works on the referral. The doctors’ offices have local DMEs who compete for business while the manufacturer reps put on pressure to write brand-specific equipment. ... About 25% of scripts are brand-specific.”
- “I have been seeing more centers being brand-specific. ResMed has been effectively selling their heated tube product. We’re seeing a lot of centers specifying those although all three carry them.”
- “Respiroics came out recently with their heated tube model, and they can afford to cut pricing. It may increase market share.”
- “Our sales are going up. There are two aspects: There are new diagnosis cases and CPAP setups, and you’re also selling the ‘razors’ [CPAP supplies]. The business is in the razors: the replacement masks, tubing, filters for the machines. We’ve made some big changes with our resupply business, and we’re up 40% over last year.”
- “Historically, Respiroics has contracts with the large players ... and they can offer the best pricing because of their volume. ResMed’s take is ‘we are the best,’ so pricing will be higher. Fisher & Paykel does the ‘we try harder.’ They can be very aggressive as they try to get market position, but they’re a distant third.”
- “With the downward pricing, in order to compete with each other they have to come out with more sophisticated equipment, and they usually attempt to raise pricing through the special features. But insurers don’t care about features, and they pay the same. There’s also downward pressure on billing codes.”
- “Private insurers are making massive shifts in sleep medicine with in-home studies, and patients have to get authorization even if they have PPO insurance. There are more and more requirements.”
- “There’s certainly growing awareness of sleep apnea, its consequences and the undetected cases. The potential is huge.”

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*Manager, Midsize DME
(Specializing in sleep apnea)
California*

➤ RN and president of a regional DME in North Carolina

CMS’ competitive bidding program and tighter regulations will continue, and manufacturers will pass on the upcoming device tax. ResMed and Respiroics will continue to be leaders. This source views ResMed’s new high-end [ventilator](#) as an exciting product that will more quickly move patients out of the hospital to their homes.

- “Many of us in this business are so used to being used and abused. Most providers are excellent, but a few bad apples get all the publicity. There’s a lack of trust, such as CMS taking readily available replacement schedules and saying, ‘We don’t want to adhere to that.’ It affects us, but the Medicare recipient is the one left out.”
- “The manufacturers are at their lowest possible cost, and now there’s even a device tax. The device manufacturers will pass that on.”
- “The top three are ResMed, Respiroics and Fisher & Paykel. ResMed and Respiroics will continue to go head to head and have good products.”
- “The sleep apnea market is growing due to increasing awareness of patients and to physicians willing to screen patients.”
- “ResMed has a new product that will be huge. They’re coming out with a high-end ventilator that will really help people get out of the hospital. It’s a very high-end IVAP but easy to use. It’s for a small segment.”

ResMed has a new product that will be huge. They’re coming out with a high-end ventilator that will really help people get out of the hospital. It’s a very high-end IVAP but easy to use. It’s for a small segment.

*RN & President
Regional DME, North Carolina*

- “As far as CPAPs, what’s increasing are sophisticated CPAPs that tell us more data about the patient’s sleep.”
- “[Ventus Medical Inc.’s] [Provent](#) is something to look at and is a small piece of the puzzle. When it works, it works very well.”

➤ **Vice president of finance for a home service company in the Pacific Northwest**

This source expects 30% CMS reimbursement cuts. To survive, the source’s company will ask ResMed and Respirationics for price cuts and will focus on serving rural areas for more clients. ResMed and Respirationics each control nearly one-half of the source’s service area. Patients rarely question the ordered brand. The sleep apnea market is on the increase. In-home testing is just starting to take off, and 20% of patients will have in-home testing by next year. The source’s company has a 92% compliance rate because it works carefully with each patient.

- “Round-two bidding is starting, when the new rates will come out. We bid to win. I know we will be offered a contract and a 30% cut. To survive, we are expanding business to focus on rural areas, a whole new shift. DMEs make less than 3%, and there is little to cut from.”
- “We will need to go back to ResMed and Respirationics and say that we need to pay less. We will be more aggressive in our quarterly buys with them. Our sales reps will work with us. Our success is their success.”
- “You can’t shove the extra prices onto Medicare patients. That’s part of the [ADMs](#). It’s always been a rule that you can’t ‘upscale’ Medicare patients.”
- “We are strong and not overleveraged. We think we will be fine [after the Medicare cuts].”
- “I hope other insurance companies won’t follow CMS’ cuts. We had to drop UnitedHealth last year because of their cuts. We accept [Aetna \[Inc./AET\]](#), but they only give a basic mask. The patient has to pay for the upgrade.”
- “I haven’t heard about mask restrictions.”
- “Both ResMed and Respirationics are great machines. Fisher & Paykel is good as well. DeVilbiss Healthcare is smaller. ... DeVilbiss may carry 3% of the market.”
- “The sleep apnea market is absolutely increasing.”
- “Most of our physicians write the requested brand in the prescription. What brand is sold where really depends on the quality of the sales rep. ... The sales reps are hard-working and very good.”
- “The patients just go along with what is ordered. We rarely have a patient specify a certain brand.”
- “We co-market with the sales reps, so it works both ways. People know to order from us.”
- “Most patients are being tested in the lab, but we are just starting to see a shift to in-home testing. Last year 99% were lab tested, and 1% was done at home. Today we see 90% lab testing and 10% in home. In one year, it will be 80% in lab, 20% in home. After that, in-home testing will really take off.”

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*VP of Finance, Home Service Company
Pacific Northwest*

➤ **Respiratory therapist and educator for a home health service in the Midwest**

This source has not noticed any Medicare or insurance cuts, and said mask regulations are the same. The service equally stocks ResMed, Respirationics and Fisher & Paykel. Doctors prescribe only settings, not brands. Cases have increased slightly because growing public and physician awareness.

- “Fees are the same. They are determined by the different insurance companies. We are not affected by Medicare cuts in our area. There will be tighter regulations, but I haven’t seen anything yet. The cuts may not affect patients, but they will affect the suppliers’ ability to supply.”
- “Mask cuts may affect the patients, but we haven’t been hit yet.”
- “We sell the three top brands, ResMed, Respirationics and Fisher & Paykel.”
- “The doctors do not recommend a brand; they just write a prescription for the settings. The patients come in, and we show them the different styles. We talk about fit, what feels good. They pick out a brand depending on what is most comfortable to them. All the pumps are just about the same, so it is really the mask they are deciding on. The masks are interchangeable with the tubing, but they get a free mask to start out with, and we generally match the masks to pumps. Of course, it also depends on their insurance.”
- “There is an increase in patients ordering apnea devices, but it is not significant. I think there is more awareness of the problem, and more doctors are prescribing the tests.”

- “Our patients are often the elderly although CPAP patients are getting younger and younger.”

➤ **Respiratory therapist for a home health service in the Southwest**

CMS reimbursement cuts have not affected this home health agency, but the source has encountered some health insurance coverage issues. The service carries Respironics and Fisher & Paykel. Patients typically do not have a preference, but some patients have spoken highly of the [ResMed S9](#), which has prompted the source to consider selling the device. Mask restrictions will be a problem for older patients with sensitive skin. Oral devices may help improve patient compliance but lack a significant market.

- “We haven’t heard about lower Medicare, Medicaid pricing.”
- “Some insurances are good, others don’t pay. Each is different.”
- “We mainly carry Respironics because we get a decent price with them. We also carry Fisher & Paykel. People don’t seem to have a preference.”
- “We’ve been looking at the ResMed S9. People seem to like those devices.”
- “There will be a problem if there are tighter regulations for mask replacement. It will be harder for our older patients. We measure the masks carefully, but we don’t know how they are sleeping. The mask moves around and maybe rubs on the top of their nose. Older people have very sensitive skin, and that can cause problems.”
- “We haven’t started selling oral devices yet. There isn’t a huge market. The oral device may help some patients be compliant. But if they have central apnea, the oral appliance won’t help.”

3) PHYSICIANS AND DENTISTS

These eight sources, comprising six physicians and two dentists, said the sleep apnea diagnostic and treatment population is growing. ResMed and Respironics are the clear leaders in CPAP device manufacturing. Pricing pressure stemming from competitive bidding and reimbursement cuts from CMS and insurance companies is leading to increased in-home testing and the use of lower-grade equipment. The use of oral devices is on the rise, particularly when a CPAP patient has compliance challenges. Dentists are realizing the financial opportunities and flocking to conferences and seminars to learn about sleep apnea treatments.

➤ **Physician and researcher specializing in internal, pulmonary and sleep medicine**

The universe of diagnosed OSA patients is expanding. CPAP is the “gold standard.” Respironics and ResMed are neck and neck. Price pressure from third-party payers is driving the trend toward in-home testing. Oral appliances are likely to persist as a solution for some mild to moderate OSA patients. Other newer technologies are expensive and unproven.

- “CPAP is considered the gold standard for sleep apnea patients. The manufacturers involved are reputable companies with good products. ResMed and Respironics tend to leapfrog each other from year to year. There are no material differences between them.”
- “The OSA is large and will continue to grow as more patients are identified. Medical indications for sleep apnea are broadening. The population is getting older and fatter.”
- “There is a definitive push away from in-lab sleep studies toward home studies as a result of cost-containment efforts.”
- “Oral appliances are here to stay in some fashion, especially for mild to moderate cases.”
- “Newer technologies like [HGNS](#) [hypoglossal nerve stimulation] are expensive and will not be effective for everyone. For HGNS, the response rate is still unknown.”

CPAP is considered the gold standard for sleep apnea patients. The manufacturers involved are reputable companies with good products. ResMed and Respironics tend to leapfrog each other from year to year. There are no material differences between them.

*Physician & Researcher
(Internal, pulmonary & sleep medicine
specialty)*

➤ **Critical care/sleep medicine specialist for a long-established sleep center**

This sleep specialist’s main concern is the effect of competitive bidding on DMEs, saying the resulting restriction in equipment will lead to poor patient compliance. [Apria Healthcare](#) has particularly poor service in the area. ResMed and

Respironics are the leaders, but Provent is an exciting innovation. Additional reimbursement reductions are a concern as current reimbursement often does not even cover costs. As a result, this center does not accept Medicaid.

- “Competitive bids are horrible. Customer support [by the large DMEs] is abysmal already, and then you lose staff, which directly affects patient success. The equipment is poor, and there’s no teaching. CMS is shooting themselves in the foot.”
- “The biggest issue is the DME companies. They will say the folks are compliant because they deliver the machine, but then they take the machine away.”
- “We’re scared about the CMS competitive bidding because we already don’t cover our costs. We have to exclude [Medicaid] because it doesn’t pay the cost of the sleep study.”
- “The high-end equipment is important. Those ‘bells and whistles’ churn out important data. Those data cards don’t just measure compliance; they tell me if the patient is still having events.”
- “With the DME we use, patients can give some input on equipment. They certainly don’t have that with Apria. Apria underbid and has all the HMO business in the area. They’re horrible.”
- “ResMed and Respironics are the gold standard. I don’t think Fisher & Paykel is very good.”
- “Provent is exciting. A lot of things are still experimental such as oral appliances and [nerve] stimulators.”
- “Procedures are growing. Primary physicians are more aware that patients’ insomnia cases may be sleep apnea.”

➤ Medical director of a pediatric sleep center on the East Coast

This source was not aware of any pending reimbursement cuts, perhaps because of her focus on pediatric patients. Three brands of apnea devices are approved for pediatrics: Respironics, ResMed and [SleepNet](#), but none stands out. Increasing obesity rates play a role in the growing number of children with sleep apnea. The source has not experienced pricing changes, but said reimbursers should consider for a child’s need for frequent mask changes. In-home studies are just beginning in pediatrics and will have to be done carefully. Compliance runs the same in children and adults.

- “I haven’t heard about any Medicaid changes, but our population is relatively immune.”
- “There are three brands of devices approved for kids under age seven: Respironics, ResMed and SleepNet. I can’t say that we gravitate toward any one brand.”
- “The population is definitely growing. More kids are overweight and obese and are no longer surgical candidates. We will definitely see more and more patients with sleep apnea.”
- “You need to be flexible with kid masks. Kids get fitted early for their masks, try them out before testing. The mask fit changes frequently because kids are growing, gaining weight, their anatomy changes.”
- “Up until this past weekend, I didn’t think home testing would happen in peds. But already there is a push in [Massachusetts](#). This is problematic, and we need to be proactive in developing a triage to manage the home study care of a select group of carefully chosen children. Even adolescents are not reliable.”
- “Compliance in kids is no worse than adults. Kids don’t have that absolute resistance like you see in adults. They don’t have an underlying prejudice and refuse to come in for testing. Compliance requires an intrinsic support and education system. We are building up our program with follow-up.”
- “The American Academy of Pediatrics just published clinical practice [guidelines](#) for diagnosis and treatment of sleep apnea. The overnight test is the gold standard, but there are not enough clinicians.”
- “While we see all types of sleep disorders, such as tonsils or adenoids, 70% to 80% of the kids are referred to us for sleep apnea. We are at a crossroads now, and it is very frustrating.”

➤ Physician and director for a major academic sleep center, Maryland

This source views the increasing requirement for at-home sleep studies by CMS and insurers as the most important trend. Currently making referrals for outpatient studies, his center is setting up a system to offer the equipment. All major manufacturers are represented in outpatient equipment. His scripts for sleep equipment are brand-agnostic.

- “I haven’t seen a reduction in fees for sleep lab studies. I’m not sure how much more CMS can reduce it. ... But in academia, the business offices handles that. Private offices would be more aware of reductions.”
- “Within neurology, we’re slowly increasing in sleep apnea cases—more strokes, memory dysfunction as well as insomnia. The growing public awareness is good for us.”
- “There’s many more outpatient sleep studies being required by CMS and insurers, and there’s no question that will continue. What it does is change the specific equipment. Outpatient studies are not titrated, so they use automated titration equipment that could be slightly more in cost but probably not much more.”

- “I think volume [of our in-patient sleep studies] has been fairly flat. We don’t offer the at-home, but we’re in the process to have the equipment for that.”
- “I think all the manufacturers are represented in the automated equipment.”
- “My scrips are open-ended. ... I’m not all that familiar with the individual manufacturers’ equipment differences.”
- “I don’t think patients really understand the differences, so they go with the recommended equipment.”

➤ **Sleep medicine specialist and director of a new sleep center**

This source was aware of CMS’ competitive bidding program but not enough to comment. He also was largely unaware of vendors’ market share. His center uses all equipment vendors, and has seen patient volume grow 10% year to year.

- “I’ve heard about CPAPs being competitively bid, but I don’t know anything about it.”
- “We use all [manufacturer] companies. We try not to limit to one company or another. ResMed and Respirationics are both good to us. The issue is not the quality of the manufacturers’ equipment; the difficulty is our center growing market share.”
- “I wish manufacturers would make more masks and more sizes to find the right one for each patient. We need a few more sizes. We don’t want to limit manufacturers because one company’s mask will fit one patient and another best fits another patient.”
- “It’s a new market and we’re growing in that market, about 10% year to year.”
- “I haven’t heard anything about tighter mask regulations. You’re scaring me.”

➤ **Assistant professor of sleep medicine for a large East Coast medical center**

This source had not heard of any CMS reimbursement or mask replacement changes, but said health insurance companies would follow CMS’ lead. CPAP manufacturers offer similar quality. Physicians do not order a specific brand, and patients have their own preferences. The field is definitely growing. In-home testing is not as complete as lab testing. Oral appliances are becoming more popular but are not as effective as CPAP.

- “I haven’t heard of any new Medicare fee changes, but if Medicare changes, the other insurance companies will follow in time. The same goes for mask replacements.”
- “There are a number of companies manufacturing CPAP, and they are equally as good.”
- “The physicians here just order a CPAP, and the patients try out the different types in clinic. They pick out the brand they prefer.”
- “More people are asking about sleep apnea because there is more talk about it. The field is increasing.”
- “In-home testing is not as good as lab testing. Lab testing is more complete.”
- “The fees for this program have remained the same. Some insurance companies are better than others, but that is always the case.”
- “More people are using oral appliances, and a lot of companies are making them. [But] I don’t think they are as effective as CPAP.”

➤ **Indiana-based cosmetic dentist**

This dentist, who has 28 years of experience, has added sleep apnea treatment to his services because he believes doing so will be highly lucrative. He said he joined hundreds of other dentists at conferences in the last six months to learn about accreditation and training for sleep apnea. He is unfamiliar with the competitive landscape for CPAP devices, as his practice will use custom-made oral appliances to treat patients. He does not plan to offer CPAP devices out of concern that he might jeopardize his referral sources.

- “I’m seeing an increase in sleep apnea patients because I’m bringing up the topic to my patients and there is increasing knowledge among people in general.”
- “Dentists are seeing this as an opportunity with the increased recognition of sleep apnea. There’s an increased interest as people realize the relevance of the problem and dentists realize there’s a significant amount of income to be made.”
- “If a patient refuses the CPAP, then the oral appliance [offered by dentists] is an option. There are studies that are showing an oral appliance is just as effective.”
- “I’m installing software that allows conversion from dental to medical terms and allows me to switch to medical billing for sleep apnea. Many patients have good health insurance but lousy dental insurance. If we

Dentists probably don’t want to use a CPAP because you could ruin your referral source from the sleep center that does use CPAP.

Indiana-based Cosmetic Dentist

- get the diagnosis, there is a possibility we can get coverage on medical for patients as opposed to dental.”
- “I don’t take Medicaid or Medicare at the moment.”
- “Dentists probably don’t want to use a CPAP because you could ruin your referral source from the sleep center that does use CPAP.”
- “I don’t know a lot about the companies that make CPAP devices. The best device really depends on the cost factor and what works best for the patient.”

► Family dentist in California specializing in dental sleep medicine

Patients have several good equipment choices for CPAP. The oral appliance market and awareness of sleep disorders are growing. [Narval](#), ResMed’s OSA oral appliance, is well designed but not CMS-approved. CMS has [approved](#) only TP Orthodontics Inc.’s [Herbst hinge device](#), which reportedly is made in only two laboratories. In the past few months, CMS has cut reimbursements for oral devices by one-third.

- “There are a number of good manufacturers of the CPAP. It is a matter of individual choice.”
- “More people are becoming aware of sleep problems and its health consequences because of the media. People are becoming more obese. Semi drivers are being tested because of insurance. Some must get treatment to continue with their jobs.”
- “ResMed saw that people were not always compliant with the CPAP throughout a night or for the long term. There are studies from Australia and France from the last couple of years showing that an oral device can be just as effective as the CPAP for OSA. ResMed thinks that oral appliances will be used more in the future, and this is why they have gotten into this market. ResMed designed and has been marketing an oral appliance in Europe for a while. This year they started marketing [the Narval] in the United States.”
- “The Narval is a good appliance. ... I have tried many of the appliances, so I can tell my patients the pros and cons of the different types. Other manufacturers include Herbst, [SomnoMed Inc.’s] [SomnoDent](#), [Airway Management’s] [TAP](#) and [Glidewell Laboratories’ Myerson] [EMA](#). These manufacturers are used most often.”
- “Last year I signed up for Medicare as a DME provider. The fee that I would receive was decreased by about one-third after three months, before I was even completely signed up. But I decided to stay with it because of the great need for this service.”
- “Many dentists say they do sleep apnea but may not have much background. You can look on the Internet now and see how many people are getting into this. But medical billing is not as easy as they might think.”
- “Most sleep physicians will usually recommend the [PAP](#) or surgery first although the oral appliance is listed as an alternative under medical OSA management.”
- “Clinic sleep studies may decrease in the future because of the high costs, and the home sleep tests may be used more. The advantage is that you can sleep in a home environment. But the test may not be done correctly, and other sleep problems may not be diagnosed.”
- “Many home testing devices are available now. There is talk that this may be the future, as it is very expensive to have people working all night, the bedrooms, etc. I have an [Itamar \[Medical Ltd.\]](#) home sleep test and an overnight pulse oximeter. The results are printed out for the patient when they return the next day. I use the device for screening or to evaluate and titrate the oral appliance, before the patients return to their sleep physician for a lab study with the appliance.”

Last year I signed up for Medicare as a DME provider. The fee that I would receive was decreased by about one-third after three months, before I was even completely signed up. But I decided to stay with it because of the great need for this service.

*Family Dentist
(Dental sleep medicine specialty)
California*

4) SLEEP APNEA EQUIPMENT SALES PROFESSIONALS

These five sources, representing three CPAP companies and two oral device companies, consider CPAP to be the gold standard for treatment and ResMed and Respironics to be the industry leaders. Competitive bidding and reduced reimbursement will not affect the two companies’ market share. Emerging trends include the increase in home testing, the use of oral devices, and growth in sleep apnea treatment for perioperative patients. One source expects equipment

manufacturers to begin buying DMEs or selling directly to consumers in an effort to remain competitive. Another said Provent has bypassed the distribution channel and already is marketing directly to patients.

➤ **Sales director for a CPAP manufacturer**

CPAP is the standard therapy. No new innovations pose a significant threat to CPAP technology. The most promising area for market growth lies in perioperative OSA screening. Medicare is reducing consumable allowances and requires compliance verification for payment. Despite significant third-party pricing pressure, manufacturers remain price-competitive in order to maintain a profit margin. ResMed and Respirationics have approximately equal market share for machines. Respirationics has data management/algorithm advantages while ResMed dominates the mask market. Brand decisions can be made anywhere along the distribution channel.

- “CPAP device sales volume is steady. Despite screening trends that identify more patients, these patients cannot always afford the therapy.”
- “Nothing currently in the innovation pipeline looks as effective as CPAP. With any new idea, however, a small percentage of patients may respond. I do not see a major impact on CPAP sales anytime in the near future.”
- “The insurers exert downward price pressure, and there is definite bidding at the DME level. But CPAP manufacturers attempt to stay in close price competition with each other. Despite the price pressure, the manufacturers need to remain profitable.”
- “ResMed and Respirationics effectively have 50-50 market share for the blowers. Respirationics offers more advanced software and algorithms. ResMed has had the mask advantage historically, controlling approximately 70% of share. Respirationics is responding with newer mask designs. Others including DeVilbiss and Fisher & Paykel are at a noise level. They serve little pockets. These players offer a much more narrow product line and have weak distribution networks.”
- “Brand decision can be driven by the physician, the DME, the sleep lab or the patient. A lot of the success of a specific brand lies in the relationship within the distribution channel.”
- “Good DMEs have better compliance. Some drop ship, but it is the exception rather than the rule.”
- “Medicare has a 90-day compliance requirement or payment is stopped. Monitoring compliance falls to the DME.”
- “Medicare is reducing consumable [mask and disposable] allowances.”
- “Insurance carriers have been slow to enforce home sleep studies, but they have been increasing the pressure to do so. It is all cost-related. Third-party payers vary in how they handle ... patients. [Kaiser Permanente](#) puts all positive [PSG](#) patients on auto-titrate. Some carriers direct positive patients to the lab for titration. In-lab sleep centers are definitely losing business, both for the initial PSG study and the follow-up titration.”
- “OSA is diagnosed on presentation. Although the trend is toward home testing for confirmation, the home sleep units are not that sophisticated. They offer 3-channel analysis versus 27 channels at the lab.”
- “Cardiologists would rather treat patients traditionally than investigate and treat for OSA. They are reluctant to embrace CPAP devices as a therapeutic tool. The population of OSA/CPAP patients could expand dramatically if more cardiovascular specialists would embrace sleep studies as an additional diagnostic.”
- “A more promising area of potential market expansion lies in perioperative screening. Studies have shown that patients with three or more OSA criteria have poorer surgical outcomes. The idea is to identify these patients and get them CPAP-compliant before their procedure. This improves outcomes, decreases intensive-care stays, and controls overall procedure costs.”

Cardiologists would rather treat patients traditionally than investigate and treat for OSA. They are reluctant to embrace CPAP devices as a therapeutic tool. The population of OSA/CPAP patients could expand dramatically if more cardiovascular specialists would embrace sleep studies as an additional diagnostic.

Sales Director, CPAP Manufacturer

➤ **Patrick Maley, president of [Apnea Sciences](#)**

CPAP is the standard for OSA. ResMed and Respirationics dominate the machine market together, but ResMed has a distinctive mask advantage. Physicians, sleep clinics and DMEs exhibit strong brand loyalty. Third-party cost containment is apparent in the push toward home sleep studies. Oral appliances are gaining acceptance and may prove effective in as high as 70% of cases. Newer technologies are expensive and unproven. Combination technologies are a new trend.

- “ResMed and Respirationics have approximately equal market share for the blower at 40% each. The balance is addressed by the smaller companies and alternative therapies.”
- “People love the ResMed mask.”
- “Five years ago there was no reimbursement for home sleep studies. Today there is increasing pressure from third-party payers to go that direction. Home studies are less expensive and are effective in 85% of cases.”
- “Sleep doctors develop a loyalty to a brand and that brand’s sales representative. It is difficult to get a provider to switch.”
- “CPAP compliance is approximately 60%. Oral appliances are becoming a more accepted, secondary option. Oral appliances are particularly effective in mild to moderate OSA, which constitutes 60% to 70% of the patient population.”
- “Like CPAP, oral appliances are available by prescription only. The recommendation for a device or brand can be made by the physician, the sleep center or the DME.”
- “Provent has decided to eliminate distribution channels and go direct. This could be a real challenge. The device appears to work in only 50% of cases.”
- “Surgery is a last resort. It is invasive and expensive.”
- “HGNS is too expensive even if it works. There is a \$20,000 potential cost associated with the technology.”
- “The up-and-coming trend is toward combination technologies: oral appliances plus CPAP devices.”

The up-and-coming trend is toward combination technologies: oral appliances plus CPAP devices.

President, Apnea Sciences

➤ Business manager for a CPAP manufacturer

CPAP technology remains the default therapy for OSA patients. The patient population will continue to expand because of increased awareness, expanded screening programs, and the availability of alternative therapies. ResMed and Respirationics share the vast majority of the CPAP market. The CPAP device is typically selected by the physician or sleep lab, which tend to be brand-loyal. Tighter reimbursement trends are driving diagnosis away from the labs and toward in-home sleep studies.

- “Although CPAP is the gold standard, it is also an archaic system. ResMed and Respirationics systems are very similar. They share the majority of the CPAP market and compete closely on price.”
- “The physician or sleep lab typically selects the CPAP brand for the patient. Many are aligned with a specific device manufacturer.”
- “CPAP prescriptions are probably increasing. There is increased awareness of OSA leading to increased diagnosis. The availability of alternative therapies ... also drives more people to getting a definitive diagnosis.”
- “There is definitely an increase in the trend toward in-home versus in-lab studies. This is insurer-driven. By Nov. 1, California insurers are expected to dictate that home sleep studies must be accomplished first. This has already happened in Massachusetts. Positive in-home sleep studies can then be titrated in-lab or at home with auto-titrate.”
- “There is no perfect OSA therapy. Each has its challenges. But there is plenty of room for competitors.”
- “Awareness of the link between OSA and cardiovascular disease has existed for many years, but the majority of CV physicians do not order sleep studies. They will talk it, but they do not walk it. I do not believe this is where the market growth explosion will occur.”
- “The trend toward identifying perioperative OSA will contribute to identifying new patients.”
- “The market will expand as a direct result of patient demand. People know they snore and have sleep apnea, but they do not want to wear the mask. As more alternate technologies become available, the consumer will drive demand for them.”
- “Surgical intervention for OSA is becoming less and less popular. It is expensive, invasive and inexact.”
- “Oral appliances for OSA are only effective in a small percentage of cases. They are likely to remain a niche market only.”
- “Publicity and visibility to new OSA therapies effectively uncover larger patient populations.”

Provent placements are on the increase. The device was originally targeted for CPAP-noncompliant patients. Provent is FDA-cleared for all variants of OSA, however, so the focus is expanding beyond CPAP failures alone.

Business Manager, CPAP Manufacturer

- “Provent placements are on the increase. The device was originally targeted for CPAP-noncompliant patients. Provent is FDA-cleared for all variants of OSA, however, so the focus is expanding beyond CPAP failures alone.”
- “The advantages of Provent include greater comfort and no need for electricity or water. The technology is based on the patient’s own breathing patterns. It typically takes three to seven nights to acclimate, but the company has introduced a ramping process and more patient-centric education, which is reducing the acclimation time.”
- “Provent costs are typically paid out of pocket although it has been reimbursed by insurers on a case-by-case basis.”
- “The Provent system may be successful in as much as 75% of apnea cases, particularly mild to moderate OSA patients.”
- “New technologies like hypoglossal nerve stimulation are still under development. The technology holds some promise, but the effectiveness is unknown at this point.”
- “[Apnicure \[Inc.\]](#) is another technology just approved in 2012. It involves a vacuum to stabilize the tongue and increase the size of the airway. It also holds some promise but is not currently reimbursed.”

➤ CEO of an online medical equipment distributor

Sleep apnea product sales have risen substantially for this source who said insurers such as Medicare and Blue Cross Blue Shield are increasingly having patients buy automated CPAPs and then seek reimbursement. Patients are buying masks themselves, particularly from ResMed. The source prefers auto CPAPs from Resironics and DeVilbiss. Equipment manufacturers will acquire DMEs in order to remain competitive.

- “My sleep apnea products are up 2,000% to 3,000% over last year. Online retail is where it’s at.”
- “I elected not to take insurance and sell automatic CPAPs at the lowest rate. What insurance companies are doing is telling patients to buy a CPAP, make sure it’s an automatic CPAP and they’ll reimburse the patient 80% or whatever the agreed amount is.”
- “I think competitive bidding is great. Reimbursement should be going down. It’s repulsive how much they get for doing so little.”
- “Tighter mask regulations aren’t important. People are just going out and buying masks. Ninety percent of our CPAP business is masks. We do sell a lot of ResMed masks.”
- “Philips is a worldwide company. Resironics has an advantage over a company like ResMed because they have a lot of money.”
- “How manufacturers will stay competitive in this environment is they are going to buy an Apria or a Lincare and take it direct. Then they’ll take all those patients and convert them. It’s happening in the other areas.”
- “I haven’t looked at the products from China. I see it happening in the next five years. It’s another way to save millions of dollars for taxpayers, so I would consider them. My goal is to get the best products, especially if made in the U.S.”
- “Sleep study fees will be obsolete in the future. There’s a need for some sleep studies ... but not 75% to 80% of sleep apnea cases.”

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CEO, Online Medical Equipment Distributor

➤ Vice president of sales and marketing for an oral appliance company

ResMed will survive the increase in competitive bidding and competition. However, its oral device is not well made and will not be approved by Medicare. The CPAP market is being pressured by a lack of patient compliance, competitive bidding, and a decrease in replacing disposable parts. Oral appliances can provide relief to these problems, but dentists have little history of working with medical insurance companies. Oral appliances now comprise 2% to 3% of the market, and that percentage will increase slowly during the next few years.

- “ResMed does a good job of everything. They make good masks. Competitive bidding and increased competition are not leading to decreased market share for ResMed, but it will be a huge issue for a couple companies.”
- “ResMed’s oral device isn’t good. It is a flimsy design and can’t protrude the mandible. It has proven to be ineffective in many studies. Their device will not be approved for Medicare coverage, which will be a problem.”
- “There are three basic problems with CPAP market: 1) Patients often are not compliant within 90 days, meaning that their devices are taken away. Medicare and insurances won’t pay for them after a certain period. 2) Competitive bidding, which has occurred in nine areas around the country, is driving reimbursements down by

35% to 45% on machines and disposables. It is affecting revenues. 3) There is a movement to not replace parts unless nonfunctional and broken. They won't automatically pay for disposables."

- "The oral appliance market is very small, 2% to 3%. It will grow slowly in the next few years to 5% to 8% and eventually more because at least one-half of the people do not comply with CPAP. It's a matter of patient access. Dentists are not vigilant in getting into medical insurance. We need to have this insurance ratio go up; then patients would not have to pay out of pocket for oral devices."
- "There is 85% to 90% compliance for oral devices. This is a more stable area than CPAP."
- "A lot of dentists are opting out of Medicare because the reimbursement is not enough."
- "TAP has 75% of the oral market, and SomnoMed has most of the rest. Now with the Medicare approval of Herbst, that essentially kicks everyone out."
- "The FDA and Medicare just came out supporting Herbst. Dentists who are prescribing other oral appliances, even the most popular ones, could have problems without an FDA approval."
- "The CMS and FDA policy change and appliance approval are a mess right now. They approved only two of three Herbst appliances because two labs got early approval during competitive bidding. However, these labs have no traceable [FDA 510\(k\)](#) registration. This was a classic disconnection; there aren't any kickbacks. There are thousands of dental labs, and the FDA got flooded with requests, it got so out of hand. They need to reclassify the policy. We are in the process of reapplying for the 510(k); we are refilling out everything."

5) INDUSTRY SPECIALISTS

These eight sources reported growth in the sleep apnea market and pricing pressure from reduced reimbursements and increased competitive bidding. ResMed and Respirationics are the clear market leaders. Fisher & Paykel and DeVilbiss hold niche positions with quality products. In-home sleep studies are on the rise because of third-party payers' cost-containment measures. One source said small DMEs will be forced out of business because reduced reimbursements will result in tight margins. The use of oral treatment devices is on the rise. A source representing an oral appliance lab said the devices comprise 5% of the market today but that usage will grow 10 to 15 times in the next 10 years. Other new treatments will serve only a small number of patients.

➤ Executive at an OSA patient education organization that provides CPAP supplies and instruction

ResMed and Respirationics compete head to head in the CPAP market. Respirationics has an advantage in data management, while ResMed dominates the mask market. Continued price pressure from payers is driving in-home sleep studies and default therapy. CPAP is the established therapeutic standard. New technologies are promising but unproven.

- "Downward price pressure from payers is consistent across the board. The allowed number of masks and other disposable components is going down."
- "Payers drive the clinical patterns for care. Aetna, United, Harvard Pilgrim [Healthcare Inc.] and others are making in-lab sleep studies difficult. Within two years, every payer will bias payment toward home sleep studies unless significant comorbidities exist."
- "Physicians claim the diagnostic value is much higher for in-lab sleep studies. They want to be able to rule out other problems. But the truth is that OSA can be presumptively diagnosed on presentation, in about 20 seconds. The payer is driving cheaper approaches to diagnosis. There is a trend now from presumptive diagnosis to default CPAP therapy. The additional sleep studies are done only if CPAP does not resolve the problem."
- "The direct-to-CPAP approach makes sense to me. CPAP is a no-harm therapy and an effective approach to cost containment. Payers are partnering with utilization management companies like [CareCore National \[LLC\]](#) and [CareCentrix \[Inc.\]](#) to drive behavior toward the lowest cost options."
- "CPAP systems have two basic parts: a blower and a mask. The software algorithms may vary somewhat, but the basic CPAP brands are functionally equivalent. DME companies will buy whichever is cheaper."
- "CPAP therapy brand selection is made either by the physician or the DME. Some physicians are closely involved with the process, but in general they leave it up to the DME. The patient load is simply too high for a lot of personalization by the provider. Some MDs will make mask

The Respirationics system has better data capabilities, which makes it more useful for home sleep studies.

*Executive
OSA Patient Education Organization*

recommendations based on previous patient success.”

- “Mask comfort is a significant driver when patients are given the option. Currently, ResMed manufactures the most frequently used masks. The company is good at developing their brand and in-lab presence. ResMed probably controls 75% of the mask market.”
- “Respironics has recently come out with better mask options, but they have a lot of catch-up to do.”
- “Fifty percent to 60% of patients will not start out with a good mask fit. About half of new patients quit CPAP therapy altogether within two to three months.”
- “ResMed and Respironics each have about 45% of the blower market. The remaining share is split between the small players including Fisher & Paykel and DeVilbiss.”
- “In general, Respironics has a friendlier, more supportive approach with DMEs. ResMed has a reputation for heavy-handed treatment of their DME partners.”
- “The Respironics system has better data capabilities, which makes it more useful for home sleep studies.”
- “There are new technologies for OSA therapies. Provent uses the patient’s own breathing patterns. Apnicure is an interesting development that uses positive pressure to pull the tongue forward. These new devices may encroach on the CPAP market if they prove clinically effective and demonstrate better patient compliance, particularly if there are associated cost savings.”

► Executive at a nonprofit organization focused on sleep apnea

Pricing in the OSA market have been pressured downward by third-party payers and reduced Medicare reimbursement. CPAP devices are the most effective, especially for severe cases. Respironics and ResMed lead the market, with ResMed slightly behind Respironics. ResMed offers more mask variation and increased patient comfort, but its machine technology is very similar to Respironics. Other vendors such as Fisher & Paykel and DeVilbiss have much less share. Alternatives such as dental appliances and [expiratory positive airway pressure](#) (EPAP) devices are not as universally effective. CPAP alternatives are typically investigated secondarily and only for CPAP failures. Surgery and other innovations such as HGNS are still under development. In-lab sleep studies are on the decline. The CPAP device brand is typically recommended by the physician. Many DME distributors, particularly large organizations like Apria, directly ship to patients, who then often receive little to no educational/utilization support and have low compliance rates.

- “There is a lot of downward reimbursement pressure. It has a negative impact on the OSA market as a whole.”
- “The payers are directing patients away from in-lab sleep studies and toward more cost-efficient home studies. Still, a lot of people who need them are not getting them done.”
- “Home studies are self-administered. The accuracy depends on the severity of the patient’s sleep apnea, but many of the testing devices are not sufficiently accurate to be of diagnostic value.”
- “Patients are frequently left on their own to figure out the CPAP. The resulting high level of noncompliance then results in significant health consequences.”
- “Philips/Respironics and ResMed are the CPAP leaders. I believe Respironics may be slightly ahead, but their shares are similar. There are other good CPAP products, but the leaders have very well-developed networks. The smaller companies have difficulty gaining market share.”
- “ResMed offers an alternative to Respironics. They have greater variation in masks to address individual patient comfort, which is a differentiator. The basic technology is equivalent to Respironics.”
- “The positive pressure [CPAP] devices are the default OSA therapy. They work best, especially for severe cases. There are really not any substantial studies to show the performance of alternative therapies such as oral appliances and surgical intervention. In the case of oral appliances, another factor is that there are far fewer dentists involved with OSA, compared with ENTs and pulmonary physicians.”
- “Newer technologies including hypoglossal nerve stimulation and expiratory PAP are innovative solutions. The Provent uses the patient’s own breathing, so requires no electricity or water. As I understand, Provent works in approximately 50% of OSA cases. It is probably a good fit for CPAP failures, but it is not as effective for severe apnea. The device cannot reach the required level of positive airway pressure.”

I am not aware of a patient CPAP device preference. They would rather not have any device at all. The CPAP brand is typically recommended by the physician. Unfortunately, if the patient is uncomfortable with the original device/mask, they will often just give up on CPAP altogether.

*Executive, Nonprofit Organization
(Focused on sleep apnea)*

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➤ **State sleep society chair with 19 years of industry experience**

Competitive bidding has hurt the sleep apnea industry, primarily because of underbidding by small DMEs. Tighter mask regulations will worsen and hurt mask manufacturers (primarily ResMed) and potentially R&D. Manufacturers are expanding into other markets such as COPD and rheumatology.

- “The competitive bidding was bad for everybody. Some [particularly small players] bid extremely low for the contract and couldn’t even keep the contract, but they lowered reimbursement for everybody else. It’s next to impossible to deliver the care that people need. Some [DMEs] went for more of the insurance business to increase their volume. Or you cut costs by not going to people’s homes or shipping devices to them, or if you’re big enough you negotiate with the manufacturers on what you’ll purchase. The end point is the patient doesn’t do as well and you end up with more complications.”
- “We’re already seeing [tighter mask regulation]. We’re just at the tip of the iceberg. With current economies, patients are willing to wait much longer for their supplies, and they delay because they don’t want to pay their copay. If mask manufacturers are hurt because fewer orders coming in, what happens to R&D?”
- “ResMed and Respirationics are neck to neck, and it’s based on the preference of doctors. In our area it’s 60% [brand-specific]. The reps do a great job. If it’s up to the DME, they pick the lowest cost.”
- “Both Respirationics and ResMed have really strong products. They’re also neck to neck in the in-home testing market. Doctors have been forced to be on board, and now both companies are taking advantage of that.”
- “Fisher & Paykel have a good solid machine, good quality, lasts the tests of time, but they have to compete with the other two. From a cost perspective, Fisher & Paykel is more reasonable, but they’re so far behind.”
- “Instead of products, we’re going to see manufacturers start selling machines for other than sleep apnea, such as the COPD population, which can keep them out of the hospital. ... In some areas Respirationics machine does several modes of therapy.”
- “Volumes are increasing because of comorbidities that we now know can be complications of sleep apnea, and treating them lessens hospitalizations for things like stroke and heart disease. ... It’s not as high as it used to be because of the reimbursement issue.”

➤ **Sleep apnea consultant and former sleep disorders program director**

Shrinking reimbursement is resulting in more cost-containment measures in sleep study screening and disposable supplies. CPAP remains the standard therapy. ResMed has a clear advantage with better mask design and comfort. Developing technologies will fill a niche among noncompliant CPAP patients, rather than erode significant CPAP share. The population of diagnosed OSA patients is growing.

- “CPAP pricing is very competitive. There is a lot of downward pressure on reimbursement.”
- “Medicare requires proof of compliance before fees are paid, creating a more than 30-day lag for payment. Medicare is also squeezing reimbursement and allowances for supplies. Patients used to be allowed a new mask every six months. Now it is an annual allowance.”
- “Small DMEs are being forced out as a result of the tight margins. The ones who provide high-touch service and education still have a niche, and their compliance rates are high. Big DMEs like Apria provide little to no patient support. This decreases compliance rates significantly. The first few weeks on CPAP are critical to ongoing compliance. The national average for large DMEs is 41% CPAP compliance.”
- “The trend toward in-home sleep studies is being pushed by the third-party payers. Physicians prefer the detailed information they get from the lab, but patients prefer home [studies]. Until recently, the home devices/data was relatively poor. Now home studies provide solid information.”
- “The use of home studies may serve to increase overall study volume for labs. Positive home studies should be titrated in the lab. Since reimbursement is the same for polysomnography or titration, labs could see overall revenue growth as a result in the shift toward first-

I have not seen anything yet that has come along that will erode any significant CPAP market share. But technology cannot be stopped. Ten years ago I would have never thought home studies would be a factor.

*Sleep Apnea Consultant & Former
Sleep Disorders Program Director*

line home studies.”

- “Physicians usually have a preference of CPAP brand. Because 90% of compliance is dependent on mask fit and ResMed’s mask designs are more advanced and comfortable, ResMed is preferred.”
- “CPAP is the established and reliable OSA therapy. Alternative technologies are likely to fill niches. Oral appliances are getting more traction because more dentists are becoming familiar with sleep apnea. Oral appliances can be a good fit for noncompliant CPAP patients, especially those with mild to moderate OSA.”
- “I have not seen anything yet that has come along that will erode any significant CPAP market share. But technology cannot be stopped. Ten years ago I would have never thought home studies would be a factor.”
- “The diagnosed OSA population is expanding. A traditional sleep center patient is a male, 25 to 55 years old, overweight, unfit, a snorer. Today’s cardiology focused sleep centers have a lot of fit, female, post-menopausal patients with severe sleep apnea. Pulmonologists and neurologists used to dominate the field. Cardiologists are becoming more involved now. If and when they embrace routine sleep study screening, the market will explode. Fifty percent of cardiology patients have a sleep disorder.”

➤ **President of an oral appliance laboratory**

ResMed, Resironics and Fisher & Paykel are all good companies. However, ResMed makes a poor oral device, which will never win approval. (Resironics and Fisher & Paykel currently do not offer an oral device.) The oral appliance market is expected to increase by 10- to 15-fold in the next 10 years. Oral appliances are less expensive, do not require replacing disposable parts, and have a 93% compliance rate compared to a 30% CPAP compliance rate. Oral and CPAP devices are starting to be used in tandem. Eventually, CPAP will be used only for neurological or genetic sleep apnea (5% of the market), and the oral appliance market will hold 95% of the market, which has OSA.

- “ResMed is a good CPAP company; so are the other guys, Resironics and Fisher & Paykel. But ResMed makes a horrible oral device. No one likes it, and it won’t be approved.”
- “The oral appliance market is definitely gaining steam, and it will greatly reduce the CPAP market. The oral appliance market will increase by 10 to 15 times in the next 10 years. Right now the oral appliance market is 5% of the obstructive sleep apnea market.”
- “We doubled in size last year. We are gaining so much steam. ... The oral appliances are making a difference.”
- “The CPAP will always be around because there is a small percentage, maybe 5%, whose sleep apnea problems are neurological or a genetic disorder and not obstructive, when the tongue gets in the way. OSA causes 95% of all cases, and oral appliances can address these cases.”
- “The [American Sleep Disorders Association](#) came out with a statement last year recommending oral appliances as the first line of defense for mild to moderate obstructive sleep apnea. That has brought oral appliances to everyone’s attention.”
- “Compliance for our oral device is 93%, way better than for CPAP, which is around 30%, and herein lies the issue.”
- “CPAP and a combination therapy with an oral device will gain momentum. Dentists are starting to work with medical doctors.”
- “To date, the FDA has only approved two labs in the United States for sleep apnea oral appliances.”

CPAP and a combination therapy with an oral device will gain momentum. Dentists are starting to work with medical doctors.

President, Oral Appliance Laboratory

➤ **Medical director of clinical coverage for a health plan, East Coast**

This source uses ResMed and Resironics equipment and is satisfied with both vendors. Patient volumes for sleep apnea are definitely going up. The source was not aware of further CMS cuts. A more liberal policy would be less expensive than handling complaints of leaky masks. Patients are followed carefully at home for 12 months, and rarely are patients denied equipment because of noncompliance.

- “I’ve not heard about CMS cuts related to sleep disorders, but I would imagine there will be less money coming in. I’m not sure if other insurance companies will follow.”
- “The sleep testing numbers are definitely going up.”
- “Some patients decide they can’t afford the copays, so they chose not to do the program.”
- “We are looking to liberalize our present policy for mask replacement. We currently have a six-month policy, but one of our members, who is a practicing oncologist, noticed that his mask was leaking after just a few months.”

We are in the process of looking at competitors' policies. From an economic standpoint, it would be less expensive to have a flexible plan and a proper mask fitting, than to deal with and overturn complaints."

- "CMS currently has a six-month policy on masks and a three-month policy on tubing. Most masks are made well. This is not a bad policy."
- "The vendors take care of at-home monitoring, to ensure compliance. They follow the patients carefully for the first 12 months to ensure that they are doing OK. Some patients may get a warning if they are not using the equipment appropriately. In rare cases, the patient is denied, and the equipment is taken away after a year. The patients may or may not appeal that process."
- "[Testing for] sleep apnea addresses a lot of health issues. Under our plan, oral appliances for obstructive sleep apnea are considered a medical necessity."

➤ Volunteer sleep apnea educator and CDL CPAP user

This source's comments and opinions are limited to the unique requirements of commercial drivers. As many as 30% of the 11.5 million CDL holders in the United States suffer from sleep apnea. The Department of Transportation (DOT) is expected to mandate a sleep study for all drivers with more than [35 body mass index](#). CPAP is the only OSA therapy approved for CDL truckers. ResMed offers the most commonly used and least problematic unit. In-lab sleep studies are still a requirement for DOT medical clearance.

- "ResMed and Resironics are the CPAP market leaders and really the only options for drivers. Each provide a 12-volt power supply, temperature and altitude tolerance, humidification, and means to assure data integrity. The smaller players like Fisher & Paykel and DeVilbiss have no external power supply. The Somnetics [International Inc.] [Transcend Portable CPAP](#) has good direct battery power but no humidification. Humidification is essential for truckers."
- "Every CPAP system has its advantages and disadvantages. ResMed has the largest market share because it has the fewest issues. The intake filters, however, need to be replaced. This can be an inconvenience. The Resironics humidification chamber is difficult to open and clean. Both ResMed and Resironics have good data management packages that make hacking very difficult. Fisher & Paykel CPAP is bomb-proof, easy to open and clean, with good pricing, but it does not offer an external power supply. The DeVilbiss system is very easy to hack, so does not offer data integrity security."
- "Cost and reimbursement are big issues. Approximately 50% of commercial drivers are independent operators. Less than 20% of them have medical insurance."
- "Some large companies already require a sleep study screen for all drivers. The company covers the cost of the screening and CPAP therapy."
- "Qualcomm [Inc./QCOM] is working with one of the major fleet management companies to build a CPAP communication/compliance data management [system](#). None of the CPAP manufacturers is validated yet."
- "Regulation dictates in-lab sleep studies for truckers. If a driver is positive, s/he leaves with a CPAP. Their compliance data has to be verified to get a DOT medical card."
- "Oral appliances are not approved for commercial drivers. There is no way to assure compliance and the efficacy is questionable. I believe this restriction is applicable for FAA certifications also."
- "Surgery is not recommended as a first line of treatment for truckers. The initial procedure is expensive and leaves the driver out of work for months. Then the driver needs to be assessed annually, which is not covered by insurance."
- "For other technologies like HGNS, compliance would be difficult to prove even if the therapy is effective. Practical issues like power supply would also have to be addressed."

➤ Assistant professor at a pediatric sleep center

CMS cuts of 30% are coming, but mask regulations will be difficult to enforce in the pediatric market. Compliance is the same in kids and adults, although children need to wear their masks for more than four hours per night. Better pediatric devices are needed. Sleep apnea is increasing in the patient population; currently, 1% to 3% of children are affected.

- "Medicare is definitely cutting costs for sleep apnea 30%. It is just a matter of time."
- "I haven't heard about mask regulations changing, but that will be difficult for growing kids."
- "Few CPAP devices are approved for pediatrics. Resironics is one. I'm not sure what brands patients prefer."
- "One percent to 3% of kids have sleep apnea. The increase is mimicking the increase in obesity, just like in adults."

- “We need better pediatric devices, but there is not a lot of money in pediatrics. We have a lot of hoops to go through to get products approved.”
- “Forty percent of the kids are compliant, about the same as the adults. It’s best to get the kids to wear the masks. The kids are going through critical growing periods, metabolic function changes, and it could affect them cognitively.”
- “If adults wear the masks just four hours at night, or 50% of the time, they are compliant. But kids sleep more, and four hours is not enough time for them to benefit.”

Secondary Sources

The sleep apnea diagnostic and treatment market is expected to grow to \$8.4 billion by 2018. ResMed’s plans for future growth are in new markets, including the treatment of non-sleep apnea breathing disorders. A poll of a sleep apnea patient forum’s CPAP users revealed that ResMed and Respironics were the clear leaders in CPAP equipment.

➤ Aug. 11 HME News [article](#)

ResMed was featured in the August issue of HME News. The company is looking for a 10% per-year growth rate and expects to achieve it through new markets, including the treatment of sleep disorders other than sleep apnea.

- “Michael ‘Mick’ Farrell, president of ResMed Americas, likes to call the company a 22-year-old start-up. That would explain why, earlier this year, ResMed was nimble enough to shake up its management team and business units, creating a company that Farrell says is poised to continue growth in its existing core market of sleep-disordered breathing and explore growth in new markets.”
- ““Sleep-disordered breathing (SDB) is really our bread and butter. But that market is growing in the 6% to 8% range in the Americas, and we’re positioning ourselves for growth of 10% or more. So we have to look at ways to expand SDB growth by working with our HME partners to market to primary care physicians and new referral sources, but also to explore new potential areas for growth,” [said Farrell].”
- ““Homecare and sub-acute ventilation is an enormous opportunity for us. Also, there is the dental SDB market. We made an acquisition in 2009 of a company that has a dental sleep medicine device in France. We have expanded that throughout northern Europe and now we’re just starting to bring that over to North America. How can we best partner up with physicians, sleep labs, and HME providers to allow access to this product? Additionally, there’s the cardiac market. For 10 years or more, we have been investigating and researching the heart failure markets in the United States and in Europe. We’re more than halfway through a large trial looking at 1,260 heart failure patients who have central sleep apnea, Cheyne-Stokes respiration, and/or OSA, getting these patients on treatment and turning their lives around. There’s also the perioperative care market: Models where hospitals screen and diagnose OSA pre-op and ensure that the patient is on treatment in the hospital and moves to a discharge planner to ensure subsequent sleep therapy in the home is an enormous opportunity.”

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HME News Article

➤ Oct. 5 *San Francisco Chronicle* [article](#)

The global sleep apnea market is expected to reach \$8.4 billion by 2018 because of increased knowledge in both the medical community and the general population. Approximately 100 million people worldwide suffer from sleep apnea, including more than 18 million in the United States. The sleep apnea treatment market is expected to grow the fastest, at 18.9% CAGR, in the Middle East, Asia-Pacific, and Latin America.

- “The global market for Sleep Apnea Diagnostic and Therapeutic Devices is projected to reach US\$8.4 billion by 2018, driven by rising awareness of Sleep Apnea in both the general population and medical fraternity, and increased penetration of devices. Rising obesity levels, development of latest technologies in both Diagnostic

and Therapeutic segments, large base of undiagnosed sufferers, knowledge regarding the inter-relationship between Sleep Apnea and other conditions, and the usage of devices for Home Sleep Testing constitutes the other factors expected to drive market growth in the future.”

- “There are around 84 types of sleep disorders presently known, of which [Obstructive Sleep Apnea \(OSA\)](#) is the most frequently occurring type, with about 100 million individuals across the world suffering from OSA. Of this, about 83% of the cases are still undiagnosed. However, the awareness of the disease condition, and of the co-morbid conditions, among patients and doctors is growing. Against this backdrop, given the large percentage of undiagnosed sufferers, there exist vast prospects for sleep apnea diagnostic and therapeutic devices. Increasing preference for home diagnostics is encouraging individuals to undergo sleep testing in the comfort of their homes, increasing the rate of diagnosis.”
- “Sleep apnea is seen in more than 18 million individuals in the US. The sleep therapy sector presents lucrative growth opportunities given the increasing number of patients diagnosed with OSA in the US. Nevertheless, growth is expected to mainly surge from the emerging markets, including the Middle East, Asia-Pacific, and Latin America. The regions together are projected to surge ahead, exhibiting a CAGR of 18.9% over the analysis period. With better equipped sleep labs and increasing knowledge among general physicians, the markets are geared up for significant growth. Europe and Japan offer more significant growth opportunities compared to the US, given the fact that penetration rates are much lower than in the United States.”

➤ **October poll of 48 [Apnea Board](#) members**

Forty-nine Apnea Board members were polled to determine which CPAP machine they use. ResMed and Respirationics emerged as the clear leaders.

- ResMed 29 users
- Respirationics 15 users
- Fisher & Paykel 3 users
- DeVilbiss 1 user

Additional research by Linda Richards, Renee Euchner, Steve Evans and Pam Conboy

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