ResMed's Hold on CPAP Market Will Be Weakened by CMS Bid Program

Companies: AMS:PHIA/PHG, ASX:SOM, BX, LNCR, NZE:FPH, RMD

March 8, 2013

Research Question:

Will the 47% Medicare reimbursement cut scheduled for July 1 derail ResMed's growth and give rise to low-cost competition?

Summary of Findings

- All 16 sources expect ResMed Inc. (RMD) to lower its prices in order to remain competitive once the second round of the CMS' Competitive Bidding Program cuts takes effect on July 1. This will lead to reduced margins for ResMed and other CPAP equipment manufacturers that follow suit on pricing.
- ➤ ResMed and Philips Respironics (Philips Electronics N.V./AMS:PHIA/PHG) will hold onto their lead positions but will lose some market share. Low-cost competitors operating offshore and online will claim more share as DME suppliers and patients look for lower-priced equipment. The CMS' low reimbursement rates are expected to be accepted by DMEs inexperienced in the sleep device field, calling into question their quality of patient care and follow-up support.
- Philips Respironics could be shielded from greater share losses by its larger, more diverse product line and improving mask quality.
- ➤ CMS reimbursement cuts are expected to create extreme hardships for small DME suppliers, rural and small sleep clinics, and equipment manufacturers with limited product lines. This could lead to reduced competition—the opposite outcome expected from the CMS' Competitive Bidding Program.
- ➤ Home testing for sleep disorders continues to gain traction and is expected to increase the diagnoses of obstructive sleep apnea, which will lead to more treatment and higher equipment sales.
- ➤ One primary source and one secondary source discussed efforts by trade association groups and some members of Congress to replace the Competitive Bidding Program with the industry-preferred Market Pricing Program by year's end.

| | ResMed Pricing | Low-Cost Competition | Home Testing |
|-----------------------|-------------------|-------------------------|--------------|
| Sleep Therapy Clinics | 1 | 1 | 1 |
| Sales Professionals | 1 | 1 | 1 |
| Industry Specialists | 1 | 1 | 1 |
| Medical Professionals | 1 | 1 | → |

Silo Summaries

1) SLEEP THERAPY CLINIC MANAGERS

All four sources expect ResMed and Philips Respironics to remain the CPAP industry equipment leaders but to be affected by slower growth, lower prices and possibly the need to produce lower-cost equipment in light of increased competition. Home testing is expected to increase the rate of obstructive sleep apnea (OSA) diagnoses and the purchase of equipment. Two sources view Respironics' larger product line as a competitive advantage, but all four sources said ResMed has superior quality products. Smaller sleep labs and DME suppliers will be challenged to stay in business as a direct result of CMS reimbursement cuts. DMEs' quality of care also will suffer as these providers will not be able to offer as much patient education and follow-up services.

2) EQUIPMENT SALES PROFESSIONALS

These five sales professionals representing an online CPAP equipment retailer, two DME suppliers and two manufacturers of sleep apnea oral appliances said ResMed will remain a market leader but will be affected by CMS cuts and will need to lower its prices. This will result in lower margins. Four of the five sources expect increased competition from lower-cost providers. The two sources representing the oral appliance segment think their alternative treatments will gain share. Home testing is expected to increase the number of patients diagnosed with sleep apnea, which will boost DME suppliers' supply sales.

3) INDUSTRY SPECIALISTS

These three sources expect prices for CPAP equipment to decrease and the major equipment manufacturers to maintain their leadership positions. Two sources think ResMed is more at risk of losing share than Respironics, which has a larger and more diverse product line. Smaller companies and some DMEs may go out of business and lessen patients' access to services and follow-up. Low-cost, offshore competitors are on the rise, but the quality of their equipment is questionable.

4) SLEEP APNEA MEDICAL PROFESSIONALS

These four sources said ResMed will have to lower prices and yet increase its product diversity and innovation in order to remain an industry leader. Lowercost competitors are expected to continue to emerge, but their equipment quality is an issue. One source expect oral devices to gain traction because of their lower cost and high compliance rates.

Background

Sources for Blueshift Research's Oct. 18, 2012, report said ResMed was secure in its lead position despite its increasing challenges that included declining CMS and health insurance reimbursements, the CMS' Competitive Bidding Program, and greater competition from low-cost vendors. ResMed continued to post record growth throughout 2012. However, the second round of cuts from the program is expected to take place by July 1, and Blueshift's Feb. 22 Whisper found that these cuts of 47% are much higher than the 28% expected by the industry.

CURRENT RESEARCH

In this next study, Blueshift assessed whether the 47% cuts on July 1 will derail ResMed's growth and create more room for low-cost competitors. We employed our pattern mining approach to establish sources in five independent silos:

- 1) Sleep therapy clinic managers (4)
- 2) Sleep apnea equipment sales professionals (5)
- 3) Industry specialists (3)
- 4) Sleep apnea medical professionals (4)
- 5) Secondary sources (3)

We interviewed 16 primary sources, including five repeat sources, and identified three of the most relevant secondary sources focused on the sleep disorder diagnosis and treatment community.

Next Steps

Blueshift will monitor the CMS' July 1 round of reimbursement cuts for sleep disorder treatment equipment to determine how they affect ResMed and Philips Respironics. We will determine if DME suppliers have resorted to offering lower-cost equipment, which could eat into ResMed's share. We also will monitor industry efforts to replace the CMS' Competitive Bidding Program with the Market Pricing Program. Finally, we will research the health insurance industry's position on reimbursement for sleep apnea equipment.

Silos

1) SLEEP THERAPY CLINIC MANAGERS

All four sources expect ResMed and Philips Respironics to remain the CPAP industry equipment leaders but to be affected by slower growth, lower prices and possibly the need to produce lower-cost equipment in light of increased competition. Home testing is expected to increase the rate of obstructive sleep apnea (OSA) diagnoses and the purchase of equipment. Two sources view Respironics' larger product line as a competitive advantage, but all four sources said ResMed has superior quality products. Smaller sleep labs and DME suppliers will be challenged to stay in business as a direct result of CMS reimbursement cuts. DMEs' quality of care also will suffer as these providers will not be able to offer as much patient education and follow-up services.

- Sleep clinic manager whose service area will be affected by CMS's July 1 cuts; repeat source
 - The resulting cuts of about 35% in this source's area were in line with his expectations. Both ResMed and Respironics are offering package deals with lower pricing and may be forced to develop lower-cost equipment in response to increased competition. Although ResMed continues to have the best products, Respironics benefits from a larger product line. Meanwhile, DeVilbiss Healthcare LLC has gained share in the Veterans Administration (VA) system. An increase in home testing will boost demand for equipment. Smaller DMEs and sleep labs will close as a result of the CMS cuts.
 - "[The cuts are] what we expected. We went from \$780 reimbursement diagnostic code to \$425. We've already had to change our staffing."



- "I don't think ResMed's growth will be derailed, but the slope of their growth won't be the same. A lot of the cuts will come from the DMEs instead of the sleep labs."
- "ResMed and Respironics are putting more time in their corporate contracts. In the future, insurers will say, 'Send all your patients to [Blackstone Group LP's/BX] Apria.' Or [the vendors] will develop competitive equipment that is lower-cost. ResMed may stop with the Mercedes and Lexus and go with more Hyundais."
- "We've already asked for better pricing. Both ResMed and Respironics are more creative. ResMed threw in two Apnea links and an oxygenator for CPAP testing. It was 'buy today and we'll do this for you.' ... Respironics has a package deal using 50 CPAPs today, and they'll throw in 20 masks. We're definitely working to maximize our revenue."
- "The price break [between ResMed and Respironics] is not so big that it swings everybody to the other machine. A lot is service and quality, and it's not \$200 less, usually \$30 to 40 less. If you do 200 of them, that adds up, but it's negotiable. Plus, they come up with these great deals to make up for it."
- "Respironics will benefit more because of their larger product line. They'll bid in some nebulizers with the CPAP and the whole package. ResMed still has the best products, the best masks."
- "Every product ResMed comes up with is a winner. Respironics will have new products, but I often think this is really worthless. ... The technicians will pick the ResMed over Respironics 9.5 times out of 10 because it's so easy to titrate."

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Sleep Clinic Manager

- "DeVilbiss is making moves on the VA with their equipment; they're here more because we have a large VA hospital. But it's not the same. I would take a Fisher & Paykel [Healthcare Corp. Ltd./NZE:FPH] over a DeVilbiss. I don't know if they'll gain share. A lot is marketing. ResMed and Respironics have made a commitment. They both have great sales reps. Fisher has a very limited sales force. We see their rep once a quarter, as opposed to Respironics where we have one [sales rep] in town. And our ResMed rep is only 200 miles away."
- "The home market is helping [ResMed and Respironics] because of access to more patients. It's a conversion from in-house to home studies, but there's no new growth. Price is the same."
- "The home test market has really taken off like fire. ... We're doing the home sleep market, but instead of \$700 we were getting it's \$150. Aetna [Inc./AET] was the first insurer that required that change last June, when they refused to pay for an in-house test."
- "Smaller labs will close. The two-bed labs will probably close because there's no need for them with at-home sleep studies. The small DMEs will close, with the Aprias and Lincares [Lincare Holdings Inc./LNCR] taking more business."

Office manager of an East Coast university-based sleep center in a region to be affected by the CMS round-two cuts

ResMed will retain its leadership position because of its superior equipment, but the use of lower-price equipment may become a trend. This source already has experienced service problems with DMEs like Apria Healthcare, and is concerned the upcoming CMS bids will aggravate poor service problems. The center tests a large number of children under age 18, who are not approved for home testing.

- "I don't think [ResMed] will be hurt. They and Respironics have the superior machines that our companies use and that our doctors prefer. ... I haven't heard this, but they might have to use lower-cost equipment since insurers are looking into cutting costs. I don't know. There might be ways to do that without sacrificing care."
- "I'm aware of the bids going out to DMEs and them starting July 1. I'm anxious. I'm going to lose some of my very good companies. The [awarded DMEs] do the bidding and then can't do the required work in the back office, or they can't spend the necessary time educating the patient. I try to steer away from those companies, or for example, anybody who doesn't send me the compliance forms."

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Office Manager, University Sleep Center East Coast

- "I had a terrible time with [a local Medicare provider] because Apria was the company they said I had to use. We got so many phone calls from patients. I called our hospital's head of managed care about how I shouldn't be forced to use one company and he had to go to the top, but I was able to use a service where Apria was only the preferred vendor so I could go elsewhere. I'm getting 10 times the positive response."
- "Those under age 18 don't get an at-home test. We do two children and six adults each night. We have a long wait list to see the doctor."
- "We are not doing in-home sleep studies. Our doctors don't agree with it. But our [local] Blue Cross Blue Shield is requiring it, so I don't know what will happen. We have so many patients whom we find major problems with because in-home studies don't do the EKG and don't monitor oxygen levels. We do a much more comprehensive study."

Manager for a Southern university-based sleep lab in the CMS' round-two cut area

ResMed is more vulnerable because its product base is more limited than Philips Respironics'. Both companies will continue to be top competitors, but will need to reduce pricing. ResMed makes a better mask, and makes efforts to improve patient compliance. The sleep market is overpriced, and more reasonable prices eventually will stick. In the meantime, everyone—including sleep clinics—will feel the Medicare cuts.

- "The two companies will need to maneuver prices around a bit to maintain sales. I can see them being neck-and-neck."
- "ResMed makes a better product. They put more energy and research into it. The goal is to get compliance up, and ResMed does work on this."
- "We have a good relationship with ResMed, but we only offer limited supplies such as masks."
- "Making cuts will affect everyone across the board. The cuts will certainly affect all of us. Somewhere along the line it will affect sleep clinics. If patients can't afford a set-up, they will cancel the test."
- "I could see low prices sticking. More reasonable prices would be the new normal."
- "Sleep studies are too expensive, and the equipment is too expensive. The sleep field skyrocketed in the last 10 years without much follow-up. Some physicians opened up their own back-room centers in their offices and charged very high fees. They increased the cost for everyone. The prices kept going up and up, and now it is time to pay the piper."

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> Manager, University Sleep Lab South

- "Sleep studies cost somewhere between \$1,500 and \$5,000. Some insurances are now requiring split nights. Rather than a two-night stay, the insurance carriers will pay for a one-night stay with a mask on at midnight, for half of the night. Other insurances are requiring precertification for sleep studies."
- "Home studies save on cost on the front end. This wouldn't adversely affect ResMed or the other companies." People still need equipment,"
- "Sleep apnea problems are here to stay. America as a whole has more overweight citizens, and we haven't even scratched the surface of this field. The industry will survive and keep growing; we just need to decide on a price point."
- "Less than 5% of our patients use oral appliances. Oral appliances will never be that big. They are not a onesize-fits-all, and they are still uncomfortable to wear. Nasal pillows are the preferred way to go for many people. It's just a much smaller mask."

Director of a California sleep center in the CMS round-two area

How ResMed and the other manufacturers will be affected by the CMS' program is unclear. Quality is important, and lowcost manufacturers will not take share away from the leaders. Home testing will benefit manufacturers because more patients will have access to testing and treatments. Patients with secondary coverage should not be affected by the cuts. Hospitals are required to accept Medicare rates, and their clinics will have to do quality work for less funding.

- "I'm not sure [how ResMed and the other competitors] will be affected by the cuts. I don't know enough about their costs and business."
- "Lower-cost competitors will not infringe on market leaders. Quality is still important."
- "In-home testing is helping [manufacturers] because more patients will have access to testing."



- "[Medicare reimbursement] is still going to be 80% [reimbursement]/20% [copay for the patients]. So if patients have secondary coverage, I wouldn't think [the cuts] would affect them."
- "Hospitals are still required to accept Medicare rates, so again, I don't see why people with Medicare would defer testing and treatment. The clinics will bear the decrease in reimbursement and will have to figure out how to do the same quality work with less money."

2) SLEEP APNEA EOUIPMENT SALES PROFESSIONALS

These five sales professionals representing an online CPAP equipment retailer, two DME suppliers and two manufacturers of sleep apnea oral appliances said ResMed will remain a market leader but will be affected by CMS cuts and will need to lower its prices. This will result in lower margins. Four of the five sources expect increased competition from lower-cost providers. The two sources representing the oral appliance segment think their alternative treatments will gain share. Home testing is expected to increase the number of patients diagnosed with sleep apnea, which will boost DME suppliers' supply sales.

Sales representative for an Internet wholesaler

ResMed should continue to stay on top. Not all patients are on Medicare, and price cuts will not affect overseas sales, which accounted for 43.7% of the company's fourth-quarter revenue. Competitors will equally feel the cuts, and the top three will continue to compete in pricing and product launches. All DME suppliers have notified this source of impending price hikes for product accessories. Low-cost competition may not happen because wholesalers will not recommend ineffective products. Home testing will help DMEs by identifying people who need equipment.

"ResMed is worldwide. Because only U.S. sales will be affected by Medicare and because most apnea patients are not on Medicare, they continue to stay on top."

It is really hard to say how the companies major affected, but I imagine that each of them will feel the change.

> Sales Representative Internet Wholesaler

- "It is really hard to say how the major companies will be affected, but I imagine that each of them will feel the change."
- "All three top manufacturers are developing new products all of the time. They are always trying to improve things for the consumer to top the competition."
- "All DMEs have told us that they are increasing pricing of accessory products in April. We haven't seen it yet, but we know it is coming. We are expecting prices to be three times as much. We will have to charge more and also work harder to make up the difference."
- "Low-cost competitors may not happen. Some of them will not be approved in the process. I would not recommend the low-cost masks and equipment to our customers. This is something for their health, and it has to be good."
- "In-home is not a bad thing. A lot of the machines analyze pressures, oxygen levels. This just helps identify more people who need equipment."
- "People come to us if they haven't met their insurance deductible. Our prices are lower than going through insurance."

Vice president of sales and marketing for an oral appliance company; repeat

Price cuts will catch up with ResMed, and the company will be neck-and-neck on pricing with Philips Respironics. Low-cost companies already are affecting the market, but their masks will have to comfortable and effective to maintain sales. Home tests increase the number of diagnoses and ultimately will help DME suppliers.

- "I don't see how ResMed can go unscathed in the long run. They have held pricing to some extent, and it has angered customers. When there is fallout of the small DMEs, the national [DMEs] will dictate price."
- "ResMed and Resperonics will continue to modify their prices to compete. The companies will feel this."

Low-cost manufacturers are starting to make a dent. The cheap Chinese and Taiwanese blowers are already on Lincare's formulary. Masks are harder to change unless the cheap ones can duplicate comfort and performance.

> VP of Sales & Marketing Oral Appliance Company



- "Low-cost manufacturers are starting to make a dent. The cheap Chinese and Taiwanese blowers are already on Lincare's formulary. Masks are harder to change unless the cheap ones can duplicate comfort and performance."
- "In-home testing should help [DMEs because] they will get more folks diagnosed."
- "Medicare cuts will affect ASPs [average sale prices]."

Respiratory manager and sales for a home respiratory group on the East Coast

Medicare bidding wars and reimbursement cuts will affect DME suppliers and small sleep centers and will only add to patient confusion. ResMed will face more lower-priced competitors, hospital and physician-formed DMEs, and improved products by Philips Respironics and Fisher & Paykel. Home testing will benefit DME suppliers. Insurance companies are putting sensors on machines to ensure patient compliance.

- "The Washington cuts will make it hard for DME companies to stay alive, for mom-and-pop centers to stay alive. It has hurt all the small companies in the area except the low bidder."
- "There is more and more competition, especially over pricing. More companies will be forced to go with a good price, and there will be more lower-priced competitors. Some sell low-quality products that malfunction, and they are difficult to deal with all the way around. We have also dealt with wholesalers EVO and some others because we are invested in the patients. Those who won the bidding don't deserve it, but a lot of companies will buy whatever they can get."
- "A lot of hospitals and physicians are now doing their own DME. Physicians are opening up centers and offering their own products. This will cut into other companies as well."
- "The three leaders have been ResMed, Respironics and Fisher & Paykel. ResMed masks were the top of the line, the go-to. I like their products, and they were always trying to improve. But other manufacturers have also improved their products, and now Resperonics has good masks."

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Respiratory Manager Home Respiratory Group, East Coast

- "ResMed can be cocky, and they are not always fair."
- "Home testing will help the DMEs because more people will be willing to do the tests. It will improve their status. Patients like being at home and not going to a strange place. The flip side is that this makes our work harder. Patients haven't been titrated, and we aren't sure of how much air to give and the correct pressures or the type of mask to give. Lab experience gives all this information."
- "We didn't win a Medicare bid, and we are losing 25% of our clientele. [Medicare] only picked a select number of companies to use, and now people can't go to who they want to go to. This is more of a disadvantage to the patients, and it is very confusing to them. Folks are forced to go with the lower bidder. But if they have bought a machine from us and it needs to be serviced, then what do they do? The company they have been sent to will not help them. Medicare won't repair the machine."
- "There are just certain territories that have the bidding, only certain regions. And right next door will be areas that aren't in the bidding. We service both areas. I suppose we could try to service more folks outside the bidding areas."

California business manager for a sleep disorder device manufacturer

ResMed is the leader in the treatment of sleep disorders, with strong physician and clinic relationships that will help it to absorb the CMS cuts. Companies like Fisher & Paykel and DeVilbiss that have less share will be more adversely affected by the reimbursement cuts. Home testing will boost the number of people diagnosed with sleep disorders. The CMS program has created quality-of-care issues; some DMEs with no sleep-disorder experience have been winning regional bids for the sale, distribution, patient education and service of CPAP equipment.

"The reality is that ResMed is the market leader. Because a lot of physicians are deeply embedded with CPAP companies, the industry leaders' ResMed and Respironics products will still be prescribed. I think the cuts will have an impact on ResMed but less so than what the other manufacturers will experience. They have the established relationships with physicians and sleep labs and they have the volume that can absorb the cuts more easily than the midlevel players."

- "In the next year the middle players in the field, Fisher & Paykel and DeVilbiss ... will be adversely affected by the cuts. They don't have the market share."
- "The key here is 'single payment.' CPAP companies make most of their money from the recurring cost of peripherals: masks, hoses, interfaces, etc. If the single payment applies to all pieces of CPAP equipment, then it will definitely affect ResMed's margins."
- "It may even the playing field for non-CPAP therapies. If costs come into play, it may change prescribing habits on what types of treatments and equipment get prescribed by physicians. If physicians are not making the amount of money they are used to making off CPAP, they may be willing to offer patients validated alternatives such as oral appliances or [Ventus Medical Inc.'s] Provent."
- "These cuts have been rolling out on a regional basis for a year or so now, starting in North Carolina. All you hear is people talking about what a mess it's going to be because in the Charlotte area; 90% of the bidding companies that received CMS contracts were either companies not located in the region or were not in the home respiratory care space previously. There was great concern about the service that these companies would be providing to patients. ... It's just about getting the money as opposed to providing a quality service to patients.
- "By making testing more accessible, you will increase the number of patients getting diagnosed. By having alternatives to CPAP available, you increase the number of patients willing to come in for testing. Once

tested and diagnosed, their physicians can prescribe the appropriate therapy. Many sleep physicians still consider CPAP the only 'first-line therapy.' They will not recommend OAs [oral appliances] unless the patient has failed CPAP."

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Business Manager Sleep Disorder Device Manufacturer California

CEO of an East Coast DME supplier; repeat source

ResMed is expected to maintain its leadership position but will lose share because its pricing is too high and leaves no room for DME suppliers. Also, its overall revenue will be challenged by the new market dynamics.

- "ResMed's market will shrink. ResMed's wholesale rates are the same as or greater than the reimbursement rates. We won't be able to provide ResMed products to Medicare patients unless they change their arrogant ways and cost structure. But not giving patients a ResMed machine won't hurt the patient or us."
- "Growth will be difficult. They can maintain leadership, but market revenue will be smaller."
- "It's going to change behavior, and it's going to change product-and patients will miss out on support. Medicare never really provided patient support, but the previous fee had enough in it for us to be able to provide ongoing support."
- "Most of ResMed's customers don't want to work with them anyway."
- "Other, lower-cost products are becoming attractive. Asian companies are entering the U.S. market."
- "[Home testing] will help in theory; the same or more people will be diagnosed. But home testing usually requires a more expensive machine—an auto PAP machine. The Medicare rate for a basic machine and an auto PAP machine is currently the same, but with the cuts access to the more expensive machines will decrease for some patients."

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> CEO, DME Supplier Fast Coast



3) INDUSTRY SPECIALISTS

These three sources expect prices for CPAP equipment to decrease and the major equipment manufacturers to maintain their leadership positions. Two sources think ResMed is more at risk of losing share than Respironics, which has a larger and more diverse product line. Smaller companies and some DMEs may go out of business and lessen patients' access to services and follow-up. Low-cost, offshore competitors are on the rise, but the quality of their equipment is questionable. Home testing is increasing; two of the three sources expect this trend to result in greater diagnoses of sleep disorders, which will benefit equipment providers. One source expects Congress to overturn the CMS bidding program by the end of 2013. He also believes ResMed's business plan is not sustainable because it does not support the trade associations.

Executive director of a trade association

ResMed has lowered its prices as far as it can go; Philips Respironics and Fisher & Paykel can lower their prices even further because of their vast product lines. ResMed does not work with local associations, and frequently is the cause of insurance conflicts. The market will see an influx of offshore, low-quality equipment, which consumers initially will use but with negative consequences. Younger patients are more likely than Medicare patients to use sleep apnea equipment. New laws likely will be passed by the end of the year to overrule the unfair Medicare practices.

- "ResMed will lower its prices, but it is beaten down as far as it can go. It is a more honorable company than the others in that respect. The current retail level is low enough to allow a service component. Philips and Fisher & Paykel can lower their prices more because they have a broader base of products and can spread the pain."
- "ResMed, in particular, has a whole lot less to do with associations than Resperonics. They don't come to meetings; they are not supportive. That's a mistake. ResMed is shortsighted. They fail to support and work with local dealers, and this action is not sustainable. Philips has members at the highest levels, and they sponsor our activities. They are winners and working more appropriately."
- "ResMed is forever creating conflicts with Blue Cross. They make unilateral decisions and try to sell it to Blue Cross without our knowledge; then they report to us later."
- "We will see more offshore equipment, but it is of poor quality and shorter lasting. Consumers will use these products at first. Users don't have time to do research, and they don't have the knowledge base to make comparisons. They don't know good service; they rely on health professionals to help them. They will learn after they use these products for a while. We will start seeing horrible results following untreated sleep apnea. More problems will happen, and people will need to be killed before something is done."
- "A home test can be done with accuracy; at least it gets the treatment started. Home studies should grow and produce sufficient information for more prescriptions. This would be good for any business. ... If problems persist, then a patient may need a follow-up institution test, but this should be on demand, as needed."
- "The percentage of apnea patients who are covered by Medicare is actually small. Most sleep apnea is in younger people. In that respect, sales will be impacted to a lesser degree than you'd assume."
- "I don't think Medicare is going to get by with it this year. In all the 38 years that I've been fighting Medicare, this is the first year that Congress is united behind our plan. We need to make a paradigm shift. We have sponsors in both houses who are revising the current legislation to replace the bidding system. Medicare may well make their cuts by July 1, but this Congress will approve our alternative plan before Christmas. Then things will change. The question is, how much harm will happen before we are able to intervene?"
- "If the Medicare plan goes through, the government will be at the mercy of a few survivors, who then can change anything they want. Their plan will cause suppliers to go out of business, will decrease DME prices and will ultimately hurt the patient the most."

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Executive Director, Trade Association

- "Medicare has been cheating even the lower bidders by verbally committing them to a low price, but when they go to sign the contact, the stated price is even lower than the agreed-upon price. Companies are refusing to sign the contacts, which is why the bidding has been extended. We will know next week if more companies signed or if they have to rebid once again."
- "We need to ensure that efficient companies can survive; we need to pay them enough."
- "I've never seen the government do something so outrageous. The system has too many holes in it. Medicare has operated with total disregard to the people. They are very secretive about their methods, and they need to disclose their under-the-table methodologies. They have designed a train wreck of a system that is unsustainable. Their competitive bidding is a lost effort."
- "Insurance companies want to reduce rates. We are working with insurance companies, taking our argument to Blue Cross, convincing them that this is a bad idea. The services are worth more than the equipment. If patients don't receive instructions, you might as well just use the equipment for a doorstop."

Sleep researcher at a Midwest medical center

ResMed and its competitors will have to reduce revenues. Established companies will find a way to make the system work, but smaller competitors may go out of business. Cheaper masks from offshore companies may be popular, but only time will tell if they are efficacious. Home studies are being driven by insurance companies. They will help the manufacturers of CPAP machines because more equipment will be ordered.

- "We need to reduce health costs. Isn't that what this is all about? Big and small companies alike will have to make some changes, reduce some revenue to make this work for everyone."
- "The big companies, that includes ResMed, will find a way to make it work for them. The smaller companies are most likely going to struggle, and some may go out of business."
- "Offshore masks may become more popular because they would be less expensive. Now, if they work as well is a different matter. Fitting is important, and it determines what device is used and whether the patient is being treated effectively. We'd have to ask the nurse practitioners who fit the patients how that will work."
- "Home studies would improve things for the manufacturer because more patients would be prescribed for CPAP. This would also be beneficial for the home monitoring devices that these companies make. The home study devices would be purchased on a large scale."

The big companies, that includes ResMed, will find a way to make it work for them. The smaller companies are most likely going to struggle, and some may go out of business.

> Sleep Researcher, Medical Center Midwest

- "There's been a shift toward home study or outpatient care. The insurance companies, including our own local healthcare plan, are pushing for this. If there is a first failure of home study, then the patient is brought into the lab. The very important concern is the possibility of a misdiagnosis or ineffective application of treatment. This area has been little studied. There is no research on the cost-savings benefits. We haven't even started to access the benefits or the risks."
- "These companies are worried about themselves, but quite honestly, I'm worried about the patients. Can they get the right diagnosis, the proper treatment?"

COO of a sleep apnea treatment center company offering an alternative treatment to CPAP therapy

Although the push toward lower-cost equipment represents a challenge, both ResMed and Respironics have the monies required for restructuring and partnership building in the new environment. The DMEs awarded the bids stand to benefit most, with the higher volume counteracting the reimbursement cuts. Overall, DMEs and CPAP providers that establish the best partnerships with physicians will be the winners. Respironics has a slightly better product line than ResMed.

- "[CMS reimbursement cuts] will definitely affect ResMed, but I also think the bigger CPAP vendors will benefit the most. They have the money to do the proper restructuring. ... Respironics [has] a bit better product line. This is from the view of the end user and from the perspective of the physicians we talk to."
- "It helps those [DMEs] who win the bid. The gain in volume is more important with the lowered reimbursement."
- "[The lower-cost equipment] will be the concern for us. How is the quality of the lower-cost equipment going to be, and is it effective? How does the patient react to it? Is the patient going to be as comfortable? How many fall off and do not stay with the regimen? How does it affect the physicians who recommend the patient?"

- "DMEs are in a good position if they have the right relationship with the physician. They can push a physician and become a partner with them to get the right sleep apnea treatment."
- "I have a colleague who is a smaller [DME] provider and didn't get the bid, but he's pretty positive because with the Medicare changes he can build the right relationships with physicians and educate them about how we differentiate, especially in the non-Medicare market."
- "We use the statistic that 50% to 60% of people are undiagnosed with sleep apnea. This offers a huge opportunity for the sleep community in the treatment of sleep apnea."
- "I don't think the in-home market is helping one [CPAP vendor] over another. ... If the test is inconclusive, we can order the sleep lab. It postpones the acquisition of the CPAP if it's inaccurate, so it hurts the patients most."

[CMS reimbursement cuts] will definitely affect ResMed, but I also think the bigger CPAP vendors will benefit the most. They have the money to do the proper restructuring. Respironics [has] a bit better product line. This is from the view of the end user and from perspective of the physicians we talk to.

COO, Sleep Apnea Treatment Center

4) SLEEP APNEA MEDICAL PROFESSIONALS

These four sources said ResMed will have to lower prices and yet increase its product diversity and innovation in order to remain an industry leader. Lower-cost competitors are expected to continue to emerge, but their equipment quality is an issue. One source expect oral devices to gain traction because of their lower cost and high compliance rates. A source said the CMS bidding program was creating "suicide bidding" that would lead to a decline in the quality of patient care. Two of the four sources think home testing will lead to increased diagnosis of sleep apnea, while one thinks diagnoses will remain flat. The fourth did not comment.

Family dentist in California specializing in dental sleep medicine; repeat source

ResMed, Philips Respironics and Fisher & Paykel will compete in pricing. Medicare cuts will affect "everyone's profits." ResMed has responded to industry changes by offering other apnea devices such as a nasal pillow and an oral device, which eventually will be approved. These alternatives may gain in popularity as pricing becomes an issue for apnea masks or as difficulties with lower-quality masks become apparent. Home testing will allow more people to be diagnosed and treated.

- "All DMEs, not just ResMed, will have to cut back. Things have to come down, and there will be more pricing competition. The three big manufacturers—ResMed, Resperonics, and Fischer & Paykel—will have to compete with each other for lower pricing, and this will cut into their profits. It will cut into everyone's profits. I'm not sure what will happen in this current climate."
- "ResMed may be looking for other ways to stay afloat. The ResMed sales guy was just here last week, looking for business. ResMed wants to get a contract with Kaiser, and they found out I did SomnoMed [Ltd./ASX:SOM]. They gave me a ResMed oral appliance as a sample to compare with the SomnoMed oral appliance. But the ResMed device doesn't have enough vertical occlusion."
- "I'm still contracted to Kaiser to use the SomnoMed oral device. About 15 of my patients are on Kaiser and use the device, but it is not a big money maker for me. It takes me about 60 days to get paid."
- "ResMed's oral device will be approved, but it will take awhile. They also make a nasal pillow, another mask alternative that people may turn to."
- "At first, the Herbst oral appliance with the hinge was the only approved device because it was used by the Army. It's only made by a few manufacturers. But now other oral devices are approved."
- "There may be low-priced competitors coming in, and quality may be a problem. But overall there are problems with the masks. People with allergies have problems using a mask, and it is difficult if you have small nasal passages. Masks apply too much pressure, and some

All DMEs, not just ResMed, will have to cut back. Things have to come down, and there will be more pricing competition. The three big manufacturers-ResMed, Resperonics, Fischer & Paykel—will have to compete with each other for lower pricing, and this will cut into their profits. It will cut into everyone's profits.

> Family Dentist, Dental Sleep Medicine Specialty California



- patients have problems with gum irritation."
- "Eventually, oral devices are going to become more popular although they can't be used on the more visibly obese. I've had good results with oral devices. They are very effective, maybe not as effective as a mask-not 100% but they are 90%, which is better than nothing. The mask compliance rate is very low, but the oral compliance rate is high. People may also turn to the nasal pillows, another mask alternative."
- "My patients use in-home testing, and they are more comfortable doing it. There are pros and cons of this, but it depends on other comorbidities. Certainly, it allows more people to be diagnosed and treated."
- "There is so much fraud in Medicare because they don't pay people enough to stay in business."
- "If manufacturers and clinics can't make money, they can't stay in business. You can't make a night guard for \$500, and the patients need to be educated. That is really the costly part. You can't stay in business if you just break even."
- "I've been trying to sign up for Medicare, but it's been very difficult. Medicare was paying nearly \$1,700 for the appea device and counseling awhile back. But then Medicare dropped the cost to \$1,100. That's about my limit. If they drop it more than that—and it sounds like it might—I may have to reconsider."
- General practitioner who recommends sleep studies in California; repeat source ResMed, Philips Respironics and Fisher & Paykel will compete in pricing and continue to remain the top companies, but no market player will be spared from the CMS cuts. Low-cost masks do not fit well and do not provide the needed oxygen. Home tests are being promoted by insurance companies for the cost savings.
 - "ResMed will be affected just like the other companies. They will all try to stay competitive, yet make money. The top companies will continue to be the top companies; they'll just make a bit less money on CPAP."
 - "Medicare is creating havoc, and everyone, from the companies to the clinics and patients, will feel the cuts."
 - "ResMed masks seem to fit better in general, but my patients use a variety of masks, mostly from the top three."
 - "Low-cost masks are already available, and I can tell you right now, they often don't work. They're uncomfortable; they just don't fit. And if they don't fit, they aren't going to help the patient. I'm not going to recommend them."

ResMed will be affected just like the other companies. They will all try to stay competitive, yet make money. The top companies will continue to be the top companies; they'll just make a bit less money on CPAP.

> General Practitioner, Recommends Sleep Studies California

"In-home studies seem to be OK for most patients. If there is a problem, they can also do a more extensive test at a clinic. Now I hear that insurances are cutting back a bit, and they may be promoting home tests because they are less expensive."

Physician at a large medical center sleep clinic in the Midwest

ResMed and other CPAP manufacturers will need to be innovative in order to maintain sales and market positions. Some vendors may not be able to stay in business, and equipment may become more readily available online. The Medicare cuts also will adversely affect patients, who may have to travel farther to get equipment and care.

- "Many vendors may disappear, and patients will have to drive long distances to get equipment."
- "It is very likely that patient access to PAP and oxygen equipment will be made much more difficult primarily due to the 'suicide bidding' taking place now."
- "I would not be surprised to see busier Internet marketing."
- "I expect care to decline notably as vendor monitoring and attention to follow-up turns all to book work."

It is very likely that patient access to PAP and oxygen equipment will be made much more difficult primarily due to the 'suicide bidding' taking place now.

Physician, Large Center Sleep Clinic Midwest

Professor of respiratory medicine and a clinical physician at a major East Coast university

ResMed is a strong company that will deal with the reimbursement cuts and downward pricing pressure through diversification and innovation. The cuts will give rise to low-cost competition, and DMEs will experience margin declines. Home tests will not increase the diagnoses of sleep apnea.

- "It sounds like there's going to be downward price pressure, but overall the machines will still be prescribed. Doctors are at arm's length from the costs of the equipment as they are focused on the therapeutic results."
- "The DME providers will probably have to survive on smaller margins, yet deliver the same service. Their service helps patients get accustomed to using CPAP."
- "I assume some lower-cost competitors are trying to infiltrate, but I have no idea who they are."
- "I think [home testing is] neutral right now. I think we will continue to diagnose at about the same rate whether it's in homes or in clinics."

Secondary Sources

A review of Internet sites covering the sleep disorder and treatment community revealed that the CMS Competitive Bidding Program has been criticized by homecare organizations and some politicians. A few congressional staff members engaged in angry discussions with CMS regarding the proposed 47% reimbursement cuts expected to take effect on July 1. Efforts to replace the Competitive Bidding Program with the industry-favored Market Pricing Program will be discussed by Congress in May, Finally, a survey conducted by HME News revealed that 68% of health equipment providers would not sign CMS contracts at current pricing levels.

Feb. 18 Bid New Blog posting

The CMS Competitive Bidding Program came under heavy criticism from American Association for Homecare, a group representing homecare organizations. The system is said to be out of control with hidden costs exceeding any savings suggested by CMS. Legislation has been introduced to replace the program with the Market Pricing Program.

- "'It's ironic that a program that is supposed to increase competition among providers is actually reducing competition, costing jobs in communities, and putting Medicare patients at risk,' said Tyler Wilson, president of the Washington-based American Association for Homecare."
- "'This program is spiraling out of control. Providers, consumer advocates and economists are urgently calling on Congress to adopt a better system."
- "Rep. Tom Price (R-Ga.), who is a past chairman of the Republican Study Committee, the caucus of conservative Republicans that forms the majority of the majority in the House, is preparing legislation to fix the problem. Price, a licensed physician, introduced legislation in the previous Congress to establish the Market Pricing Program, which will reform the current system by creating local bidding regions that are smaller and more homogenous that the current Metropolitan Statistical Areas and will make the bid price that actual clearing price, not a median price of other winning bids."
- "'The hidden costs of the bidding program are far exceeding any savings to the government from reduced claims on home medical equipment."

Feb. 8 Sleep Scholar article

Several congressional staff members had an angry closed-door meeting with CMS to discuss the medical reimbursement cuts facing DMEs as a result of the Competitive Bidding Program. DMEs favor the Market Pricing Program and are hoping for program reconsideration during budget talks scheduled for May.

- "In the wake of massive Medicare reimbursement cuts across several sectors of DME (including a 47% cut to CPAP), staff members for several House Representatives held a closed-door meeting with CMS officials earlier this week."
- "Reports drifting in to the National Association of Independent Medical Equipment Suppliers (NAIMES) indicate that House staffers were 'very angry and frustrated to the point of walking out.' Wayne Stanfield, founder of NAIMES, reports that one health legislative aid expressed 'anger and irritation at CMS' lack of response to almost any questions asked."
- "On average, DME suppliers took a 45% reimbursement hit across eight product categories. In the realm of sleep, a full-face mask used with PAP device will now garner a \$99 single payment amount (SPA). Click here for

- the full list of SPAs affecting sleep-related equipment. Click here for the official CMS press release/announcement."
- "DME providers continue to fight competitive bidding in hopes of replacing it with an industry-favored Market Pricing Program (MPP). Advocates at the American Association for Homecare plan to push the replacement measure as part of a debt ceiling package, or a budget continuing resolution, that Congress will discuss in May."

Feb. 15 HME News article

A recent survey of home medical equipment providers revealed that 68% would refuse CMS contracts because of the low pricing brought about by the Competitive Bidding Program. The respondents that would accept the low-price contracts expect to profit from increased volume and a reduction of services. If the program is not replaced or repealed, 22% of survey respondents expect to go out of business.

- "Two weeks after CMS's announcement of severe cuts in Round 2 single payment amounts, providers were saying 'no' to contracts. In a recent HME NewsPoll, 68% of providers said they do not plan to accept a CMS contract for Round 2 of competitive bidding."
- "Of the 32% of respondents who said they would accept a contract for Round 2 of competitive bidding, 36% said they were banking on increased volume to offset lower reimbursement, while 27% said they would reduce services."
- "While many respondents were optimistic about finding new channels of revenue outside of Medicare, 22% percent indicated they would sell or close their business. 'There is no way we could survive at those rates,' one respondent said. 'If we cannot repeal and replace competitive bidding, we will not be able to keep the doors open.'"

Additional research by Linda Richards, Renee Euchner and Laura MacFarlane

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