



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Opportunities Missed to
Contain Spending on Sleep
Apnea Devices and Improve
Veterans' Outcomes

AUDIT

REPORT #19-00021-41

JANUARY 14, 2020



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Executive Summary

The VA Office of Inspector General (OIG) conducted this audit to determine if the Veterans Health Administration (VHA) is efficiently managing positive airway pressure devices (sleep apnea devices) and supplies provided to veterans diagnosed with sleep apnea. Positive airway pressure therapy is the most common treatment for sleep apnea.

Since fiscal year (FY) 2013, sleep apnea has become the most prevalent service-connected disability of all the respiratory disabilities for which veterans receive benefits. The OIG found that in FY 2019, about 1.3 million veterans enrolled in VHA have a sleep apnea diagnosis, an increase of about 384,000 veterans (44 percent) from FY 2015.¹ The number of veterans who receive sleep apnea devices and supplies from VHA increased approximately 96 percent—from about 342,000 in FY 2014 to about 669,000 in FY 2018. VHA spent an estimated \$147.6 million in FY 2014 on sleep apnea devices and supplies. By FY 2018, that amount grew to an estimated \$233.9 million, an increase of about 59 percent.

What the Audit Found

The OIG found that VHA did not manage the issuance of sleep apnea devices and associated supplies in an efficient manner. Almost half of the 250,000 veterans who were issued a sleep apnea device from October 2016 through May 2018 used the device less than 50 percent of the time. The mismanagement occurred in part because VHA did not identify veterans who were not using their devices as recommended and follow up with them in a timely manner. Furthermore, VHA lacks guidance on alternatives to purchasing sleep apnea devices for all veterans or to take back devices not being used.

VHA's sleep-related breathing-disorder source book recommends sleep medicine clinicians follow up with veterans within 30 to 90 days after issuing the device to confirm they are using it as intended. However, the OIG estimated that about 50,900 of the almost 114,000 veterans who were not consistently using their sleep apnea device did not receive the necessary follow-up care. Sleep medicine clinicians at VA medical facilities told the audit team they were unable to use available device usage data to proactively monitor veterans' use on a large scale because they do not have enough staff resources. The OIG found that VHA did not have a staffing model for sleep medicine, though it is developing one, according to the former chief officer for specialty care.

Sleep clinicians can readily obtain most veterans' device usage data from the manufacturers' secure servers. Most sleep apnea devices purchased by VHA come equipped with built-in

¹ OIG audit team's analysis of VHA's Support Service Center data using the applicable ICD-9 and ICD-10 codes (International Classification of Diseases) for FY 2015 through FY 2019.

modems that can facilitate the automatic transmittal of veterans' usage data wirelessly. VHA requires veterans to enroll in its wireless monitoring program before their data is automatically transmitted to manufacturers' servers. Users who do not want to transmit their data can extract the device's memory card to provide the data to their sleep clinician. Clinicians or other designated staff must still have time, however, to review those results.

It would be difficult to identify all the reasons why some veterans do not consistently use their prescribed sleep apnea devices. Some clinical notes for veterans not consistently using the devices described not being able to tolerate the face mask during sleep and feelings of claustrophobia.

When veterans do not use their prescribed sleep apnea devices consistently, the therapy is not effective. Also, with an average annual cost of about \$540 per veteran for sleep apnea devices and an additional average annual cost of about \$190 per veteran for device supplies, VHA is exposed to significant financial risk when veterans do not regularly use their devices as recommended by VHA's source book to derive benefit from the expenditures.

The OIG estimated that VHA could save up to about \$39.9 million per year by implementing alternative processes used by private healthcare systems and private and federal health insurers. For example, VHA could loan sleep apnea devices to veterans during a trial period, rather than purchasing them for each individual veteran regardless of whether they will be used consistently. VHA also could reduce the risk of needlessly purchasing supplies for veterans who will not or cannot use their devices, thereby potentially saving up to an estimated \$12.4 million per year.

The number of veterans diagnosed with sleep apnea and the number of veterans receiving devices and supplies have increased dramatically in five years. If this trend continues, it is reasonable to assume that VHA will continue to have at least a similar demand on the issuance of sleep apnea devices and supplies, as well as clinician monitoring of device usage, that it experienced in the last five years. Therefore, if VHA does not act to change its current sleep apnea device issuance practices and leverage opportunities to reduce spending, the OIG estimated VHA is at risk of potentially spending \$261.3 million over the next five years on sleep apnea devices and supplies that veterans will not use.

The OIG recognizes that additional costs may be incurred if VHA implements an alternative to purchasing sleep apnea devices, such as leasing or loaning them. For example, if VHA were to refurbish these devices in-house, it would incur costs associated with replacing certain items, such as air filters, prior to reissuing the device for use. Additional costs were not considered by the team when identifying how much VHA could potentially save, because the cost associated with this process would be dependent on what alternative, if any, VHA implements.

What the OIG Recommended

The OIG recommended the under secretary for health determine if sleep medicine staffing levels are sufficient for monitoring sleep apnea device use and conducting follow-up appointments. The OIG also recommended the under secretary ensure VHA is leveraging existing technologies to routinely monitor veterans' use of sleep apnea devices in a consistent and effective manner to more promptly identify individuals at risk of noncompliance with recommended therapies. The OIG further recommended the under secretary coordinate with appropriate offices to assess whether purchasing sleep apnea devices is in VHA's best interest while still meeting veterans' needs. If developing and implementing an alternative practice would be a better use of funds, the under secretary should make and provide clear guidance on any changes to current VHA processes. The under secretary should also designate an office with the authority to ensure medical facilities implement the resulting recommendations.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with the recommendations. The executive in charge provided corrective action plans that are responsive to the intent of the recommendations. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified. The executive in charge also provided general and technical comments. Appendix D includes the full text of the executive in charge's comments, including general and technical comments and the OIG's response to the technical comments.



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Abbreviations

CAPRI	Compensation and Pension Record Interchange
CMS	Centers for Medicare and Medicaid Services
CPRS	Computerized Patient Record System
FTE	full-time equivalent
FY	fiscal year
NPPD	National Prosthetics Patient Database
OIG	Office of Inspector General
PSAS	Prosthetic and Sensory Aids Service
REVAMP	Remote Veteran Apnea Management Platform
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted this audit to determine if the Veterans Health Administration (VHA) is efficiently managing positive airway pressure devices (sleep apnea devices) and supplies provided to veterans diagnosed with sleep apnea.

Sleep Apnea

Sleep apnea is a disorder characterized by pauses in breathing or periods of shallow breathing during sleep, and may cause affected individuals to be sleepy throughout the day or have difficulties concentrating. In 2014, the National Healthy Sleep Awareness Project estimated that at least 25 million adults in the United States have sleep apnea.² Some common risk factors associated with sleep apnea include age, excess weight, and large neck size. Males may also be at higher risk than females. If untreated, sleep apnea can increase an individual's risk of high blood pressure, heart disease, Type 2 diabetes, stroke, and depression.

Treatment for individuals diagnosed with sleep apnea depends on the severity of the condition and can include positive airway pressure therapy, weight loss, or surgery. Positive airway pressure therapy is the most frequent treatment for individuals diagnosed with moderate to severe sleep apnea. However, studies indicate that about 30 percent to 40 percent of all patients do not comply with the requirements of positive airway pressure therapy.³

A positive airway pressure therapy device is essentially a small box with a motorized fan inside. The fan draws in air and pressurizes it. The air intake section of the device has a filter to eliminate the intake of dust, smoke, or other impurities in the air. Individuals wear a face mask during sleep that is connected to the device with a tube and air is forced into the nasal passages at pressures high enough to overcome obstructions in the airway and allow for easier and more regular breathing. The filter, hose, and mask should routinely be replaced. Figure 1 is an illustration of a person sleeping with a mask connected by a hose to a sleep apnea device.

² American Association of Sleep Medicine, "Stop the snore: Sleep apnea action urgent for those at risk," news release, August 12, 2014, accessed November 2, 2018,

<https://aasm.org/stop-the-snore-sleep-apnea-action-urgent-for-those-at-risk/>.

³ Pamela Samson, Kenneth R. Casey, James Knepler, Ralph J. Panos, "Clinical Characteristics, Comorbidities, and Response to Treatment of Veterans with Obstructive Sleep Apnea, Cincinnati Veterans Affairs Medical Center, 2005–2007," *Preventing Chronic Disease* 9:110117 (January 2012), accessed May 2, 2019,

https://www.cdc.gov/pcd/issues/2012/11_0117.htm, and Brian W. Rotenberg, Dorian Murariu, and Kenny P. Pang, "Trends in CPAP adherence over twenty years of data collection: a flattened curve," *Journal of Otolaryngology--Head and Neck Surgery* 45:43 (2016), accessed May 9, 2019, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4992257/>.



Figure 1. Image of individual sleeping with a mask attached to a sleep apnea device

Source: Image retrieved from VA Office of Information Security Field Security Service Bulletin No. 328, *Wireless Positive Airway Pressure Monitoring for Sleep Apnea*, January 19, 2016.

Since 2009, sleep apnea devices have had built-in wireless modems designed to transmit a patient's device usage and efficiency data to manufacturers' servers.⁴ Treating clinicians, including VHA sleep medicine clinicians, can access usage data on the manufacturer's server through a secure website.

Sleep Apnea Diagnoses and Spending Increasing

The OIG found that in fiscal year (FY) 2019 about 1.3 million veterans enrolled in VHA have a sleep apnea diagnosis, an increase of about 384,000 veterans (44 percent) from FY 2015.⁵ The number of veterans who receive sleep apnea devices and supplies such as masks, hoses, and air filters from VHA increased by about 96 percent—from about 342,000 in FY 2014 to an estimated 669,000 in FY 2018.

⁴ Systematizing Sleep Services Workgroup, "White Paper: Use of Wireless Monitoring and Cloud-Based Storage of Continuous Positive Airway Pressure Device Data to Improve Veteran Sleep Apnea Care," February 5, 2016.

⁵ OIG audit team's analysis of VHA's Support Service Center data using the applicable ICD-9 and ICD-10 codes (International Classification of Diseases) for FY 2015 through FY 2019.

According to the audit team's analysis of VHA's National Prosthetics Patient Database (NPPD), VHA spent an estimated \$147.6 million in FY 2014 on sleep apnea devices and supplies.⁶ By FY 2018, that amount grew to an estimated \$233.9 million, an increase of about 59 percent. According to a survey conducted by the OIG, nearly all the sleep apnea devices VHA purchases are manufactured by two companies: ResMed and Philips Respironics.

Figure 2 details an annual comparison of VHA's spending on sleep apnea devices and associated supplies for veterans from FY 2014 through FY 2018.

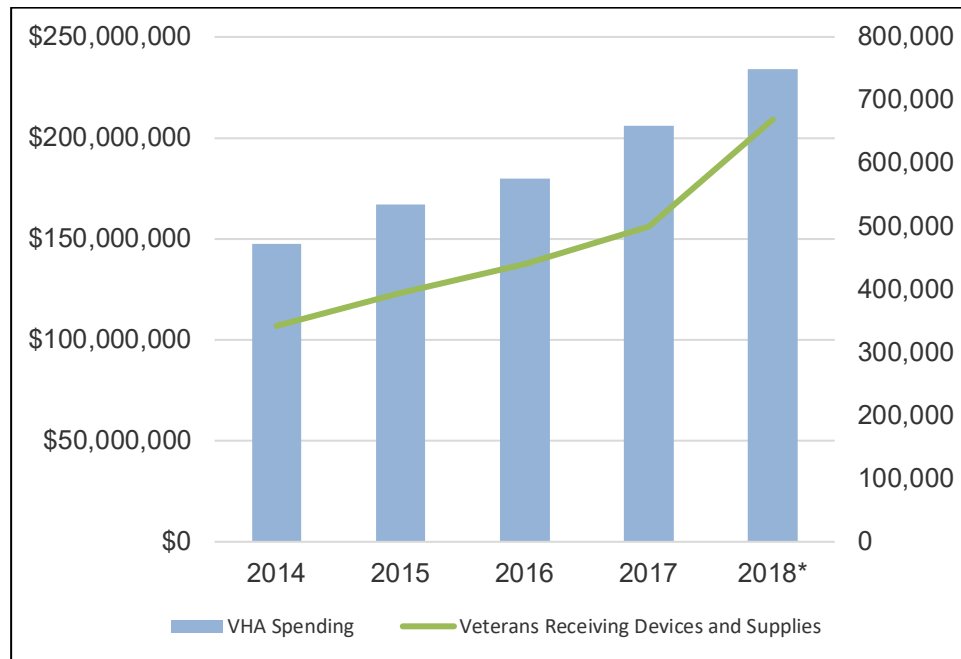


Figure 2. Trends in veterans receiving sleep apnea devices and supplies and VHA's commensurate spending from FY 2014 through FY 2018

Source: OIG analysis of the NPPD from October 2014 through May 2018

*FY 2018 numbers are based on an estimate of average annual spending and average annual number of veterans served from October 2017 through May 2018.

Veterans with a sleep apnea diagnosis requiring the use of a breathing assistance device are rated as at least 50 percent service-connected when VA determines the condition was incurred or aggravated during active military service.⁷ VA does not require veterans to use their breathing assistance device to manage their sleep apnea in order to obtain or maintain their service-connected disability rating for the disorder.⁸ Since FY 2013, sleep apnea has become the

⁶ The NPPD captures data on veterans, their eligibility for receiving prosthetic(s), and the type of prosthetic treatment received at a facility. The database also captures facility information on prosthetics costs, vendor sources, and purchasing agents.

⁷ 38 C.F.R. § 4.97 (2006).

⁸ VA Manual M21-1, part III, sub. iv, chap. 4, sec. F, "Respiratory Conditions," February 19, 2019.

most prevalent service-connected disability of all the respiratory disabilities for which veterans receive benefits.⁹ VHA provides sleep apnea treatment and devices for veterans regardless of whether they have a service-connected disability specifically for this disorder.

VHA Guidelines on Sleep Apnea Device Therapy

VHA developed a source book that includes the following guidelines specific to sleep apnea device therapy:

- Veterans should use their devices at least 70 percent of nights to attain maximum treatment benefits.
- Sleep medicine clinicians should follow up with veterans within 30 to 90 days after the sleep apnea devices are issued to confirm that veterans are following their treatment plans.
- Sleep medicine clinicians should conduct at least annual follow ups with veterans thereafter.
- Outsourced sleep apnea therapy services (care in the community) must be supplemented with in-house monitoring performed by VHA sleep medicine clinicians for proper patient care.¹⁰

The guidelines included in the source book reflect guidance developed by the Centers for Medicare and Medicaid Services (CMS) and used in studies issued by the American Academy of Sleep Medicine. VHA has no other national policy, directive, or care guidelines related to treating veterans diagnosed with sleep apnea or how sleep apnea devices and supplies should be provided to veterans.

VHA's Sleep Medicine Program Governance

To provide context for the results and recommendations of this audit, it is important to understand VHA's governance structure and oversight responsibilities for veterans to receive sleep apnea devices in the most cost-effective manner while meeting their care needs. According to the national program director for pulmonary, critical-care, and sleep medicine, VHA's governance over sleep apnea treatment and resource management is split between two VHA program offices and the medical facilities. The national program director for pulmonary,

⁹ According to VBA's *Annual Benefits Reports* for FYs 2014 through 2017, the number of veterans receiving benefits for a sleep apnea diagnosis has increased 60 percent from 176,000 to 282,000.

¹⁰ From the *Sleep-Related Breathing Disorders Source Book*, issued by the VA Sleep Field Advisory Group in January 2014. The *Sleep-Related Breathing Disorders Source Book* is VHA's clinical case management guide and establishes practice guidelines for diagnosing, treating, and providing continuing care for veterans with sleep-related breathing disorders, including sleep apnea. This document will be referred to as the source book in this report.

critical-care, and sleep medicine issues policy, although the program office has no governance responsibility over medical facilities' implementation of its policies. This oversight responsibility is assigned to the assistant deputy under secretary for health for operations and management for clinical operations.

According to the national program director for pulmonary, critical-care, and sleep medicine, sleep medicine clinicians' responsibilities at the medical facility level include determining the need for sleep-related breathing disorder care based on the results of a veteran's sleep study and providing veterans with the appropriate therapy, much of which is related to sleep apnea. This can include

- Providing veterans with the appropriate sleep apnea device,
- Fitting veterans with the appropriate mask,
- Determining and setting up sleep apnea devices with the appropriate air pressure,
- Providing follow-up care to confirm veterans are adhering to the treatment plan, and
- Ensuring that veterans are resupplied with device filters, hoses, and masks as needed.

Figure 3 details VHA's sleep medicine program governance.

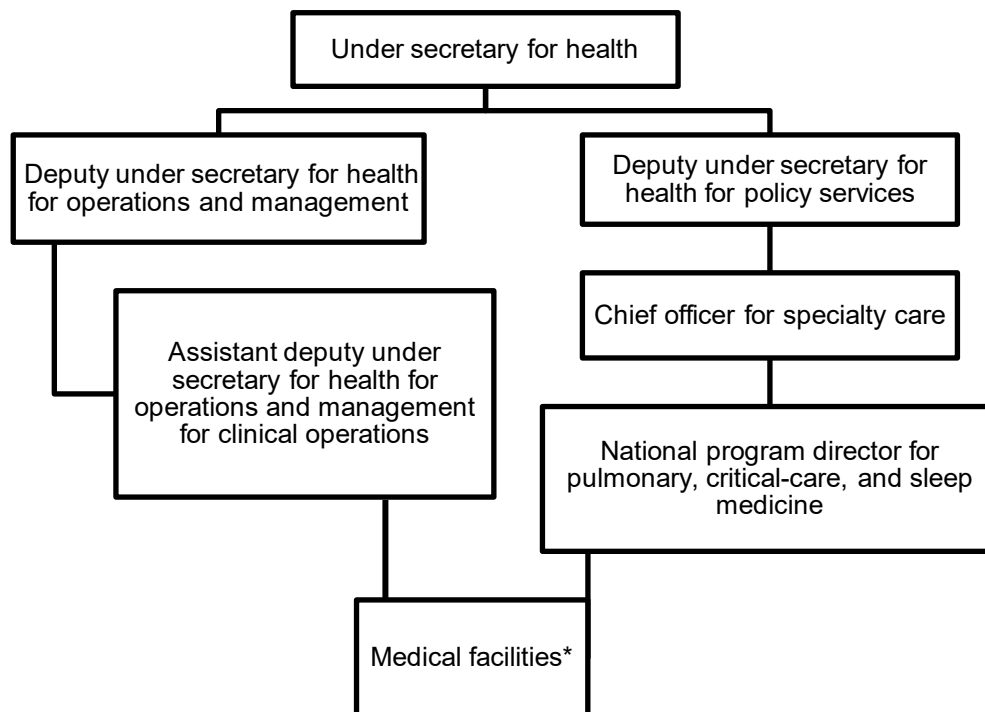


Figure 3. VHA's sleep medicine program governance

Source: OIG analysis of VHA organizational chart, dated February 2, 2019, and interviews with the national program director for pulmonary, critical-care, and sleep medicine.

*Responsibility for sleep medicine at the facility level may fall to the chief of sleep medicine or chiefs of other services such as pulmonary, neurology, and cardiopulmonary.

Prosthetic and Sensory Aids Service Roles and Responsibilities

VHA's Prosthetic and Sensory Aids Service (PSAS), led by a national program director, is responsible for procuring prescribed sleep apnea devices and associated supplies, such as masks and hoses, and providing them to eligible veterans for use outside of VA medical centers or facilities. The PSAS purchases all devices for veterans, whether care was provided by a VA medical facility or non-VA care provider.

Figure 4 details the reporting structure for the PSAS.

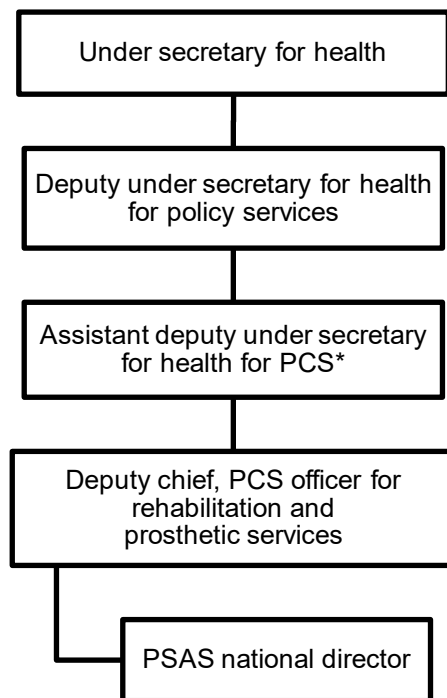


Figure 4. PSAS reporting structure

Source: OIG analysis of VHA organizational chart, February 2, 2019, and rehabilitation and prosthetic services organizational chart, dated September 2016.

*PCS=Patient Care Services

Results and Recommendations

Finding: VHA Missed Opportunities to Reduce Spending on Sleep Apnea Devices Many Veterans Did Not Use

VHA did not manage the issuance of sleep apnea devices and associated supplies in an efficient manner. Almost half of the estimated 250,000 veterans (about 46 percent) issued a sleep apnea device from October 2016 through May 2018 did not use the devices consistently (more than half the time).¹¹ This occurred in part because VHA did not identify and follow up in a timely manner with veterans who were not consistently using their devices. VHA currently purchases sleep apnea devices and issues them permanently to veterans who are prescribed device therapy, but it lacks guidance used by the private sector and others on alternatives to purchasing and issuing sleep apnea devices.

When veterans do not use their prescribed sleep apnea devices consistently, the therapy is not effective.¹² Also, with an average annual cost of about \$540 per veteran for sleep apnea devices and an additional average annual cost of about \$190 per veteran for device supplies, VHA is exposed to significant financial risk when veterans do not use them regularly.¹³

VHA's source book recommends sleep medicine clinicians follow up with veterans soon after issuing the devices to confirm they are using the devices as intended. Follow up can also help avoid ongoing spending for unused devices. A private healthcare organization and private insurers have implemented practices to reduce such costs. For example, according to a representative from Kaiser Permanente, the company first loans devices to patients for a trial period to determine if the patients will adhere to the therapy before purchasing the devices for permanent use. The audit team estimates VHA could reduce its annual spending on sleep apnea devices by as much as \$39.9 million with up to an additional \$12.4 million on related supplies if it implements alternatives to its current practice of purchasing and issuing devices permanently to veterans who are not consistently using them.

¹¹ To calculate the number of veterans who did not use their sleep apnea devices consistently, the audit team obtained veterans' sleep apnea device usage reports, when available, and identified veterans who used their devices less than 50 percent of nights (N=113,762).

¹² VHA, *Sleep-Related Breathing Disorders Source Book*.

¹³ Supplies are provided to veterans at various times throughout the year.

What the OIG Did

The audit team reviewed a random sample of 223 veterans from among 275,800 who received at least one VHA-purchased sleep apnea device from October 2016 through May 2018.¹⁴ Using the Compensation and Pension Record Interchange (CAPRI),¹⁵ the team reviewed these veterans' electronic healthcare records to determine if medical facility clinicians were monitoring prescribed sleep apnea device usage and providing follow-up care to users.¹⁶ The team requested veterans' sleep apnea device usage data reports from VHA for the most recent 12-month period available at the time of the audit. The team reviewed the reports provided to measure the extent to which veterans used their devices. Appendix B provides more information about the team's sampling methodology.

To gain an understanding of VHA's guidelines for diagnosing sleep-related breathing disorders, issuing sleep apnea devices and supplies, and monitoring patient compliance, the team conducted extensive interviews. The OIG interviewed officials from VHA's PSAS, an information system security officer, and Veterans Integrated Service Network (VISN) prosthetic representatives, as well as officials from VA medical facilities including clinicians from the pulmonary, sleep medicine, and prosthetics programs. To learn more about facility-level sleep apnea treatment practices and sleep medicine capacity, the team surveyed 137 sleep medicine clinicians using an electronic questionnaire, obtaining about an 88 percent response rate. The team also conducted site visits to the Audie L. Murphy VA Hospital in San Antonio, Texas, and the Orlando VA Medical Center in Florida. Appendix A provides more information about the audit team's overall methodology.

This section discusses the following issues related to the audit team's finding that VHA could have reduced spending on sleep apnea devices that veterans were not using:

- Many veterans did not use prescribed sleep apnea devices consistently.
- VHA needs to better identify and follow up with veterans who do not use their sleep apnea devices at least half the time.
- VHA lacks guidance on alternatives to permanent issuance of purchased devices.

¹⁴ In some cases, veterans may be issued multiple sleep apnea devices. For example, a veteran may be issued a continuous positive airway pressure (CPAP) device initially. If this therapy is ineffective or the veteran cannot tolerate it, they may be issued a bilevel positive airway pressure (BiPAP) device.

¹⁵ CAPRI is an information technology system that provides users with access to veterans' electronic health records throughout the VA. Information contained in veterans' electronic health records includes the diagnosis of the veterans' medical conditions, any service-connected disabilities, and follow-ups with clinicians and the associated progress notes.

¹⁶ Using information from the *Sleep-Related Breathing Disorders Source Book*, the team defined "follow-up" as any instance of communication—such as in-person or via telephone—between a sleep clinician and a veteran in which specific assessments, interventions, and instructions were included (e.g., documenting and correcting problems, determining adherence, and checking device condition).

Almost Half of Veterans Did Not Use Their Prescribed Sleep Apnea Devices Consistently

According to the source book, adherence to positive airway pressure therapy is a prerequisite for successful long-term sleep apnea management. The guidelines recommend veterans use their sleep apnea devices at least 70 percent of nights. The audit team examined reports from VHA on veterans' device usage. The team found some veterans did not consistently use their devices at therapeutic levels. About 54 percent of the veterans (136,000 of 250,000) to whom VHA provided a device from October 2016 through May 2018 used their devices more than 50 percent of the time. About 46 percent of veterans (114,000 of 250,000) did not use their sleep apnea devices more than half the time; and of those, about 81 percent (92,100 of 114,000) rarely used their devices (less than 20 percent of the time). Figure 5 details the audit team's findings on the frequency at which veterans used their prescribed sleep apnea devices.

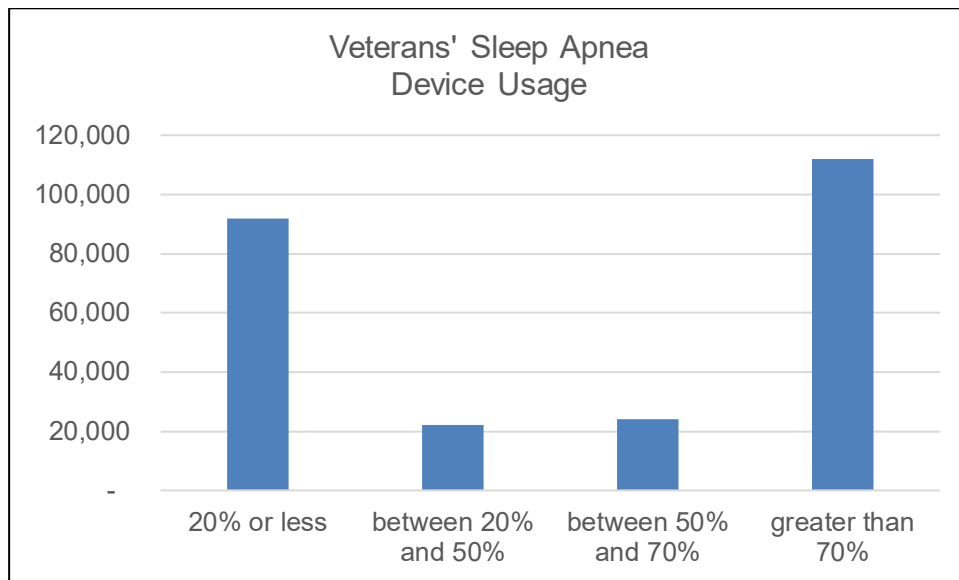


Figure 5. Veterans' estimated usage of prescribed sleep apnea devices received October 2016 through May 2018.

Source: VA OIG analysis of statistically sampled veterans for which VHA purchased at least one sleep apnea device during the review period.

Veterans' usage confirms that patients find it difficult to adhere to sleep apnea therapy. Studies that included a review of private-sector patient adherence to positive airway pressure therapy showed that 30 percent to 40 percent of patients generally do not adhere to positive airway

therapy.¹⁷ VHA sleep medicine clinicians also reported that they were similarly aware many veterans were unable to successfully tolerate sleep apnea device therapy.

The audit team found it difficult to identify all the reasons why some veterans do not consistently use their prescribed sleep apnea devices. When veterans did not receive follow-up care from a sleep medicine clinician, there was no documentation in their health records to explain inadequate or inconsistent use. When follow-up care was provided, clinical notes described some reasons for intolerance, which included an inability to tolerate the face mask during sleep and claustrophobia.

Example 1

A veteran, who in March 2015 reported having severe claustrophobia, received a sleep apnea device in July 2017 from a Connecticut VA medical center. After receiving the device, the veteran only used it for three hours and 13 minutes over three nights, according to the audit team's analysis of the device's usage data. In this case, facility sleep medicine clinicians followed up with the veteran in September 2017 for a clinical assessment to determine if the veteran was compliant with the therapy. The veteran reported not wanting to use the device "in the first place" and declined any additional efforts to increase the use of the sleep apnea device.

VHA issues sleep apnea devices to veterans on a permanent basis, and the audit team was not able to find any evidence in the veteran's health care record that the little-used sleep apnea device was returned to the facility. Without changes to its practices, VHA is at risk of spending on average an estimated \$39.9 million annually on devices veterans do not use or use too infrequently to have a positive effect on their sleep apnea condition.

Medical facilities spend on average about \$190 per veteran on sleep apnea device supplies ordered through their local PSAS. Veterans are eligible to receive supplies such as masks, air filters, and tubes every six to 12 months; however, there is no requirement to ensure veterans are using their devices before providing the requested supplies. Medical facility PSAS purchasing agents reported that when veterans contact the facility for supplies, the purchasing agents only check VA's Computerized Patient Record System (CPRS) to verify the veteran has an active consult less than a year old before providing sleep apnea device supplies.

While the audit team did not identify any trends across the sample of veterans it reviewed that would indicate facilities were providing veterans with excess supplies, there is a risk that up to an estimated \$12.4 million VHA spends annually on sleep apnea device supplies is spent on

¹⁷ Pamela Samson, et al., "Clinical Characteristics, Comorbidities, and Response to Treatment of Veterans with Obstructive Sleep Apnea, Cincinnati Veterans Affairs Medical Center, 2005–2007," *Preventing Chronic Disease* 2012, 9:110117 (2012), and Rotenberg, et al., "Trends in CPAP adherence over twenty years of data collection: a flattened curve," *Journal of Otolaryngology—Head and Neck Surgery* 45:43 (2016).

veterans who do not use their devices frequently enough to warrant resupply of these items, because sleep clinicians are not acting in a timely manner to identify those veterans and there is no requirement to ensure the veteran used the device.

As the number of veterans diagnosed with sleep apnea and the number of veterans receiving devices and supplies has increased dramatically in five years, it is reasonable to assume that if this trend continues, VHA will continue to experience at least similar demands on the issuance of devices and supplies, as well as clinician monitoring of usage data. Therefore, the audit team estimates that VHA is at risk of potentially spending \$261.3 million over the next five years on sleep apnea devices and supplies that veterans will not use if current practices persist.¹⁸

VHA Did Not Effectively Identify and Follow Up with Veterans Who Did Not Use Their Sleep Apnea Devices At Least Half the Time

Sleep medicine clinicians did not identify and follow up in a timely manner with veterans who were not consistently using their devices. This is important because sleep medicine clinicians need to identify those veterans who will not use or cannot tolerate the device, so they can help improve veterans' adherence to the therapy either by fitting them with new or different masks or providing coaching on how to best use the device. It also affords the opportunity to find possible alternatives. Moreover, follow up could prompt VHA to recover any unwanted or unused devices, resulting in potential cost savings.

VHA's source book recommends medical facility sleep clinicians routinely follow up with veterans soon after being prescribed a sleep apnea device by scheduling follow-up appointments. Only about 55 percent of the about 114,000 veterans who were not consistently using their devices received follow-up care from a sleep medicine clinician after they were issued a device. An estimated 50,900 veterans received no follow-up care after receiving their sleep apnea device.

Sleep Medicine Clinicians Reported Staffing Shortages

Sleep medicine clinicians interviewed by the audit team reported that staffing shortages affected medical facilities' ability to follow up with veterans in a timely manner. About 81 percent of sleep medicine clinicians (97 of 120) responded to OIG's survey that their medical facility did not have enough staff to conduct follow ups at the same frequency as recommended by VHA's source book to confirm veterans are using their sleep apnea devices as recommended.

¹⁸ The potential impact of \$261.3 million is based on the estimated average annual amounts spent on sleep apnea devices that veterans did not consistently use (\$39.9 million) and on supplies provided to these veterans (\$12.4 million), projected over five years. See Appendix C for additional details.

According to VHA's Support Service Center, sleep medicine encounters have increased significantly in recent years.¹⁹ Sleep medicine clinicians who responded to the OIG survey reported having authorized staffing levels of about 850 full-time equivalents (FTEs) during FY 2018, compared to a VHA survey where these same facilities reported having about 772 FTEs on staff in 2014.²⁰ This represents an increase of about 10 percent from FY 2014 to FY 2018. While this increase does not account for all medical facilities, the data support that staffing levels have not kept pace with increases in the overall sleep medicine patient workload.

VHA is poorly positioned to assess the extent to which its medical facilities' sleep medicine capacities are adequate to confirm veterans are receiving timely follow-up care, because it does not have a sleep medicine staffing model. According to the national program director for pulmonary, critical-care, and sleep medicine and the VHA national lead for the Office of Rural Health TeleSleep program, sleep medicine is not recognized as a separate specialty within VHA. Instead, sleep medicine is included within other specialties such as neurology and pulmonary, making it difficult to identify and assess sleep medicine staffing levels. The former chief officer for specialty care reported that VHA is developing a staffing model for sleep medicine.

VHA Could Leverage Data for Directing Follow-up Care to Veterans That Can Improve Outcomes and Conserve Sleep Medicine Resources

The audit team found medical facilities are not leveraging device usage data, which is often readily available on device manufacturers' servers, to identify and support veterans who are not using their sleep apnea devices. Using available information on the veterans who are struggling to comply with their sleep apnea device therapy would allow medical facilities to focus their follow-up efforts to those veterans most at risk of stopping the therapy. For example, 45 percent (50,900) of the nearly 114,000 veterans not using their devices consistently also did not receive follow-up care. Sleep medicine clinicians could determine if identified veterans are experiencing issues using their devices or if the veterans simply cannot or do not want to use the devices. As stated earlier, in either case, the follow up affords the opportunity for clinicians to work with the veteran to identify alternative treatments that meet the veteran's needs as well as cost savings for VHA.

Wireless monitoring of sleep apnea device data is considered the standard of care in the private sector. In January 2016, VA's Office of Information Security issued a bulletin, *Wireless Positive*

¹⁹ Sleep medicine encounters have increased about 220 percent from about 533,000 in FY 2014 to about 1.7 million in FY 2018 according to the data.

²⁰ FTEs for FY 2018 are based on responses from 94 sleep clinicians surveyed by the audit team. According to the VHA national lead for the Office of Rural Health TeleSleep program, the 2014 FTE data were gathered by VHA sleep clinicians as part of an effort to assess the state of VHA sleep medicine programs.

Airway Pressure Monitoring for Sleep Apnea, allowing clinicians to access device usage data on manufacturers' servers through secure websites.²¹ The data can be used to determine compliance with sleep apnea device therapy and identify veterans who are not using their devices frequently enough to achieve optimal results.

Most sleep apnea devices purchased by VHA come equipped with built-in modems that can facilitate the automatic transmittal of veterans' usage data wirelessly. Only an estimated 12,300 veterans of an estimated 275,800 received VA-issued devices that did not have a modem from October 2016 through May 2018. VHA requires veterans to enroll in its wireless monitoring program before their data is automatically transmitted to manufacturers' servers. Veterans who do not want their information captured automatically on manufacturers' servers, or whose devices do not have a modem, can still extract the device's memory card and provide its data to their sleep clinicians. Clinicians must still have time, however, to review those results.

According to OIG's survey, 108 of 120 sleep medicine clinicians (90 percent) reported using data captured by the veteran's sleep apnea device to monitor usage. Manufacturers capture usage data by the device's serial number and store this information on a secure server. VHA sleep medicine clinicians can access the data through manufacturers' secure websites to view and monitor veterans' device usage. All but three of 108 survey respondents reported monitoring a veteran's sleep apnea device usage at different intervals (daily, monthly, or annually). Most reported monitoring a veteran's device usage during their scheduled follow-up appointment (about 59 percent) or when they attend a walk-in sleep medicine clinic (about 68 percent). Monitoring veterans' device use during their scheduled follow-up appointment or during the walk-in clinic is not enough to identify those veterans who are having issues, because an estimated 50,900 veterans who did not use their devices consistently also did not receive follow-up care.

However, sleep medicine clinicians told the audit team that they were unable to use available device usage data to proactively monitor veterans' use of their devices on a large scale because they do not have enough staff resources to do so. Eighty-two percent of survey respondents reported that their medical facility does not have enough sleep medicine staff to proactively monitor veterans' sleep apnea device usage data.

Software Programs Show Promise in Integrating Usage Data

VHA is piloting the Remote Veteran Apnea Management Platform (REVAMP). REVAMP pairs with a veteran's sleep apnea device and allows the veteran and his or her sleep medicine clinician to track the veteran's sleep data. REVAMP also has the capability to provide veterans with support to troubleshoot issues related to using the device and can be used to order supplies like filters, hoses, and masks. Additionally, a built-in messaging system allows veterans to

²¹ VA Office of Information Security Field Security Service Bulletin No. 328, *Wireless Positive Airway Pressure Monitoring for Sleep Apnea*, January 19, 2016.

electronically communicate with their sleep clinician via secure messaging. REVAMP is still a pilot program and has not been launched at all medical facilities.

About 42 percent of respondents (50 of 120) reported their facilities are enrolled in REVAMP. However, 30 percent reported that while they were enrolled in REVAMP, they never used it. Sleep medicine clinicians reported to the audit team that using REVAMP is not efficient because it is not integrated with the CPRS. Clinicians must manually input information from REVAMP into the CPRS to ensure that information is captured in the veteran's health record.

The VHA national lead for the Office of Rural Health TeleSleep program, who is involved with the development of REVAMP, said the program may not be considered for integration into the CPRS because VHA is considering the use of a commercial off-the-shelf product—Somnoware—to replace it.²² This official reported that Somnoware resembles REVAMP in its functionality and costs less. Somnoware is reportedly integrated into most major electronic medical record systems, including the Cerner electronic health system that VA is implementing. However, Somnoware is not currently approved for use within the VA network. This official said VHA will continue to push the use of REVAMP until Somnoware is approved for use within VA's network, which is expected to happen within the next year.

VHA needs to ensure facilities are maximizing the use of technologies to the greatest extent possible. Increased use of technologies to facilitate follow ups can help sleep medicine clinicians more quickly identify those veterans who will not or cannot use their devices. This in turn will allow facilities to make informed decisions about how to most effectively allocate their resources.

VHA Lacks Guidance on Alternatives to Permanent Issuance of Purchased Sleep Apnea Devices

Few VA medical facilities have taken steps to reduce their spending on sleep apnea devices by implementing processes, for example, to take back unused or little-used sleep apnea devices for cleaning and reissuance. Of the 120 sleep clinicians who responded to OIG's survey, only four reported that their facilities clean and reissue returned sleep apnea devices. At one of these medical facilities, veterans are required to sign a document when they receive their sleep apnea devices agreeing to return the devices to the medical facilities if they do not use the devices. VHA nationally has not taken steps to identify best practices and implement national processes to curb its spending on sleep apnea devices. As a result, VHA spent an estimated \$66.3 million

²² According to Somnoware's website, <https://www.somnoware.com/blog/chronic-care-management-for-copd-and-sleep-apnea>, accessed October 4, 2019, it is headquartered in Sunnyvale, California, and offers a cloud-based software that allows respiratory care providers to estimate population risk, automate diagnosis workflow, and optimize patient outcomes.

from October 2016 through May 2018 on sleep apnea devices that veterans did not use at least half of the time—and often far less.²³

Medicare covers a leased sleep apnea device for a 12-week trial period for beneficiaries.²⁴ Thereafter, Medicare will continue to pay for leased sleep apnea devices for up to 13 months, after which time the device is paid off and becomes the property of the patient. However, Medicare will only cover the monthly lease expense beyond the 12-week trial period if patients adhere to its usage guidelines. If patients do not adhere to usage guidelines, Medicare will not cover the lease costs for the sleep apnea device beyond the trial period. Beneficiaries must then assume the cost of leasing the sleep apnea device. According to a VHA sleep medicine clinician who worked in the private sector, beneficiaries may also be required to return the device to the vendor.

A private-sector healthcare organization, Kaiser Permanente, and health insurers like Blue Cross/Blue Shield of Massachusetts and Cigna adopted practices like those of CMS to reduce spending on unused or little-used devices. According to a representative from Kaiser Permanente, the company loans sleep apnea devices to patients for a trial period of one to two weeks prior to purchasing the devices. If the patient uses the sleep apnea device consistently, then Kaiser Permanente purchases and issues the patient a new device.

VHA Does Not Have Clear Guidance on Sleep Apnea Device Cleaning and Reuse

VHA does not have clear guidance on whether unused or little-used devices can be cleaned and reissued to veterans. For example, facility sleep medicine clinicians reported a belief to the audit team that VHA policies prevent medical facilities from taking back veterans' unwanted and unused sleep apnea devices. The audit team, however, determined that there was no VHA policy or directive that prohibits reuse of sleep apnea devices. The only documentation provided regarding the reuse of sleep apnea devices was an April 2012 email from a program analyst from VHA's PSAS to the then acting national program director for critical-care/TeleICU/Lung Disease. The email said the PSAS national program office wanted to issue a memorandum to the field to have all sleep apnea devices deemed single-use. However, according to the PSAS program analyst who sent the email, a memorandum or policy was never issued. As a result, there is no VHA policy that prohibits medical facilities from cleaning and reissuing returned devices.

²³ See table B.7 in appendix B for calculation of the amount VHA spent on sleep apnea devices that veterans used less than half of the time.

²⁴ CMS determined that a trial period of 12 weeks was beneficial in identifying individuals who positively responded to the use of a sleep apnea device. CMS, "Decision Memorandum for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2)," March 13, 2008.

According to the director of the VHA National Infectious Diseases Service and an Infectious Diseases Service staff physician, manufacturers' instruction for use, per Food and Drug Administration approval, is the determining factor if their devices can be cleaned for reuse. The National Infectious Diseases Service director said sleep apnea devices were considered single-use; however, newer devices do not have to be single-use. Additionally, the director said there is nothing stating sleep apnea devices cannot be reused if the manufacturer provides instructions for preparing a device for reuse and this process is done correctly. The Infectious Diseases Service staff physician said the manufacturers' process must have approval from the Food and Drug Administration. The Food and Drug Administration classifies sleep apnea devices as Class II devices, which require the implementation of special controls. These special controls include labeling the devices with useful life information and cleaning instructions.²⁵

The audit team confirmed with representatives from Philips Respironics that this manufacturer's device can be used with multiple patients. Philips Respironics also provides a cleaning service; however, according to a company representative, this service is not currently offered to VA. The team found a document published by ResMed that supports the reuse of this manufacturer's sleep apnea devices.²⁶ Additionally, according to a Kaiser Permanente representative, they use ResMed sleep apnea devices for their loaner program—further supporting the reuse of these devices.

Sleep labs at VHA medical facilities do already clean and reuse sleep apnea devices used to conduct inpatient sleep tests, according to sleep medicine clinicians. These devices are not that different from the sleep apnea devices VHA purchases for veterans for home use.²⁷ According to the director of sleep medicine services at the Albuquerque VA Medical Center, the cleaning of devices in medical facilities' in-house sleep labs includes changing the air filter, cleaning the humidifier reservoir, if there is one, and replacing the hose and mask. VHA has opportunities to apply those processes to reduce the costs associated with purchasing and issuing sleep apnea devices to veterans for home use. VHA must, however, have processes in place to ensure sleep apnea devices are cleaned and fully sanitized in a manner that eliminates any risk to veterans.

VHA's Sleep Apnea Device Ownership Unclear After Issuance

In determining whether VHA can properly retake unused sleep devices, it is useful to contrast the program with the telehealth program, which also issues devices to veterans for home use. VHA's management of sleep apnea devices differs from its management of devices issued by VHA's telehealth program. The PSAS purchases all sleep apnea devices for veterans and it is assumed

²⁵ 21 C.F.R. § 868.5273 (2018).

²⁶ ResMed, "Reimbursement Fast Facts: Integrated Devices," 1017447/2 2015-05, accessed June 6, 2019, https://www.resmed.com/us/dam/documents/articles/1017447_Reimbursement_FF_Payment_Categories.pdf.

²⁷ Sleep apnea devices used to conduct in-house sleep tests can be remotely controlled by sleep medicine clinicians. These devices also collect more data to help sleep medicine clinicians determine if a patient has sleep apnea.

that once purchased the device becomes the property of the veteran, which prevents VHA from taking the devices back. A program analyst from VHA's PSAS said it has always been assumed that veterans own all the devices they receive; however, there is nothing in writing that specifically states this.

According to VHA telehealth officials, telehealth devices are owned by VA and are retrieved from veterans when they have completed treatment. Furthermore, when the patient is discharged, the equipment is retrieved and refurbished at VA's Denver Logistics Center before being reissued to another patient.²⁸

VHA's Integrated Product Team to Assess Sleep Apnea Device Purchases

An integrated product team chartered in December 2016—including VHA's PSAS, the sleep medicine program, the Denver Logistics Center, and the National Acquisitions Center—is developing a program and contract requirements to optimize the value and efficiency for the purchase and distribution of sleep apnea devices and associated supplies. The PSAS national director told the audit team that the group is expected to assess whether VHA can develop a refurbishing program for returned sleep apnea devices modeled after the telehealth refurbishing program and private industry practices. The timeline for doing so, however, was not firm.

Vague Guidance Across Responsible Offices

VHA has not implemented alternative processes to purchasing sleep apnea devices in part because of vague guidance communicated between sleep medicine clinicians and PSAS personnel. The apparent determination that sleep apnea devices should be single-use was based on a 2012 email sent from a PSAS program analyst to the then national program director for pulmonary, critical-care, and sleep medicine. The then national director sent the email to other members of the PSAS and some sleep medicine clinicians within VHA.

The email indicated sleep apnea devices should not be reused because of an absence of sufficient instructions for cleaning these devices. According to the PSAS program analyst, the email was based on a decision made by a former representative from the National Infectious Diseases Service.²⁹

To adequately determine whether VHA should implement alternatives to purchasing sleep apnea devices, the appropriate offices, including the Office of Procurement, Acquisitions, and

²⁸ VHA Office of Connected Care, *Home Telehealth Operations Manual*, December 2017.

²⁹ The audit team was unable to contact the former representative from the National Infectious Diseases Service because the program analyst from the PSAS was unable to recall the name of the individual who made the determination.

Logistics; the PSAS; sleep medicine; and the VHA National Infectious Diseases Service need to communicate and assess the feasibility of developing and implementing an alternative practice.

Because VHA's governance over sleep apnea treatment and resource management is fragmented across two VHA program offices and numerous medical facilities, the under secretary for health should designate an office with the authority to ensure medical facilities implement any processes and recommendations from the assessment.

Conclusion

As the number of veterans receiving sleep apnea devices and related supplies for them has increased, VHA is missing opportunities to ensure patients issued the devices are meeting treatment goals. VHA does not routinely identify and follow up with veterans issued sleep apnea devices within 30 to 90 days as recommended in VHA's source book to assess whether veterans are using their devices as recommended. The audit team learned both staffing and technology challenges contributed to that lack of follow-through. Veterans who are unable or unwilling to use the devices as recommended would benefit from discussions about alternate treatments or some modifications to the current therapy. Although VHA personnel recognized the problems with interoperability of data systems that could help address these obstacles, firm timelines for implementation were not yet set.

VHA has missed opportunities to significantly save taxpayer dollars used for these devices. Assessments and clear guidance for alternatives to purchasing a device for a single user has not been completed. Applying lessons learned from both federal and private sectors could result in millions of dollars in cost savings for VHA annually. Implementing processes that would help ensure veterans will use a sleep apnea device prior to their purchase could reduce VHA's spending on devices and supplies. For example, by loaning devices for veterans to test following diagnosis and then monitoring device use, VHA can identify veterans who will not tolerate the therapy or need additional support and services (such as fitting a different mask). VHA can then issue a device permanently to veterans who have demonstrated an ability and willingness to use the devices as recommended. Those who cannot tolerate sleep apnea device therapy would be able to return their loaner devices without VHA expending funds for devices or related supplies. This type of program, already used for some VHA devices, is dependent on having processes to safely clean and reissue devices. Based on manufacturers' feedback, such a process seems feasible.

VHA's lack of action has exposed it to significant financial risk. The OIG estimates that if VHA acted to implement alternatives to purchasing sleep apnea devices, such as the alternatives used by other medical device providers, VHA could save up to about \$39.9 million per year. VHA also could reduce the risk of purchasing supplies for veterans who will not or cannot use their devices, thereby potentially saving up to an estimated \$12.4 million per year. However, if VHA continues to take no action to leverage opportunities to reduce its spending on sleep apnea devices and supplies, it is at risk of potentially spending \$261.3 million on sleep apnea devices

and supplies—that veterans will not use at least half the time and often far less, if at all—over the next five years.³⁰

The OIG recognizes that if VHA implements an alternative to purchasing sleep apnea devices like leasing or loaning devices, additional costs may be incurred. For example, if VHA were to refurbish these devices in-house, it would incur costs associated with replacing certain items, such as air filters, prior to reissuing the device for use. The audit team estimated the cost associated with the purchase of new air filters for sleep apnea devices that veterans used less than 50 percent of the time to be \$1.2 million. The cost for refurbishing sleep apnea devices was not considered by the team when identifying how much VHA could potentially save, because the cost associated with this process would be dependent on what alternative—such as loaner pool or leasing—if any, VHA implements.

Recommendations 1–3

The OIG recommended the under secretary for health conduct the following actions:³¹

1. Develop a mechanism to assess whether staffing levels within sleep medicine programs are sufficient for monitoring sleep apnea device use and conducting follow-ups with veterans.
2. Ensure the Veterans Health Administration is leveraging existing technologies to make sure medical facilities are routinely monitoring veteran use of sleep apnea devices in a consistent and effective manner to more promptly identify individuals at risk of noncompliance with recommended therapies.
3. Coordinate with the appropriate offices and services, including the Office of Procurement, Acquisitions, and Logistics, Prosthetic and Sensory Aids Service, sleep medicine, and the Veterans Health Administration National Infectious Diseases Service, to (a) assess the viability, potential patient care, and financial impact of an alternative to purchasing sleep apnea devices; (b) make and provide clear guidance on any changes to current Veterans Health Administration processes, including device returns, cleaning, and reissuance; and (c) designate an office with authority to ensure medical facilities implement any processes and recommendations from the assessment.

³⁰ The potential annual cost savings for devices (\$39.9 million) and supplies (\$12.4 million) is based on the average annual cost that VHA spent on sleep apnea devices that veterans used less than 50 percent of the time and the associated supplies provided to these veterans. The potential spending of \$261.3 million is based on the total potential annual savings for devices and supplies, projected over five years.

³¹ Recommendations directed to the under secretary for health were submitted to the executive in charge who has the authority to perform the functions and duties of the under secretary.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with Recommendations 1 through 3 of the report and provided technical comments. The executive in charge also provided general comments regarding developments to improve veterans' access to sleep apnea diagnostic testing, efforts to contain costs for sleep apnea devices, and new information resources for sleep medicine clinicians. To address Recommendation 1, the executive in charge reported the national director for pulmonary, critical-care, and sleep medicine will assemble a team of subject matter experts charged with evaluating and developing a mechanism to assess staffing models needed for sufficient adherence to monitoring and providing follow-up care to veterans using sleep apnea devices. In response to Recommendation 2, the executive in charge reported the national director for pulmonary, critical-care, and sleep medicine will identify at each facility performing sleep services the use and method of monitoring sleep apnea devices, sleep apnea device adherence levels, and presence and use of standardized protocols for evaluating and managing nonadherence to prescribed therapies. Sites that are not using existing technologies or meeting targets will be required to develop an action plan for follow up until compliant. In response to Recommendation 3, the executive in charge reported the national director for pulmonary, critical-care, and sleep medicine, in collaboration with the Office of Procurement, Acquisitions, and Logistics; PSAS; and the national program director for Infectious Diseases Service will review, evaluate, and develop a process to

- Assess the viability and financial impact of an alternative to purchasing sleep apnea devices and the potential effect on patient care,
- Establish and provide clear guidance on any changes to current VHA processes, including device returns, cleaning, and reissuance, and
- Work with the deputy under secretary for health for operations and management to develop authority to ensure medical facilities implement any processes and recommendations from the assessment.

Once the evaluation is completed, a plan will be developed to provide written guidance on the expected process moving forward.

OIG Response

The executive in charge's comments and corrective action plans are responsive to the intent of the recommendations. The OIG will monitor the implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified. Appendix D includes the full text of the executive in charge's comments, including general and technical comments. This appendix also includes the OIG's response to the executive in charge's technical comments.

Appendix A: Scope and Methodology

Scope

The audit team conducted its work from October 2018 through October 2019. The scope of the audit included an examination of data, documentation, and information related to veterans issued a VHA-purchased sleep apnea device between October 2016 and May 2018.³²

Methodology

To gain an understanding of VHA's guidelines for diagnosing sleep-related breathing disorders, issuing sleep apnea devices and associated supplies, and monitoring for patient use, the team examined relevant criteria, guidance, and a VHA Directive. Applicable criteria included the following:

- *Sleep-Related Breathing Disorders Source Book*, 3rd Edition, Version 2.1, VHA, The VA Sleep Field Advisory Group, January 2014.
- VA Office of Information Security Bulletin FSS No. 263: Application Info: REVAMP, *Remote Veteran Apnea Management Platform (REVAMP)*, October 2, 2015.
- VA Office of Information Security Bulletin FSS No. 328: *Wireless Positive Airway Pressure Monitoring for Sleep Apnea*, January 19, 2016.

The audit team interviewed key staff from the VHA's PSAS; an information system security officer; VISN prosthetic representatives; and VA medical facility staff including individuals from the pulmonary, sleep medicine, and prosthetics programs about their roles and responsibilities and the process for providing veterans with sleep apnea devices and associated supplies, as well as the process for monitoring usage of devices and performance of follow ups with veterans. The team also interviewed representatives from CMS, a private healthcare organization, and the Department of Defense, as well as representatives from sleep apnea device manufacturers, to gain an understanding of industry standards for managing sleep apnea devices, frequency and method of patient follow-up care, and monitoring device usage.

The team requested veterans' sleep apnea usage data reports for the most recent 12-month period and reviewed reports provided to determine if veterans were adhering to usage guidelines

³² The population of veterans for whom VHA purchased a sleep apnea device included female and male veterans, veterans who had a service-connected disability for sleep apnea, and veterans who did not have a service-connected disability for sleep apnea.

identified in VHA's source book. Usage data reports were provided by individuals from the VISNs and VA medical facilities.

National Prosthetics Patient Database

To identify the number of veterans for whom VA purchased at least one sleep apnea device, the audit team used NPPD data from October 2016 through May 2018. The team obtained a data extract from the NPPD that identified a universe of 275,800 veterans. The team reviewed a sample of 223 veterans from the audit universe. Appendix B provides details on the statistically sampled population.

Site Visits

The audit team visited the Audie L. Murphy VA Hospital in San Antonio, Texas, and the Orlando VA Medical Center in Florida. The sites were judgmentally selected based on several factors, including the number of veterans reviewed at each location, veteran use of sleep apnea devices, and facility personnel's performance of follow ups. During the site visits, the team interviewed staff responsible for overseeing and managing sleep apnea diagnosis and treatment, including the chiefs of sleep, chiefs of prosthetics, sleep lab supervisors, a respiratory therapist, and prosthetic purchasing agents. The interviews provided information on how veterans diagnosed with sleep apnea get the necessary follow-up care and sleep apnea devices and associated supplies.

Data Collection Instrument

The audit team developed an electronic data collection instrument to review a random sample of 223 unique veterans for whom VHA purchased at least one sleep apnea device during the review period. The team reviewed selected veterans' medical records in CAPRI and analyzed veterans' use of their sleep apnea devices. This instrument was used to assess whether VHA performed follow-up visits, provided veterans with sleep apnea devices and supplies, and monitored veteran use of devices as recommended in VHA's source book. The instrument included information such as veteran diagnosis date, device usage, and follow-up care appointments.

The team took steps in the development of the data collection instrument to ensure the collection of accurate information and incorporated second-level reviews of the analysis of veterans' medical records and device usage data.

Survey of Facility Sleep Medicine Clinicians

The audit team conducted an electronic survey of 137 VHA sleep medicine clinicians from February 22 through March 5, 2019.³³ The survey was designed to collect information on the management of sleep apnea devices and associated supplies, medical facilities' enrollment in the Wireless Positive Airway Pressure Monitoring program and REVAMP, frequency of veterans' follow-up appointments, and challenges with providing sleep apnea care. The team obtained responses from 120 sleep medicine clinicians, resulting in about an 88 percent response rate.

Fraud Assessment

The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The team exercised due diligence in staying alert to any fraud indicators:

- The team coordinated with the OIG's Office of Investigations concerning potential fraud indicators.
- The team considered potential fraud indicators when reviewing documentation collected during data gathering, such as looking at the cost of sleep apnea devices to determine if there were any significant variations in price to VA.

The OIG did not identify any instances of fraud or potential fraud during this audit.

Data Reliability

The OIG used computer-processed data from the NPPD to identify the total number of veterans for which VHA purchased a sleep apnea device. To assess the reliability of the NPPD data, the audit team compared a sample of NPPD transactions to supporting source documentation such as sleep apnea consults and hard copy vendor invoices. The team concluded that the NPPD data that included information on VHA's purchase of sleep apnea devices and associated supplies for veterans were appropriate and sufficient for the purpose of this audit.

Government Standards

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

³³ The audit team requested VHA provide sleep medicine points of contact for all VA medical facilities. Based on the information provided, the team identified 137 sleep medicine points of contact.

Appendix B: Statistical Sampling Methodology

Sampling Methodology

The audit team obtained a data extract from the NPPD of all sleep apnea devices and associated supplies purchased from October 2016 through May 2018. From the data, the team selected a stratified random sample of 304 veterans for whom VHA purchased a sleep apnea device. This sample was composed of 209 primary samples and 95 secondary samples. The secondary samples were selected to account for any sampled veterans who were excluded from the review due to reasons such as unavailability of sleep apnea device usage data and sleep apnea devices provided to non-veteran patients. From the stratified random sample, the team reviewed a sample of 223 veterans. Because the team's results were based on the random sample of veterans, the team projected findings from this sample onto the universe of veterans from October 2016 through May 2018.

Population

The universe of veterans for whom VHA purchased at least one sleep apnea device from October 2016 through May 2018 was 275,800.

Sampling Design

The sampling design for the selection of veterans who received a sleep apnea device was organized by VISN. Table B.1 identifies each VISN, the number of unique veterans in each VISN, and the number of veterans selected.

Table B.1. Unique and Sampled Veterans by VISN

VISN	Unique veterans	Primary sample	Secondary sample
1	10,048	8	5
2	8,792	7	5
4	9,339	7	5
5	6,949	5	5
6	21,401	16	5
7	23,143	17	5
8	26,744	20	5
9	9,539	7	5
10	18,543	14	5
12	11,588	9	5
15	12,442	9	5
16	17,893	14	5
17	22,911	17	5
18	9,463	7	5
19	17,624	13	5
20	14,929	11	5
21	7,408	8	5
22	12,299	9	5
23	14,745	11	5
Total	275,800	209	95

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018.

Weights

The OIG calculated estimates in this report using weighted sample data. Samples were weighted to represent the population from which they were drawn. The audit team used the weights to compute estimates. For example, the team calculated the error rate point estimates by summing the sampling weights for all sample records that contained an error, then dividing that value by the sum of the weights for all sample records.

Projections and Margins of Error

The point estimate (e.g., estimated error) is an estimate of the population parameter obtained by sampling. The margin of error and confidence interval associated with each point estimate is a

measure of the precision of the point estimate that accounts for the sampling methodology used. If the OIG repeated this audit with multiple samples, the confidence intervals would differ for each sample but would include the true population value 90 percent of the time.

The OIG statistician employed statistical analysis software to calculate the weighted population estimates and associated sampling errors. This software uses replication or Taylor-Series Approximation methodology to calculate margins of error and confidence intervals that correctly account for the complexity of the sample design.

Table B.2 details the audit projection for the number of veterans who were not using their devices consistently. These projections are the basis of the estimated potential monetary benefits for the audit, detailed in Appendix C.

Table B.2. Veterans Using Devices Less than 50 Percent of the Time

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Veterans using device <=50% of nights	113,762 (45%)	15,460	98,302	129,222	90
Veterans using device >50% of nights	136,307 (55%)	15,578	120,729	151,885	107
Total	250,069	7,705*	242,364*	257,774*	197**

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

**The margin of error and confidence intervals represent a measure of uncertainty for the row estimates and do not total.*

***The difference between the sample of 223 and the sample count of 197 relates to instances where veterans' usage data reports were not readily available because the devices purchased did not include a wireless modem or the data reports were not provided.*

Table B.3 details the audit projection for the breakdown by percentage of veterans' estimated usage of prescribed sleep apnea devices.

Table B.3. Veterans' Estimated Usage of Prescribed Sleep Apnea Devices

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Less than or equal to 20%	92,101 (37%)	14,858	77,243	106,959	73
>20% and ≤50%	21,661 (9%)	8,634	13,027	30,295	17
>50% and ≤70%	24,016 (10%)	9,013	15,003	33,029	19
>70%	112,291 (45%)	15,298	96,993	127,589	88
Total	250,069	7,705*	242,364*	257,774*	197

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

*The margin of error and confidence intervals represent a measure of uncertainty for the row estimates and do not total.

Table B.4 details the audit projection for the breakdown by percentage of the number of veterans who used their sleep apnea devices less than 50 percent of the time.

Table B.4. Veterans' Estimated Usage of Prescribed Sleep Apnea Devices for those using Less than 50 Percent of the time

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Less than or equal to 20%	92,101 (81%)	14,858	77,243	106,959	73
>20% and ≤50%	21,661 (19%)	8,634	13,027	30,295	17
Total	113,762	15,460*	98,302*	129,222*	90

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

*The margin of error and confidence intervals represent a measure of uncertainty for the row estimates and do not total.

Table B.5 details the audit projection for the number of veterans who did not use their device consistently and whether they had a follow-up with a sleep medicine clinician.

Table B.5. Veterans Who Used Their Device Less than 50 Percent of the Time and Whether They Had a Follow-Up with a Sleep Medicine Clinician

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Veterans with no follow-up, or VHA attempted follow up but veteran did not follow through	50,947 (45%)	12,273	38,674	63,220	40
Veterans with follow up	62,815 (55%)	13,084	49,731	75,899	50
Total	113,762	15,460*	98,302*	129,222*	90

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

*The margin of error and confidence intervals represent a measure of uncertainty for the row estimates and do not total.

Table B.6 details the audit projection for the number of prescribed sleep apnea devices with and without modems.

Table B.6. Veterans' Prescribed Sleep Apnea Devices with and without Modems

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Had Modem	263,542 (96%)	5,381	258,161	268,924	210
No Modem	12,258 (4%)	5,381	6,877	17,639	13
Total	275,800	0*	275,800*	275,800*	223

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

*The margin of error and confidence intervals represent a measure of uncertainty for the row estimates and do not total.

Table B.7 details the audit projection for the amount spent on sleep apnea devices and associated supplies for veterans that did not consistently use their devices.

Table B.7. Amount Spent on Sleep Apnea Devices and Supplies for Veterans Who Used Their Devices Less than 50 Percent of the Time (Dollars in Millions)

Category	Estimate	Margin of error	90% confidence interval lower limit	90% confidence interval upper limit	Count from sample
Veterans not consistently using their devices	113,762	N/A*	N/A	N/A	90
Value of sleep apnea devices provided to veterans not consistently used	\$66.3	\$10.4	\$56	\$76.7	90
Value of supplies provided to veterans not consistently used	\$20.6	\$4.1	\$16.4	\$24.7	90
Total Value—devices and supplies	\$86.6	\$13.2	\$73.4	\$99.9	90

Source: VA OIG analysis of statistically sampled veterans for whom VHA paid for a sleep apnea device from October 2016 through May 2018

*N/A=sampling information is included in Table B.2.

Appendix C: Potential Monetary Benefits in Accordance with Inspector General Act Amendments

Recommendation	Explanation of Benefits	Better Use of Funds (in millions)	Questioned Costs (in millions)
1–3	Value of funds spent on sleep apnea devices that veterans will not consistently use, and the associated supplies, over the next five years if action is not taken	\$261.3 ³⁴	
	Total	\$261.3	

³⁴ To estimate the potential impact over the next five years, the OIG calculated the average annual amount spent on sleep apnea devices that veterans used less than 50 percent of the time at \$39.9 million, and the associated supplies at \$12.4 million, and projected this amount over five years. The amount of \$261.3 million was arrived by using unrounded dollar amounts the team calculated for how much VHA spent on sleep apnea devices that veterans used less than 50 percent of the time and the cost associated supplies. If the rounded dollar amounts that are presented in the body of this report were used, the five-year estimated impact would be \$261.5 million.

Appendix D: Management Comments

Department of Veterans Affairs Memorandum

Date: NOV 26, 2019

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Veterans Health Administration: Opportunities Missed to Contain Spending on Sleep Apnea Devices and Improve Veterans' Outcomes (VIEWS 01790611)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review and comment on the Office of the Inspector General (OIG) draft report, Veterans Health Administration: Opportunities Missed to Contain Spending on Sleep Apnea Devices and Improve Veterans' Outcomes.
2. I concur with OIG recommendations 1 through 3 and provide the attached action plan and general and technical comments.
3. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison Office at VHA10EGGOALAction@va.gov.

(Original signed by)

Richard A. Stone, M.D.

Attachments

**VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan**

OIG Draft Report: Opportunities Missed to Contain Spending on Sleep Apnea Devices and Improve Veterans' Outcomes

Date of Draft Report: October 25, 2019

Recommendations/ Actions	Status	Target Completion Date
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The OIG recommends the Under Secretary for Health conduct the following:

Recommendation 1: Develop a mechanism to assess whether staffing levels within sleep medicine programs are sufficient for monitoring sleep apnea device use and conducting follow-ups with veterans.

VHA Comments: Concur

The National Program Director for Pulmonary, Critical Care and Sleep Medicine will assemble a team of subject matter experts charged with evaluating and developing a mechanism to assess staffing models needed for sufficient adherence to monitoring and follow-up care of veterans using sleep apnea devices.

Status: In Progress Target Completion Date: July 2020

Recommendation 2: Ensure the Veterans Health Administration is leveraging existing technologies to make sure medical facilities are routinely monitoring veteran use of sleep apnea devices in a consistent and effective manner to more promptly identify individuals at risk of noncompliance with recommended therapies.

VHA Comments: Concur

The National Program Director for Pulmonary, Critical Care and Sleep Medicine will identify the following at each facility performing sleep services:

- Use and method of monitoring sleep apnea devices
- Sleep Apnea device adherence levels
- Presence and use of standardized protocols for evaluating and managing non-adherence to prescribed therapies

Sites that are not utilizing existing technologies or meeting targets will be required to develop an action plan for follow-up until compliant.

Status: In Progress Target Completion Date: August 2020

Recommendation 3: Coordinate with the appropriate offices and services, to include the Office of Procurement, Acquisitions, and Logistics, Prosthetic and Sensory Aids Service, Sleep Medicine,

and the VHA National Infectious Diseases Service, to (a) assess the viability, potential patient care, and financial impact of an alternative to purchasing sleep apnea devices; (b) make and provide clear guidance on any changes to current VHA processes, including device returns, cleaning, and reissuance; and (c) designate an office with authority to ensure medical facilities implement any processes and recommendations from the assessment.

VHA Comments: Concur

The National Program Director for Pulmonary, Critical Care and Sleep Medicine in collaboration with the Office of Procurement, Acquisitions, and Logistics, Prosthetics and Sensory Aid Service, and the National Program Director for Infectious Diseases Services will review, evaluate and develop a process to address

- assessing the viability and financial impact of an alternative to purchasing sleep apnea devices and the potential effect on patient care;
- establishing and providing clear guidance on any changes to current VHA processes, including device returns, cleaning, and reissuance; and
- working with the Deputy Under Secretary for Health for Operations and Management to develop authority to ensure medical facilities implement any process and recommendations from the assessment.

Once the evaluation has been completed, a plan will be developed to provide written guidance on the expected process moving forward.

Status:
In Progress

Target Completion Date:
November 2020

VHA Technical Comments and OIG Response

OIG Draft Report, Opportunities Missed to Contain Spending on Sleep Apnea Devices and Improve Veterans' Outcomes

Comment 1

Draft location: page i, paragraph 1 & 2, sentences 2 and 5

Comment and Justification: The first paragraph uses the term positive airway pressure (PAP) device, however in the second paragraph the term sleep apnea device is used. Throughout the document, sleep apnea device is used rather than PAP device. There are many more devices used to treat sleep apnea other than PAP devices. These include dental and surgically implanted devices, which do not have wireless access. Since it is obvious that the report is specific to PAP devices, I would suggest using that term throughout the document.

OIG Response: Page i of this report states that positive airway pressure devices will be referred to as sleep apnea devices. The OIG recognizes that there are many types of devices that could be classified as "sleep apnea devices". However, this report only discusses positive airway pressure devices and therefore we do not believe this will cause any confusion. As a result, no changes were made to the report.

Comment 2

Draft location: page 18, footnote 28

Comment and Justification: The proposed cost savings based on average annual costs spent on devices and supplies does not consider the increase in cost of instituting a program that would be able to affect those savings. Increased numbers of salaries for clinicians would greatly offset a large proportion of those estimated savings.

OIG Response: Page ii of this report states: the OIG recognizes that additional costs may be incurred if VHA implements an alternative to purchasing sleep apnea devices, such as leasing or loaning them. For example, if VHA were to refurbish these devices in-house, it would incur costs associated with replacing certain items, such as air filters, prior to reissuing the device for use. Additional costs were not considered by the audit team when identifying how much VHA could potentially save, because the costs associated with this process would be dependent on what alternative, if any, VHA implements. As a result, no changes were made to the report.

Comment 3

Draft location: page 13-14

Comment and Justification: The discussion of software usage and any efficiencies possible through their use is premature. The Remote Veteran Apnea Management Platform (REVAMP) program has not been changed from an innovative design to an integrated program available for use across the Veterans

Health Administration. The Somnoware program is due to begin a pilot to determine if it will meet the needs of clinicians and produce any efficiencies at all.

OIG Response: As the report states, the OIG is aware that this program is still in the pilot stage. This information was provided to show that VHA was proactive in building a program that could be used to better track veterans' use of sleep apnea devices. In addition, the OIG chose to include REVAMP in this report in order to provide additional awareness to VHA sleep clinicians of the program's availability. As a result, no changes were made to the report.

Comment 4

Draft location: Appendix B

Comment and Justification: The statistics were performed on less than 0.1% of the population under study. The samples were weighted and subjected to a Taylor-Series approximation, then extrapolated to represent a larger population. VHA does not think this statistical method is accurate when performed in this way. While there are estimated accuracy measurements, the conclusions and projections are all based on this process without any independent confirmation of accuracy.

OIG Response: The sample for this project was sized appropriately for needs of the audit. Population size has little to do with sample size mathematically unless the population is very small. The variance calculation methodology chosen for this sample takes the variations in sample weights and the sample design into account to provide a correct value for the margin of error for each sample estimate. This methodology is proven in the statistical science literature and is considered a best practice among sampling statisticians. The OIG finds no merit in this comment. No statistical support is cited for VHA's opinion that it is not accurate. As a result, no changes were made to the report.

VHA General Comments

OIG Draft Report, Opportunities Missed to Contain Spending on Sleep Apnea Devices and Improve Veterans' Outcomes

There have been several developments to improve access with limited resources.

1. The Veterans Health Administration's (VHA) TeleSleep program, funded by the Office of Rural Health fiscal year 2017 (FY17), evaluates how health care systems can leverage existing resources and implement new delivery systems for sleep care, including synchronous telehealth, home sleep apnea testing (HSAT; asynchronous telehealth), remote monitoring of positive airway pressure (PAP) devices, virtual web-based care programs, and electronic consultation to improve Veteran access to sleep care. This program has demonstrated effectiveness in reaching rural Veterans through hub-spoke models (7 hubs, 42 rural spoke sites). Within the first two fiscal years, the TeleSleep program served 100,204 Veterans, 32,749 of whom were rural, through 214,952 clinical encounters.
2. The TeleSleep program procured 1,283 Home Sleep Testing devices and supplies and distributed them to 54 Department of Veterans Affairs (VA) Sleep programs across the nation to increase access to diagnostic sleep testing. Home testing has now surpassed in-house polysomnography to become the major means of testing for sleep apnea within the VA.
3. Sleep Medicine now accounts for the third largest store and forward telehealth program nationally as a result of increased adoption of HSAT.
4. Adoption of HSAT within VA has helped to reduce utilization of community care and is the primary strategy to retain sleep care within VA, reducing wait times for testing and therefore provision of continuous PAP (CPAP) devices to those who require treatment.
5. Sleep Stop Codes have been nationally implemented (FY15) and recently updated (FY20) with telehealth codes. This will enable identification of the type and volume of sleep services provided in VA.
6. An Integrated Product Team was formed in 2016 with goals of standardizing national pricing for PAP devices and supplies, and to streamline acquisition and distribution of these devices and supplies to Veterans and VA Medical Centers.
7. Sleep Medicine was the first specialty to obtain approval for remote monitoring of data from patients' home treatment devices in 2015. This opened the gates to implementation and expansion of telemedicine for Sleep and has facilitated approval for devices in other specialty care areas (i.e., glucose monitoring for diabetes).
8. Remote Veteran Apnea Management Platform (REVAMP) was developed by VA as a virtual sleep apnea care pathway for Veterans, allowing remote monitoring of PAP devices and collection of patient responses to treatment. This web-application was funded by the VA Center for Innovation and is now part of the Office of Connected Care's portfolio. It won the 2018 Federal Health Information Technology Award.
9. Toolkits and resources have been developed and curated in a central repository as a resource for all VHA sleep programs. These resources focus on facilitating telemedicine, establishing remote monitoring programs, and improving workflow efficiency.

10. The Healthcare Analytics and Information Group (HAIG) was enlisted to assess the state of Sleep services across the nation. The survey has been nearly completed and data analysis will follow. This survey will give the most detailed picture of sleep services the VA has obtained to date.
11. A Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) program for Sleep services was developed in Veterans Integrated Service Network 20. A workgroup was established with the Employee Education System to create a centralized repository of patient training and education videos about sleep apnea and CPAP devices (including trouble-shooting and self-management), as well as provider training videos to facilitate a broader reach in training non-sleep practitioners in CPAP management.

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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