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August 5, 2016

VIA HAND DELIVERY

Kimberly R. Martone, Director of Operations
Department of Public Health - Office of Healthcare Access
410 Capitol Avenue
MS# 13HCA
Hartford, CT 06134

Re: The Waterbury Hospital
Certificate of Need Application – Regional Sleep Laboratory

Dear Ms. Martone:

I enclose for filing an original and four (4) copies of The Waterbury Hospital's Certificate of Need Application for the Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut. Also enclosed is a disc containing the entire submission and a check for the $500.00 filing fee.

Please feel free to contact me with any questions. Thank you for your attention to this matter.

Very truly yours,

David S. Hardy

DSH/cf
Enc.

cc: Michele Volpe, Esq., Counsel for Prospect Medical Holdings, Inc.

{N5253320}

Application Checklist

Instructions:

1. Complete the following checklist and **submit** as the first page of the CON application:

☒ Attached is a paginated hard copy of the CON application (all social security numbers must be redacted), including a completed affidavit, signed and notarized by the appropriate individuals.

☒ (**New**). A completed supplemental application form specific to the proposal type, available on OHCA's website under OHCA Forms (see previous page for the list of supplemental forms).

☒ Attached is the CON application filing fee in the form of a check made out to the "Treasurer State of Connecticut" in the amount of $500.

☒ Attached is evidence demonstrating that public notice has been published in a **suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON** application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication)*

☒ Attached is a completed Financial Worksheet (A, B or C) available at OHCA's website under OHCA Forms.

☒ Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.

☒ The following have been submitted on a CD:

1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format; and
2. An electronic copy of the completed application forms in **MS Word** (the applications) and **MS Excel** (Financial Worksheet)

For OHCA Use Only:

Docket No.: _____ **Check No.:** 9151.6
OHCA Verified by: KM **Date:** 24/16

TABLE OF CONTENTS

State of Connecticut
Department of Public Health
Office of Health Care Access

Certificate of Need Application
Main Form
Required for all CON applications

Contents:

Supplemental Forms

In addition to completing this **Main Form** and **Financial Worksheet (A, B or C)**, the applicant(s) must complete the appropriate **Supplemental Form** listed below. All CON forms can be found on the OHCA website at OHCA Forms.

Conn. Gen. Stat. Section 19a-638(a)	Supplemental Form
(1)	**Establishment of a new health care facility (mental health and/or substance abuse)** - *see note below**
(2)	**Transfer of ownership of a health care facility** (excludes transfer of ownership/sale of hospital – see "Other" below)
(3)	**Transfer of ownership of a group practice**
(4)	**Establishment of a freestanding emergency department**
(5) (7) (8) (15)	**Termination of a service:** - inpatient or outpatient services offered by a hospital - surgical services by an outpatient surgical facility** - emergency department by a short-term acute care general hospital - inpatient or outpatient services offered by a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended
(6)	**Establishment of an outpatient surgical facility**
(9)	**Establishment of cardiac services**
(10) (11)	**Acquisition of equipment:** - acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners - acquisition of nonhospital based linear accelerators
(12)	**Increase in licensed bed capacity** of a health care facility
(13)	**Acquisition of equipment utilizing [new] technology** that has not previously been used in the state
(14)	**Increase of two or more operating rooms** within any three-year period by an outpatient surgical facility or short-term acute care general hospital
Other	**Transfer of Ownership / Sale of Hospital**

*This supplemental form should be included with all applications requesting authorization for the establishment of a **mental health and/or substance abuse treatment facility**. For the establishment of other "health care facilities," as defined by Conn. Gen. Stat § 19a-630(11) - hospitals licensed by DPH under chapter 386v, specialty hospitals, or a central service facility - complete *the Main Form* only.

**If termination is due to insufficient patient volume, or it is a subspecialty being terminated, a CON is not required.

General Information

Name of Applicant:	Name of Co-Applicant:
The Waterbury Hospital	

Connecticut Statute Reference:
C.G.S. Section 19a-638(a)(5)

Main Site

MAIN SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	MAIN SITE NAME
Southbury		Outpatient Sleep Laboratory	Southbury Sleep Lab

STREET & NUMBER	
1284 Strongtown Road	
TOWN	ZIP CODE
Southbury, CT	06488

Operator

OPERATING CERTIFICATE NUMBER	TYPE OF FACILITY	LEGAL ENTITY THAT WILL OPERATE OF THE FACILITY (or proposed operator)
		The Waterbury Hospital

STREET & NUMBER	
64 Robbins Street	
TOWN	ZIP CODE
Waterbury, CT	06708

Chief Executive

NAME		TITLE	
Darlene Stromstad		President/CEO	
STREET & NUMBER			
64 Robbins Street			
TOWN		STATE	ZIP CODE
Waterbury		CT	06708
TELEPHONE	FAX	E-MAIL ADDRESS	
203-573-7101	203-573-6161	dstromstad@wtbyhosp.org	

		Title of Attachment:
Is the applicant an existing facility? If yes, attach a copy of the resolution of partners, corporate directors, or LLC managers, as the case may be, authorizing the project.	YES ☒ NO ☐	N/A (no resolution required for action)
Does the Applicant have non-profit status? If yes, attach documentation.	YES ☒ NO ☐	Attachment 1

Identify the Applicant's ownership type.	PC ☐ Other: LLC ☐ Corporation ☒
Applicant's Fiscal Year (mm/dd)	Start 10/01 End 09/30

Contact:

Identify a single person that will act as the contact between OHCA and the Applicant.

Contact Information			
NAME		TITLE	
Darlene Stromstad		President/CEO	
STREET & NUMBER			
64 Robbins Street			
TOWN	STATE	ZIP CODE	
Waterbury	CT	06708	
TELEPHONE	FAX	E-MAIL ADDRESS	
203-573-7101	203-573-6161	dstromstad@wtbyhosp.org	
RELATIONSHIP TO APPLICANT	President/CEO		

Identify the person primarily responsible for preparation of the application (optional):

Prepared by			
NAME		TITLE	
STREET & NUMBER			
TOWN	STATE	ZIP CODE	
TELEPHONE	FAX	E-MAIL ADDRESS	
RELATIONSHIP TO APPLICANT			

Affidavit

Applicant: The Waterbury Hospital
Project Title: Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut

I, Darlene Stromstad, (Name) President/CEO (Position – CEO or CFO)

of The Waterbury Hospital being duly sworn, depose and state that the The Waterbury Hospital complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Signature 7/27/16 Date

Subscribed and sworn to before me on 7/27/16

Jan Balcarini

Notary Public/Commissioner of Superior Court

My commission expires: 7-31-16

{N5239210}

Affidavit

Applicant: The Waterbury Hospital
Project Title: Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut

I, Darlene Stromstad, (Name) President/CEO (Position – CEO or CFO)

of The Waterbury Hospital being duly sworn, depose and state that the The Waterbury Hospital complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Signature 7/27/16 Date

Subscribed and sworn to before me on 7/27/16

Joan Balcavinic

Notary Public/Commissioner of Superior Court

My commission expires: 7-31-16

Executive Summary

The purpose of the Executive Summary is to give the reviewer a conceptual understanding of the proposal. In the space below, provide a succinct overview of your proposal (this may be done in bullet format). Summarize the key elements of the proposed project. Details should be provided in the appropriate sections of the application that follow.

The Waterbury Hospital is requesting Certificate of Need ("CON") authorization for the consolidation of its sleep laboratory services to a single location in Middlebury, Connecticut.

Key Elements of the Proposal

The Waterbury Hospital ("Hospital") is a tax exempt Connecticut nonstock corporation and has operated a 6 bed sleep lab, the Regional Sleep Laboratory, at 1625 Straits Turnpike in Middlebury, Connecticut ("Middlebury Sleep Lab") since 2005. Middlebury Sleep Lab experienced significant growth between 2005 and 2008 with demand beginning to out-pace capacity and the Hospital sought to expand its services to Southbury. On February 19, 2009, the State of Connecticut Office of Health Care Access ("OHCA") granted a Certificate of Need under Docket Number: 08-31211-CON ("CON") to the Hospital to establish and operate a second sleep laboratory at the Crowne Plaza Hotel, 1284 Strongtown Road, Southbury, Connecticut ("Southbury Sleep Lab") to be operated under the Hospital's acute care hospital license. Southbury Sleep Lab opened in April 2009 and completed its first patient study on April 29, 2009.

Because of increased competition from other hospital providers as well as the advent of home-based sleep testing, the expected volume did not materialize. The following table summarizes the projected as well as actual total sleep study volume for the Hospital's sleep lab service.

FY 2010		FY 2011	
Projected*	Actual	Projected*	Actual
1805	1395	2022	1192

*DN: 08-31211-CON

Based on declining volume and the cost in-effectiveness of maintaining two sleep lab locations, the Hospital consolidated sleep lab services to Middlebury Sleep Lab effective August 31, 2011. As indicated by the table below, Middlebury Sleep Lab was and remains able to accommodate all referred volume. Indeed, Middlebury Sleep Lab still has capacity to accommodate anticipated future growth.

FY 2012	FY 2013	FY 2014	FY2015	FY2016*
1115	995	937	1022	671

*8 months actual

Middlebury Sleep Lab serves the Hospital's service area which consists of the following towns: Beacon Falls, Bethlehem, Cheshire, Middlebury, Morris, Naugatuck, Oakville, Oxford, Plantsville, Plymouth, Prospect, Seymour, Southbury, Southington, Terryville, Thomaston, Torrington, Waterbury, Watertown, Wolcott and Woodbury. No new services are proposed.

Pursuant to Section 19a-639 of the Connecticut General Statutes, the Office of Health Care Access is required to consider specific criteria and principles when reviewing a Certificate of Need application. Text marked with a "§" indicates it is actual text from the statute and may be helpful when responding to prompts.

Project Description

1. **Provide a detailed narrative describing the proposal. Explain how the Applicant(s) determined the necessity for the proposal and discuss the benefits for each Applicant separately (if multiple Applicants). Include all key elements, including the parties involved, what the proposal will entail, the equipment/service location(s), the geographic area the proposal will serve, the implementation timeline and why the proposal is needed in the community.**

Response:

The Waterbury Hospital ("Hospital") is a tax exempt Connecticut nonstock corporation and has operated a 6 bed sleep lab, the Regional Sleep Laboratory, at 1625 Straits Turnpike in Middlebury, Connecticut ("Middlebury Sleep Lab") since 2005. Middlebury Sleep Lab experienced significant growth between 2005 and 2008 with demand beginning to out-pace capacity and the Hospital sought to expand its services to Southbury. On February 19, 2009, the State of Connecticut Office of Health Care Access ("OHCA") granted a Certificate of Need under Docket Number: 08-31211-CON ("CON") to the Hospital to establish and operate a second sleep laboratory at the Crowne Plaza Hotel, 1284 Strongtown Road, Southbury, Connecticut ("Southbury Sleep Lab") to be operated under the Hospital's acute care hospital license. Southbury Sleep Lab opened in April 2009 and completed its first patient study on April 29, 2009.

Because of increased competition from other hospital providers as well as the advent of home-based sleep testing, the expected volume never materialized. Based on declining volume and the cost in-effectiveness of maintaining two sleep lab locations, the Hospital consolidated sleep lab services to Middlebury Sleep Lab effective August 31, 2011. The Hospital's two Sleep Lab locations were in close proximity to one another, and the patients in the area served by the Southbury location were and have been conveniently served by the Middlebury location.

2. **Provide the history and timeline of the proposal (i.e., When did discussions begin internally or between Applicant(s)? What have the Applicant(s) accomplished so far?).**

Response:

The Hospital closed the Southbury location and consolidated the sleep laboratory services in the Middlebury location effective August 31, 2011.

3. **Provide the following information:**

   a. **utilizing OHCA Table 1, list all services to be added, terminated or modified, their physical location (street address, town and zip code), the population to be served and the existing/proposed days/hours of operation;**

Response:

OHCA Table 1 has been completed to show the existing services offered by the Regional Sleep Laboratory, its physical location, the population served and the existing hours of operation.

b. identify in OHCA Table 2 the service area towns and the reason for their inclusion (e.g., provider availability, increased/decreased patient demand for service, market share);

Response:

OHCA Table 2 has been completed to show the service area towns.

4. List the health care facility license(s) that will be needed to implement the proposal;

Response:

No additional health care facility licenses are needed.

5. Submit the following information as attachments to the application:

a. **a copy of all State of Connecticut, Department of Public Health license(s) currently held by the Applicant(s);**

Response:

See Attachment 2 (Waterbury Hospital License Record)

b. **a list of all key professional, administrative, clinical and direct service personnel related to the proposal and attach a copy of their Curriculum Vitae;**

Response:

Jay Kenkare, M.D. is the Medical Director of the Regional Sleep Laboratory. He is Board Certified in Sleep Medicine and Internal Medicine by the American Board of Internal Medicine. He is a member of the American Academy of Sleep Medicine.

Dr. Kenkare graduated from the Robert Wood Johns Medical School at Rutgers University. He completed his Internal Medicine Residency Training at Yale School of Medicine followed by a fellowship in sleep medicine.

c. **copies of any scholarly articles, studies or reports that support the need to establish the proposed service, along with a brief explanation regarding the relevance of the selected articles;**

Response:

Not applicable. The Regional Sleep Laboratory has been providing services for many years.

d. **letters of support for the proposal;**

Response:

Not applicable. The Regional Sleep Laboratory has been providing services for many years.

e. **the protocols or the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet the protocols or guidelines.**

Response:

Not applicable. The Regional Sleep Laboratory has been providing services in accordance with relevant guidelines for many years.

f. **copies of agreements (e.g., memorandum of understanding, transfer agreement, operating agreement) related to the proposal. If a final signed version is not available, provide a draft with an estimated date by which the final agreement will be available.**

Response:

Not applicable.

Public Need and Access to Care

> § *"Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;" (Conn. Gen. Stat. § 19a-639(a)(1))*

6. Describe how the proposed project is consistent with any applicable policies and standards in regulations adopted by the Connecticut Department of Public Health.

Response:

Connecticut General Statutes § 19a-637 states in part that OHCA "shall promote the provision of quality health care in a manner that ensures access for all state residents to cost-effective services so as to avoid duplication of health care services and improve the availability and financial stability of health care services through the state."

The consolidation of sleep laboratory services to a single location was cost-effective and avoided duplication of health care services, thereby supporting the financial stability of health care services in the region.

> § *"The relationship of the proposed project to the statewide health care facilities and services plan;" (Conn. Gen. Stat. § 19a-639(a)(2))*

7. Describe how the proposed project aligns with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan, available on OHCA's website.

Response:

The Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan is "intended to provide improved patient access to services by: providing better access to services through planned geographic distribution; enhancing primary care access and availability by identifying gaps in services and unmet need, and lowering overall cost to the health care system by limiting duplication of services."

The consolidation of sleep laboratory services to a single location was cost-effective and avoided duplication of health care services.

> § *"Whether there is a clear public need for the health care facility or services proposed by the applicant;" (Conn. Gen. Stat. § 19a-639(a)(3))*

8. With respect to the proposal, provide evidence and documentation to support clear public need:

a. identify the target patient population to be served;

Response:

Not applicable. The Regional Sleep Laboratory has been providing services to existing patient populations in the greater Waterbury area for many years.

b. discuss how the target patient population is currently being served;

Response:

The Regional Sleep Laboratory currently serves the target patient population.

c. document the need for the equipment and/or service in the community;

Response:

The need for the services provided by the Regional Sleep Laboratory is evidenced by its current and historic utilization by patients in the Greater Waterbury area for many years.

d. explain why the location of the facility or service was chosen;

Response:

The Hospital determined that the Middlebury location could more efficiently serve the same patients served by the Southbury location.

e. provide incidence, prevalence or other demographic data that demonstrates community need;

Response:

Not applicable.

f. discuss how low income persons, racial and ethnic minorities, disabled persons and other underserved groups will benefit from this proposal;

Response:

No changes in access for this patient population are anticipated as a result of this proposal.

g. list any changes to the clinical services offered by the Applicant(s) and explain why the change was necessary;

Response:

Not applicable.

h. explain how access to care will be affected;

Response:

The same care accessed at the Southbury location has continued to be accessed at the Middlebury location.

i. discuss any alternative proposals that were considered.

Response:

Not applicable.

§ "Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons; (Conn. Gen. Stat. § 19a-639(a)(5))

9. **Describe how the proposal will:**

   a. **improve the quality of health care in the region;**

   b. **improve accessibility of health care in the region; and**

   c. **improve the cost effectiveness of health care delivery in the region.**

Response:

The consolidation of sleep laboratory services to a single location was cost-effective and avoided duplication of health care services, thereby supporting the financial stability of health care services in the region.

10. **How will this proposal help improve the coordination of patient care (explain in detail regardless of whether your answer is in the negative or affirmative)?**

Response:

The consolidation of sleep laboratory services to a single location has reduced the administrative burden associated with coordination of patient care.

11. **Describe how this proposal will impact access to care for Medicaid recipients and indigent persons.**

Response:

Not applicable. The consolidation of sleep laboratory services to a single location has not impacted access for Medicaid recipients and indigent persons.

12. **Provide a copy of the Applicant's charity care policy and sliding fee scale applicable to the proposal.**

Response:

The charity care policy and sliding fee scale applicable to the proposal are provided as Attachment 3.

> § *"Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;" (Conn.Gen.Stat. § 19a-639(a)(10))*

13. **If the proposal fails to provide or reduces access to services by Medicaid recipients**

or indigent persons, provide explanation of good cause for doing so.

Response:

Not applicable.

> § *"Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care." (Conn. Gen. Stat. § 19a-639(a)(12))*

14. Will the proposal adversely affect patient health care costs in any way? Quantify and provide the rationale for any changes in price structure that will result from this proposal, including, but not limited to, the addition of any imposed facility fees.

Response:

The consolidation of sleep laboratory services to a single location has not adversely affected health care costs.

Financial Information

§ *"Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;" (Conn. Gen. Stat. § 19a-639(a)(4))*

15. Describe the impact of this proposal on the financial strength of the state's health care system or demonstrate that the proposal is financially feasible for the applicant.

Response:

Not applicable. The consolidation took place effective August 31, 2011, and the operation of the Regional Sleep Laboratory has since been financially feasible.

16. Provide a final version of all capital expenditure/costs for the proposal using OHCA Table 3.

Response:

Not applicable.

17. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Response:

Not applicable.

18. Include as an attachment:

a. **audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, provide other financial documentation (e.g., unaudited balance sheet, statement of operations, tax return, or other set of books). Connecticut hospitals required to submit annual audited financial statements may reference that filing, if current;**

b. **completed Financial Worksheet A (non-profit entity), B (for-profit entity) or C (§19a-486a sale), available on OHCA's website under OHCA Forms, providing a summary of revenue, expense, and volume statistics, "without the CON project," "incremental to the CON project," and "with the CON project." Note: the actual results reported in the Financial Worksheet must match the audited financial statement that was submitted or referenced.**

Response:

Not applicable. The Regional Sleep Laboratory does not maintain financial statements. Its financial data is subsumed within the financial data for Waterbury Hospital.

19. Complete OHCA Table 4 utilizing the information reported in the attached Financial Worksheet.

Response:

OHCA Table 4 has been provided.

20. Explain all assumptions used in developing the financial projections reported in the Financial Worksheet.

Response:

It is assumed that historic utilization trends will continue.

21. Explain any projected incremental losses from operations resulting from the implementation of the CON proposal.

Response:

Not applicable.

22. Indicate the minimum number of units required to show an incremental gain from operations for each projected fiscal year.

Response:

Not applicable.

Utilization

§ "The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;" (Conn. Gen. Stat. § 19a-639(a)(6))

23. Complete OHCA Table 5 and OHCA Table 6 for the past three fiscal years ("FY"), current fiscal year ("CFY") and first three projected FYs of the proposal, for each of the Applicant's existing and/or proposed services. Report the units by service, service type or service level.

Response:

Please see **OHCA Table 5** and **OHCA Table 6** for the historic and projected utilization for the

Regional Sleep Laboratory.

24. **Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected service volume; explain any increases and/or decreases in volume reported in OHCA Table 5 and 6.**

Response:

As presented in response to Question 20 above, it is assumed that historic utilization trends will continue.

25. **Provide the current and projected patient population mix (number and percentage of patients by payer) for the proposal using OHCA Table 7 and provide all assumptions. Note: payer mix should be calculated from patient volumes, not patient revenues.**

> § *"Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;" (Conn. Gen. Stat. § 19a-639(a)(7))*

Response:

The current and projected estimated patient population mix for Waterbury Hospital has been provided in **OHCA Table 7**. The population mix observed in FY 2015 will remain constant through FY 2018 with or without the proposal.

26. **Describe the population (as identified in question 8(a)) by gender, age groups or persons with a specific condition or disorder and provide evidence (i.e., incidence, prevalence or other demographic data) that demonstrates a need for the proposed service or proposal. Please note: if population estimates or other demographic data are submitted, provide only publicly available and verifiable information (e.g., U.S. Census Bureau, Department of Public Health, CT State Data Center) and document the source.**

Response:

Please refer to Question 8e above for utilization volume demonstrating the need for the services currently provided by the Regional Sleep Center. No services have been modified or terminated as a result of the consolidation of services to the Middlebury location.

27. **Using OHCA Table 8, provide a breakdown of utilization by town for the most recently completed fiscal year. Utilization may be reported as number of persons, visits, scans or other unit appropriate for the information being reported.**

Response:

Please see **OHCA Table 8**.

§ "The utilization of existing health care facilities and health care services in the service area of the applicant;" (Conn. Gen. Stat. § 19a-639(a)(8))

28. **Using OHCA Table 9, identify all existing providers in the service area and, as available, list the services provided, population served, facility ID (see table footnote), address, hours/days of operation and current utilization of the facility. Include providers in the towns served or proposed to be served by the Applicant, as well as providers in towns contiguous to the service area.**

Response:

Not applicable. The Applicant is not proposing to provide new or duplicative services, and the existing need for the services of the Regional Sleep Laboratory is demonstrated by the patient data provided herein.

29. **Describe the effect of the proposal on these existing providers.**

Response:

Not applicable. The consolidation of services to the Middlebury location took place effective August 31, 2011

30. **Describe the existing referral patterns in the area served by the proposal.**

Response:

The Regional Sleep Laboratory receives referrals from Alliance Medical Group, Inc., the medical foundation through which The Waterbury Hospital employs its physicians, as well as other physicians in the community.

31. **Explain how current referral patterns will be affected by the proposal.**

Response:

The Applicant has not experienced any changes in referral patterns as a consequence of the consolidation.

> § *"Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;" (Conn. Gen. Stat. § 19a-639(a)(9))*

32. **If applicable, explain why approval of the proposal will not result in an unnecessary duplication of services.**

Response:

Not applicable.

> § *"Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region;" (Conn. Gen. Stat. § 19a-639(a)(11))*

33. **Explain in detail how the proposal will impact (i.e., positive, negative or no impact) the diversity of health care providers and patient choice in the geographic region.**

Response:

The consolidation of services in Middlebury has had no impact on the diversity of health care providers and patient choice in the geographic region.

Tables

TABLE 1
APPLICANT'S SERVICES AND SERVICE LOCATIONS

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
Outpatient Sleep Laboratory	1284 Strongtown Road, Southbury	Greater Waterbury	N/A	Proposed Termination
Outpatient Sleep Laboratory	1625 Straits Turnpike, Middlebury	Greater Waterbury	*Office*: Monday through Friday, 8 a.m. to 4 p.m. *Sleep Studies*: Monday through Friday, 7 p.m. to 7 a.m.	N/A

[back to question]

TABLE 2
SERVICE AREA TOWNS

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
Beacon Falls	Existing Patient Data
Bethlehem	Existing Patient Data
Cheshire	Existing Patient Data
Middlebury	Existing Patient Data
Morris	Existing Patient Data
Naugatuck	Existing Patient Data
Oakville	Existing Patient Data
Oxford	Existing Patient Data
Plantsville	Existing Patient Data
Plymouth	Existing Patient Data
Prospect	Existing Patient Data
Seymour	Existing Patient Data
Southbury	Existing Patient Data
Southington	Existing Patient Data
Terryville	Existing Patient Data
Thomaston	Existing Patient Data
Torrington	Existing Patient Data
Waterbury	Existing Patient Data
Watertown	Existing Patient Data
Wolcott	Existing Patient Data
Woodbury	Existing Patient Data

* Village or place names are not acceptable.

[back to question]
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TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	N/A
Land/Building Purchase*	N/A
Construction/Renovation**	N/A
Other (specify)	N/A
Total Capital Expenditure (TCE)	$0
Lease (Medical, Non-medical, Imaging)***	N/A
Total Lease Cost (TLC)	N/A
Total Project Cost (TCE+TLC)	$0

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

[back to question]

TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2016	FY 2017	FY 2018
Revenue from Operations	N/A	N/A	N/A
Total Operating Expenses	N/A	N/A	N/A
Gain/Loss from Operations	N/A	N/A	N/A

* Fill in years using those reported in the Financial Worksheet attached.

[back to question]

TABLE 5
HISTORICAL UTILIZATION BY SERVICE

Service**	Actual Volume (Last 3 Completed FYs)			CFY Volume* (X months actual)
	FY 2013***	FY 2014***	FY 2015***	FY 2016***
Outpatient Treatment for Sleep Disorders	995	937	1022	671 (8 months) (1007 projected)
Total	995	937	1022	1007

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than 6 months, report actual volume and identify the period covered.

** Identify each service type and level adding lines as necessary. Provide the number of visits or discharges as appropriate for each service type and level listed.

*** Fill in years. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

[back to question]

TABLE 6
PROJECTED UTILIZATION BY SERVICE

Service*	Projected Volume		
	FY 2016	FY 2017	FY 2018
Outpatient Treatment for Sleep Disorders	1007	1022	1022
Total	1007	1022	1022

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.

** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

[back to question]

TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX

Payer	Current FY 2016**		Projected					
			FY 2017**		FY 2018**		FY 2019**	
	Discharges	%	Discharges	%	Discharges	%	Discharges	%
Medicare*		46.5%		46.5%		46.5%		46.5%
Medicaid*		28%		28%		28%		28%
CHAMPUS & TriCare		.5%		.5%		.5%		.5%
Total Government		**75%**		**75%**		**75%**		**75%**
Commercial Insurers		23.5%		23.5%		23.5%		23.5%
Uninsured		1%		1%		1%		1%
Workers Compensation		.5%		.5%		.5%		.5%
Total Non-Government		**25%**		**25%**		**25%**		**25%**
Total Payer Mix		**100%**		**100%**		**100%**		**100%**

* Includes managed care activity.
** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided. New programs may leave the "current" column blank.

[back to question]

TABLE 8
UTILIZATION BY TOWN

Town	Utilization FY 2015
All Towns Identified in Table 2	1022 patient encounters

* List inpatient/outpatient/ED volumes separately, if applicable
** Fill in most recently completed fiscal year.

[back to question]

TABLE 9
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
N/A	N/A	N/A	N/A	N/A	N/A

* Provide the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

[back to question]

ATTACHMENT 1

U. S. TREASURY DEPARTMENT
WASHINGTON 25

OFFICE OF
COMMISSIONER OF INTERNAL REVENUE

ADDRESS REPLY TO
COMMISSIONER OF INTERNAL REVENUE
AND REFER TO

IT:P:ER-CSG

RECEIVED NOV 26
NOV 21 1951
Tax Enforcement Office

The Waterbury Hospital
c/o Charles V. Wynne, Superintendent
64 Robbins Street
Waterbury, Connecticut

Gentlemen:

It is the opinion of this office, based upon the evidence presented, that you are exempt from Federal income tax under the provisions of section 101(6) of the Internal Revenue Code and corresponding provisions of prior revenue acts, as it is shown that you are organized and operated exclusively for charitable purposes.

Accordingly, you will not be required to file income tax returns unless you change the character of your organization, the purposes for which you were organized, or your method of operation. Any such changes should be reported immediately to the collector of internal revenue for your district in order that their effect upon your exempt status may be determined.

You will be required, however, to file an information return, Form 990A, annually, with the collector of internal revenue for your district so long as this exemption remains in effect. This form may be obtained from the collector and is required to be filed on or before the fifteenth day of the fifth month following the close of your annual accounting period.

Contributions made to you are deductible by the donors in computing their taxable net income in the manner and to the extent provided by section 23(o) and (q) of the Internal Revenue Code, as amended, and corresponding provisions of prior revenue acts.

Bequests, legacies, devises, or transfers, to or for your use are deductible in computing the value of the net estate of a decedent for estate tax purposes in the manner and to the extent provided by sections 812(d) and 861(a)(3) of the Code and corresponding provisions of prior revenue acts. Gifts of property to you are deductible in computing net gifts for gift tax purposes in the manner and to the extent provided in section 1004(a)(2)(B) and 1004(b)(2) and (3) of the Code and corresponding provisions of prior revenue acts.

Form 6976—Rev. Dec. 1950
(1491M-1)

16—61000-2

SLP0028

The Waterbury Hospital

In the event you have not filed a waiver of exemption certificate in accordance with the provisions of section 1426(1) of the Code, no liability is incurred by your organization for the taxes imposed under the Federal Insurance Contributions Act. Tax liability is not incurred by your organization under the Federal Unemployment Tax Act by virtue of the provisions of section 1607(c)(8) of such Act.

The collector of internal revenue for your district is being advised of this action.

Bureau ruling of February 9, 1937, holding you exempt from Federal income tax under section 101(6) of the Revenue Act of 1936 and corresponding provisions of prior revenue acts, is hereby affirmed and Bureau ruling of October 25, 1951, holding you not exempt under section 101(6) of the Code, beginning with the year 1951, is hereby revoked.

By direction of the Commissioner.

Very truly yours,

E. J. McSweeney

Deputy Commissioner

Form 6976-2—Rev. Dec. 1950
(1491M-1)

Copy

Internal Revenue Service

Department of the Treasury

Washington, DC 20224

The Waterbury Hospital
64 Robbins Street
Waterbury, CT 06721

Person to Contact:

Telephone Number:

Refer Reply to:

Date: OP:E:EO:R:2

JAN 17 1985

Legend:

H = The Waterbury Hospital
P = Greater Waterbury Health Network, Inc.
X = Greater Waterbury Health Services, Inc.
Y = Greater Waterbury Health Foundation, Inc.
Z = Greater Waterbury Management Resources, Inc.

Dear Ladies and Gentlemen:

This is in reply to the ruling request of November 7, 1984, which was submitted on behalf of H, P, X, and Y. These organizations have asked for a number of rulings regarding the income tax consequences of a proposed corporate reorganization and the related transactions described below. This letter will rule on the ruling requests of all four entities.

H is a nonprofit corporation engaged in the operation of an acute care teaching hospital. H's purposes are to provide hospital and medical facilities and services, research, and carry on related activities to assist, protect, promote, and improve the health of the general public. H is exempt from income tax under section 501(c)(3) of the Internal Revenue Code and is classified as other than a private foundation under sections 509(a)(1) and 170(b)(1)(A)(iii).

H represents that it recently evaluated its current corporate structure, programs, assets and possible future plans for the hospital. As a result, H's Board of Trustees determined that it was in the best interests of the hospital to reorganize its corporate structure through the creation of several additional corporations to which existing assets and/or programs could be transferred and which could undertake new programs.

P is a nonprofit corporation organized exclusively for charitable, scientific and educational purposes to serve as the parent entity whose function it will be to plan, develop, coordinate and direct the system of related and integrated health care entities. P's activities will include: general supervision and coordination of the health systems' activities, exploration and development of new health care-related services, and, development and/or offering of educational and scholarly programs related to health care. It was represented P would receive, maintain, and distribute funds and other assets, administering and applying them exclusively for the benefit of H and its affiliates. P will control its present affiliates, H, X, and Y and its wholly-owned subsidiary, Z. P is the sole member of H, X, and Y and is the sole stockholder of Z. As such P will have exclusive power with respect to each entity to elect, remove

and fill vacancies among these organizations' Directors and Trustees and to amend the organizations' governing documents.

X is a nonprofit corporation organized exclusively for charitable, scientific and educational purposes to engage in the establishment and sponsorship of new health care-related services and facilities including free standing ambulatory surgical centers, magnetic resonance imaging centers, home health care agencies, medical office buildings, primary care centers, and clinical laboratories. X is recognized as tax exempt under section 501(c)(3) and classified as other than a private foundation under section 509(a)(2) of the Code.

Y is a nonprofit corporation organized exclusively for charitable, scientific and educational purposes to support and encourage health care-related services for the advancement of health and well-being of the general public through fund-raising and fund management. Y is recognized as tax exempt under section 501(c)(3) and is classified as other than a private foundation under sections 509(a)(1) and 170(b)(1)(A)(vi) of the Code.

H represents that under the proposed plan of reorganization, it will retain the operation of the present hospital facilitites and services and will continue to employ the personnel necessary to support its operations. H will transfer to P an as yet undetermined amount of cash and liquid investments and P will then determine whether these assets should be retained by P or be transferred to its affiliates. H will retain all its other property, assets and liabilities, including hospital buildings and other physical facilities related to inpatient and outpatient care.

H also represents that it may perform various management services for P or for P's tax-exempt affiliates, and may charge a fee for those services. According to H, any such fee may exceed its costs, but in no event will the fee exceed comparable commercial rates. Also, any management services will be related to the normal functioning of H and the actual services to be performed on behalf of other organizations will be similar to the services currently performed on behalf of the Hospital. Employees currently responsible for management of H will not be transferred to other organizations in connection with the corporate reorganization. These employees will continue to be employed by H and their services will be provided to other organizations on a contractual basis, as necessary.

Future programs not directly related to H's inpatient programs are likely to be undertaken by P or its affiliates other than H which are controlled by P. Individuals who provide services to support any such programs will become employees of a corporation other than H.

H represents that its Board of Trustees and community membership have approved the corporate reorganization to be effective upon receipt of the rulings requested herein. Upon H's receipt of the rulings, P will become the sole member of H through amendment of H's Certificate of Incorporation and By-Laws. The present community membership of H will then become the membership of P.

H represents that the proposed corporate reorganization will permit the segregation of management functions and assets, enhance management accountability, and attract and effectively use specialized management skills. Other benefits expected from the reorganization include improved reporting under governmental regulatory programs; protecting assets from potential liability; and, isolation of tax-exempt activities from possible future unrelated business activities. The benefits derived will lead to more efficient operations and thereby reduce health care costs and further exempt purposes.

Section 501(c)(3) of the Code provides for exemption for organizations organized and operated exclusively for charitable, educational, and scientific purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.

Section 511 of the Code imposes a tax on the unrelated business taxable income (as defined in section 513) of organizations described in section 501(c).

Section 512 of the Code defines "unrelated business taxable income" as the gross income derived by any organization from any unrelated trade or business (as defined in section 513) regularly carried on by it less allowable deductions.

Section 513 of the Code defines "unrelated trade or business," for any organization subject to tax under section 511, as any trade or business the conduct which is not substantially related (aside from the need of the organization for income or funds or the use it makes of the profits derived) to the exercise or performance by such organization of its charitable, educational or other purpose or function constituting the basis for its exemption under section 501.

Section 1.513-1(d)(2) of the Income Tax Regulations provides that a trade or business is "related" to exempt purposes only where the conduct of the business activity has a causal relationship to the achievement of an exempt purpose, and is, "substantially related" for purposes of section 513, only if the causal relationship is a substantial one.

Section 514(b)(1) of the Code defines "debt-financed property" as any property which is held to produce income and with respect to which there is an acquisition indebtedness at any time during the taxable year.

Rev. Rul. 78-41, 1978-1 C.B. 148, described a trust whose sole purpose was to accumulate and hold funds for use in satisfying malpractice claims against a hospital. The trust was determined to be an integral part of the hospital because it was controlled by the hospital and because it was performing a function that the hospital could do directly. The organization was ruled to be exempt under section 501(c)(3) of the Code.

Rev. Rul. 67-149, 1967-1 C.B. 133, described an organization that was formed for the purpose of providing financial assistance to several different types of organizations which were exempt from Federal income

tax under section 501(c)(1) of the Code. It carried on no operations other than receiving contributions and incidental investment income and making distributions of income to such exempt organizations at periodic intervals. The organization did not accumulate its investment income. The organization was ruled to be exempt under section 501(c)(3) of the Code.

Rev. Rul. 69-545, 1969-2 C.B. 117, provides that a non-profit organization whose purpose and activity are providing hospital care is promoting health and may, therefore, qualify as organized and operated in furtherance of a charitable purpose if it meets the other requirements of section 501(c)(3) of the Code.

Under the proposed reorganization, P, the parent entity, will operate for the benefit of its tax-exempt subsidiaries by providing them with financial, management and advisory support services. The reorganization will facilitate the realization of benefits discussed above by permitting more effective or efficient use or resources, as well as providing the ability to shift resources to meet the ever-changing community health needs. In addition, providing management services on an institution-by-institution basis can be expensive and the consolidation of these activities result in reduced health care costs and better utilization of available management talent. In short, the proposed corporate reorganization will enable the related and integrated health care providers to define operational responsibilities more clearly by separating management and planning, fund-raising, and taxable business activities from the operation of the hospital and the provision of health care services.

Because P can be considered an integral part of the affiliated exempt organizations within the meaning of Rev. Rul. 78-41, supra, and because it is performing functions which H has historically carried on, the proposed reorganization will not affect the exempt status of P. Similarly, since X and Y will continue to engage solely in activities related to their exempt purposes as defined by section 501(c)(3), their exempt status will not be adversely affected by the reorganization and related transactions.

The purposes and activities of H will not be alterd as part of the reorganization. It will continue to provide primary acute care and related medical services to the public on the same basis as in the past. Since H will continue to meet the requisite criteria so as to qualify as a hospital within the meaning of Rev. Rul. 69-545, supra, its exempt status will not be affected by the reorganization or related transactions. Furthermore, the reorganization and related transactions contemplated will not change H's status as a hospital under sections 509(a)(1) and 170(b)(1)(A)(iii).

When all the functions were originally accomplished by H, it was evident that H's resources were devoted to the achievement of its charitable purposes. It follows that the transfer of certain assets to various exempt members of the health care system will not affect the exempt status of any of the organizations involved because the transferred assets will be put to the same charitable uses as they had been by H. The tax on unrelated business income imposed by section 511 of the Code will not be applicable

because section 513(a) of the Code and section 1.513-1(d)(2) of the regulations exclude from the definition of unrelated trade or business any trade or business which contributes importantly to the accomplishment of an organization's exempt purpose. The ongoing asset transfers and provision of services among the related tax-exempt corporations will contribute importantly to the provision of health care to the community because the health care system concept will provide the ability to shift resources to meet the ever-changing community health needs. Therefore, the transactions described above will not result in unrelated business income under sections 511 through 514 of the Code for any transferor or transferee except with respect to transactions involving Z, the for-profit subsidiary, to the extent, if any, calculated in accordance with section 512(b)(13).

Based on the information furnished, we rule that:

1.) the corporate reorganization described above will not affect the tax-exempt status of H under section 501(c)(3) of the Code or its non-private foundation classification under section 509(a);

2.) the corporate reorganization will not jeopardize the tax-exempt status of P, X, and Y under section 501(c)(3) of the Code;

3.) the transfer of assets between and among P, X, and Y will not result in unrelated business taxable income to any of these organizations under sections 511 through 514 of the Code; and

4.) the provision of management and other services on a fee-for-service basis by and among P and the other exempt entities with which it is affiliated will not result in unrelated business taxable income to P or such other exempt entities under sections 511 through 514 of the Code.

This ruling is directed only to the organization that requested it. Section 6110(j)(3) of the Code provides that it may not be used or cited as precedent.

Because this letter could help resolve any future questions about your exempt status and unrelated trade or business activities, you should keep it for your permanent records.

We are informing your key District Director of this ruling. If you should have any questions, please contact the person whose name and telephone number are shown above.

Sincerely yours,

J. E. Griffith

J. E. Griffith
Chief, Exempt Organizations
Rulings Branch

ATTACHMENT 2

(N5250103)

State of Connecticut

Lookup Detail View

Name

Name
WATERBURY HOSPITAL

License Information
FLIS

License Type	License Number	Expiration Date	Granted Date	License Name	License Status
General Hospital	60	09/30/2017	10/01/2009		ACTIVE

Generated on: 7/25/2016 9:24:09 AM

ATTACHMENT 3

(N5250103)

2016 FEDERAL POVERTY GUIDELINES (FPG)
ANNUAL & MONTHLY INCOME LEVELS
FROM 100% to 250%

FAMILY	FPG (100%)		125% of FPG		150% of FPG		175% of FPG		185% of FPG		200% of FPG		235% of FPG		250% of FPG	
SIZE	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH	YEAR	MONTH
1	$11,880	$990	$14,850	$1,238	$17,820	$1,485	$20,790	$1,733	$21,978	$1,832	$23,760	$1,980	$27,918	$2,327	$29,700	$2,475
2	$16,020	$1,335	$20,025	$1,669	$24,030	$2,003	$28,035	$2,336	$29,637	$2,470	$32,040	$2,670	$37,647	$3,137	$40,050	$3,338
3	$20,160	$1,680	$25,200	$2,100	$30,240	$2,520	$35,280	$2,940	$37,296	$3,108	$40,320	$3,360	$47,376	$3,948	$50,400	$4,200
4	$24,300	$2,025	$30,375	$2,531	$36,450	$3,038	$42,525	$3,544	$44,955	$3,746	$48,600	$4,050	$57,105	$4,759	$60,750	$5,063
5	$28,440	$2,370	$35,550	$2,963	$42,660	$3,555	$49,770	$4,148	$52,614	$4,385	$56,880	$4,740	$66,834	$5,570	$71,100	$5,925
6	$32,580	$2,715	$40,725	$3,394	$48,870	$4,073	$57,015	$4,751	$60,273	$5,023	$65,160	$5,430	$76,563	$6,380	$81,450	$6,788
7	$36,730	$3,061	$45,913	$3,826	$55,095	$4,591	$64,278	$5,357	$67,951	$5,663	$73,460	$6,122	$86,316	$7,193	$91,825	$7,652
8	$40,890	$3,408	$51,113	$4,259	$61,335	$5,111	$71,558	$5,963	$75,647	$6,304	$81,780	$6,815	$96,092	$8,008	$102,225	$8,519
*	$4,160	$347	$5,200	$433	$6,240	$520	$7,280	$607	$7,696	$641	$8,320	$693	$9,776	$815	$10,400	$867

*For family units over 8, add the amount shown for each additional member.

Notes:

Federal Poverty Guidelines: 2016 Federal Poverty Guidelines (FPG) annual income levels are published in the Federal Register of January 25, 2016, Volume 81, Number 15, on pages 4036-4037.

Percentage Calculations: Annual income levels provided above for 125%-250% of FPG are derived by multiplying the FPG annual income for each family size by the appropriate percentage and rounding to the nearest whole dollar. Monthly income levels for FPG and 125%-250% of FPG are derived by dividing each annual income level by 12 and rounding to the nearest whole dollar.

Calculated and prepared by Healthcare Facility Regulation Division/Office of Health Planning, Georgia Department of Community Health, January 26, 2016.

SLP0038

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
OFFICE OF HEALTH PLANNING
INDIGENT INCOME LEVELS FOR 2016

ANNUAL & MONTHLY INCOME LEVELS FOR FAMILIES AND INDIVIDUALS AT 125% OF 2016 FEDERAL POVERTY GUIDELINES

FAMILY SIZE	2016 INCOME LEVEL FOR 125% FPG	
	ANNUAL	MONTHLY
1	$14,850 per year	$1,238 per month
2	$20,025 per year	$1,669 per month
3	$25,200 per year	$2,100 per month
4	$30,375 per year	$2,531 per month
5	$35,550 per year	$2,963 per month
6	$40,725 per year	$3,394 per month
7	$45,913 per year	$3,826 per month
8	$51,113 per year	$4,259 per month
For family units over 8, add $5200 per year or $433 per month for each additional member.		

Notes:

Federal Poverty Guidelines: "2016 Poverty Guidelines for the 48 Contiguous States and the District of Columbia" as published in the Federal Register of January 25, 2016, Volume 81, Number 15, on pages 4036 - 4037.

125% FPG Calculation: The annual income levels at 125% FPG provided above are derived by multiplying the federal poverty guidelines annual income for each family size by 1.25 (125%) and rounding to the nearest whole dollar. These annual figures are then divided by 12 and rounded to the nearest whole dollar to derive the monthly income levels.

DCH Indigent Income Level: The Georgia Department of Community Health's Office of Health Planning defines an indigent patient as being a patient who is income tested and found to be at or below 125% of the FPG.

Calculated and prepared by Healthcare Facility Regulation Division/Office of Health Planning, Georgia Department of Community Health, January 26, 2016.

are working to improve language accessibility within their states; and

• Recommendations for state-specific capacity building for the 20 states intended to enhance statewide language access, which will include the development of language access plans.

An objective review of was conducted that assessed the grantee's application using criteria related to the project's approach, the organization's capacity, and the development of costs for the project's budget.

Statutory Authority: Section 310 of the Family Violence Prevention and Services Act, as amended by Section 201 of the CAPTA Reauthorization Act of 2010, Pub. L. 111–320.

Christopher Beach,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–01329 Filed 1–22–16; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the Department of Health and Human Services (HHS) poverty guidelines to account for last calendar year's increase in prices as measured by the Consumer Price Index.

DATES: *Effective Date:* January 25, 2016, unless an office administering a program using the guidelines specifies a different effective date for that particular program.

ADDRESSES: Office of the Assistant Secretary for Planning and Evaluation, Room 404E, Humphrey Building, Department of Health and Human Services, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: For information about how the guidelines are used or how income is defined in a particular program, contact the Federal, state, or local office that is responsible for that program. For information about poverty figures for immigration forms, the Hill-Burton Uncompensated Services Program, and the number of people in poverty, use the specific telephone numbers and addresses given below.

For general questions about the poverty guidelines themselves, contact Kendall Swenson, Office of the Assistant Secretary for Planning and Evaluation, Room 422F.5, Humphrey Building, Department of Health and Human Services, Washington, DC 20201—telephone: (202) 690–7507—or visit *http://aspe.hhs.gov/poverty/*.

For information about the percentage multiple of the poverty guidelines to be used on immigration forms such as USCIS Form I–864, Affidavit of Support, contact U.S. Citizenship and Immigration Services at 1–800–375–5283.

For information about the Hill-Burton Uncompensated Services Program (free or reduced-fee health care services at certain hospitals and other facilities for persons meeting eligibility criteria involving the poverty guidelines), contact the Health Resources and Services Administration Information Center at 1–800–275–4772. You also may visit *http://www.hrsa.gov/gethealthcare/affordable/hillburton/*.

For information about the number of people in poverty, visit the Poverty section of the Census Bureau's Web site at *http://www.census.gov/hhes/www/poverty/poverty.html* or contact the Census Bureau's Customer Service Center at 1–800–923–8282 (toll-free) and *https://ask.census.gov* for further information.

SUPPLEMENTARY INFORMATION:

Background

Section 673(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1981 (42 U.S.C. 9902(2)) requires the Secretary of the Department of Health and Human Services to update the poverty guidelines at least annually, adjusting them on the basis of the Consumer Price Index for All Urban Consumers (CPI–U). The poverty guidelines are used as an eligibility criterion by the Community Services Block Grant program and a number of other Federal programs. The *poverty guidelines* issued here are a simplified version of the *poverty thresholds* that the Census Bureau uses to prepare its estimates of the number of individuals and families in poverty.

As required by law, this update is accomplished by increasing the latest published Census Bureau poverty thresholds by the relevant percentage change in the Consumer Price Index for All Urban Consumers (CPI–U). The guidelines in this 2016 notice reflect the 0.1 percent price increase between calendar years 2014 and 2015. After this inflation adjustment, the guidelines are rounded and adjusted to standardize the differences between family sizes. In rare circumstances, the rounding and standardizing adjustments in the formula result in small decreases in the poverty guidelines for some household sizes even when the inflation factor is not negative. In order to prevent a reduction in the guidelines in these rare circumstances, a minor adjustment was implemented to the formula beginning this year. In cases where the year-to-year change in inflation is not negative and the rounding and standardizing adjustments in the formula result in reductions to the guidelines from the previous year for some household sizes, the guidelines for the affected household sizes are fixed at the prior year's guidelines. As in prior years, these 2016 guidelines are roughly equal to the poverty thresholds for calendar year 2015 which the Census Bureau expects to publish in final form in September 2016.

The poverty guidelines continue to be derived from the Census Bureau's current official poverty thresholds; they are not derived from the Census Bureau's new Supplemental Poverty Measure (SPM).

The following guideline figures represent annual income.

2016 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household	Poverty guideline
1	$11,880
2	16,020
3	20,160
4	24,300
5	28,440
6	32,580
7	36,730
8	40,890

For families/households with more than 8 persons, add $4,160 for each additional person.

2016 POVERTY GUIDELINES FOR ALASKA

Persons in family/household	Poverty guideline
1	$14,840
2	20,020
3	25,200
4	30,380
5	35,560
6	40,740
7	45,920
8	51,120

For families/households with more than 8 persons, add $5,200 for each additional person.

2016 POVERTY GUIDELINES FOR HAWAII

Persons in family/household	Poverty guideline
1	$13,670
2	18,430
3	23,190
4	27,950
5	32,710
6	37,470
7	42,230
8	47,010

For families/households with more than 8 persons, add $4,780 for each additional person.

Separate poverty guideline figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period. (Note that the Census Bureau poverty thresholds—the version of the poverty measure used for statistical purposes—have never had separate figures for Alaska and Hawaii.) The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. In cases in which a Federal program using the poverty guidelines serves any of those jurisdictions, the Federal office that administers the program is generally responsible for deciding whether to use the contiguous-states-and-DC guidelines for those jurisdictions or to follow some other procedure.

Due to confusing legislative language dating back to 1972, the poverty guidelines sometimes have been mistakenly referred to as the "OMB" (Office of Management and Budget) poverty guidelines or poverty line. In fact, OMB has never issued the guidelines; the guidelines are issued each year by the Department of Health and Human Services. The poverty guidelines may be formally referenced as "the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2)."

Some federal programs use a percentage multiple of the guidelines (for example, 125 percent or 185 percent of the guidelines), as noted in relevant authorizing legislation or program regulations. Non-Federal organizations that use the poverty guidelines under their own authority in non-Federally-funded activities also may choose to use a percentage multiple of the guidelines.

The poverty guidelines do not make a distinction between farm and non-farm families, or between aged and non-aged units. (Only the Census Bureau poverty thresholds have separate figures for aged and non-aged one-person and two-person units.)

Note that this notice does not provide definitions of such terms as "income" or "family," because there is considerable variation in defining these terms among the different programs that use the guidelines. These variations are traceable to the different laws and regulations that govern the various programs. This means that questions such as "Is income counted before or after taxes?", "Should a particular type of income be counted?", and "Should a particular person be counted as a member of the family/household?" are actually questions about how a specific program applies the poverty guidelines. All such questions about how a specific program applies the guidelines should be directed to the entity that administers or funds the program, since that entity has the responsibility for defining such terms as "income" or "family," to the extent that these terms are not already defined for the program in legislation or regulations.

Dated: January 21, 2016.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2016–01450 Filed 1–22–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Committee.

Date: February 18–19, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Ritz-Carlton Hotel, Plaza II, 1150 22nd Street NW., Washington, DC 20037.

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892934, (240) 669–5023, *fdesilva@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "Comprehensive Resources for HIV Microbicides and Biomedical Prevention (N01)".

Date: February 18, 2016.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health Room 3F100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jay R. Radke, Ph.D., AIDS Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G11B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC–9823, Bethesda, MD 20892–9823, (240) 669–5046, *jay.radke@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 19, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–01313 Filed 1–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Media-Smart Youth Leaders Program

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 16, 2015, pages 62541–62542, and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, may not conduct or

Supplemental CON Application Form

Termination of a Service

Conn. Gen. Stat. § 19a-638(a)(5),(7),(8),(15)

Applicant: The Waterbury Hospital

Project Name: Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut

Affidavit

Applicant: The Waterbury Hospital
Project Title: Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut

I, Darlene Stromstad, President/CEO
(Name) (Position – CEO or CFO)

of The Waterbury Hospital being duly sworn, depose and state that the The Waterbury Hospital complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Signature 7/27/16
Date

Subscribed and sworn to before me on 7/27/16

Jan Balzarini

Notary Public/Commissioner of Superior Court

My commission expires: 7-31-16

Affidavit

Applicant: The Waterbury Hospital
Project Title: Consolidation of Sleep Lab Services to the Regional Sleep Laboratory in Middlebury, Connecticut

I, Darlene Stromstad, President/CEO
(Name) (Position – CEO or CFO)

of The Waterbury Hospital being duly sworn, depose and state that the The Waterbury Hospital complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Darlene Stromstad 7/27/16
Signature Date

Subscribed and sworn to before me on 7/27/16

Jan Balzarini
Notary Public/Commissioner of Superior Court

My commission expires: 7-31-16

1. **Project Description: Service Termination**

   a. Please provide

      i. a description of the history of the services proposed for termination, including when they commenced ,

      ii. whether CON authorization was received and,

      iii. if CON authorization was required, the docket number for that approval.

   b. Explain in detail the Applicant's rationale for this termination of services, and the process undertaken by the Applicant in making the decision to terminate.

   c. Did the proposed termination require the vote of the Board of Directors of the Applicant? If so, provide copy of the minutes (excerpted for other unrelated material) for the meeting(s) the proposed termination was discussed and voted on.

Response:

The Waterbury Hospital ("Hospital") is a tax exempt Connecticut nonstock corporation and has operated a 6 bed sleep lab, the Regional Sleep Laboratory, at 1625 Straits Turnpike in Middlebury, Connecticut ("Middlebury Sleep Lab") since 2005. Middlebury Sleep Lab experienced significant growth between 2005 and 2008 with demand beginning to out-pace capacity and the Hospital sought to expand its services to Southbury. On February 19, 2009, the State of Connecticut Office of Health Care Access ("OHCA") granted a Certificate of Need under Docket Number: 08-31211-CON ("CON") to the Hospital to establish and operate a second sleep laboratory at the Crowne Plaza Hotel, 1284 Strongtown Road, Southbury, Connecticut ("Southbury Sleep Lab") to be operated under the Hospital's acute care hospital license. Southbury Sleep Lab opened in April 2009 and completed its first patient study on April 29, 2009.

Because of increased competition from other hospital providers as well as the advent of home-based sleep testing, the expected volume did not materialize. The following table summarizes the projected as well as actual total sleep study volume for the Hospital's sleep lab service.

FY 2010		FY 2011	
Projected*	Actual	Projected*	Actual
1805	1395	2022	1192

*DN: 08-31211-CON

Based on declining volume and the cost in-effectiveness of maintaining two sleep lab locations, the Hospital consolidated sleep lab services to Middlebury Sleep Lab effective August 31, 2011. As indicated by the table below, Middlebury Sleep Lab was and remains able to accommodate all referred volume. Indeed, Middlebury Sleep Lab still has capacity to accommodate anticipated future growth.

FY 2012	FY 2013	FY 2014	FY2015	FY2016*
1115	995	937	1022	671

*8 months actual

The consolidation does not require the approval of the Hospital's Board of Directors.

2. Termination's Impact on Patients and Provider Community

a. For each provider to which the Applicant proposes transferring or referring clients, provide the below information for the last completed fiscal year and current fiscal year.

TABLE A
PROVIDERS ACCEPTING TRANSFERS/REFERRALS

Facility Name	Facility ID*	Facility Address	Total Capacity	Available Capacity	Utilization FY XX**	Utilization Current CFY***
N/A	N/A	N/A	N/A	N/A	N/A	N/A

* Please provide either the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

** Fill in year and identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.). Label and provide the number of visits or discharges as appropriate.

*** For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

a. Provide evidence (e.g., written agreements or memorandum of understanding) that other providers in the area are willing and able to absorb the displaced patients.

Response: The patient data provided for the Regional Sleep Laboratory in Middlebury reflects absorption of patients from the Southbury location.

b. Identify any special populations that utilize the service(s) and explain how these populations will maintain access to the service following termination at the specific location; also, specifically address how the termination of this service will affect access to care for Medicaid recipients and indigent persons.

Response: The Southbury location of the Sleep Laboratory did not service special populations, and its closure did not affect access to care for Medicaid recipients and indigent persons.

c. Describe how clients will be notified about the termination and transfer to other providers.

Response: Patients utilizing the Southbury location were notified that they could obtain the same services at the Middlebury location.

d. For DMHAS-funded programs only, attach a report that provides the following information for the last three full FYs and the current FY to-date:
   i. Average daily census;
   ii. Number of clients on the last day of the month;
   iii. Number of clients admitted during the month; and
   iv. Number of clients discharged during the month.

   Response: Not applicable.

PROOF OF NEWSPAPER PUBLICATION

{N5250103}

Real Estate For Sale

Lots for sale

BANTAM LAKE bldg lot on 5 ac priv. community. Tennis, boat, water & sewer incl. 860-868-1256

Mobile home

NAUGATUCK 4 units to choose from starting at $29,900 incl. pool & clubhouse 203-729-8277

NAUGATUCK Quiet park! 3 BR, 1 bath, new carpet & lino $32,900 Liberty 860-747-6881 860-940-1204

PROSPECT like new! 2BR 1 bath, w/appl. & shed, $59,590 Liberty 860-747-6881; 203-592-7641

Commercial

Business for sale
Commercial for sale, lease, rent

Commercial for sale, lease, rent

WATERBURY barber shop/salon. Downtown, renovated, high traffic. 646-342-7475

WATERBURY DOWNTOWN LEASE 600-5,000 sq. ft. Call for details. 203-841-2500 x121

Announcements

Absolutely free
Lost & found
Special notices

Absolutely free

KITTENS Free kittens avail. now! 4 cute blk to a good home. Ask for Michael. 203-598-9200

TREADMILL Bow flex, and exercise bike. Call 203-733-2748

Lost & found

FOUND Small brownish/red dog, corner of Cherry and East Main. Call 203-819-2477

LOST CAT gray male with clipped ear, vicinity of Williams & North Main St. Thomaston. 860-283-5041

LOST DOG Sm Shih Tzu Female Baldwin area by city gas any information call 203-510-2926

Legals/ Public Notices

LEGAL NOTICE

The Town of Plymouth will accept sealed bid proposals for Bid#: 16-06 ANCILLARY FORCES. Bid proposals will be accepted at the Town of Plymouth Mayor's Office, 80 Main Street, Terryville, CT 06786 until 10:00 a.m. on August 1, 2016 at which time they will be opened and read aloud. Bids must be in a plain envelope and clearly marked "Bid#: 16-06 ANCILLARY FORCES".

All questions pertaining to the project bidding must be submitted in writing to the Director of Public Works no later than 4:00 p.m. on July 25, 2016 at the above mentioned address or may be asked at a mandatory pre-bid meeting to be held at the Plymouth Town Hall at 10:00 a.m. on July 25, 2016.

Copies of plans and specifications may be obtained at the Town of Plymouth Public Works Office, 80 Main Street, Terryville, CT. Contract Drawings and Project Manual will be available after July 18, 2016 between the hours of 9:00 a.m.-4:00 p.m., Monday- Thursday and Fridays between the hours of 9:00 a.m. - 11:00 am. The Town of Plymouth reserves the right to accept or reject any or all bids if deemed in the best interest of the Town.

Charles J. Wiegert
Director of Public Works
Dated the 14th day of July, 2016

R-A July 14, 2016

NOTICE OF SERVICE OF PROCESS
BY PUBLICATION
STATE OF NORTH CAROLINA
MECKLENBURG COUNTY
IN THE GENERAL
COURT OF JUSTICE
DISTRICT COURT DIVISION
FOR THE ADOPTION OF MORGAN
SHEA SHOAF
FILE NO. 16-SP-001617

TO: The unknown father of Morgan Shea Shoaf, a female child born on October 3, 2007

Legals/ Public Notices

NOTICE TO CREDITORS
ESTATE OF Shirley J. Whitney
(15-01062)

The Hon. Thomas P. Brunnock, Judge of the Court of Probate, District of Waterbury Probate Court, by decree dated May 16, 2016, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim.

Thomas P. Brunnock, Judge

The fiduciary is:
Joseph Mancini
c/o Atty P. Michael Margolis
Butler, Norris & Gold
254 Prospect Avenue
Hartford, CT 06106

R-A July 14, 2016

NOTICE OF SERVICE OF PROCESS
BY PUBLICATION
STATE OF NORTH CAROLINA
MECKLENBURG COUNTY
IN THE GENERAL
COURT OF JUSTICE
DISTRICT COURT DIVISION
FOR THE ADOPTION OF MORGAN
SHEA SHOAF
FILE NO. 16-SP-001616

TO: The unknown father of Christopher Michael Shoaf, a male child born on January 7, 2002, in Norwalk, CT

Take notice that a petition seeking relief against you has been filed in the above-entitled special proceeding, before the Clerk of Superior Court. The nature of the relief being sought is the adoption of Christopher Michael Shoaf. The child was conceived on or about April 5, 2001 in Norwalk, CT. The child was born to Kimberly Grisham, a 31 year-old white female, who was born in Florida and grew up in Norwalk, CT. You are required to make defense to such petition not later than forty (40) days after the first date of publication of this notice on July 5th, 2016, which date is the date of the first publication. If you fail to do so, the party seeking service against you will apply to the court for the relief sought. Any parental rights you may have will be terminated upon entry of a Decree of Adoption.

This, the thirtieth day of June, 2016
Thomas and Patricia Pansa
15816 Gathering Oaks Dr.
Huntersville, NC 28078

R-A July 7, 14 & 21, 2016

Request for Quotation #02-1611

The State of Connecticut Judicial Branch invites experienced and qualified contractors to submit sealed quotations to perform first priority snow plowing at various courthouses throughout the state.

Mandatory Site Visits are scheduled to begin on Monday, July 25, 2016. Complete details are available in the bid package.

Legals/ Public Notices

STATE OF CONNECTICUT
SUPERIOR COURT
JUVENILE MATTERS
ORDER OF NOTICE

Notice to: William Gordon
Father of a child
born to Jaselyn Seda
on 8/16/2006
of parts unknown

A petition has been filed seeking: Motion for Reinstatement of Parental Guardianship of the minor child of the above named.

The petition, whereby the court's decision can affect your parental rights, if any, regarding minor child(ren) will be heard on 7/28/2016 at 10:00a.m. at 60 Housatonic Avenue, Bridgeport, CT 06604

Therefore, ORDERED, that notice of the hearing of this petition be given by publishing this Order of Notice once, immediately upon receipt, in the Waterbury Republican, a newspaper having circulation in the town/city of Waterbury, CT.

BY THE COURT
Hon. Michael G. Maronich, Judge
Elizabeth Occhiainti, Deputy Clerk
Date signed: 6/15/16

Right to Counsel: Upon proof of inability to pay for a lawyer, the court will make sure that an attorney is provided to you by the Chief Public Defender. request for an attorney should be made immediately in person, by mail or by fax at the court office where your hearing is to be held.

R-A July 14, 2016

Legal Notice
Town of Kent
Zoning Board of Appeals

At the regular meeting of the Kent Zoning Board of Appeals on July12, 2016, the following action(s) was taken:

Approved with Conditions: Application #03-16, Jay Hoefer for John O'Hara, 337 Kent Road, Certificate of Approval for Motor Vehicle Sales, Services and Repair Uses, Map 6 Block 11 Lot 6.

Dated at Kent, CT
This 12th day of July, 2016
Anthony DiPentima,Chairman
RA July 14, 2016

STATE OF CONNECTICUT
SUPERIOR COURT
JUVENILE MATTERS
ORDER OF NOTICE

NOTICE TO:Sean Dauber,Father of female children born on 7-13-02, 9-1-05, 11-5-12 and male children born on 6-4-09, 2-22-11, and 10-26-13 to Katherine B. In the town of Danbury, CT

of parts unknown

A petition has been filed seeking:

Termination of parental rights of the above named in minor child(ren)

Legals/ Public Notices

STATE OF CONNECTICUT
SUPERIOR COURT
ORDER OF NOTICE
IN FAMILY CASES
JUDICIAL DISTRICT OF WATERBURY
AT WATERBURY
NOTICE TO: MOORE, RODERICK
RETURN DATE: 8/9/16

The Court has reviewed the Motion for Order of Notice and the Complaint / Application / Motion which asks for:
divorce
(dissolution of marriage)

The Court finds that the current address of the party to be notified is unknown and that all reasonable efforts to find him/her have failed. The Court also finds that the last known address of the party to be notified was: Bronson St., Waterbury, CT 06702. The Court Orders that notice be given to the party to be notified by having a State Marshal or other proper officer place a legal notice in: Republican-American, a newspaper circulating in Waterbury, CT containing a true and attested copy of this Order of Notice and, if accompanying a Complaint for divorce (dissolution of marriage), complaint for dissolution of civil union, legal separation or annulment, or if accompanying an Application for custody or visitation, a statement that Automatic Court Orders have been issued in the case as required by Section 25-5 of the Connecticut Practice Book and are a part of the Complaint on file with the Court.

The notice shall appear once a week for two successive weeks concluding 7/28/16 and proof of service shall be filed with this Court;

A True Copy Attest:
Willie J. Davis Jr.
State Marshal

Patricia Martins, TAC
Date signed 6/13/16
R-A July 7 & 14, 2016

STATE OF CONNECTICUT
SUPERIOR COURT
ORDER OF NOTICE
IN FAMILY CASES
JUDICIAL DISTRICT OF MILFORD
AT MILFORD
NOTICE TO:
TAYLOR, LARRY ALFONSO
RETURN DATE: 6/14/16

The Court has reviewed the Motion for Order of Notice and the Complaint / Application / Motion which asks for:
divorce
(dissolution of marriage)

The Court finds that the current address of the party to be notified is unknown and that all reasonable efforts to find him have failed. The Court also finds that the last known address of the party to be notified was: 139 Lewis Street #17, Naugatuck Valley, CT. The

Legals/ Public Notices

SUPERIOR COURT
JUDICIAL DISTRICT
AT LITCHFIELD
RETURN DATE: AUGUST 9, 2016
TOWN OF HARLAND
VS.
EDWARD J. TEDESCO; EILEEN P. TEDESCO; LYNDA G. TEDESCO; VICTOR M. ROSATI, if living, and if not living, his widow and heirs; MARGARET M. ROSATI, if living, and if not living, her widower and heirs; JOAN D. MERICLE; KAREN M. THOMAS; MARIE C. ROSATI, if living, and if not living, her widower and heirs; STATE OF CONNECTICUT, DEPARTMENT OF SOCIAL SERVICES; STATE OF CONNECTICUT, DEPARTMENT OF ADMINISTRATIVE SERVICES; and STATE OF CONNECTICUT.

NOTICE TO THE WIDOW, WIDOWERS AND HEIRS OF VICTOR M. ROSATI, MARGARET M. ROSATI AND MARIE C. ROSATI

The Plaintiff has named you as a defendant in the complaint brought to the above named court seeking foreclosure of unpain municipal taxes encumbering property at Riverton Road, Hartland, Connecticut in which you may have an interest as a widow, widowner, or heir to the defendants Victor M. Rosati, Margaret M. Rosati or Marie C. Rosati. The complaint is returnable to the above named court on August 9, 2016, and will be pending therein after that date. The plaintiff has represented to said court, by means of an affidavit annexed to the said complaint, that despite all reasonable efforts to ascertain such information, it has been unable to determine the residence of the Defendants, Victor M. Rosati, if living, and if not living, his widow and heirs, Margaret M. Rosati, if living, and if not living, her widower and heirs, or Marie C. Rosati, if living, and if not living, her widower and heirs.

Now, therefore, it is hereby ordered that further notice of the institution and pendency of this action be given to such defendants VICTOR M. ROSATI, IF LIVING, AND IF NOT LIVING, HIS WIDOW AND HEIRS, MARGARET M. ROSATI, IF LIVING, AND IF NOT LIVING, HER WIDOWER AND HEIRS and MARIE C. ROSATI, IF LIVING, AND IF NOT LIVING, HER WIDOWER AND HEIRS by some officer or person causing a true and attested copy of this order to be published in the Waterbury Republican-American once a week for 2 successive weeks, commencing before July 26, 2016 and that return of such service be made to this court.

BY THE COURT (Pickard, J.)
Sarah O'Brien
Temporary Assistant Clerk
Dated: June 24, 2016
A TRUE & ATTESTED COPY
BONNIE FIENEMANN
State Marshal
Litchfield County
An Indifferent Person
R-A July 14 & 21, 2016

LEGAL NOTICE
NOTICE TO TAXPAYERS
PINE MEADOW FIRE DISTRICT

Notice is hereby given to all persons liable by law to pay property taxes to the Pine Meadow Fire District. County

Legals/ Public Notices

PUBLIC NOTICE

Statute Reference:
19a-638 et seq. of the Connecticut General Statutes
Applicant: The Waterbury Hospital
Addresses:
64 Robbins Street, Waterbury, CT 06708; 1625 Straits Turnpike, Middlebury, CT 06762; 1284 Strongtown Road, Southbury, CT 06488
Towns:
Waterbury, Middlebury, Southbury
Proposal: The Waterbury Hospital plans to file an application with the Office of Health Care Access for Certificate of Need authorization for the consolidation of its sleep laboratory services to a single location in Middlebury, Connecticut.
Capital Expenditure: $0

R-A July 14-July 16, 2016

WATERBURY ZONING
BOARD OF APPEALS
PUBLIC HEARINGS

Notice is hereby given that the following Public Hearing will be held at a meeting of the Zoning Board of Appeals at the date, time and place noted below:

DATE:
Wednesday, July 20, 2016
TIME: 6:25 P.M.

PLACE: CITY HALL –
2ND FLOOR
ALDERMANIC CHAMBERS
235 GRAND STREET
WATERBURY, CT

1. PL2016-0220 Variance from Section 4.09, Master Standards Development Table; RL District: to allow building height of 38 feet and 3 stories where the lesser of 2.5 stories or 35 feet is permitted. Location: 52 Tower Road; Applicant: Israel Weisz.

2. PL2016-0229 Variance from Section 4.09, Master Standards Development Table; RM District: front yard setback - 15 ft required, 6.1 ft provided; Sec. 4.06.02 (iv) Exceptions to district development standards: to allow the unenclosed stairs to leave a 6.1 front yard where minimum of 9 ft is required; and Sec. 5.04.08 - 4.09 RM side yard - 6 ft required, 3.5 ft provided. Location: 61 Oak Street; Applicant: Glendon Roberts

3. PL2016-0232 Variance from Section 4.09 MINIMUM FRONTAGE FOR A LOT FROM 6 FET REQUIRED TO ZERO FT PROVIDED; from Section 4.09 REARYARD SETBACK FROM 25 FT REQUIRED TO 10.50 FT PROVIDED. Location: 270 DeCicco Road. Applicant: Daniel Angelicola.

4. PL2016-0235 Special Exception: RM District; Change from one Non-Conforming Use to another, i.e. Personal, Business and Repair Services(barber shop) to retail sales (organic juice sale). Location: 890 North Main Street. Applicant: Robert Sergeant.

5. PL2016-0236 Variance from Section 9.02.04(vii); General Performance Standards. IL Dis-

Legals/ Public Notices

LEGAL NOTICE
Notice of Public Hearing for the Town of Morris 2016-2107 Budget
July 21, 2016 at 7pm
Morris Community Hall,
3 East Street, Morris, CT 06763
RA 7/14/2016

CITY OF WATERBURY
INLAND WETLANDS AND
WATERCOURSES COMMISSION
LEGAL NOTICE

Public Notice as provided under Connecticut General Statues, as amended, is herewith given of the Official Actions and Decisions of the Inland Wetlands and Watercourses Commission of the City of Waterbury at its meeting held on July 6, 2016.

1.PL 2016-0231 Wetlands Permit to conduct regulated activity; Location: 39 Red Maple Lane; Applicant: Dasmir Kalkil - **APPROVED WITH CONDITIONS.**

ATTEST: James A. Sequin, AICP
City Planner
203-574-6817
RA 7/14/2016

Legals/ Public Notices

WATERTOWN WATER AND
SEWER AUTHORITY
NOTICE OF RESOLUTION PASSAGE
JULY 6, 2016

At the meeting of the Watertown Water and Sewer Authority held on Wednesday, July 6, 2016, the following resolution was adopted:

WATERTOWN WATER AND SEWER AUTHORITY RESOLUTION TO FUND CONCORD DRIVE/ LEXINGTON DRIVE AREA SANITARY SEWER EXTENSION AND WATER EXTENSION PURSUANT TO CONNECTICUT GENERAL STATUTES, WATERTOWN TOWN CHARTER SECTION 709 AND THE WATERTOWN CONSOLIDATION ORDINANCE

WITNESSETH:
WHEREAS, the Watertown Water and Sewer Authority (hereinafter "Authority") has determined that the construction of a proposed Sanitary Sewer and Water Extension Project up to and including the area of Concord Drive and Lexington Drive, substantially in accordance with the plans as drawn by Wright-Pierce, Incorporated, and dated April, 2016, excepting from both the Water and the Sewer extension that portion of the proposed project which calls for the construction a sewer pumping station, is a matter of public convenience, public health and an abatement of sewage pollution and the provision of potable water, and is therefore a necessity and should be proceeded with forthwith; and

WHEREAS, the Authority has conducted public hearings on this proposed project including a public hearing on July 6, 2016 pursuant to Connecticut General Statutes §7-247a; and

WHEREAS, The Authority has conducted a thorough investigation of the financial and engineering matters that may be involved in the proposed sewer extension, as designed by Wright-Pierce, and the cost of said project is estimated to be Three Million, Eight Hundred and Seventy Thousand, Three Hundred Thirty Dollars ($3,870,330.00), of which Two Million, Four Hundred Ninety-Five Thousand, Three Hundred Thirty Dollars ($2,495,330.00) is to be a General Benefit to be paid by the general taxes/revenues of the Town of Watertown as new capacity for commercial, industrial and residential areas not presently in the Authority's service area; and the remaining One Million, Three Hundred Seventy-Five Thousand Dollars ($1,375,000.00) of the cost of the project to be a Special Benefit to be assessed to the properties to be benefited by the availability of the proposed sewer mains; provided that any shortfall in the collection and application of special benefit assessment revenues with respect to the project shall be deemed to create a General Benefit to be paid by the general taxes/revenues of the Town of Watertown; and

WHEREAS, The Authority has conducted a thorough investigation of the financial and en-

SLP0048

Apartments for rent

WATERBURY Large 2 bedroom. Section 8 welcome. $950 per month. 203-578-7362.

WATERBURY Lawlor St 2BR 2nd flr HW flr W/D hkup off-st prkg good area $850. John 914-497-3580.

WATERBURY Lg 4Br, 2nd Flr, Willow St, w/d hkup. $750/mo. Call 203-650-9363

WATERBURY spacious studio & 1BR & 2BR. $625, $750 & $850. Call for details 203-906-0817

WATERBURY tired of viewing dirty, neglected apts, ours are clean and updated. 1 & 2 Br. avail. 203-729-2269, 203-805-1680

WATERBURY Town Plot 2 BR, appl WD hkup, w/w, busline, no pets $850 cr ck sec 860-274-9554

WATERBURY/WOLCOTT LINE 2 - 2BR's $925/$1000, yard, 1.5 ba, HT/HW incl., renov., prkg, lots of closets. 203-217-1733.

Waterbury/Wolcott Line Mod. elev. bldgs convenient well maintained **HILLTOP MANOR** Studios $570; 1 BR from $670; **LIBERTY COURT** heat, HW, elect. incl.; studios $650+; 1 BR $790+; Both incl. prkg., carpet/HW flrs, sec. & laundry. No pets. Mgmt: 203-755-0621; 203-470-9808

WATERTOWN 1 BR 1st flr, quiet, conv. downtown loc, cats OK, newly renov $675. 203-206-7627

RepublicanAmerican Classifieds

Condos for rent

TERRYVILLE Winfield Condos 2BR, 1.5 bath, appl's includ. Finish FR. No Pets $1050/mo 203-232-1433.

WATERBURY 1BR condo Pine Village. $725/mo plus 2 mos. sec. Call 754-2278

WATERBURY 2BR 1.5 BA W/D, $895 + sec. Sec 8 No pets. 203-879-4126; 203-577-7516

WATERBURY 379 Perkins Ave. 1 BR $700/mo. utilities not included. 631-219-2955 /516-429-7045

WATERBURY 515 Scott Rd. 2BR, 1.5 ba. condo. new carp/paint, WD hkup, no pets/smk. $900 cr ck/sec. Cathy, CT Condo Connection 203-910-5865

WATERBURY East End 1400 s.f. 3 BR, 2.5 bath end unit, quiet location. Very nice! No pets $1000. 203-510-2281

Garages for rent

Rooms

WATERBURY Twn Plot 2rm priv bth in home $140/wk 2wks dep fully furn elect-cable incl 203-706-0495

Wanted to rent

WOLCOTT spacious studio, reas, decent location, have cat & rabbit, pay cash. 860-201-4742

Real Estate For Sale

Condos

OAKVILLE 2BR, 2 full ba., beautiful corner condo. 2 car att gar. By owner. $330,000. 860-601-0524.

Lots for sale

BANTAM LAKE bldg lot on 5 ac priv. community. Tennis, boat, water & sewer incl. 860-868-1256

Mobile home

NAUGATUCK 4 units to choose from starting at $29,900 incl. pool & clubhouse 203-729-8277

NAUGATUCK Quiet park! 3 BR, 1 bath, new carpet & lino $32,900 Liberty 860-747-6881 860-940-1204

PROSPECT like new! 2BR 1 bath, w/appl. & shed, $59,500 Liberty 860-747-6881; 203-592-7641

Commercial

Business for sale
Commercial for sale, lease, rent

Commercial for sale, lease, rent

WATERBURY DOWNTOWN barber shop/salon. newly renovovated, ideal loc. $600/mo. 646-342-7475

WATERBURY DOWNTOWN LEASE 600-5,000 sq. ft. Call for details, 203-841-2500 x121

Announcements

Absolutely free
Lost & found
Special notices

Absolutely free

KITTENS Free kittens avail.

Legals/ Public Notices

INVITATION TO BID

Sealed proposals for the construction of the Expansion of Riverbend Park at Nancy Avenue Beacon Falls, Connecticut, will be accepted until 2 PM on **August 8th, 2016** at the office of The Town Clerk, Beacon Falls Town Hall, 10 Maple Avenue, Beacon Falls, CT 06403. The proposals will be publicly opened at **6:15 PM on August 8th, 2016** at the Beacon Falls Senior Center, 57 North Main Street, Beacon Falls CT 06403.
Bid Documents are available at the Town Clerk Office, Beacon Falls Town Hall, 10 Maple Avenue, Beacon Falls, 06403. **No bid will be accepted after the posted time of 2 PM on August 8th 2016.**
Bids are to be mailed or hand delivered. Electronic transmissions or facsimiles will not be accepted. When bid documents are obtained, the bidder must provide: name, address, telephone number, fax number, and email address, if available.
Bid documents include Plans and Specifications. The project is subject to the Davis Bacon Act and prevailing wage rate requirements. A site visit is scheduled for 10 AM on July 30, 2016
The Town of Beacon Falls is an affirmative action/equal opportunity employer. Minority business enterprises, women business enterprises and small business enterprises are encouraged to apply.
The Town of Beacon Falls reserves the right to waive any informality in any bids, to reject any or all bids or any part of any bid when it is determined to be in the best interest of the Town and is not responsible for the cost of preparing bids.
RA 7/15/2016

INVITATION TO BID

The Town of Thomaston invites interested parties to submit bids to repave the side and rear parking area at the Thomaston Fire Department, 245 South Main Street, Thomaston, CT 06787. Bids will be accepted on or before August 1, 2016 at 10:00 AM. Prospective bidders can schedule an on-site visit by contacting Ken Koval, Building Committee Chairman, at 203-910-2998. The complete request for proposals can be obtained in the First Selectman's Office, Thomaston Town Hall or at: www.thomastonct.org/Content/Bid_Information.asp.
R-A July 15, 2016

CITY OF WATERBURY
DEPARTMENT OF PUBLIC WORKS
BUREAU OF
PARKS AND GOLF COURSES

Legal Notice
Litchfield Planning and Zoning Commission

Notice is hereby given that the Planning and Zoning Commission of Litchfield, Connecticut will hold public hearings on July 18, 2016 at 7:00 P.M. at the Town Hall Annex 80 Doyle Road Bantam, CT, for the following applications:

Doyle - 308 Norfolk Rd. - Interior lot for 3 lot resubdivision.
Doyle - 308 Norfolk Rd. - Three lot re-subdivision with interior lot.

At this hearing interested persons may appear and be heard and written communication will be received. Copies of the applications are on file in the Land Use Office of the Town of Litchfield at the Town Hall Annex, 80 Doyle Road, Bantam, Connecticut.

Planning and Zoning Commission

R-A July 5 & 15, 2016

LEGAL NOTICE
NOTICE TO CREDITORS
ESTATE OF: Anthony Parente

The Hon. Peter E. Mariano, Judge of the Court of Probate, District of Naugatuck, by decree dated April 5, 2016, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim.

Michele M. Rupsis, Clerk

The fiduciary is:
Amanda Parente
c/o Patrick D. Skuret, Esq.
215 Division Street, PO Box 158
Ansonia, CT 06401

R-A July 15, 2016

LEGAL NOTICE
TOWN OF CORNWALL
NOTICE OF DECISIONS
PLANNING AND ZONING COMMISSION

Pursuant to the provisions of Section 8-28 of the General Statutes, as amended, notice is hereby given that at a regular meeting, July 12, 2016 held in the Cornwall Library, the Cornwall Planning and Zoning Commission made the following decision: By unanimous vote to approve Amendments to the Zoning Regulations to add language to Article 1, Section 1 - "Purpose", to add, delete, and modify language in Section 5.11 – "Farmers Market, to modify language in Section 9.15.2 "Parking", to delete language in Section 5.2 "Minimum Livable Floor Area" and to modify language in Section 8.10.4.2 "Accessory Apartment" with modifications, effective date 15 days after date of publication and SP#239 – Steven Madeux, applicant owner – Special Permit(s) for a Roadside Produce Stand as per Section 8.13 "Roadside Produce Stand et al" and Section 8.18 "Traditional Home Enterprise for the preparation and sales of goods produced in a garden – 17 Hollenbeck Road (Route

PUBLIC NOTICE

Statute Reference:
19a-638 et seq. of the Connecticut General Statutes
Applicant: The Waterbury Hospital
Addresses:
64 Robbins Street, Waterbury, CT 06708; 1625 Straits Turnpike, Middlebury, CT 06762; 1284 Strongtown Road, Southbury, CT 06488
Towns:
Waterbury, Middlebury, Southbury
Proposal: The Waterbury Hospital plans to file an application with the Office of Health Care Access for Certificate of Need authorization for the consolidation of its sleep laboratory services to a single location in Middlebury, Connecticut.
Capital Expenditure: $0

R-A July 14-July 16, 2016

REQUEST FOR QUALIFICATION
#03-1619

The State of Connecticut Judicial Branch, on behalf of the Office of Victim Services (OVS) is soliciting responses to this Request for Qualifications (RFQ) from qualified individuals to serve as a Regional Coordinator for the Gail Burns-Smith Sexual Assault Forensic Examiners Program (SAFE).

Response to this Request for Qualification must be received by Monday, August 15, 2016.

Request for interest packages may be obtained at Judicial Purchasing Services at: 90 WASHINGTON STREET, 4th Floor, Hartford, CT or call (860) 706-5200 to request by mail, or access the web site below.

PLEASE CHECK THE JUDICIAL WEB SITE AT:

www.jud.ct.gov/external/news/busopp/

JUDICIAL BRANCH
PURCHASING SERVICES
90 WASHINGTON STREET
HARTFORD, CT 06106

An Equal Opportunity/Affirmative Action Employer
RA July 15, 2016

LEGAL NOTICE

At the regular meeting held July 13, 2016 Sharon Planning & Zoning Commission voted unanimously to approve the application of Applewood Tree Care LLC, with conditions, for an accessory apartment at 180 Sharon Valley Road, owned by Jeffrey Hoskins and Jennifer Tierney. This application is on file in the Land Use Office.
Dated this 14 Day of July, 2016
Elizabeth M. Hall,
Vice Chairman
RA 7/15/2016

TOWN OF WATERTOWN
Legal Notice

The Zoning Board of Appeals of the Town of Watertown will hold a public hearing at 7:00PM on Wednesday, July 27, 2016 at

FATHER/SON LOOK-A-LIKE CONTEST

OFFICIAL CONTEST RULES

NO PURCHASE NECESSARY TO ENTER OR TO WIN. A PURCHASE WILL NOT INCREASE YOUR ODDS OF WINNING. ALL FEDERAL, STATE, LOCAL AND MUNICIPAL LAWS AND REGULATIONS APPLY. VOID WHERE PROHIBITED.

Eligibility: Subject to the additional restrictions below, the "Father-Son Look-Alike" Contest is open to Connecticut residents. Employees of the Republican-American, hereinafter referred to as "Sponsor" and the immediate family members of, and any persons domiciled with any such employees, are not eligible to enter or to win.

How To Enter: Submit a photo for the "Father-Son Look-alike" using the entry form at www.rep-am.com/fatherson beginning 12:01 a.m. EST on June 26, 2016, through 12 p.m. (noon) on July 30, 2016. Completely fill out the entry form and submit your photo. Photos must be submitted in JPG or GIF format. All photos must be submitted through www.rep-am.com/fatherson or mail your picture along with your name, address, telephone number and e-mail address to: Father-Son Look Alike Contest, Republican-American, P.O. Box 2000, Waterbury, CT 06722-2000. Only one photo may be submitted per Father-Son entry.

Photo received will be placed on an online ballot, which will be available on www.rep-am.com starting June 26, 2016 through July 30, 2016. The voting period will begin at 12:01 a.m. on July 3, 2016 and end at 11 pm on July 30, 2016.

Restrictions: Multiple entries by means of software generated or other automated processes will be disregarded. Sponsor will not be responsible for incomplete, lost, late, misdirected or illegible entries. All entries become property of Sponsor and none will be returned. Any questions regarding the number of entries submitted shall be determined by Sponsor in their sole discretion, and Sponsor reserves the right to disqualify any entries by persons determined to be tampering with or abusing any aspect of the Contest.

Participation: By participating, entrants agree to be bound by these Official Rules and the decisions of Sponsor. In the event the contest is compromised by tampering or other causes beyond the reasonable control of Sponsor which corrupts or impairs the administration, security, fairness or proper operation of the contest, Sponsor reserves the right in its sole discretion to suspend, modify or terminate the contest. Should the contest be terminated prior to the stated expiration date, Sponsor reserves the right to award prizes based on the entries received before the termination date.

Winner Selection: Winners will be determined by the number of votes received online. To be eligible to vote in the contest, one must register as a voter at www.rep-am.com; registration will be at no cost. The top vote-getters during the contest period will be awarded a choice of one of the following prizes. The contestant with the most votes gets to choose first, and then the chosen prize will be removed from the prize pool. The contestant with the 2nd highest number of votes then chooses their prize and that prize is removed, then the third, fourth, etc until all prizes are claimed.

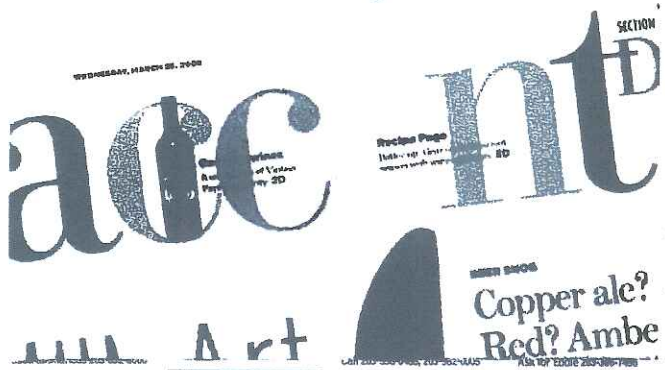
PRIZE POOL

One Regal Entertainment Gift Pack For Two Tickets plus $10 Concession

$70 Gift Certificate towards an Oil Change & Tire Rotation at Terryville Chevrolet in Woodbury

$50 Gift Card to Dippy's Ice Cream & Cakes in Waterbury

For all things food, read Wednesday Accent



Asphalt paving

BRASS PAVING LLC - CT #575141 Paving driveways, sealing & repairs. Free est. 203-574-2693

MARINI PAVING 860-274-3978 * Driveways * Repairs * Seal Coating * Drainage #563045. 203-410-9226

SPINO'S PAVING Comm'l and resid'l driveways, parking areas, plow damage repair and curbing replaced. Free estimates. CT Lic #579761. 203-574-2547 cell 203-537-3151

THEPUBBLEPAVERS.COM One call for all your pavement needs! The area's largest residential paving contractor. No money down. We guarantee your satisfaction! Visit us online or call 860-945-0873. CT #612743

Carpentry

DN Carpentry Window, doors, decks, baths, drywall, trim, paint, fin.bsmt. #614783, Ins. 203 233 0795

Electrical

DW ELECTRICAL Any size jobs, srvc grounding, upgrades, rem. Free est #182995. 203-592-3562

MIELE ELECTRIC, Everything Electrical. Service Upgrades, Generators 125712. 203-757-7423

General services

HOME HEALTH CARE Local LPN (exp. & licensed) will provide home care $25/hr. 203-695-9065

Gutters

PEET SEAMLESS GUTTERS & SERVICES 860-283-2252

Hauling services

ALL ABOUT SERVICE S&P CARTING trash & cleanup 10-40 yard roll off containers. Same day svc. Ins V/MC 203-758-4656

JOE ROCCO RUBBISH REMOVAL Est. Clear-outs Bsmnts, Attics, Gar., Demolition removal, All unwanted items. Roll off - 8-30 Yd. Mstrcard/Visa 203-509-3297.

JUNK REMOVAL furn., appliances, shed, attic, basement, piano removal, 20% off, 203-535-9817, 860-575-8218

Home improvement

BUDGET PAINTING & Remod roofs, siding & painting, fully insured #0638113. Call 203-982-5353

RICH'S HOME IMPROVEMENT painting, sheetrock, trim, roof, deck, ins. #566055 203-704-7520

Landscaping & lawns

ABILITY SPRING CLEANUP trim hemlocks, mowing, gutters, shrubs, sm brush, 203-753-2870.

DB LANDSCAPE Lawn mowing starts at $25. mulching, trimming, stone work, free estimate, #0633401; 203-704-1640

Spring Cleanups/Property Maint. Weekly cut. East Mtn., Prospect, Naugatuck areas. 203-232-6342

Lawn/garden equipment repair

WOLCOTT POWER SALE & SERVICE. All makes & models. 203-879-6712

Masonry

ALFRED MASONRY 30+yr exp. Pools, deck, stamp conc, patios, retain. walls, stucco Ins #565904. Free est. Call 860-274-7977

GENERAL MASONRY ★ 203-233-0149 Stone/brick walls, walks, chimneys, fp's, patios. Ins. Free est CT 609333

KONSTANDING MASONRY Stone pavers, steps, Patios, Chimney, repairs & more. Call 203-528-8294

PAUL'S MASONRY Stone, brick, block, walks, patios, FP's free est. CT #0635508. 203-706-9281

Painting

A & D PAINTING Int/Ext, res/comm. Unbeatable price & quality. #619126. Free Est. adpaintingct.com 860-283-5095

ARMEND'S PAINTING LLC Int/ext carpentry low prices! Free est. CT#0631318. 203-597-7179

ASHLEY'S PAINTING LLC Interior & exterior. Call for estimate. 860-331-5308 Hic# 0642743

PAUL DEVINO PAINTING CO. LLC 1-2-3 fam. houses. Factories, shop, plaza, hotels, condos, schools, offices, church, low price free est lic 627846. 203-509-4488

ROCCO's PAINTING Res. Free est & cleanup. CT# 561112. 30+ yrs exp 203-574-1906

Plumbing

CAPINERA PLUMBING & HEATING Gas pipe, boilers HW heaters, & repairs #202962. 203-575-1551

CHRIS SHEPPARD PLUMBING repair, wtr heater, lawn hose bibs, gas, #283570 203-305-0072

Power washing

AFFORDABLE POWER WASH Our trucks carry water. Free est. Ins. & CT Lic.# 574575. 203-591-7075

Roofing

DIDONATO ROOFING Remodeling & Siding. Reasonable rates. Sr. discount. #563098. 203-509-2773

DIDONATO ROOFING Remodeling & Siding. Reasonable rates. Sr. discount. #563098. 203-509-2773

Lema Construction Roofing, Siding, Gutters clean, & Chimney repair, Lic.#636570. 203-510-3830

S&S Roofing Quality work, at a sensible price. A+ Rated BBB. Lic.#573533. Steve Biff Saunders. Veteran Owned. 860-283-8990.

Tree care

A A A HOME TREE REMOVAL Lowest Price, 20 yrs exp., sr disc., free est. Fully Ins'd 860-249-3094

Tag/estate sales

THOMASTON ESTATE SALE 108 Elm St. Thurs., Fri. & Sat. 9-4. Antiques, Hitchcock, furniture, tools, etc.

TORRINGTON Sat. 7/16 8-4. Hshld items, toys, furniture, electronics, men's clothes & more. 17 Warder Lane.

WATERBURY 1 Ranzado St. Saturday July 16 ONLY. 9am-3pm: Household items, furniture and much more!

WATERBURY 148 Stillson Rd. Huge Sat. 9-3 tools, hsld, ACs, ladders, boating, clothing, auto access

WATERBURY 1613 Thomaston Ave, Fri. Sat 9-3. size 3 clothes good cond hsld. Formerly "Memories"

WATERBURY 176 Hubbell Ave, Sat & Sun. 8-2. Hhsld items, in/outdoor tools, clothes & more.

WATERBURY 299 Peach Orchard Rd. Sat/Sun. 8-4. 3 hshlds moving. Desks, sofa, recliner set, clothes, etc. 10 tables full.

Tag/estate sales

WOODBURY 527 Flanders Rd. SAT. 7/16 9a-4p. Antiques, unusual hard to find items!

WOODBURY ESTATE 858 Main St N, Fri. 10-5, Sat 9-5 & Sun 12-5. Vin clothes, furn, collect's & more

Wanted to buy

ACCORDIANS ACOUSTIC GUITARS amp drums, musical instrument. Cash paid any cond 508-688-5138.

ACCORDIANS, advertising, all antiques, audio, amps, guitars, musical instr, old toys, watches, art, radios. HAM EQ 860-707-9350

Antiques/Collectibles/Old Items Jwlry, Art, Signs, Toys, Silvr, Gold Call about anything 203-828-8129

MACHINIST TOOLS AND TOOLING, CARBIDE INSERTS, SMALL LATHES 860-985-5760

WANTED Diabetic Test Strips, Cash paid. Will pick up. Call Don 203-733-8234

Wood

Wood refinishing /chair repair

KITCHEN CABINETS RESTORED Furn. wobbly chairs, loose & broken posts #563142 203-754-1092

Legals/ Public Notices

Bidders' Conference

To: Prospective Bidders
Invitation to Bid
Bid Title: Wilby School Based Health Center
Estimated Bid Range: $23,000-$28,000

Bids will be received at:
StayWell Health Center
Attention: Jill Schoenfuss
80 Phoenix Avenue,
Waterbury, CT 06702

Bid Opening
Date:
July 25, 2016
Time: 11:00pm
Location:
80 Phoenix Ave
Waterbury, CT.

Pre-Bid Meeting
Date: July 25, 2016
Time: 10:00 am
Location:
460 Bucks Hill
Waterbury, CT.

Bid Closing
Date: August 5, 2016
Time: 4:00 pm
Location:
80 Phoenix Ave, Ste 204
Waterbury CT

ED THE TREE MAN LLC Large Takedown Specialist, 75' Bucket truck, Stump grinding, Tree Fertilization & Pesticide Management. Chipper & 24 Hr Emergency Serv-Firewood CT Lic. Arborist #S-5765 Bus. Reg: 9-2358 Free Est./Ins. (203) 758-0261

GMZ TREE SERVICES 60' bucket truck & climbing, 24 hr. service. #0630169. 203-942-6351

LOG DOGS COMPLETE TREE SERVICE Lot clearing. Free est. 203-271-3355. 5% of every job donated to local dog rescue. www.logdogstreeremoval.com

P.F.D. LLC Bucket truck service & climbing, tree remov., chipper, stump grinding, 24 hr serv., Sr. Disc. #618879. Free Est. 860-274-8094

Legals/ Public Notices

NOTICE OF APPROVAL
TOWN OF THOMASTON
PLANNING AND ZONING COMMISSION

The Planning and Zoning Commission of the Town of Thomaston, CT at a resular meeting held on Wednesday, November 6, 2013, voted to approve application #2013-09-27-01 of Kevin Greene for a change of zone from RA-80 residential to M1 light manufacturing at 555 Waterbury Road, Assessor's Map 63 Block 05 Lot 02.

Dated at Thomaston, CT this 16th Day of July, 2016

Ralph Celone, Chairman
Thomaston Planning and Zoning Commission
RA July 16, 2016

NOTICE OF APPROVAL
TOWN OF THOMASTON
PLANNING AND
ZONING COMMISSION

At a regular meeting held on July 6, 2016, the Thomaston Planning and Zoning Commission, Thomaston, CT voted to approve site plan application #2016-06-30-01 of Deziel Paving

PUBLIC NOTICE

Statute Reference:
19a-638 et.seq. of the Connecticut General Statutes
Applicant: The Waterbury Hospital
Addresses:
64 Robbins Street, Waterbury, CT 06708; 1625 Straits Turnpike, Middlebury, CT 06762; 1284 Strongtown Road, Southbury, CT 06488
Towns:
Waterbury, Middlebury, Southbury
Proposal: The Waterbury Hospital plans to file an application with the Office of Health Care Access for Certificate of Need authorization for the consolidation of its sleep laboratory services to a single location in Middlebury, Connecticut.
Capital Expenditure: $0

R-A July 14-July 16, 2016

TOWN OF SHARON
PO Box 385, 63 Main Street
Sharon, CT 06069
SHARON HISTORIC DISTRICT
LEGAL NOTICE

On Monday, July 25, 2016 at 6:00 PM the Sharon Historic District Commission will hold a public hearing on the following application : Alterations to 9 South Main Street – Christ Church Episcopal. The hearing will be held at Sharon Town Hall, 63 Main Street, Sharon, CT on the second floor.
This application is on file at the Sharon Land Use Office. At this hearing, interested persons may be heard and written communications received.
Dated this 15th Day of July, 2016.
John Baroody
Chairman
RA 7/16/2016

Legals/ Public Notices

LEGAL NOTICE
FORECLOSURE AUCTION SALE
Case Name:
US Bank Trust, as Trustee
v.
Brad J. Musselman, Et Al

Docket No. LLI-CV-16-6013153-S

Property Address:
28 Winthrop Street, Torrington, CT 06790

Property type:
Multi-Family Dwelling Unit

Date of Sale:
Saturday, July 30, 2016
at 12:00 p.m. noon

Committee Name:
John E. Hudson, Esq.

Committee Phone Number:
(860) 489-2790

See Foreclosure Sales at www.jud.ct.gov
July 16 & 23, 2016

LEGAL NOTICE
FORECLOSURE AUCTION SALE

Docket No:
LLI-CV16-6013039-S
Property Address:
301 Carbide Road, Litchfield

$50 Gift Card to Danielle Elizabeth Garden Center in Woodbury

$50 Gift Card to AJ's Steak & Pizza in Goshen

$50 Gift Card to Juniper's Restaurant in Middlebury

$25 Gift Card to Chili's Restaurant in Waterbury

$25 Gift Card to Starbucks Coffee

$10 Gift Card to da capo ristorante in Litchfield

Winner Notification and Acceptance: Winners will be notified by email using the email address on the entry form on Monday, July 31st after their selection. Sponsor will call during its regular business hours at the phone number provided on the entry form and is not required to leave any message. Failure to reach winner by phone may result in disqualification of winner, forfeiture of his or her interest in all prizes, and selection of a substitute winner from among all remaining eligible entries. Winners may waive their right to receive prizes. Prizes are non-assignable and nontransferable. No substitutions allowed by winner. Prizes and individual components of prize packages are subject to availability and Sponsor reserves the right to substitute prizes of equal or greater value. Winners are solely responsible for reporting and payment of any taxes, title, license and services fees. Winner automatically permits the use of their name, address and photo for Republican American promotional purposes.

Sponsor: The "Father-Son Look-alike" contest is sponsored by Republican-American. The decisions of Sponsor regarding the selection of winners and all other aspects of the contest shall be final and binding in all respects. Sponsor is not responsible for typographical printing or other inadvertent errors in these Official Rules or in other materials relating to the contest. The list of winners will be available after July 30, 2016. If you have any questions regarding this contest, please contact Tgonsalves@rep-am.com

SLP0050

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND ON WHITE PAPER

CARMODY
TORRANCE | SANDAK | HENNESSEY LLP
50 Leavenworth Street
Waterbury, CT 06702

WEBSTER BANK
WATERBURY, CT

51-7010/2111

244188

DATE
August 04, 2016

PAY **Five Hundred & 00/100**

AMOUNT
500.00

VOID IF NOT CASHED WITHIN 1 YEAR

TO THE ORDER OF: TREASURER-STATE OF CONNECTICUT

MP

SECURITY FEATURES INCLUDED. DETAILS ON BACK

[redacted]

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Thursday, August 25, 2016 9:03 AM
To: 'dstromstad@wtbyhosp.org'; 'dhardy@carmodylaw.com'
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie
Subject: Completeness Questions: 15-32113-CON
Attachments: 16-32113 Waterbury sleep Completeness 8.25.16.pdf; 16-32113 Waterbury sleep Completeness 8.25.16.docx

Good morning Ms. Stromstad and Mr. Hardy:

Attached please find a pdf and word version of completeness questions regarding your Certificate of Need application for the termination of Waterbury Hospital's sleep lab services at its Southbury site (docket number 15-32113-CON).

Please confirm receipt of this e-mail and feel free to contact me if you have any questions.

Jessica

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

August 25, 2016 Via Email Only

Darlene Stromstad
President/CEO, Waterbury Hospital
64 Robbins Street
Waterbury, CT 06708
dstromstad@wtbyhosp.org

David S. Hardy
159 Church Street
New Haven, CT 06509-1950
dhardy@carmodylaw.com

RE: Certificate of Need Application Completeness Questions
The Waterbury Hospital's application for the termination of sleep lab services in Southbury, CT (Docket No. 16-32113-CON)

Dear Ms. Stromstad and Mr. Hardy:

On August 5, 2016, OHCA received a Certificate of Need application from The Waterbury Hospital ("Hospital" or "Applicant") for the termination of its sleep lab services at its off-site location in the Crowne Plaza Hotel, 1284 Strongtown Road, Southbury, CT ("Southbury Lab"). OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). Provide responses to the question below in both a Word document and PDF format as an attachment to a responding email.

Please note that pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request no later than sixty days from the date of this email transmission. Therefore, please provide your written responses to OHCA no later than **Monday, October 24, 2016**, otherwise your application will be automatically considered withdrawn.

Please provide:

Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

1. The number of sleep lab studies performed each year at the Southbury Lab from FY2008 through FY2011;

2. The number of sleep lab studies performed at the Middlebury Lab for each of FY2008 through FY2011;

3. The towns of origins for the patients treated at the Southbury Lab in FY2011;

4. The number of home-based sleep tests conducted each year from FY2008 through FY2011;

5. A description of any benefits to home-based sleep studies;

6. Scholarly article(s) or other evidence demonstrating the trend of increasing use of home-based sleep studies;

7. An explanation as to how the second table on page 5 of the application demonstrates the Middlebury Lab has additional capacity to accommodate anticipated future growth;

8. The following information for the Middlebury Sleep Lab to demonstrate it has had the capacity to accommodate patients from Southbury:

Program Capacity	Middlebury Sleep Lab
Beds	
Days of Operation Per Week	
Current Capacity	
FY2015 Volume	
FY2015 % Utilization	
FY 2016 Projected Volume	

9. The following historic revenues and expenses reflecting closure of the closure of the Southbury Lab:

	FY 2012	FY 2013	FY2014
Reduced Revenue from Operations*			
Reduced Total Operating Expenses*			
Gains/Losses from Operations			

* As a result of the proposal/closure of the Southbury Lab

10. A break-down and description of any cost savings realized as a result of termination of the Southbury Lab (e.g., reduction in costs for medical personnel salaries, space rental, equipment);

11. A break-down and description of any reduced revenue as a result of the termination of the Southbury Lab (e.g., reduction in income from patient charges);

12. The payer mix, as provided on page 22 of the application, for FY2009, FY2010 and FY2011;

13. The names and locations of other sleep study providers in the area; and

14. An explanation as to why the Applicant did not apply for a Certificate of Need prior to terminating services at the Southbury Sleep Lab in 2011

Repeat each question before providing your response, paginate and date your response, i.e., each page in its entirety. Information filed after the initial CON application submission (e.g., completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please begin your submission using **Page 52** and reference "**Docket Number: 16-32113-CON**." Please email your responses to all of the following email addresses: **OHCA@ct.gov, jessica.schaeffer-helmecki@ct.gov, kaila.riggott@ct.gov .**

If you have any questions concerning this letter, please feel free to contact me at (860) 509-8075.

Sincerely,

J Schaeffer Helmecki

Jessica Schaeffer-Helmecki
Planning Analyst

Attachment

Cc: Michele Volpe, Esq., Counsel for Prospect Medical Holdings, Inc.

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Thursday, August 25, 2016 9:05 AM
To: Greer, Leslie
Subject: FW: Completeness Questions: 15-32113-CON

Leslie, below is the delivery receipt for the Completeness Questions for 15-32113 for the record. Thank you.

From: Microsoft Outlook
Sent: Thursday, August 25, 2016 9:03 AM
To: Schaeffer-Helmecki, Jessica
Subject: Relayed: Completeness Questions: 15-32113-CON

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'dstromstad@wtbyhosp.org' (dstromstad@wtbyhosp.org)

'dhardy@carmodylaw.com' (dhardy@carmodylaw.com)

Michelle Volpe Esq. (mmv@bvmlaw.com) (mmv@bvmlaw.com)

Subject: Completeness Questions: 15-32113-CON

Greer, Leslie

Subject: FW: Completeness Questions: 15-32113-CON

From: David S. Hardy [mailto:DHardy@carmodylaw.com]
Sent: Thursday, August 25, 2016 10:05 AM
To: Schaeffer-Helmecki, Jessica; 'dstromstad@wtbyhosp.org'
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie
Subject: RE: Completeness Questions: 15-32113-CON

Jessica,
Confirming receipt of your email. Thank you.
Dave

David S. Hardy | **Bio**
Carmody Torrance Sandak & Hennessey LLP
195 Church Street | P.O. Box 1950
New Haven, CT 06509-1950
Direct: 203-784-3119 | Fax: 203-784-3199
DHardy@carmodylaw.com | www.carmodylaw.com

Greer, Leslie

From: David S. Hardy <DHardy@carmodylaw.com>
Sent: Monday, September 12, 2016 1:59 PM
To: Schaeffer-Helmecki, Jessica; User, OHCA
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie; 'dstromstad@wtbyhosp.org'
Subject: RE: Completeness Questions: 16-32113-CON
Attachments: GWHN Sleep Lab CON Completeness Question Responses 9-12-16 (N5268180).pdf; GWHN Sleep Lab CON Completeness Responses (N5266029).docx

Jessica,
Attached are the responses to the completeness letter in Docket Number 16-32113-CON (Southbury Sleep Lab) in PDF and Word formats. Please let me know if you have any questions. Thank you very much.
Dave

David S. Hardy | Bio
Carmody Torrance Sandak & Hennessey LLP
195 Church Street | P.O. Box 1950
New Haven, CT 06509-1950
Direct: 203-784-3119 | Fax: 203-784-3199
DHardy@carmodylaw.com | www.carmodylaw.com

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Thursday, August 25, 2016 9:03 AM
To: 'dstromstad@wtbyhosp.org'; David S. Hardy
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie
Subject: Completeness Questions: 15-32113-CON

Good morning Ms. Stromstad and Mr. Hardy:

Attached please find a pdf and word version of completeness questions regarding your Certificate of Need application for the termination of Waterbury Hospital's sleep lab services at its Southbury site (docket number 15-32113-CON).

Please confirm receipt of this e-mail and feel free to contact me if you have any questions.

Jessica

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

Certificate of Need Application:
Docket Number: 16-32113-CON

The Waterbury Hospital's Application for the
Termination of Sleep Lab Services in Southbury, CT

Responses to August 25, 2016 Completeness Letter Questions:

1. The number of sleep lab studies performed each year at the Southbury Lab from FY2008 through FY2011;

   RESPONSE:

   2008 – 0 studies
   2009 – 120 studies
   2010 – 137 studies
   2011 – 47 studies

2. The number of sleep lab studies performed at the Middlebury Lab for each of FY2008 through FY2011;

   RESPONSE:

   2008 – 1416 studies
   2009 – 1357 studies
   2010 – 1249 studies
   2011 – 1149 studies

3. The towns of origins for the patients treated at the Southbury Lab in FY2011;

   RESPONSE:

   Southbury, Woodbury, Newtown, Roxbury, Shelton, Bethel, Danbury, Derby

4. The number of home-based sleep tests conducted each year from FY2008 through FY2011;

   RESPONSE:

   None. Home-based sleep tests commenced in 2012.

5. A description of any benefits to home-based sleep studies;

RESPONSE:

The purpose of a Home-based sleep study ("HST") is to diagnose obstructive sleep apnea ("OSA"). HST's are generally not capable of diagnosing any other sleep or sleep related condition. They are beneficial in diagnosing OSA in patients who are not capable of coming into a lab. They are also useful for patients who have a previous diagnosis and need a new sleep study for eligibility for supplies, or in monitoring changes in the severity of a patient's condition due to other circumstances (weight loss or gain for example). Some referring physicians request HSTs for their patients, and some patients are requesting them, because they consider HSTs less invasive, or because they believe that OSA is the likely problem and simply need confirmation. The use of HSTs is insurance driven. Most insurance carriers are mandating the use of HST in patients who have no accepted comorbidities. If the patient is considered otherwise healthy, or has other conditions that are not considered related by the insurance company, an HST can be the only option available.

6. Scholarly article(s) or other evidence demonstrating the trend of increasing use of home-based sleep studies;

RESPONSE:

Submitted herewith are examples of such articles and evidence:

CMS Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N), March 3, 2009.

"Home Sleep Apnea Testing Gaining Favor", M. Alexander Otto, *Chest Physician, The Newspaper of the American College of Chest Physicians*, Vol. 7, No. 3, March 2012.

"The Times They Are A Changin': Home Diagnosis of Sleep Apnea Has Arrived", Charles W. Atwood, Jr., MD, *Sleep*, Volume 36, No. 6, June 1, 2012.

"15% of OSA Testing Done with HSTs (and Growing)", Mike Matson, CFA, *Sleep Review, The Journal for Sleep Specialists*, February 27, 2014.

"The Future of Sleep Technology: Report from an American Association of Sleep Technologists Summit Meeting", Rita Brooks, M.Ed., Melinda Trimble, *Journal of Clinical Sleep Medicine, Official Publication of the American Academy of Sleep Medicine,* Vol. 10, No. 5, September 2014.

7. An explanation as to how the second table on page 5 of the application demonstrates the Middlebury Lab has additional capacity to accommodate anticipated future growth;

RESPONSE:

FY 2012	FY 2013	FY 2014	FY2015	FY2016*
1115	995	937	1022	671

*8 months actual

As set forth in the response to Question 8 below, the full utilization capacity for the Middlebury Lab is approximately 1,872 cases per week (36 cases per week x 52 weeks). The Lab's current utilization rate is approximately 55%.

8. The following information for the Middlebury Sleep Lab to demonstrate it has had the capacity to accommodate patients from Southbury:

Program Capacity	Middlebury Sleep Lab
Beds	
Days of Operation Per Week	
Current Capacity	
FY2015 Volume	
FY2015 % Utilization	
FY 2016 Projected Volume	

RESPONSE:

Program Capacity	Middlebury Sleep Lab
Beds	**6**
Days of Operation Per Week	**6**
Current Capacity	**36 cases per week**
FY2015 Volume	**1022**
FY2015 % Utilization	**55%**
FY 2016 Projected Volume	**998**

9. The following historic revenues and expenses reflecting closure of the closure of the Southbury Lab:

	FY 2012	FY 2013	FY2014
Reduced Revenue from Operations*			
Reduced Total Operating Expenses*			
Gains/Losses from Operations			

* As a result of the proposal/closure of the Southbury Lab

RESPONSE:

	FY 2012	FY 2013	FY2014
Reduced Revenue from Operations*	$6,300	$6,300	$6,300
Reduced Total Operating Expenses*	$100,064	$100,064	$100,064
Gains/Losses from Operations	$93,764	$93,764	$93,764

*** As a result of the proposal/closure of the Southbury Lab**

10. A break-down and description of any cost savings realized as a result of termination of the Southbury Lab (e.g., reduction in costs for medical personnel salaries, space rental, equipment);

RESPONSE:

All personnel and equipment from the Southbury Lab were absorbed into the Middlebury Lab. Savings consisted of rent ($6,758/month in 2008 and 2009 and $7347/month in 2010 and 2011), cleaning service (approximately $800/month) and telephone/communications (approximately $200/month).

11. A break-down and description of any reduced revenue as a result of the termination of the Southbury Lab (e.g., reduction in income from patient charges);

RESPONSE:

The best estimate of patient revenue lost due to the closure of the Southbury Lab is $6,300 per year. Approximately 95% of Southbury Lab patients continued services at the Middlebury Lab.

12. The payer mix, as provided on page 22 of the application, for FY2009, FY2010 and FY2011;

RESPONSE:

PAYER MIX

Payer	FY 2009		FY 2010		FY 2011	
	Discharges	%	Discharges	%	Discharges	%
Medicare*	321	21%	345	25%	334	28%
Medicaid*	151	10%	176	13%	148	12%
CHAMPUS & TriCare						
SAGA	71	5%	60	4%	81	7%
Total Government	**543**	**36%**	**581**	**42%**	**563**	**47%**
Commercial Insurers	947	64%	810	58%	627	53%
Uninsured	1	-	2	-	2	-
Workers Compensation						
Total Non-Government	**948**	**64%**	**812**	**58%**	**629**	**53%**
Total Payer Mix	**1,491**	**100%**	**1,393**	**100%**	**1,192**	**100%**

* Includes managed care activity.

13. The names and locations of other sleep study providers in the area; and

RESPONSE:

Yale New Haven Sleep Medicine Center – New Haven / North Haven
Connecticut Sleep Lab – New Britain
Sleep Wellness Center at Griffin Hospital – Derby
Saint Mary's Sleep Disorders Center – Naugatuck / Wolcott

14. An explanation as to why the Applicant did not apply for a Certificate of Need prior to terminating services at the Southbury Sleep Lab in 2011.

RESPONSE:

The Applicant did not apply for a Certificate of Need prior to terminating services at the Southbury Sleep Lab in 2011 due to inadvertence and oversight. At that point in time, as is detailed in GWHN's application for the proposed asset purchase of GWHN by Prospect (approved pursuant to OHCA Docket Number 15-32017-486 and AG Docket Number 15-486-02), the Applicant was experiencing acute financial difficulties and actively searching for a capital partner. In addition, senior leadership at GWHN changed in 2011. The previous CEO of GWHN retired, an interim CEO was hired for 6 months, and the permanent CEO hired mid-year by GWHN left, as did all other senior leaders remaining in the organization. The new management that took over GWHN had no awareness that a CON was required for the consolidation of the Sleep Lab services.

Back to National Coverage Analyses (NCA) Details for Sleep Testing for Obstructive Sleep Apnea (OSA)

Decision Memo for SLEEP TESTING for Obstructive SLEEP Apnea (OSA) (CAG-00405N)

Need a PDF?

- Decision Summary

CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

Therefore:

1. Type I Polysomnography (PSG) is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A Type II or a Type III sleep testing device is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. A Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

Back to Top

- Decision Memo

To: Administrative File: CAG # 00405N
Sleep Testing for Obstructive Sleep Apnea (OSA)

From: Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group

Louis Jacques, MD
Director, Division of Items and Devices

Jean Stiller, MA
Lead Analyst

Ross Brechner, MD, MS (Stat.), MPH
Lead Medical Officer

Subject: Coverage Decision Memorandum for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N)

Date: March 3, 2009

I. Decision

CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

Therefore:

1. Type I Polysomnography (PSG) is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

2. A Type II or a Type III sleep testing device is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. A Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

II. Background

We use the abbreviation PSG to refer to polysomnography or a polysomnogram furnished in a sleep laboratory facility. Unless we specifically describe an unattended use, we will always assume in this document that it has been attended. We note that some authors use the abbreviation NPSG to mean nocturnal PSG. We use the abbreviation HST (home sleep test) to refer to unattended multichannel sleep testing or multichannel sleep monitoring typically furnished in the beneficiary's home. However, it does not exclude these tests being performed in other settings to include a sleep lab.

OSA, sometimes referred to as Obstructive Sleep Apnea Hypopnea Syndrome-(OSAHS), is associated with significant morbidity and mortality. It is a commonly underdiagnosed condition that occurs in 4% of men and 2% of women (Young et al. 1993). The prevalence increases with age (up to 10% in persons 65 and older), as well as with increased weight. Complications associated with OSA include excessive daytime sleepiness, concentration difficulty, coronary artery disease, and stroke (Kokturk et al. 2005). It is estimated that 10% of patients with congestive heart failure (CHF) have OSA, which is independently associated with systemic arterial hypertension (Caples et al. 2005). Untreated OSA is associated with a ten-fold increased risk of motor vehicle accidents (Teran-Santos et al. 1999). The most common clinical presentation of patients with OSA is obesity accompanied by excessive daytime drowsiness (20% of adults with BMI > 30 have OSA), although other clinical findings associated with OSA include nocturnal choking or gasping, witnessed apneas during sleep, large neck circumference and daytime fatigue.

Of the three different forms of sleep apnea (obstructive, central, or mixed), OSA is the most common. Patients suffering with sleep apnea may literally stop breathing (apnea) for a short period or have decreased breathing (hypopnea), repeatedly during sleep. The apnea episodes often last for a minute or longer, and can occur hundreds of times during a single night's sleep. During the obstructive apnea episodes, either complete or partial obstruction of the airway occurs. The anatomic site of obstruction is thought to be the soft palate, extending to the base of the tongue. When patients with OSA fall asleep muscles of this region may relax to the point of permitting airway collapse and obstruction. When the airway closes, breathing stops and the sleeper awakens to open the airway. Arousals from sleep usually last only a few seconds, but these brief arousals disrupt continuous sleep and prevent persons from reaching deep stages of sleep (e.g., rapid eye movement sleep-REM), which is necessary in order for the body to rest and replenish strength. The patient repeats this cycle throughout the sleep period.

OSA has often been defined by an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of ≥ 5 events per hour during sleep (when using this less restrictive definition, the prevalence may be as high as 25% of the population) or by a higher threshold e.g. AHI of ≥ 15 per hour (the prevalence is approximately 3%). Medicare covers CPAP for the treatment of OSA if the beneficiary has an AHI or RDI ≥ 15 events/hour. Medicare also covers CPAP for the treatment of OSA if the beneficiary has a co-morbidity related to OSA and the AHI or RDI is ≥ 5. The key diagnostic finding in OSA is episodes of airflow cessation or reduction at the nose and mouth despite evidence of continuing respiratory effort.

Other common clinical findings and measurements used by physicians in the diagnosis of OSA include oxygen desaturation, abnormal oxygen desaturation index, arterial pulsatile tone changes, measurement of airflow, measurement of breathing patterns, Multiple Sleep Latency Testing (MSLT), Maintenance of Wakefulness Testing, computerized EEG analysis, autonomic arousal detection, and body movement analysis (e.g., actigraphy).

Diagnostic tests for OSA have historically been classified into four types. The most comprehensive is designated Type I attended facility based PSG, which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO_2) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed. Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society (ATS 1994) and the American Academy of Sleep Medicine (ASDA 1997) have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of CPAP.

Three categories of portable monitors (used both in attended and unattended settings) have been developed for the diagnosis of OSA. Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO_2)-this type of device monitors sleep staging, so AHI can be calculated). Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device. Some monitors, e.g. WatchPAT use an actigraphy algorithm to identify periods of sleep and wakefulness.

Young et al. (1993) note limited capacity to provide PSG testing to all persons with symptoms of OSA due to the high prevalence of OSA. Some studies have noted false-negative rates of 14 to 25% (Le Bon et al. 2000; Littner 2000). And as noted by Klingshott et al. (2000), the measures derived from PSG (e.g., AHI) correlate poorly with major consequences of OSA such as

sleepiness and cognitive impairment. Loube et al. (1999) and others have also noted that these measures do not reliably predict the response to the standard therapy for OSA, i.e., nasal CPAP.

PSG alternatives have been sought. Predictive algorithms (predictive formulae) to determine optimal CPAP (Flemons et al. 1994; Maislin et al. 1995; Rowley et al. 2000), screening oximetry (Whitlaw et al. 2005; Chiner et al. 1999), attended/unattended home diagnostic apnea monitoring devices (Sériés et al 1993; Golpe et al. 2002; Whitelaw et al. 2005), and questionnaires (e.g., Epworth Sleepiness Scale (ESS); Sleep Apnea Clinical Scores) have been developed to help diagnose OSA. Other strategies that have been suggested to reduce the delay, inconvenience and expense associated with sleep studies include split night studies (Yamashiro et al. 1995), partner titration, and home stepwise titration.

A number of treatment approaches have been recommended for patients with OSA, depending on the severity of the disorder (e.g., the degree of clinical symptoms), as well as the objective level of nocturnal respiratory and sleep disturbance (e.g., daytime sleepiness or number of obstructive events per hour of sleep). For patients with severe OSA, nasal CPAP is the treatment of choice. Its regular use improves excessive sleepiness, cognitive performance, and quality of life (Jenkinson et al. 1999; Montserrat et al. 2001). In patients with severe OSA who can not tolerate nasal CPAP, surgical procedures (e.g., uvulopalatopharygnoplasty-UPPP, maxillofacial surgery) may be indicated. In patients with mild to moderate OSA, nasal CPAP may be indicated, though conservative measures such as weight reduction, avoidance of alcohol, avoidance of sleeping in a recumbent position, or intra-oral appliances may be better tolerated.

III. History of Medicare Coverage

We received an external request from Itamar Medical requesting a National Coverage Determination (NCD) to determine whether Home Sleep Testing (HST) devices measuring the peripheral arterial tone (PAT) signal (a measure of sympathetic activation), heart rate, blood oxygen saturation, and sleep time are reasonable and necessary for the diagnosis of obstructive sleep apnea (OSA).

Itamar manufactures the Watch-PAT sleep test device that measures actigraphy, oximetry and peripheral arterial tone. Itamar also asked us to remove this technology from the Type IV classification in the current CPAP NCD and explicitly state that CPAP is covered in beneficiaries diagnosed with OSA using a clinical evaluation and a positive test using this technology.

CMS has addressed the coverage of CPAP in three separate decisions in October, 2001, April 2005, and March 2008. In each of those decisions, we limited coverage of CPAP in patients with OSA to those patients whose diagnosis was based on specific testing modalities. Initially, we limited coverage to OSA diagnosed with PSG. In the latest decision, we expanded coverage to OSA diagnosed with several types of HST. However, we have not, at a national level, specifically addressed coverage of the tests themselves. In other words, we nationally cover CPAP for beneficiaries with OSA if diagnosed with these specific tests; yet, coverage of the specific tests has previously been left to local contractor discretion.

Since Watch-PAT is only one of several diagnostic tests for OSA and we do not have an NCD on any of these tests, we have broadened the scope of this NCA to include other sleep test technologies. Based on our extensive review of the available evidence, and significant programmatic need to clarify coverage of sleep testing for OSA, we published our proposed decision concurrent with opening this NCA.

Benefit Category

Medicare is a defined benefit program. All services furnished and covered under the Medicare program must be medically reasonable and necessary, and appropriate for diagnosis and/or treatment of an illness or injury. Furthermore, physicians and nonphysician practitioners must be authorized by the State in which the services are furnished to render the services. An item or service must fall within a benefit category as a prerequisite to Medicare coverage: § 1812 (Scope of Part A); § 1832 (Scope of Part B); § 1861(s) (Definition of Medical and Other Health Services).

The above described services fall within the benefit category at §1861(s)(3) of the Social Security Act, "other diagnostic tests."

The Medicare regulations at 42 CFR 410.32(a) state in part, "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

IV. Timeline of Recent Activities

December 23, 2008	CMS posts a tracking sheet, publishes a proposed decision memorandum, and opens the initial 30 day public comment period.
January 22, 2009	Public comment period ended.

V. Food and Drug Administration (FDA) Status

Certain sleep test devices have been considered and cleared for marketing by the FDA under a 510(k) process.

VI. General Methodological Principles

When making NCDs, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for Medicare beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary under § 1862(a)(1)(A) of the Act.

A detailed account of the methodological principles of study design that are used to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index and reference test results.

Public comment sometimes cites the published clinical evidence and may give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

We recently conducted an exhaustive review of the evidence for a clinical benefit of the available diagnostic tests for OSA during the March 2008 reconsideration of the NCD on CPAP for OSA. Medicare National Coverage Determinations Manual, §240.4. A complete discussion of that review can be found at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=204.

Evidence about the diagnosis of OSA was central to the CPAP NCD reconsideration. In that reconsideration the medical community did not dispute the use of CPAP to treat OSA. Rather, the crux of the issue was whether or not home sleep testing could adequately identify symptomatic beneficiaries with OSA for whom CPAP should be covered by Medicare. Thus the evidence review, technology assessments and the MEDCAC provide information that is useful to also address the current questions.

We are providing a summary of the applicable evidence here, and are including relevant new evidence that has come to light since that review. The available evidence includes published peer reviewed medical literature, external technology assessments and recommendations from the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).

B. Discussion of evidence reviewed

1. Questions & Outcomes of Interest

Question 1: Is the evidence adequate to determine that attended facility based polysomnography accurately identifies patients with OSA who will benefit from treatment?

Question 2: For which unattended out of facility sleep test technologies is the evidence adequate to determine that sleep testing accurately identifies patients with OSA who will benefit from treatment?

As diagnostic tests, PSG and HST would not be expected to directly change health outcomes. Rather, a diagnostic test affects health outcomes through changes in disease management brought about by physician actions taken in response to test results. Such actions may include decisions to treat or withhold treatment, to choose one treatment modality over another, or to choose a different dose or duration of the same treatment. To some extent the usefulness of a test result is constrained by the available treatment options. As noted in the Background section, the number of practical treatment options for OSA is limited. Most patients are treated with CPAP; a few get oral appliances or surgery. A patient whose OSA is not readily controlled with CPAP may seek other treatment, continue CPAP with lesser benefit, or discontinue CPAP and not seek further medical treatment. In addressing the questions above, one of the factors we considered is whether there is sufficient evidence that the incremental information derived from PSG or HST leads to improved treatment of OSA by causing physicians to prescribe a different, more appropriate treatment than they would have prescribed without access to the test results.

Outcomes of interest for a diagnostic test are not limited to determining its accuracy but also include beneficial or adverse clinical effects, such as changes in management due to test findings or preferably, improved health outcomes for Medicare beneficiaries. Ideally, we would see evidence that the systematic incorporation of PSG or HST results into a treatment algorithm leads treating physicians to prescribe different and better treatment than they would otherwise have prescribed, and that those patients whose treatment is changed by test results remain on the regimen and achieve better long term OSA control documented by repeated assessments over time.

There is no anatomic or physiologic "gold standard" for the diagnosis of obstructive sleep apnea, in contrast to conditions such as cancer where a tissue biopsy result is the definitive standard reference. In studies that compare HST to facility-based PSG, the investigators have used the PSG result as the standard reference; i.e. the PSG result is used to define the true disease state for the individual patient. This is less than ideal since the true sensitivity and specificity of PSG in diagnosing OSA is not well documented and this deficiency poses a practical difficulty in diagnosing OSA. Given the absence of a true "gold standard" reference, the clinical application of terms such as sensitivity and specificity is not straightforward.

Such evidence permits only the comparison of HST to facility-based PSG. It is problematic to make the inferential leap from there to a judgment on the ability of HST or PSG to accurately identify those patients who will, if untreated with CPAP, suffer the

morbidity and mortality of obstructive sleep apnea. If an individual patient has conflicting results with these two tests, e.g. a negative HST in the face of a positive PSG, there is no available higher reference to determine whether the conflict arises from a false negative HST or a false positive PSG.

2. External technology assessments

Systematic reviews are based on a comprehensive search of published studies to answer a clearly defined and specific set of clinical questions. A well-defined strategy or protocol (established before the results of the individual studies are known) guides this literature search. Thus, the process of identifying studies for potential inclusion and the sources for finding such articles is explicitly documented at the start of the review. Finally, systematic reviews provide a detailed assessment of the studies included. CMS commissioned two TAs from AHRQ for the March 2008 CPAP NCD reconsideration:

- Home diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome, and
- Obstructive Sleep Apnea-Hypopnea Syndrome: modeling different diagnostic strategies

The full reports are available at the following CMS website: http://www.cms.hhs.gov/mcd/viewtechassess.asp?id=204.

Home diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome

Ninety-three studies were included in a review of the literature. Eligible studies assessed the ability of sleep studies at baseline to predict response to CPAP treatment or CPAP use, the comparison of measurements with portable monitors and facility-based PSG, and the safety of sleep studies.

The TA reported that the reference standard for the diagnosis of OSAHS is facility-based PSG, a comprehensive sleep study that records and evaluates a variety of cardiorespiratory and neurophysiologic signals during sleep time. It quantifies the severity of disturbances with the Apnea-Hypopnea Index (AHI). Higher AHI values imply more severe sleep disturbances. Typically, a value of 15 or more events/hour of sleep is considered to be suggestive of OSAHS. An AHI suggestive of OSAHS is neither sufficient nor necessary for the diagnosis of the condition, as the severity of symptoms has to be accounted for, and other conditions affecting sleep may need to be excluded. Baseline AHI is only modestly associated with response to CPAP use among people with high (pre-test) probability for OSAHS. The same is true for other indices obtained from sleep studies such as the mean or minimum O_2 saturation, apnea index, hypopnea index, frequency of arousals and other quantities.

Based on limited data, the authors conclude that type II monitors may identify AHI suggestive of OSAHS with high positive likelihood ratios (> 10) and low negative likelihood ratios (< 0.1) both when the portable monitors were studied in the sleep laboratory and at home. Type III monitors may have the ability to predict AHI suggestive of OSAHS with high positive likelihood ratios and low negative likelihood ratios for various AHI cutoffs in laboratory-based PSG, especially when manual scoring is used. The ability of type III monitors to predict AHI suggestive of OSAHS appears to be better in studies conducted in the specialized sleep unit compared to studies in the home setting. Some studies of type IV monitors also showed high positive likelihood ratios and low negative likelihood ratios, at least for selected sensitivity and specificity pairs from ROC curve analyses. As with type III monitors, the ability of type IV monitors to predict AHI suggestive of OSAHS appears to be better in studies conducted in specialized sleep units. Medicare beneficiaries are older on average than the studied subjects (the median average age was approximately 50 years in the analyzed studies), and may more often have conditions other than OSAHS that affect sleep (e.g., Periodic Limb Movements in Sleep and Restless Leg Syndrome; cardiac insufficiency). These conditions may be misdiagnosed as OSAHS by sleep monitors that do not record channels necessary for the differential diagnosis of OSAHS. Therefore, some type III and type IV monitors may yield more false positives among Medicare beneficiaries, compared to what was observed in the assessed studies. For studies in the home setting, there are no direct data on whether and to what extent technologist support and patient education affect the comparison of portable monitors with facility-based PSG.

For monitors that may be considered other than Type II, III, or IV, the authors found there is insufficient evidence to judge their value in diagnosing OSA. The TA differentiated Type IV monitors with three or more channels from those with one or two channels, finding greater diagnostic ability for the former. We note that the TA reviewed the Watch-PAT100 device as a Type IV device with three or more channels.

Obstructive Sleep Apnea-Hypopnea Syndrome: modeling different diagnostic strategies

The TA authors created a model to test the impact of different OSA strategies. When middle-aged people (50 years old) with symptoms and signs suggestive of OSAHS were tested in the home setting, approximately 10 percent of those with OSAHS are expected to remain undiagnosed; approximately 15 percent of those without OSAHS receive false-positive diagnoses. For older adults (70 years old), the expected number of misclassifications was larger, due to the expected increase in false positive diagnoses (30 percent). With the combination strategy that used home diagnosis and split-night PSG, almost 20 percent of middle-aged people with OSAHS received a (false) negative diagnosis, while the proportion of false positive results among 50 year-old people without OSAHS was very low (1 percent). The expected numbers were similar among older adults (70 years old).

Both for middle-aged people and for older adults, the average time spent undiagnosed was practically negligible for the strategies that use home monitoring. In the combination strategy, people with positive diagnosis with the portable monitors received a final split-night PSG diagnosis within 15 weeks on average.

When diagnosis of OSAHS and treatment initiation were managed outside the sleep laboratories in the home setting, middle-aged people with OSAHS spent on average ten weeks or nine percent of the total follow-up time in undiagnosed health states. Significantly, the corresponding mean time delay for middle-aged people is 27 weeks when they were managed with facility-based PSG. This number mainly reflects those with false negative diagnoses, who were never started on CPAP. The same delay is expected among older adults (70 years old).

With the combination strategy, using home diagnosis and split-night PSG, correctly diagnosed people initiate CPAP after approximately 15 weeks. However, one fifth of the patients are not diagnosed and, overall, the average time spent while not on CPAP ("high-risk" states) becomes 33 weeks. Similar numbers are expected among older adults who have OSAHS.

3. Internal technology assessment

Literature Search
CMS performed an extensive literature search utilizing PubMed for randomized controlled trials (RCTs), systematic reviews, and series studies evaluating the technology used for the diagnosis of OSA. The literature search was limited to humans.

There are currently several proposed mechanisms to diagnose OSA and determine the need for and benefit of OSA treatment, specifically CPAP. These include clinical diagnosis alone, PSG, home testing with various devices and a diagnosis made by using a trial of CPAP.

Clinical Diagnosis Alone and Clinical Diagnosis with PSG

Crocker et al. (1990) studied whether the number of PSGs required for diagnosis of OSA could be reduced in the population. They enrolled 100 consecutive patients (average age 50) screened by family and sleep physicians. The patients were then tested by PSG. A clinical model was created for predicting a diagnosis of OSA as compared to PSG and was applied to the next 114 consecutive patients, of whom IOS eventually had complete data. The model correctly classified 33 of 36 persons with OSA by correctly predicting an AHI > 15 and it correctly classified 35 of 69 patients by correctly predicting an AHI ≤ 15. In the model, BMI, reported apnea, age, and hypertension were statistically significant factors. The model had a sensitivity of 92% for predicting OSA when compared to PSG and a specificity of 51%. The authors concluded that clinical observation might reduce the need for PSG in the diagnosis of OSA by one-third.

Deegan et al. (1996) compared the predictive value of certain clinical features to PSG for a diagnosis of OSA. Two hundred fifty consecutive patients (average age 45) were pre-screened by a physician and had a clinical assessment and administration of a sleep questionnaire, along with PSG. One hundred thirty six (54%) had an AHI ≥ 15 (considered positive for a diagnosis of OSA) and 114 (46%) had an AHI < 15 (not considered positive for OSA). Using clinical features and oximetry, 32.4% of patients could be confidently categorized, compared to PSG, as either having a true diagnosis of OSA or not having OSA. Significant factors in the model were BMI, alcohol intake, and age. The authors concluded that clinical observation may reduce the need for PSG in the diagnosis of OSA by approximately one-third.

Haponik et al. (1984) asked whether or not PSG is necessary to assess the presence and severity of sleep-disordered breathing. They enrolled 37 patients (average age 50) with clinically suspected OSA, administered a questionnaire and did PSG testing. Compared to PSG (AHI ≥ 15 as cutoff for positive diagnosis of OSA) the clinical testing information had a sensitivity of 64% for a correct diagnosis of OSA and a specificity of 100%. The authors concluded that a single, brief clinical observation alone is an ineffective screening procedure for detecting OSA.

Julià-Serdà et al. (1984) enrolled 225 consecutive referrals to a sleep clinic (average age 45 in the non-OSA group and 52 in the OSA group) with suspected OSA to determine whether or not cephalometry was useful in sparing PSG. All subjects had clinical assessment with an ESS questionnaire, physical examination and history. In addition they also had spirometry, cephalometry, and PSG testing. A statistical model was built to estimate a patient's probability of a correct diagnosis of OSA as compared to PSG (using a cutoff value of AHI ≥ 10), based on clinical variables, physical examination, pulse oximetry, cephalometry, and soft palate and uvula measurements. The sensitivity of the model for a correct diagnosis of OSA as compared to PSG was 93% and the specificity was 83%. The authors concluded that cephalometry plus oximetry plus history and physical exam is capable of sparing the need for PSG in diagnosing OSA.

Dixon et al. (1997) attempted to create a clinical model for predicting a correct diagnosis of OSA as compared to PSG in 99 pre-operative Laparoscopic Adjustable Gastric Banding patients with average age in their four groups ranging from 35 to 44. A thorough sleep history and physical examination were performed, checking for symptoms such as nocturnal choking, waking unrefreshed, morning headaches, excessive daytime sleepiness and poor sleep quality. An ESS was administered and all patients had a PSG test. The PSG was hand scored. For a PSG cutoff of AHI ≥ 15, independent predictors for a diagnosis of OSA were observed sleep apnea (the only positive symptom predictor of an AHI ≥ 15), male sex, higher BMI, age, fasting insulin and glycosylated hemoglobin A1c. From the model created, a scoring mechanism was established and a score of > 3 had a sensitivity of 89% for a correct diagnosis of OSA as compared to PSG and a specificity of 81% for moderate/severe OSA. The authors concluded that a simple method of predicting OSA in severely obese symptomatic subjects can assist in limiting the use of PSG to those with greater risk.

Lim et al. (2006) performed a study to determine if a clinical model could be developed to predict OSA diagnosis from clinical diagnosis only. Seventy-one consecutive snorers (average age 44) referred for an evaluation for OSA were enrolled. OSA status was determined by clinical assessment based on symptoms suggestive of OSA as well as an ESS and BMI measurement. A PSG was administered and a clinical assessment model was created and used in identifying the 'non-apneic snorers' among patients referred with snoring. The model made use of the ESS score (using a cutoff of ≥ 15), the BMI (using a cutoff of ≥ 28), and the presence of symptoms such as nocturnal choking, witnessed apnea, daytime hypersomnolence or morning headaches. Compared to PSG using a cutoff of AHI > 10, the model had a sensitivity of 93.4% and a specificity of 60% for correctly diagnosing OSA. The authors concluded that identifying 'non-apneic snorers' in whom PSG could be avoided can be correctly accomplished via a clinical assessment if two out of three of the following are absent: 1) ESS score ≥ 15; 2) a BMI ≥ 28; and 3) the presence of specified symptoms such as nocturnal choking, witnessed apnea, daytime hypersomnolence or morning headaches.

Hoffstein et al. (2006) utilized data from 594 patients with an average age of 47 who were referred to a sleep clinic for suspicion of sleep apnea and whom were all seen by the same physician to determine if it was possible to develop a clinical model to predict a correct diagnosis of OSA from a clinical exam. A PSG with a cutoff of AHI > 10 was used for the diagnosis of OSA. The

independent predictors of a correct diagnosis of OSA as compared to PSG were age, sex, BMI, partner observation of apnea and pharyngeal exam findings (normal vs abnormal). Compared to PSG, the subjective (clinical) impression alone showed a sensitivity of 63% for a correct diagnosis of OSA and a specificity of 60%. The authors concluded that subjective impression alone is not enough to reliably identify patients with or without a correct diagnosis of OSA as compared to PSG.

Garcia et al. (2003) studied whether or not they could predict a correct diagnosis of OSA with a clinical model. They enrolled 227 consecutive patients (average age 58) measuring clinical signs and symptoms and performing a PSG. They then took the next 102 patients and tested their model for clinical diagnosis of OSA (total 329). They utilized an AHI ≥ 30 as a cutoff for a correct diagnosis of OSA. In the model created, they utilized a cut point of 11 for the ESS and of 30 for BMI and included other significant and independent factors of age, sex, BMI, neck circumference history and the referring physician's subjective feeling (dichotomized into 'yes' or 'no') as to each patient's probability of having an AHI ≥ 30. Compared to PSG, the model had a sensitivity of 80% for a correct diagnosis of OSA and a specificity of 93%. The authors concluded that prior to diagnostic tests for OSA; clinical data can be useful for identifying patients suspected of having AHI ≥ 30.

Kushida et al. (1997) attempted to predict OSA with a morphometric predictor model. Thirty patients (age range 15-75) were used to create the model and the model was then prospectively tested on the first consecutive 300 of a total of 423 patients referred for a diagnosis of OSA. All patients were also tested with PSG using a cutoff of AHI ≥ 10. The regression model included oral cavity measurements of the palatal height by two separate calipers measuring the distance between the mesial surfaces of the crowns of the second molars to obtain either the maxillary intermolar distance or the mandibular intermolar distance. BMI and neck circumference measurements were also made. The morphometric model had a sensitivity of 97.6% for a correct diagnosis of OSA as compared to PSG and a specificity of 100%. The authors concluded that the model may be clinically useful as a screening tool for OSA rather than as a replacement for PSG.

Pillar et al. (1994) compared a clinical diagnosis of OSA to PSG (cutoff AHI ≥ 10). Eighty-six patients (average age 47) referred to a sleep clinic for suspicion of OSA were enrolled. The authors did not mention whether or not the subjects were consecutively enrolled. All patients answered a detailed sleep questionnaire, had a brief physical examination and had PSG testing. Compared to PSG (cutoff AHI ≥ 10), a clinical diagnosis of OSA had a sensitivity of 79% and a specificity of 50%. With regards to the model, the independent factors for a true diagnosis of OSA were neck circumference, age, self reporting of apnea and falling asleep unintentionally. Compared to PSG, the sensitivity was 92% and the specificity was only 18%. The authors concluded that clinical evaluation cannot replace PSG.

Rauscher et al. (1993) enrolled 98 habitual snorers and 89 patients (average age 58 overall) with a positive diagnosis of OSA by PSG to see which snorers referred to a sleep laboratory need PSG for the diagnosis of OSA. A regression model was created that included weight, height, sex, witnessed episodes of apnea and falling asleep reading. This model was applied to 116 consecutive patients referred for investigation of heavy snoring. All patients with negative oximetry and a probability value < 0.31 for having OSA had an AHI < 10 by PSG. The authors concluded that snorers with negative oximetry classified as not having OSA by this model do not need PSG.

Viner et al. (1994) examined whether or not history and physical examination can predict a correct diagnosis of OSA as compared to PSG. They enrolled 410 patients (average age 50) referred for clinically suspected OSA. They conducted a blinded comparison of history and physical examination versus results of nocturnal PSG utilizing a cutoff point of AHI ≥ 10. The regression model created included as significant independent factors age, BMI, sex, witnessed episodes of apnea and falling asleep reading. They noted that for p < 0.20 (a predicted probability of less than 20% of having OSA) the clinical model had 94% sensitivity and 28% specificity of correctly predicting a diagnosis of OSA as compared to PSG. Subjective impression alone had a sensitivity of 52% and a specificity of 70% for correctly predicting a diagnosis of OSA as compared to PSG. The authors concluded that in patients with a low predicted probability of having a correct diagnosis of OSA, approximately one-third do not need a PSG for diagnosis.

Tsai et al. (2002) performed a study to create a decision rule for diagnostic testing in OSA. They enrolled 75 patients (average age 47) referred to a sleep clinic for suspicion of sleep apnea. No mention of consecutive selection was made. Each patient had portable RDI testing (using a cutoff of RDI ≥ 10) and nocturnal oxygen saturation measurements. During the feasibility phase, patients underwent routine clinical assessment plus the upper airway physical examination protocol (UAPP), performed by two investigators. Unreliable or time consuming measurements were eliminated from the UAPP based on clinical judgments and history of snoring and body position based on the consensus of the two investigators. A decision rule was developed using three predictors: a cricomental space (the perpendicular distance between the midpoint of the cricomental line, a straight line from the chin to the cricothyroid cartilage, and the skin of the neck) of 1.5 cm or less, a pharyngeal grade (I = palatopharyngeal arch intersects at the edge of the tongue; II = palatopharyngeal arch intersects at 25% or more of the tongue diameter; III = palatopharyngeal arch intersects at 50% or more of the tongue diameter; IV = palatopharyngeal arch intersects at 75% or more of the tongue diameter) of more than II and the presence of overbite. For patients with all 3 predictors (17%), the decision rule had a PPV of 95% and an NPV of 49% for a true diagnosis of OSA by PSG. Comparable performance was obtained in a validation sample of 50 patients referred for diagnostic testing. The authors concluded that their decision rule provides a simple, reliable and accurate method of identifying a subset patients with and, perhaps more importantly, without a true diagnosis of OSA.

Home testing for OSA
Types II, III & IV
CMS reviewed the AHRQ TA assessment above and also found some additional evidence on HST.

Ayappa et al. (2008) evaluated the ARES Unicorder, a self-applied, limited-channel portable monitoring device for the evaluation of sleep disordered breathing (SDB) using a prospective study with blinded analysis. Eighty patients with suspected OSA and 22 volunteers were enrolled of whom 97 were tested. Interventions used the ARES™ Unicorder at home for 2 nights using only written instructions. The number of men in the suspected OSA group was 60 and the number of women was 17, while in the volunteer group it was 9 and 11 respectively. The mean age in the suspected OSA group was 46 (range 26-74), while the mean age in the volunteer group was 36 (range 19-73). The mean BMI in the suspected group was 30 (range 21-70) the mean BMI was 24 in the volunteer group (range 19-32).

Within 2 weeks, they returned to the laboratory for full nocturnal polysomnography (NPSG) with simultaneous monitoring with the Unicorder. NPSGs were scored manually to obtain an apnea-hypopnea index based on Medicare guidelines (AHI4%) and a respiratory disturbance index (RDI). ARES studies were autoscored and reviewed to obtain indices based on equivalent definitions i.e., AHI4%ARES, and apnea hypopnea (events with 1% desaturation) index (AHI1%ARES). Indices from the NPSG were compared to the in-lab ARES and in-home ARES indices using mean differences and the intraclass correlations (ICC).

For the in-lab comparison, there was high concordance between AHI4%NPSG and AHI4%ARES (ICC = 0.96, mean difference = 0.5/hour) and RDINPSG and AHI1%ARES (ICC = 0.93, mean difference = 3.2/hour). For NPSG versus In-Home ARES comparison, there was good concordance between AHI4%NPSG and AHI4%ARES (ICC = 0.8, mean difference = 4.1/ hour) and RDINPSG and AHI1%ARES (ICC = 0.8 mean difference = 8.6/ hour). The diagnostic sensitivity of in-lab ARES™ for diagnosing OSA using an RDI cut-off of 15 per hour was 95% and specificity was 94%, with a positive likelihood ratio (LR+) = 17.04, and negative likelihood ratio (LR-) = 0.06. For in-home ARES data the sensitivity was 85% and specificity 91% (LR+ = 9.34, LR- = 0.17). There was good agreement between the manually scored NPSG OSA indices and the autoscoring ARES algorithm.

The authors concluded that the ARES Unicorder provides acceptably accurate estimates of OSA indices compared to conventional laboratory NPSG for both the simultaneous and in-home ARES data and that the high sensitivity, specificity, and positive and negative likelihood ratios obtained in the group they studied supported the utility of an ambulatory limited-monitoring approach not only for diagnosing sleep disordered breathing but also to rule out OSA in suitably selected groups.

Alvarez et al. (2008) aimed at evaluating the reliability of home respiratory polygraphy (using the Edentec Monitoring System polygraph) for the diagnosis of sleep apnea–hypopnea syndrome (OSA) and comparing the cost of this technique with that of nighttime polysomnography performed in a sleep laboratory. Using a prospective study design with a random sample of patients with clinically suspected OSA, the participants underwent both home respiratory polygraphy and nighttime PSG and were blinded as to the results of their first test. The study population was composed of 45 patients with a mean (SD) age of 52.3 (11) years of whom 21 (46.6%) were diagnosed with OSA, defined by an AHI> 10 by nighttime PSG. Comparison of the results between PSG and home polygraphy revealed statistically significant correlations for all comparisons. The optimal cutoff in this population was a RDI of 13.7 or more, for which the area under the receiver operating characteristic curve was 87.5% (95% confidence interval, 74.2%-95.4%). The authors concluded that home respiratory polygraphy is a reliable technique for the diagnosis of OSA and that uncertain results must be verified by nighttime PSG.

Oximetry

Both PSG and HST have an oximetry component, which monitors oxygen desaturation. A number of authors have claimed that just using the oximetry component alone can help in making a diagnosis of OSA (Nuber et al. 2000; Sériés et al 2005; Sériés et al.1993; Gyulay et al. 1993).

Gyulay et al. (1993) studied 98 non-consecutive patients referred for suspicion of sleep apnea to a sleep clinic to compare clinical assessment with home oximetry in the diagnosis of OSA. All patients answered a questionnaire, had a history and physical exam, and had PSG testing using a cutoff value of AHI ≥ 15 for diagnosis of OSA. Physicians also independently estimated the likelihood of their patient having a true diagnosis of OSA on PSG testing. Compared to PSG, the independent clinical (physician) assessment had a sensitivity of 79% and a specificity of 50% for correctly diagnosing OSA at the cutoff value of AHI ≥ 15. Compared to PSG, oximetry with a desaturation of 2% had a sensitivity of 65% and a specificity of 74% for diagnosing OSA at the cutoff value of AHI ≥ 15. For desaturations of 3%, the corresponding sensitivity and specificity were 51% and 90%, respectively. If the percentage of sleep time spent at SaO_2 < 90 was ≥ 1%, the sensitivity for a true diagnosis of OSA as compared to PSG (AHI ≥ 15) was 93% and the specificity was 51%. The authors concluded that being at SaO_2 < 90 for < 1% of the time on home oximetry practically excludes OSA.

As noted above, a number of studies have shown that oximetry measurement helps the diagnostic accuracy of OSA. Sériés et al. (1993) performed one of the earliest studies exploring this relationship. Using 240 consecutive patients with a confirmed (AHI > 10 on PSG) diagnosis of OSA (all were clinically suspected of having OSA because of loud snoring; nocturnal choking and awakenings or apneic events or all three reported by a bedmate; bad sleep quality; and daytime hypersomnolence), they found that oximetry had a 98% sensitivity for diagnosing OSA (AHI > 10), but a specificity of only 48%.

Magalang et al. (2003) explored the relationship between oximetry and OSA. They noted that several quantitative indices derived from overnight pulse oximetry have been used to predict the presence of OSA: (1) number of episodes of oxyhemoglobin desaturations below a threshold-usually a 3% or 4% decline below baseline, (2) the cumulative time spent below an oxyhemoglobin saturation of 90%, and (3) the Δ [delta] index—a measure of the variability of the oxyhemoglobin saturation. The researchers wanted to compare these indices and determine if some combination of these indices predicted an individual's AHI as measured by PSG. Using a derivation group which consisted of 224 consecutive patients, a prediction model was generated based on AHIs from the calculated quantitative indexes. The model was further validated using two groups of consecutive eligible patients (group 1 consisted of 101 patients and group 2 consisted of 191 patients). All patients underwent standard overnight PSG and measurement of arterial oxyhemoglobin (by pulse oximeter).

The major findings of the study revealed that among the different oximetry indices, the Δ index was the best predictor of the presence of OSA, though the number of desaturation events provided similar levels of diagnostic accuracy (sensitivity of a Δ index of > 0.63 in the diagnosis of OSA was 91%, while the specificity was 59%). An aggregation of the model using combinations of all oximetry indices reduced the prediction error (r^2 = 0.70, $p < 0.05$) compared to using the Δ index alone (r^2 = 0.60), improving the precision of prediction of the AHI. The correlation between the predicted and actual AHI was 0.77 when using the Δ index alone, but improved to 0.83 when using a combination of all three oximetry indices. The authors note that one limitation of the study is that the prediction model was validated using overnight pulse oximetry obtained simultaneously with PSG data in the sleep laboratory. However, one advantage of this approach is it eliminated the potential confounder of night-to-night variability of AHI, as well ensuring that oximetry data were collected in exactly the same environment as the PSG data.

Vazquez et al. (2000) studied the diagnostic performance of an automated digital oximetry analysis based on falls and recovery of oxygen saturation and compared the results to PSG. After excluding subjects not eligible for the study, 241 participants with suspected OSA were enrolled in the study and randomly assigned to either PSG or automated off-line analysis of the digitally recorded oximetry signal. Study outcomes included PSG-derived AHI, and oximeter-derived respiratory disturbance index (RDI). The study revealed that the PSG-derived AHI and the oximetry-derived RDI were strongly correlated (R = 0.97); the mean (± 2SD) of the differences between AHI and RDI was 2.18 (± 12.34)/h. Using a case definition of 15 episodes/hour for both AHI and RDI, the sensitivity and specificity were 98% and 88% respectively. The authors noted that one limitation of the applicability of this study was that the algorithm was evaluated by comparison with simultaneous PSGs. They also commented that a number of studies have shown a difference in RDI between home and hospital settings, despite using the same monitor and controlling for technical difficulty. But the authors were quick to note that by evaluating patients in the sleep laboratory, potential confounders (such as technical difficulties associated with remote monitoring, night-to-night variability, and the effects of the home environment on RDI) are eliminated.

Devices measuring peripheral arterial tone, actigraphy and oximetry

We were asked to perform a separate review of the Watch-PAT technology, as there has been some uncertainty expressed about how to classify this device in the current Type schema. Watch-PAT100 is an HST device which measures the peripheral arterial tone (PAT) and actigraphy (a measure of movement) which are recorded with an ambulatory wrist-worn device (Watch-PAT100). The PAT signal is a measure of the pulsatile volume changes at the finger tip reflecting sympathetic tone variations. The algorithm was developed using a training set of 30 patients recorded simultaneously with polysomnography and Watch-PAT100. The WATCH-PAT100 indirectly detects apnea/hypopnea events by identifying surges of sympathetic activation associated with the termination of these events. This information is further combined with heart rate and pulse oximetry data that are analyzed by the automatic algorithm of the system. This detects respiratory events and calculates the PAT RDI (PRDI).

We found 20 separate articles, papers, editorials, and fact sheets addressing this technology. Of these, CMS determined that 13 were not relevant due to qualities pertaining to sample size, type of evidence, having not been published in a peer reviewed journal or not relevant to this data needed for this NCD. The remaining 9 are reviewed below.

Pittman et al. (2004) aimed at assessing the accuracy of a wrist-worn device (Watch-PAT100) to diagnose obstructive sleep apnea in the home. Participants were not consecutive patients but were a sample of patients who disclosed on a comprehensive questionnaire between June and December of 2002 that they were interested in being contacted about research studies conducted at the sleep laboratory. All thirty subjects completed 2 overnight diagnostic studies with the test device: 1 night in the laboratory with concurrent polysomnography and 1 night in the home with only the Watch-PAT100. The mean age of these subjects was 43.2 ± 10.8 years and mean body mass index was 33.9 ± 7.1 kg/m2. The mean Epworth Sleepiness Scale score was 9.2 ± 4.7 (range 2-18). The order of the laboratory and home study nights was random.

The frequency of respiratory events on the PSG was quantified using indexes based on 2 definitions of hypopnea: the respiratory disturbance index (RDI) using American Academy of Sleep Medicine (AASM) Task Force criteria for clinical research, and the Medicare guidelines. The PRDI and oxygen desaturation index (PAT ODI) were then evaluated against the polysomnography AASM guidelines (RDI.C) and Medicare guidelines (RDI.M), respectively, for both Watch-PAT100 diagnostic nights, yielding in-lab and home comparisons. The setting for the PSGs was a sleep laboratory affiliated with a tertiary-care academic medical center. The PDG and PAT measures were compared using the mean [2 SD] of the differences and the intra-class correlation coefficient (ICC). The receiver-operator characteristic curve was used to assess optimum sensitivity and specificity and calculate likelihood ratios. For the in-lab comparison, there was high concordance between: RDI.C and PAT RDI: ICC = 0.88, mean difference 2.5 [18.9] events per hour RDI.M and PAT ODI: ICC = 0.95, mean difference 1.4 [12.9] events per hour sleep time: ICC = 0.70, mean difference 7.0 [93.1] minutes. For the home-laboratory comparison, there was good concordance between: RDI.C and PAT RDI: ICC = 0.72, mean difference 1.4 [30.1] events per hour RDI.M and PAT ODI: ICC = 0.80, mean difference 1.6 [26.4] events per hour. Home studies were performed with no technical failures.

The authors concluded in this study of a population of 30 patients suspected of having obstructive sleep apnea that the Watch-PAT100 can quantify an ODI that compares very well with Medicare criteria for defining respiratory events and an RDI that compares favorably with AASM criteria for defining respiratory events. They further believe that the device can be used with a low failure rate for single use in the lab and home for self-administered testing.

Zou et al. (2006) aimed at assessing the accuracy of a portable monitoring device based on PAT to diagnose obstructive sleep apnea (OSA) and to propose a new standard for limited-channel device validation using synchronized polysomnography (PSG) home recordings in a population-based cohort, i.e. in a population sample not preselected for OSA symptoms. The 98 subjects (55 men; age, 60 ± 7 year; body mass index, 28 ± 4 kg/m^2) from a community of 18,000 in Sweden had single-night, unattended PSG and Watch-PAT100 in the home. They were consecutively recruited from the Swedish Skaraborg Hypertension and Diabetes Project. The accuracy of the algorithms used for AHI and RDI calculation from Watch-PAT100 testing were mainly based on 2 components: the oxygen-saturation data plus an indication of autonomic activation from the PAT signal. Events for AHI and RDI calculation were defined as follows: (1) any oxygen desaturation event of 3% or more was counted into both the AHI and RDI and (2) a respiratory event detected from the PAT signal was based on a PAT-signal attenuation that was coupled with pulse-rate acceleration. Watch-PAT100 measurements on RDI, AHI, ODI, and sleep-wake detection were cross walked and compared with PSG data taken from simultaneous PSG recordings.

The mean PSG-AHI in this population was 25.5 ± 22.9 events per hour. The Watch-PAT100 RDI, AHI, and ODI correlated closely (0.88, 0.90, and 0.92; $p < .0001$, respectively) with the corresponding indexes obtained by PSG. The areas under the curve for the receiver-operator characteristic curves for Watch-PAT100 AHI and RDI were 0.93 and 0.90 for the PSG-AHI and RDI thresholds of 10 and 20 ($p < .0001$) respectively. The agreement of the sleep-wake assessment was 82 ± 7%. The authors concluded that the Watch-PAT100 was reasonably accurate for unattended home diagnosis of OSA in a population sample not preselected for OSA symptoms. The authors propose that simultaneous home PSG recordings in population-based cohorts is a reasonable validation standard for assessment of simplified recording tools for OSA diagnosis.

Pillar et al. (2002) state that arousals from sleep are associated with increased sympathetic activation and are therefore associated with peripheral vasoconstriction. The authors hypothesized that digital vasoconstrictions as measured by peripheral arterial tonometry (PAT), combined with an increase in pulse rate, will accurately reflect arousals from sleep and can provide an autonomic arousal index (AAI). According to the authors, a previously studied group of 40 sleep apnea patients simultaneously recorded by both PSG and PAT systems generated an automated algorithm using the PAT signal (and pulse rate derived from it) was developed for detection of arousals from sleep. This was further validated in this separate group of 96 subjects which included 85 patients referred with suspected obstructive sleep apnea and 11 healthy volunteers. All subjects underwent a whole night PSG with simultaneous PAT recording. The PSG recordings were manually (blindly) analyzed for arousals based on American Academy of Sleep Medicine (AASM) criteria, while PAT was scored automatically. There was a significant correlation between PSG and PAT arousals (R=0.82, p<0.0001) with good agreement across a wide range of values, and with a ROC curve having an area under the curve (AUC) of 0.88. The authors conclude that automated analysis of the peripheral arterial tonometry signal can detect EEG arousals from sleep in a relatively quick and reproducible fashion.

Bar et al. (2003) aimed at evaluating the efficacy, reliability, and reproducibility of the Watch-PAT100 device for the diagnosis of OSAS as compared to in-laboratory, standard PSG-based manual scoring. One hundred two subjects (69 patients with OSAS and 33 normal non-consecutively selected volunteers) underwent in-laboratory full PSG simultaneously with Watch-PAT100 recording. Fourteen subjects also underwent two additional unattended home sleep studies with the Watch-PAT100 alone. The PSG recordings were blindly scored for apnea/hypopnea according to the American Academy of Sleep Medicine criteria (1999) and the RDI [PSG-RDI] was calculated. The Watch-PAT100 data were analyzed automatically for the PAT RDI (PRDI) by a proprietary algorithm that was the authors reported was previously developed on an independent group of subjects. Across a wide range of RDI levels, the PRDI was highly correlated with the PSG-RDI (r = 0.88, p < 0.0001), with an area under the receiver operating characteristic curve of 0.82 and 0.87 for thresholds of 10 events per hour and 20 events per hour, respectively. The PRDI scores were also highly reproducible, showing high correlation between home and in-laboratory sleep studies (r =0.89, p < 0.001). The authors concluded that the Watch-PAT100 may offer an accurate, robust, and reliable ambulatory method for the detection of OSAS with minimal patient discomfort.

Ayas et al. (2003) aimed at assessing the accuracy of a wrist-worn device (Watch-PAT100) to diagnose obstructive sleep apnea (OSA). Thirty adult subjects (mean age was 47.0 ± 14.8 years, mean body mass index 31.0 ± 7.6 kg/m2) were recruited through advertisements and from a patient base of those with suspected OSA to participate in this study. The study included patients suspected of having sleep apnea and subjects without suspected sleep apnea. The subjects had simultaneous in-laboratory PSG and wore the Watch-PAT 100 during a full-night recording. PSG sleep and respiratory events were scored according to standard criteria. The mean PSG AHI was 23 ± 23.9 events per hour and the mean PAT AHI 23 ± 15.9 events per hour. There was a significant correlation between the two (r = 0:87, p <0:001). To assess sensitivity and specificity of Watch-PAT100, receiver operator characteristic curves were constructed using a variety of AHI threshold values (10, 15, 20, and 30 events per hour). Optimal combinations of sensitivity and specificity for the various thresholds were 82.6/71.4, 93.3/73.3, 90.9/84.2, and 83.3/91.7, respectively. The authors concluded that the Watch-PAT100 is a device that can detect OSA with reasonable accuracy and that it may be a useful method to diagnose OSA.

Pillar et al. (2003) stated that they had recently shown that automated analysis of in-lab recorded peripheral arterial tone (PAT) signal and the pulse rate derived from it can accurately assess arousals from sleep as defined by the AASM. In the current study they aimed at extending these findings to the Watch-PAT100. They recruited 68 subjects who underwent a whole night PSG with simultaneous recording of PAT signal by the ambulatory Watch-PAT100 device. The PSG recordings were blindly scored via manual analyzing for arousals based on AASM criteria, while PAT was scored automatically based on the algorithm developed previously. The authors determined that was a significant correlation between AASM arousals derived from the PSG and PAT autonomic arousals derived from the Watch-PAT100 (R=0.87, P<0.001), with consistency across a wide range of values of AHI. The sensitivity and specificity of PAT in detecting patients with at least 20 arousals per hour of sleep were 0.80 and 0.79, respectively, with a receiver operating characteristic curve having an area under the curve of 0.87. They concluded that that automatic analysis of peripheral arterial tonometry signal derived from the ambulatory device Watch-PAT100 can accurately identify arousals from sleep in a simple and time saving fashion.

Berry et al. (2008) aimed to compare portable monitoring (PM) for diagnosis of OSA using the Watch-PAT100 and unattended autotitrating positive airway pressure (APAP) for selecting an effective continuous positive airway pressure (CPAP), with polysomnography (PSG) for diagnosis and treatment of obstructive sleep apnea (OSA). The study was structured as a randomized parallel group comparison in a VA Medical Center. One hundred six patients with daytime sleepiness and a high likelihood of having OSA were recruited. The AHI in the PM-APAP group was 29.2 ± 2.3/h and in the PSG group was 36.8 ± 4.8/h (P = NS). Patients with an AHI ≥ 5 were offered CPAP treatment. Those accepting treatment (PM-APAP#= 45, PSG# = 43) were begun on CPAP using identical devices at similar mean pressures (11.2 ± 0.4 versus 10.9 ± 0.5 cm H_2O).

At a clinic visit 6 weeks after starting CPAP, 40 patients in the PM-APAP group (78.4% of those with OSA and 88.8% started on CPAP) and 39 in the PSG arm (81.2% of those with OSA and 90.6% of those started on CPAP) were using CPAP treatment (P = NS). The mean nightly adherence (PM-APAP= 5.20 ± 0.28 hours/night versus PSG= 5.25 ± 0.38 hours/night), decrease in Epworth Sleepiness Scale score (–6.50 ± 0.71 versus –6.97 ± 0.73 in the PM group as compared to the PSG group respectively), improvement in the global Functional Outcome of Sleep Questionnaire score (3.10 ± 0.05 versus 3.31 ± 0.52 in the PM group as compared to the PSG group respectively), and CPAP satisfaction did not differ between the groups. The authors concluded that PM with APAP titration resulted in CPAP adherence and clinical outcomes similar to a diagnosis and treatment plan using PSG.

Other Diagnostic Strategies

Rice et al. (2006) piloted a study to evaluate unattended cardiopulmonary (CP) sleep studies as a diagnostic and treatment tool for patients with OSA. After all 106 subjects were initially evaluated by a pulmonary physician to identify those with a high risk of OSA, an ESS was administered. Those who were felt to have a high suspicion of OSA were offered either a PSG (which could take up to 6 months to schedule), or an unattended CP sleep study. Patients electing to use the unattended CP sleep study were lodged as outpatients overnight in the medical center. The diagnostic portable system used was the Embletta PDS, which included an oral thermometer, a nasal flow sensor, a snore microphone, a pulse oximeter, and strain gauges for thoracic and

abdominal expansion. AHI was the outcome of interest. Patients with a positive CP test (an AHI of 5 events per hour or greater) were sent home with a REMstar auto CPAP system and a mask that was custom-fitted by a trained respiratory therapist.

After using auto CPAP nightly for a week (REMstar auto CPAP system adjusted to the patient's pressure needs by analyzing the shape curve of his/her airflow signal and peak flow), patients were then issued a home CPAP machine with settings based on the pressure that was found to be effective for at least 90% of the trial patients. ESS scores were measured at baseline and after 6 months of home CPAP use. Patients who had been prescribed home CPAP were assessed for global sleepiness at 12 months. CP studies were performed on 106 patients, all participants were males (mean age 59.9±10.1), mean BMI of 33.5 and mean ESS score (reference) of 13.1 ± 5.2. Of the 106 original patients, auto CPAP was initiated on 92 subjects. Based on the results of the one week auto CPAP, home CPAP was initiated on 84 patients. According to the authors, "among our patients, improvement in OSA symptoms and long-term adherence to prescribed CPAP was similar to published reports of patients who had undergone conventional PSG testing." At 6 months follow-up, 98% of CPAP patients were available; ESS scores at baseline and follow up were 14±4.6 and 10±5.6 (p=0.001), and adherence to CPAP usage was 84%.

Limitations of the study included the lack of confirmatory PSG to determine rate of false positives (but the mean AHI from this study was similar to that reported in published series of patients who had PSGs; and the absolute magnitude of ESS score improvement in this study was similar to that reported for patients who were prescribed CPAP after a PSG). Other limitations are the inability to calculate the diagnostic accuracy of a negative CP study for OSA; the fact that all subjects were male; and that adherence to prescribed CPAP was not based on objective data but rather on self-reporting.

Healthcare Disparities

Consistent with Federal priorities we also looked for evidence specific to the diagnosis and treatment of OSA (OSAHS) in minority populations. There is apparently no standardized classification schema of these populations in the medical literature, so we have relied on the authors' descriptions.

Jean-Louis (2008) and Zizi et al. (2008) examined both adherence to a recommendation for sleep apnea consultation and the epidemiology of OSA in Caribbean countries in two studies. The authors concluded that Caribbean born black patients may be underutilizing available sleep services.

Joo et al. (2007) studied a population which was 77% African American, most of whom did not have health insurance, at an urban US public hospital. Women were more likely to be non-compliant with treatment than men after adjusting for age, race, and marital status. No significant findings were reported in regards to race and OSA.

Arias et al. (2007) reported that obstructive sleep apnea is a well recognized cardiovascular risk factor affecting all ethnic groups equally in terms of prevalence of disease. They found that a wide range of ethnic differences influence the role of the established risk factors for obstructive sleep apnea and contribution of these factors to disease presentation and severity for each ethnic group.

Freidman et al. (2006) concluded that OSAHS may be more common in African Americans, but African American bed partners are more likely to accept snoring.

Buxbaum et al. (2002) determined that there was support for an underlying genetic basis for OSA in African Americans. This is apparently independent of the contribution of BMI. They studied 300 Caucasian and African-American families.

Stepanowsky et al. (2000) studied 70 African-Americans over the age of 65 years with snoring and daytime sleepiness who had sleep recording and questionnaires administered. They reported no race distinguishing results.

Young et al (1997) conducted a case-control study of 225 African Americans and 622 Caucasians, aged 2 to 86, recruited as members of families with an individual with known sleep apnea (85 index families) or as members of neighborhood control families (63 families). The subjects were studied with an overnight home sleep-study, questionnaires, and physical measurements. The study suggests that especially in younger African Americans, African Americans overall have a prevalence of sleep apnea similar to that of Caucasians, but that they have a higher AHI after correction for body mass index and age.

Ancoli-Israel et al. (1995) studied Caucasians (n = 346) and African Americans (n = 54) older than 65 yr of age for SDB (sleep disordered breathing). They concluded that African Americans had severe SDB with a relative risk twofold as great (relative risk = 2.13) as that for Caucasians, which was confirmed in a logistic regression analysis where race was associated with the presence of SDB (RDI ≥ 30) independently of age, sex, and body mass index.

4. MEDCAC

CMS convened the MEDCAC on September 12, 2007 to consider questions pertinent to the evidence for the CPAP NCD reconsideration. We believe that many of those questions about the evidence are relevant to this NCD consideration on sleep testing for OSA so we are reiterating them here. The relevant questions (as originally numbered for the MEDCAC) are described below in reference to PSG and HST technologies. Additional information about the meeting can be found at: https://www4.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=40.

The MEDCAC was asked to consider the questions below for a variety of technologies including PSG, HST, clinical examination alone, and trial by CPAP without antecedent sleep testing.

1. How confident are you that there is sufficient evidence to determine if each of the following strategies can, in routine use, produce an accurate diagnosis of OSA for the prescription of CPAP?

- Diagnosis based on clinical evaluation alone

- Diagnosis based on clinical evaluation + PSG
- Diagnosis based on clinical evaluation + home testing device

2. For each OSA diagnostic strategy for which there is enough evidence in question 1, how confident are you about its sensitivity (ability to minimize false negatives) and specificity (ability to minimize false positives)?

- Diagnosis based on clinical evaluation alone
- Diagnosis based on clinical evaluation + PSG
- Diagnosis based on clinical evaluation + home testing device Type II
- Diagnosis based on clinical evaluation + home testing device Type III
- Diagnosis based on clinical evaluation + home testing device Type IV
- Diagnosis based on clinical evaluation + home testing other device

7. How confident are you that your conclusions can be generalized to the Medicare population and to providers in community practice?

The MEDCAC expressed moderate to high confidence that there was sufficient evidence to determine whether clinical evaluation combined with PSG can, in routine use, produce an accurate diagnosis of OSA for the prescription of CPAP treatment. Considering the evidence on the ability of various diagnostic strategies to predict successful use of CPAP, the MEDCAC expressed moderately high confidence in clinical evaluation combined with PSG; and moderate confidence in clinical evaluation combined with home sleep testing.

5. Evidenced based Guidelines

We identified the following evidence based guidelines that address the diagnosis of OSA.

American Academy of Sleep Medicine
Clinical guidelines for the use of unattended portable monitors in the diagnosis of OSA in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. Collop NA, Anderson WM, Boehlecke B, Claman D, Goldberg R, Gottlieb DJ, Hudgel D, Sateia M, Schwab R; Portable Monitoring Task Force of the American Academy of Sleep Medicine. J Clin Sleep Med. 2007 Dec 15;3(7):737-47.

> Based on a review of literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) makes the following recommendations: unattended portable monitoring (PM) for the diagnosis of OSA (OSA) should be performed only in conjunction with a comprehensive sleep evaluation. Clinical sleep evaluations using PM must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination. PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM. PM is not appropriate for the diagnostic evaluation of patients suspected of having comorbid sleep disorders. PM is not appropriate for general screening of asymptomatic populations. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness. PM may also be indicated to monitor the response to non-CPAP treatments for sleep apnea. At a minimum, PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in PM. The Task Force recommends that PM testing be performed under the auspices of an AASM-accredited comprehensive sleep medicine program with written policies and procedures. An experienced sleep technologist/technician must apply the sensors or directly educate patients in sensor application. The PM device must allow for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/technologist. A board certified sleep specialist, or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, must review the raw data from PM using scoring criteria consistent with current published AASM standards. Under the conditions specified above, PM may be used for unattended studies in the patient's home. A follow-up visit to review test results should be performed for all patients undergoing PM. Negative or technically inadequate PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

Institute for Clinical Systems Improvement (ICSI)
Diagnosis and treatment of obstructive sleep apnea. Bloomington (MN): 2007 Mar. 55 p. [115 references]
http://www.guidelines.gov/summary/summary.aspx?doc_id=10809&nbr=005634&string=CPAP

Sleep Study
Key Points:

- Selection of appropriate diagnostic tests must take into account the estimated pretest probability of the patient having OSAHS, availability of credible diagnostic tests and local expertise in interpreting these tests.
- Polysomnography is the accepted standard test for the diagnosis of OSAHS.
- The benefit of using attended polysomnography for diagnosis is the ability to establish a diagnosis and ascertain an effective continuous PAP (CPAP) treatment pressure.
- Unattended portable recording (multichannel) is a second-best option for patients who have a high pretest probability of OSAHS and who do not have atypical or complicating symptoms.

Scottish Intercollegiate Guidelines Network (SIGN).
Management of obstructive sleep apnoea/hypopnoea syndrome in adults. A national clinical guideline. Edinburgh (Scotland): 2003 Jun. 35 p. (SIGN publication; no. 73). [158 references].
http://www.guidelines.gov/summary/summary.aspx?doc_id=3878&nbr=003087&string=CPAP
The SIGN guideline has the following recommendations including a letter grade for the grade of the recommendation:

A. *At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to*

the target population, and demonstrating overall consistency of results

B. *A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+*

C. *A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++*

D. *Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+*

Diagnosis
C - All patients who have suspected sleep apnoea and their partners should complete an Epworth questionnaire to subjectively assess the degree of pretreatment sleepiness.

Diagnostic Tools
B - Limited sleep studies to assess respiratory events are an adequate first-line method of diagnostic assessment for obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

American Society of Anesthesiologists
Practice guidelines for the perioperative management of patients with obstructive sleep apnea: a report by the Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea. Anesthesiology 2006 May ;104(5):1081-93. [3 references].
http://www.guidelines.gov/summary/summary.aspx?doc_id=9308&nbr=004978&string=CPAP

Preoperative Evaluation
Anesthesiologists should work with surgeons to develop a protocol whereby patients in whom the possibility of obstructive sleep apnea (OSA) is suspected on clinical grounds are evaluated long enough before the day of surgery to allow preparation of a perioperative management plan. This evaluation may be initiated in a preanesthesia clinic (if available) or by direct consultation from the operating surgeon to the anesthesiologist. A preoperative evaluation should include a comprehensive review of previous medical records (if available), an interview with the patient and/or family, and conducting a physical examination. Medical records review should include (but not be limited to) checking for a history of airway difficulty with previous anesthetics, hypertension or other cardiovascular problems, and other congenital or acquired medical conditions. Review of sleep studies is encouraged. The patient and family interview should include focused questions related to snoring, apneic episodes, frequent arousals during sleep (vocalization, shifting position, extremity movements), morning headaches, and daytime somnolence. A physical examination should include an evaluation of the airway, nasopharyngeal characteristics, neck circumference, tonsil size, and tongue volume. If any of these characteristics suggest that the patient has OSA, the anesthesiologist and surgeon should jointly decide whether to (1) manage the patient perioperatively based on clinical criteria alone or (2) obtain sleep studies, conduct a more extensive airway examination, and initiate indicated OSA treatment in advance of surgery. If this evaluation does not occur until the day of surgery, the surgeon and anesthesiologist together may elect for presumptive management based on clinical criteria or a last-minute delay of surgery. For safety, clinical criteria (see table 1 of the original Guideline document) should be designed to have a high degree of sensitivity (despite the resulting low specificity), meaning that some patients may be treated more aggressively than would be necessary if a sleep study were available.

The severity of the patient's OSA, the invasiveness of the diagnostic or therapeutic procedure, and the requirement for postoperative analgesics should be taken into account in determining whether a patient is at increased perioperative risk from OSA (see table 2 of the original Guideline document). The patient and his or her family as well as the surgeon should be informed of the potential implications of OSA on the patient's perioperative course

University of Texas, School of Nursing, Family Nurse Practitioner Program.
Screening for obstructive sleep apnea in the primary care setting.

2006 May. 13 p. [24 references]
http://www.guidelines.gov/summary/summary.aspx?doc_id=9436&nbr=005057&string=

Diagnostic Procedures

1. Laboratory studies

- Sleep questionnaire (e.g., Epworth Sleepiness Scale), screen for sleep abnormalities (Elliott, 2001) **(Strength of Recommendation: A; Quality of Evidence: Good)**

2. Diagnostic tests

- NPSG Sleep Study: Nocturnal polysomnographic diagnostic testing (Netzer et al., 2003; Schroder, 2005; Elliot, 2001; Mansfield & Naughton, 2005; Hamilton, Solin, & Naughton, 2004; Rodsutti et al., 2004) **(Strength of Recommendation: A; Quality of Evidence: Good)**

6. Professional Society Position Statements

American Academy of Neurology Professional Association (AANPA) The AANPA believes that the use of Level IV devices to diagnose OSA, or the use of devices with actigraphy, oximetry, and peripheral artery tone without respiratory airflow are premature, and that further prospective studies are needed to clarify their place in the diagnosis and treatment of OSA.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) The AAO-HNS supports the extension of Medicare coverage of OSA diagnosis to portable HST devices. They are opposed to a requirement that limits interpretation of sleep studies to a limited subspecialty group of physicians. The AAO-HNS states that such restrictions will limit access to optimal care for the diagnosis and treatment of OSA.

American Academy of Sleep Medicine (AASM) The AASM is opposed to the use of Level IV devices without a channel to measure respiratory airflow, or the use of devices with actigraphy, oximetry, and peripheral artery tone to diagnose OSA. The AASM claims that such devices provide only an indirect "respiratory analysis" measure and therefore fail to provide adequate information to differentiate between central, mixed and obstructive sleep apnea.

American Thoracic Society (ATS) The ATS endorses the CMS decision to expand testing for the diagnosis of OSA to include the use of portable monitoring devices in those adult beneficiaries with clinically suspected OSA. The ATS qualifies this position by stating the use of portable monitoring is not yet well validated in patients with underlying complex pulmonary, cardiologic or neuromuscular disorders. They recommend that these patient groups not have portable diagnostic studies performed until such a time when evidence is made available for these particular patient groups.

7. Expert Opinion

Many experts provided their opinions as comments or position statements which are considered in the relevant sections of this memorandum.

8. Public Comments

Comment period 12/23/2008 – 01-22-2009

CMS received a total of 45 comments during the public comment period which ended on January 22, 2009. Twenty two of these comments were received as part of a write in campaign. The majority of those who wrote were self identified as physicians. Eight comments were submitted by non physician clinicians including nurses, respiratory therapists and other persons who are involved in the diagnosis and treatment of obstructive sleep apnea. The remaining comments were submitted by physician professional associations, national trade associations, and manufacturers and suppliers of diagnostic tests and CPAP equipment. No comments were received from patients or on behalf of a patient.

Forty-four commenters supported at least part of the proposed decision. One commenter expressed no position. Thirty-four commenters supported the entire proposed decision, including coverage of facility based PSG, HST and Watch-PAT technologies. No commenters opposed coverage of facility based PSG. Nine commenters opposed coverage of HST or Watch-PAT technologies. One commenter supported coverage of HST but noncoverage of Watch-PAT technologies.

America's Health Insurance Plans (AHIP) believes home testing should be reserved only for beneficiaries who cannot access sleep laboratories within an appropriate time frame due to geographic limitations or clinical urgency. SleepMed opposes the policy, and references peer reviewed literature to support their position. This literature was included in evidence that we had already reviewed and considered, and we believe our decision is consistent with the available body of evidence. The remaining comments in opposition of the policy were offered by sleep physicians and other non physician clinicians who believe the evidence is insufficient for coverage of home sleep testing especially for the Medicare population and support in lab testing for the diagnosis of obstructive sleep apnea for that group. We address these comments below.

Comment
Several commenters suggested changes related to the AASM classification of sleep test technologies. One commenter recommends that the PAT devices be classified as a Type V device. Others suggested that coverage determinations for Type II and Type III devices be separate. One commenter requests that CMS inform the public about how new sleep diagnostic technologies will be incorporated into the current device categories established by CMS. This commenter is concerned about the delay in time to market for new technologies when they do not easily fit into the established categorical definitions outlined by AASM.

Response
CMS is not responsible for the existing categorization system of sleep testing devices. The system was established 15 years ago by the American Academy of Sleep Medicine (AASM). We understand that the system may pose challenges for classifying certain sleep testing devices, but CMS believes that the OSA community is best suited to seek any modification of the classification system directly with AASM. With respect to the effect of AASM classification of a sleep testing device on time to market, this comment is outside the scope of this decision. We do not believe it is necessary to separate the discussion of Type II and Type III devices. Because there has been some debate in the sleep community about the classification of devices using PAT technology, we have for clarity separately discussed the evidence regarding PAT technology.

Comment
Many physician commenters wrote in support of the CMS findings and agree that the medical evidence is sufficient to conclude that all the HST devices listed in the NCA are reasonable and necessary. These physicians state that the availability of home sleep testing will lead to improved health outcomes by allowing physicians to diagnose patients accurately and in a timely manner when properly used.

Response
CMS agrees that coverage for these diagnostic tests will result in improved health outcomes for beneficiaries who would otherwise go undiagnosed and untreated for OSA.

Comment
Several non physician clinical support staff responsible for diagnostic testing of patients with suspected OSA claim that HST and

in particular PAT type devices are easy to use and more accurate since patients sleep more naturally in the home setting. They believe this will improve access to care for patients located in outlying rural areas or for patients unwilling to test in lab.

Response
CMS agrees that the coverage of HST will improve access to care for Medicare beneficiaries suffering with OSA.

Comment
A physician professional association maintains that physicians trained in otolaryngology can interpret Level III and IV home sleep studies without additional certification. This association claims that Level III and Level IV studies are largely cardio respiratory studies that are easily interpreted by any physician. Additionally, this association does not believe a board certification is needed to interpret a Level I study. A similar view is voiced by a board certified sleep specialist, whose interest is to teach primary care physicians to diagnose and treat OSA patients. This commenter requests that CMS allow primary care physicians to use the HST technique and not restrict testing for OSA to board certified sleep physicians. Other commenters suggest that only board eligible or board certified sleep physicians be permitted to interpret sleep tests. A supplier of CPAP supplies to Medicare supports these views and believes that diagnostic tests for OSA not be restricted to particular categories of physicians.

Response
We agree that a sleep test should be interpreted by a skilled and knowledgeable physician. We also agree that a physician who is board certified or board eligible in sleep medicine is likely to have those characteristics across the spectrum of sleep disorders diagnosis and management. However, we believe there may also be other physicians that have adequate skill and knowledge to appropriately interpret sleep test results.

This decision speaks specifically to the coverage of sleep testing devices used to diagnose OSA. Comments about specific physician specialties are outside the scope of this NCA. As provided at 42 C.F.R. § 410.32, "...diagnostic tests must be ordered by the physician who is treating the beneficiary...and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

Comment
One physician professional association supports coverage for HST but only for portable monitoring systems that include measurements of airflow. Their position is that it is impossible to distinguish OSA from central or complex sleep apnea when the diagnostic test does not have an explicit measurement of airflow. This commenter states that the use of Level IV devices to diagnose OSA or the use of devices with actigraphy, oximetry, and peripheral artery tone without respiratory airflow are premature, and that further studies are needed before coverage is extended to this category of testing. One commenter states that home testing is less comprehensive than PSG and is more susceptible to patient operator error and the misinterpretation of results. Further, they state there is a lack of evidence demonstrating that actigraphy is effective at diagnosing OSA. Finally, this commenter opposes the use of home pulse oximetry alone for the diagnosis of OSA.

Response
The body of evidence pertinent to the use of HST devices for the diagnosis of OSA is more robust than it was just a few years ago. In addition to our own review of the evidence, this is supported by the more favorable September 2007 MEDCAC scores for HST compared to the September 2004 MCAC scores. Thus, we find that the evidence is sufficient to conclude that, in appropriately selected patients, some home sleep testing monitors will identify a significant proportion of patients with OSA. We expect that patients who are suspected to have central or mixed causes of sleep apnea based on clinical findings or diagnostic testing would be referred to physicians with appropriate expertise in these more complex conditions. We have not provided national coverage of home pulse oximetry alone for the diagnosis of OSA.

Comment
Several physician professional associations recommend that CMS include guidelines in the final DM to identify patients for whom HST is an appropriate diagnostic tool. These professional associations suggest that appropriate patients be identified by age restrictions, presence of high pre-testing probability for having obstructive sleep apnea, and lack of associated co-morbid medical conditions; where appropriate patients for this testing have previously undergone a complete sleep medicine evaluation. One commenter claims that portable sleep monitoring is not well validated in patients with underlying complex pulmonary, cardiologic or neuromuscular disorders. This commenter recommends that CMS prohibit home testing for beneficiaries presenting with these conditions.

Response
It is important to note that we are not requiring that HST be done in the place of PSG. If the beneficiary's treating physician has good reason to believe that HST will be an inadequate diagnostic tool for a particular beneficiary's condition, we expect that the physician would order a PSG instead. We expect the treating physician to consider all relevant information pertaining to the health status of a particular beneficiary before recommending the use of HST or PSG.

Comment
Several commenters urge CMS to add a variety of requirements to the final DM to include a complete sleep evaluation before testing and patient education on the use of home sleep test prior to their use.

Response
We require that beneficiaries have clinical signs and symptoms of OSA as a condition of coverage for sleep testing. These would logically be ascertained in the course of a sleep evaluation prior to testing. There are several evaluative instruments that might be used as part of a pre test evaluation and a requirement to use a specific algorithm is not within the scope of this decision. As with other diagnostic tests, we expect that the treating physician who orders a test will ensure that the patient is provided with sufficient information to enable the test to be performed correctly.

Comment
One commenter argues that home sleep tests are far less sensitive and specific than PSG in diagnosing OSA.

Response
Evidence collected from our internal assessment of the scientific literature and from the AHRQ TAs found that HST devices may, with high positive likelihood ratios (>10) and low negative likelihood ratios (<0.1), identify patients who have AHIs suggestive of OSAHS. Although there is published data comparing HST with PSG, in the absence of a true gold standard it is challenging to categorize the discrepancies as errors or to conclude that one testing modality is superior to another for all patient groups.

Comment
One commenter argues that coverage of home sleep testing will result in increased costs for Medicare as home sleep tests will lead to repeat PSGs in sleep labs.

Response
We believe that a beneficiary's treating physician will assess a particular case and order the appropriate sleep test for the beneficiary. If the beneficiary's treating physician orders an HST, yet has good reason to believe that the result of an HST is insufficient in light of the beneficiary's clinical findings, a subsequent PSG could be performed. We do not believe that such retest decisions will be routine, but rather such decisions would be made on a case by case basis.

Comment
One commenter recommends that CMS should increase funding for sleep labs in underserved areas instead of expanding coverage to include home sleep testing.

Response
This comment is outside the scope of this decision.

Comment
Several physician professional associations oppose the use of PAT based technologies and recommend that all portable studies include the review of the raw, originally collected data that is only available with manual scoring.

Response
Automated scoring is a feature of several sleep test technologies and is not a unique characteristic of PAT based technologies. We are not making a determination on the use of automated scoring of sleep studies in this NCD. The physician who interprets the test remains ultimately responsible for the accuracy of the interpretation.

Comment
One commenter states that CMS should prohibit the use of portable monitoring for screening beneficiaries with no signs or symptoms of a sleep disorder.

Response
This coverage decision speaks specifically to the coverage of sleep testing devices used in the diagnosis of OSA. We are not providing coverage of a screening test. Screening tests are generally not covered under Medicare. However, there are some statutory exceptions to that rule (e.g. screening mammography, screening for glaucoma, etc.)

Comment
One commenter states that their in-laboratory PSG procedure will be subject to the CMS policy referred to as "Least Costly Alternative". They suggest that Recovery Audit Contractors or Medicare Carriers will reimburse in-laboratory PSG claims by using costs associated with the least costly alternative—in this case home sleep tests—even when PSGs are indicated.

Response
This comment is beyond the scope of this NCA and we will not address it here.

Comment
One commenter asked that CMS define actigraphy with something more specific than just a "measure of movement". This commenter suggests that CMS offer specifics related to the measurement such as what part of the body is affected, how is this measured, how much movement occurs, and how is the presence or absence of movement used to establish a diagnosis of OSA?

Response
We use actigraphy to mean measurement of body movement. According to a study conducted by Jan Hedner M.D. et al. and published in a 2004 issue of the journal SLEEP, actigraphy provides a reasonably accurate estimation of sleep and wakefulness in normal subjects and patients with obstructive sleep apnea on an epoch-by-epoch basis. They conclude that actigraphy provides a useful tool for the accurate quantification of obstructive sleep apnea in the home environment.

Comment
Several commenters argued that the proposed is not consistent with the recent National Coverage Decision and the related Local Coverage Determinations (LCDs) regarding the coverage of CPAP and other respiratory assist equipment and supplies for the treatment of OSA.

Response
We believe that this NCD does not conflict with the NCD on CPAP for the treatment of OSA. Regarding LCDs, this NCD on sleep testing supersedes all applicable local policies and local Medicare contractors will take such steps that may be necessary to align their local policies with the NCD.

Comment
One commenter requests that CMS add language to the actual NCD that makes clear that the CMS policy provides coverage for

portable studies performed in any site of service a treating physician determines appropriate.

Response
This final decision covers portable sleep testing whether furnished in a facility or outside of a facility. We note for clarity that Type I sleep testing is, by definition, performed within a facility. We expect that the beneficiary's home will be the site of service when the test is not furnished in a sleep laboratory facility. However, we are permitting local Medicare contractors to determine the conditions under which other locations might be appropriate.

Comment
A commenter recommends that CMS work with FDA to develop specific standards for validation and signal display of patient-based devices.

Response
This comment is beyond the scope of this decision.

Comment
Two commenters referred to published materials.

Response
Most of these materials had already been reviewed and considered in the proposed decision. The remaining materials were not topical to the decision or reiterated or summarized existing evidence and did not represent original research.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1869(f)(1)(B) of the Act). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See §1862(a)(1)(A)of the Social Security Act.

The Medicare regulations at 42 CFR 410.32(a) state in part, "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

As a diagnostic test, the sleep test would not be expected to directly change health outcomes, i.e. there is no evidence that administration of a sleep test is, in and of itself, therapeutic. Rather, a diagnostic test affects health outcomes through changes in disease management brought about by physician actions taken in response to test results. Such actions may include decisions to treat or withhold treatment, to choose one treatment modality over another, or to choose a different dose or duration of the same treatment. To some extent the usefulness of a test result is constrained by the available management alternatives.

Based on the legal framework set forth above, this section presents the agency's evaluation of the evidence considered and conclusions reached for the assessment questions posed above.

We considered the evidence in the hierarchical framework of Fryback and Thornbury (1991) where Level 2 addresses diagnostic accuracy, sensitivity, and specificity of the test; Level 3 focuses on whether the information produces change in the physician's diagnostic thinking; Level 4 concerns the effect on the patient management plan and Level 5 measures the effect of the diagnostic information on patient outcomes. Many studies have focused on test characteristics but others have considered health outcomes, such as symptom improvement in patients who receive CPAP treatment based on sleep test results. We believe that evidence of improved health outcomes is more persuasive than evidence of test characteristics.

In evaluating diagnostic tests, Mol and colleagues (2003) reported: "Whether or not patients are better off from undergoing a diagnostic test will depend on how test information is used to guide subsequent decisions on starting, stopping, or modifying treatment. Consequently, the practical value of a diagnostic test can only be assessed by taking into account subsequent health outcomes." When a proven, well established association or pathway is available, intermediate health outcomes may also be considered. For example, if a particular diagnostic test result can be shown to change patient management and other evidence has demonstrated that those patient management changes improve health outcomes, then those separate sources of evidence may be sufficient to demonstrate positive health outcomes from the diagnostic test.

A number of issues have emerged during our review of the evidence. Some physicians express concern about the lack of timely access to PSGs while others argue that access is not problematic; stakeholders debate the comparable accuracy of home apnea monitoring and PSGs; and recent research suggests that neither PSG nor HST may be needed for the diagnosis of CPAP-responsive OSA in selected patient populations. Paradoxically, some patients' OSA symptoms may be so severe that they cannot sleep for a sufficient continuous duration to complete a PSG. Adding to the complexity of our review, the stakeholder community itself has been clearly polarized into opposing PSG and HST camps.

The relevance of OSA diagnosis is founded on the long term morbidity and mortality that have been observed in patients who display a particular constellation of symptoms, signs and test results. Absent that morbidity and mortality, a self-limited apneic episode in and of itself appears of little consequence. Hence the challenge is to select for treatment only those patients who truly have OSA and will most likely benefit from therapy, against a background of persons who may for various reasons have a normal or abnormal test on a given night.

It is important to state at the outset that sleep testing, whether via PSG or HST, is used to confirm or refute a clinical suspicion of OSA. In other words, we have no evidence that physicians refer "normal" patients, i.e. patients who manifest no symptoms or

signs of a sleep disorder, for sleep testing. Sleep testing does not occur in a vacuum, divorced from the overall clinical evaluation. We also note that this NCA speaks to sleep testing for the diagnosis of OSA; we are not establishing coverage criteria for the diagnosis of other sleep disorders, such as nocturnal seizures or restless leg syndrome. Hence the accurate identification of Medicare beneficiaries who have OSA is at the heart of this review and analysis.

PSG is utilized as a reference standard in many clinical trials; however, we do not believe it is a true gold standard though it may be the best diagnostic test for OSA at present. In a circular argument, the test result has been incorporated into the diagnosis of the disease itself. In the absence of a diagnostic gold standard, this is an understandable though not ideal concession to practicality. The accuracy and precision of PSG may be compromised by many factors such as inter-reader variability, the use of different test instruments, night to night variability in a given patient, and patient ability to sleep in a non-home setting. Even if all these variables are controlled, the PSG test itself has not been proven to identify all true cases of OSA, i.e. those persons who will develop OSA-associated morbidity and mortality if untreated.

Therefore, when PSG is performed and read with a threshold of AHI ≥ 15 events per hour for OSA, the sensitivity for detecting a true case of OSA is not known. Neither is its specificity for detecting those who do not have OSA truly known. An AHI suggestive of OSAHS does not conclusively identify those patients who will benefit from treatment. Since the true sensitivity and specificity of PSG are uncertain and the reported agreement between HST and PSG is not complete, we are concerned that some true cases of OSA are not detected by either test. Nonetheless, it is the current state of the art and we believe that the evidence is sufficient to conclude that, despite the lack of agreement on a true gold standard for diagnosis, these sleep test technologies do provide useful clinical information.

Questions

Question 1: Is the evidence adequate to determine that attended facility based polysomnography accurately identifies patients with OSA who will benefit from treatment?

Attended facility based PSG for this use is well supported by evidence based guidelines and, though imperfect as noted above, is the generally accepted reference standard for the diagnosis of OSA. The external TA is consistent with our own review of the evidence and supports this conclusion.

> The reference standard for the diagnosis of OSAHS is facility-based polysomnography (PSG), a comprehensive sleep study that records and evaluates a variety of cardiorespiratory and neurophysiologic signals during sleep time. It quantifies the severity of disturbances with the Apnea-Hypopnea Index (AHI).

Based on our prior and current review of the evidence we believe that PSG accurately identifies patients with OSA who will benefit from treatment and therefore improve health outcomes by identifying patients with OSA.. The external TA is consistent with our own review of the evidence and supports this conclusion.

> The mainstay of treatment is considered to be continuous positive airway pressure (CPAP). Other treatments for the condition exist and are reserved for specific cases (e.g., surgical interventions and oral-dental appliances to improve the stereometry of the upper airway).
>
> CPAP treatment of OSAHS has been associated with beneficial health outcomes. Observational evidence from prospective comparative studies associates CPAP treatment of OSAHS with fewer cardiovascular events. Furthermore, patients with OSAHS have an increased risk for car accidents. CPAP has been associated with a reduction in the risk for motor vehicle accidents among people with OSAHS.
>
> However, apart from the aforementioned considerations there is no extensive randomized evidence on outcomes such as deaths, strokes and cardiovascular events. There is randomized evidence that CPAP versus no treatment or sham CPAP treatment of OSAHS is associated with improvements in the Epworth Sleepiness Scale (a subjective symptom score), objective wakefulness tests and selected components of the SF-36 questionnaire (e.g., the vitality component, which is more relevant to OSAHS patients compared to other SF-36 components). Randomized studies suggest that CPAP may also be inversely associated with intermediate clinical outcomes (e.g., hypertension).
>
> Typically, the diagnosis of OSAHS is made after a positive comprehensive sleep study with multichannel polysomnography (PSG) in specialized sleep laboratories. For patients who meet the diagnostic criteria, a second session is needed for the titration.

Therefore, we conclude that PSG is reasonable and necessary for the diagnosis of OSA.

Question 2: For which unattended out of facility sleep test technologies is the evidence adequate to determine that sleep testing accurately identifies patients with OSA who will benefit from treatment?

We note evidence from our internal assessment and from the AHRQ TAs that HST devices may, with high positive likelihood ratios (> 10) and low negative likelihood ratios (< 0.1), identify patients who have AHIs suggestive of OSAHS. Although there is published data comparing HST with PSG, in the absence of a true gold standard it is challenging to categorize the discrepancies as errors.

The body of evidence pertinent to the use of HST devices for the diagnosis of OSA is significantly more robust than it was a few years ago. This is supported by the more favorable September 2007 MEDCAC scores for HST compared to the September 2004 MCAC scores. Thus, we find that the evidence is sufficient to conclude that, in appropriately selected patients, some home sleep testing monitors will identify a significant proportion of patients with OSA who will respond clinically to CPAP and will exclude a significant proportion of those who will not.

Specifically, we believe that Type II and Type III sleep testing devices, based on our prior and current review of the evidence, identify beneficiaries with OSA who will benefit from treatment and thus improve health outcomes by identifying patients who are likely to respond to CPAP therapy as we discussed above. Therefore, we conclude that Type II and Type III sleep testing devices are reasonable and necessary for the diagnosis of OSA.

The TA analyzed Type IV monitors with three or more channels separately from those with only one or two channels. The TA included devices measuring actigraphy, oxygenation, and PAT in its analysis of Type IV monitors measuring three or more channels. The quality of the evidence on the former is described as higher than on the latter. We also note that the TA did not include all Type IV monitors.

> "...However, especially for type IV devices, we excluded the few studies that did not measure directly at least one respiratory signal or the O_2 saturation. Thus, studies using only static charge-sensitive mattresses, only Holter recordings for heart rate, or studies that used only analysis of snoring sounds were excluded. Similarly, we excluded studies that that used pulse oximetry but analyzed only the variability of the heart rate (i.e., used oximetry in lieu of ECG to detect pulse rate) and did not evaluate O_2 saturation patterns. In general, monitors that did not record a respiratory signal or SaO_2 during sleep rely on "indirect" assessment of respiratory disturbances in people suspected for OSAHS, and most often were described in older studies. The frequency of respiratory disturbances is a key issue in the diagnosis of OSAHS, and is assessed by the vast majority of modern monitors."

Based on this, as well as our prior and current review of the evidence, we believe Type IV sleep testing devices that measure three or more channels, one of which is airflow, can identify beneficiaries with OSA who will benefit from treatment and thus improve health outcomes. Therefore, we conclude that Type IV sleep testing devices that measure three or more channels, one of which is airflow, are reasonable and necessary for the diagnosis of OSA.

Though devices measuring actigraphy, oxygenation, and PAT may be classified as Type IV devices, we are, for clarity, providing a specific conclusion regarding such technology. We have reviewed the evidence submitted by the requestor, as well as other evidence as cited in this decision memorandum, and we conclude that these devices are reasonable and necessary for the diagnosis of OSA.

Healthcare Disparities

There are generally sparse data with respect to ethnic or racial disparities in the field of OSA. The data that are available are generally not of high methodologic rigor and mostly pertain to epidemiology of OSA as opposed to diagnosis and treatment of OSA. There are little to no data on home sleep testing in minorities. There are little to no data in the literature to suggest that the measurement of respiratory-related events during sleep is influenced by gender or race. There are little to no data on treatment of obstructive sleep apnea in minorities.

X. Conclusion

CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

Therefore:

1. Type I Polysomnography (PSG) is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

2. A Type II or a Type III sleep testing device is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. A Type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

APPENDIX A

General Methodological Principles of Study Design
(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e.g., using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-

morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

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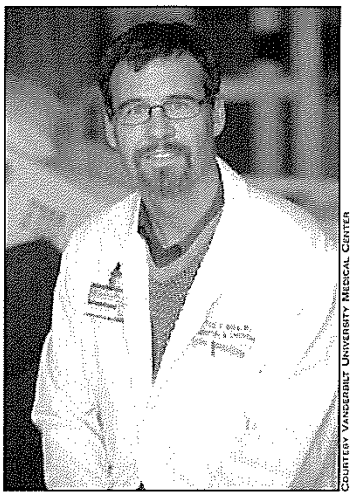

COURTESY VANDERBILT UNIVERSITY MEDICAL CENTER

"Our nurses love the trophic feeds. Starting at 10-20 cc/hr and running it for 6 days is a lot less hassle than worrying about trying to ramp it up and get to goals," Dr. Todd W. Rice said.

ALI Patients Do Well With Trophic Feeding

BY DIANA MAHONEY
Elsevier Global Medical News

HOUSTON – Restricting the amount of initial enteral intake in mechanically ventilated patients who have acute lung injury neither reduces the duration of mechanical ventilation nor improves mortality relative to full enteral feeding, but the nutritional strategy may be slightly easier on the stomach, according to a study reported at the annual congress of the Society of Critical Care Medicine.

The importance of nutrition support in critically ill patients with acute lung injury (ALI) is well accepted as a means of maintaining gut integrity, modulating both stress and the systemic immune response, and attenuating disease severity, but conflicting data regarding the timing, formulation, and amount of enteral nutrition have contributed to uncertainty about the optimal feeding protocol, said Dr. Todd W. Rice, FCCP, of Vanderbilt University Medical Center in Nashville, Tenn.

"How much nutrition we need to promote the protective benefits, we don't know. Providing a little bit of nutrition – called trophic feeding – has been shown to decrease intestinal intolerances, compared with full-calorie feeds, but it may do so at the risk of malnutrition, worse immune function, and loss of muscle strength," he said. Full-calorie feeding, on the other hand, may lead to more intolerances, may cause hyperglycemia and other imbalances, may increase septic complications, and may fuel the inflammatory fire, he added.

In the current study, which was published simultaneously in JAMA, Dr. Rice and colleagues in the EDEN (Early vs.

See **ALI** • *page 4*

Home Sleep Apnea Testing Gaining Favor

Insurers like the lower price tag.

BY M. ALEXANDER OTTO
Elsevier Global Medical News

PHOENIX – Sleep medicine doctors need to get ahead of the curve on home sleep apnea testing or risk being put out of business, according to Dr. Charles W. Atwood Jr., FCCP, director of the Sleep Disorders Program at the Veterans Affairs Pittsburgh Healthcare System.

Those "who can integrate this are going to survive, and [those] who can't integrate this are not going to do as well," said Dr. Atwood, who is also an associate professor of medicine at the University of Pittsburgh.

Home sleep apnea testing (HSAT) is gaining traction among U.S. insurers because, among other things, it costs a lot less than traditional sleep lab apnea screening. Physician reimbursement is generally in the range of $180, compared with $700 or so for polysomnography. The Centers for Medicare and Medicaid Services is on board, as well, and has begun reimbursing for HSAT.

HSAT patients hook themselves up before bed to one of several HSAT devices on the market. The monitors typically measure airflow, respiratory effort, and heart rate, and include pulse oximetry. Results are later interpreted in the doctor's office.

HSAT has only about 10% of the U.S. sleep study market at the moment, "quite small despite all the attention it gets," but with a lower price tag and studies showing that it is a viable alternative to polysomnography, the market is "likely to continue to increase. Most private [insurance] companies are going to want you do to this," Dr. Atwood said at a meeting on

See **Apnea** • *page 2*

INSIDE

Adult Asthma Phenotypes No Help in Kids

BY PATRICE WENDLING
Elsevier Global Medical News

KEYSTONE, COLO. – Adult asthma phenotypes offer little guidance in the identification and management of severe, therapy-resistant asthma in children.

Cluster analysis was recently used to identify two subgroups with discordance between symptom expression and eosinophilic airway inflammation specific to refractory adult asthma (Am. J. Respir. Crit. Care Med. 2008; 178:218-24). In addition, a treatment strategy based on minimizing eosinophilic inflammation proved superior to standard care in reducing exacerbation frequency (Lancet 2002;360:1715-21).

Recent efforts to replicate the findings in severe pediatric asthma, however, met with disappointing results, study coauthor Dr. Andrew Bush said at a meeting on allergy and respiratory diseases.The ability to identify asthma phenotypes that exhibit differences in clinical response could enable

See **Asthma** • *page 15*

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Wake-Up Call for Sleep Docs

Apnea • *from page 1*

sleep medicine held by the American College of Chest Physicians.

Sleep medicine physicians "need to think about companies that want to contract with primary care providers or insurance companies and get an exclusive contract that bars you from doing this kind of work. That has happened in certain markets, and it's really devastated traditional sleep labs," Dr. Atwood said.

Forestalling that means "getting to your insurance companies first and saying, 'Look, we know this is coming. This is something that we can do. You'll be happy with our services. Let's talk,' " he said.

In the meantime, "network with your primary care and other referrers to make sure that they know you are doing this. They will want to know who's going to take care of these patients if they can't get a traditional sleep study," he said.

Overall, home sleep apnea testing "is not that hard," said Dr. Atwood, who researches HSAT and is a consultant for companies that make the devices.

Pick one system and get to know it well, and start with the easiest, least-complicated patients. Give some thought to who is going to teach patients how to use the devices – how-to videos are available for many – and how to get the devices back after patients are done with them. FedEx and UPS are options.

"You'll also need to think about what to do with negative studies," he noted. You could take them at face value, repeat the test, or send patients to sleep labs for follow-up.

Home tests won't work in about 10%-15% of patients, mostly because they will be noncompliant or will slip the pulse oximeter off while asleep. Also, because home testing generates fewer signals than does polysomnography, "you have to get comfortable making decisions with less information," Dr. Atwood said.

Nonetheless, he and his colleagues found that HSAT patients had no worse 3-month functional outcomes and continuous positive airway pressure (CPAP) adherence than did patients whose sleep apnea was diagnosed in a lab (Am. J. Respir. Crit. Care Med. 2011;183:1238-44).

Dr. Atwood receives commercial research support from Philips Respironics, Resmed, Embla, and Vapotherm. He is a consultant to Carecore, Resmed, and Philips Respironics. ■

COMMENTARY

Dr. Paul Selecky, FCCP, comments: Wise advice in these changing times in sleep medicine reimbursement. Resisting the changes is folly. Better that our professional organizations help us adapt before the payers demand what kind of study we can order.

APAP a Good Alternative to CPAP for Uncomplicated Apnea

BY M. ALEXANDER OTTO
Elsevier Global Medical News

PHOENIX – For uncomplicated, moderate to severe obstructive sleep apnea, autoadjusting positive airway pressure is as effective as continuous positive airway pressure titrated in a sleep laboratory, according to Dr. Neil Freedman, FCCP, a sleep medicine specialist and pulmonologist in Bannockburn, Ill.

Randomized controlled trials that compared lab-titrated continuous positive airway pressure (CPAP) to autoadjusting positive airway pressure (APAP) in unattended settings have shown similar compliance, apnea-hypopnea index (AHI), and daytime sleepiness improvements (Sleep 2010;33:267-71).

That raises the possibility of sending uncomplicated OSA patients home with APAP machines to see how they do, instead of to a sleep lab. With insurance companies, among others, interested in that option, "in the near future patients who need CPAP – if they have uncomplicated sleep apnea – are going to get an unattended APAP trial whether they're going to be treated long-term with it or they are going to be pushed to CPAP," Dr. Freedman said at a meeting on sleep medicine held by the American College of Chest Physicians.

APAP machines don't provide continuous pressure, but instead detect and respond to changes in upper airway flow or resistance patterns; the idea is to use the minimal effective pressure needed to maintain airway patency, which can change for various reasons, even body position.

Initially, machines are typically set to a minimum pressure of 4 cm H_2O and a maximum pressure of 20 cm H_2O. Dr. Freedman starts on the higher side with obese patients and those with worse symptoms, and includes heated humidification and a gradual ramp-up to therapeutic pressures at the start of sleep. "The overwhelming majority" of patients are going to need pressure of 8-12 cm H_2O. If patients need more than 14 cm H_2O, "there's probably something else going on."

Despite APAP's effectiveness, the machines use different technologies and algorithms to treat events, so data from one APAP study is specific to the device used and cannot be generalized to other machines.

Dr. Freedman said he had no relevant disclosures. ■

IN THIS ISSUE

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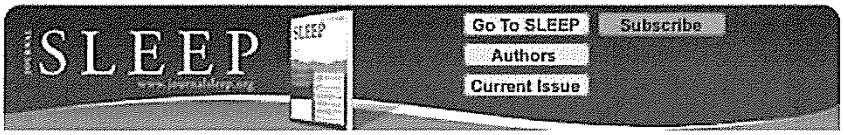

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"The Times They Are A Changin:" Home Diagnosis of Sleep Apnea Has Arrived

Charles W. Atwood, Jr., MD

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See the article "A Multisite Randomized Trial of Portable Sleep Studies and Positive Airway Pressure Autotitration Versus Laboratory-Based Polysomnography for the Diagnosis and Treatment of Obstructive Sleep Apnea: The HomePAP Study" on page 757.

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As anyone in the clinical practice of sleep medicine is keenly aware, the traditional approach to the diagnosis of and initiation of continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) is undergoing a sea change. Since 2008, and the Centers for Medicare and Medicaid Services (CMS) approval of home sleep testing for the diagnosis of OSA when CPAP is to be prescribed, the door to the non-laboratory diagnosis of sleep apnea has been opening ever more steadily.[1] The concern many sleep medicine practitioners have is that, while there may be some advantages to home testing for sleep apnea in terms of a more realistic "ecology" for the patient, clinical outcomes will not be as good as they are with sleep laboratory and PSG diagnosis and CPAP titration.

To address the need for better evidence supporting the use of home OSA testing, the evidence base for home sleep apnea testing has been also been growing. Since 2007 we have seen clinical trials[2–5] published that have begun to consistently demonstrate that clinical outcomes relevant to OSA patients are essentially the same regardless of whether the diagnosis and initiation of positive airway pressure therapy is performed in the home setting or in the laboratory setting. In this edition of *SLEEP*, Rosen and colleagues[6] have published the latest contribution to this literature, the HomePAP study.

The HomePAP study investigators performed a multisite, randomized, open label, parallel group clinical trial, which compared a home-based unattended sleep apnea monitor for the diagnosis of OSA, and then followed that with a trial of autotitrating CPAP for patients who were positive for OSA on the diagnostic study with a sleep laboratory-based diagnostic polysomnogram followed by a CPAP titration performed in a sleep laboratory. The study population was middle-aged (average age 46 ± 12 years), 60% male, 64% Caucasian, and obese (average BMI 37.2 ± 8.7) and lived in proximity to 1 of 7 academic sleep medicine centers where they were referred for evaluation. The population was prescreened significantly to select for patients who were excessively sleepy, as determined by an Epworth Sleepiness Scale value of 12 or higher,[7] and likely to be overweight due to the requirement they have an increased neck circumference of a minimum of 43 cm. Finally, all patients who went on to the treatment phase had a minimum apnea-hypopnea index (AHI) of 15 events per hour. Thus, subjects in this study appear to be very typical of the kinds of patients referred to sleep medicine centers for an OSA evaluation.

SLP 084

The key findings of the HomePAP study demonstrated that the CPAP usage was 4.7 ± 2.1 hours in the home setting arm compared with 3.7 ± 2.4 hours in the sleep laboratory arm. Moreover, the home evaluation arm used autotitrating CPAP therapy 62.8% ± 29.2% of the nights in the study, compared with 49.4% ± 36.1% of the nights in which CPAP was used by those subjects in the sleep laboratory arm. Furthermore, functional outcomes including the Epworth Sleepiness Scale score [7] and the Functional Outcomes of Sleep Questionnaire (FOSQ)[8] both improved significantly from baseline to the 3-month assessment point during the CPAP intervention within the 2 groups. There was no difference between the groups for either of these outcomes at the 3-month point.

The HomePAP trial is the largest study to date examining a home-based diagnostic and treatment algorithm compared to a sleep laboratory based evaluation and treatment approach. However, there are 4 previous North American randomized trials with findings very similar to the HomePap study. Mulgrew and colleagues[4] from Vancouver, BC demonstrated that home autotitrating CPAP treatment for OSA yielded clinical outcomes equivalent to those achieved in a traditional sleep laboratory CPAP titration. Patients were screened for sleep apnea symptoms and underwent a home sleep apnea test prior to randomization in their study. Berry and colleagues[2] performed a randomized trial of 106 patients referred to a sleep medicine clinic at a Veterans hospital. After prescreening to select for patients with a high likelihood of sleep apnea, the investigators found that after 3 months of CPAP therapy based on either a home autotitrating CPAP trial or a laboratory-based CPAP titration, CPAP usage and functional outcomes were comparable. Similar findings were found by another group of investigators from Canada using a randomized crossover trial design.[5] Finally, a VA trial of 296 patients randomized to a home diagnostic and autotitrating CPAP algorithm versus a traditional sleep laboratory approach showed that improvement in the FOSQ at 3 months was identical between the 2 groups, and that CPAP adherence was not significantly different between the home group and the sleep laboratory group, with a nonsignificant trend toward better CPAP usage in the home arm compared to the laboratory arm.[3] The HomePAP study by Rosen et al.[6] showed a similar trend. This finding of a trend toward better adherence in the VA trial[3] and the HomePAP[6] study is intriguing, has not been fully explained yet, and deserves further study.

Is the home diagnosis and initiation of CPAP therapy for sleep apnea now "ready for prime time?" The accumulated evidence strongly supports this. The results from 5 randomized trials in the past 5 years demonstrate essential equivalency between the home diagnostic and treatment approach and the lab diagnostic and treatment approach for initial CPAP adherence and initial functional outcomes. Yet, not all the questions have been answered. Important concerns relating to improvement in sleepiness and maintenance of alertness, long-term adherence to therapy, impact on other comorbidities, and finally, patient preferences about diagnostic and treatment options need to be further examined. The HomePAP study approach of selecting patients on the basis of sleep apnea symptoms and focusing home testing for OSA in these more symptomatic patients will appeal to many practitioners. This approach may give confidence to practitioners beginning to adopt this diagnostic and treatment approach in their practices. It is very likely that over the next few years home sleep apnea testing will continue to grow and may replace polysomnography as the initial diagnostic test for many patients. When this occurs, sleep medicine will have evolved into a discipline with more than one test to evaluate its patients, ideally fitting the right test to the right patient in the right setting. This is a goal everyone should be able to support.

DISCLOSURE STATEMENT

Go to:

Dr. Atwood has indicated no financial conflicts of interest.

CITATION

Go to:

Atwood CW. "The times they are a changin:" home diagnosis of sleep apnea has arrived. *SLEEP* 2012;35(6):735-736.

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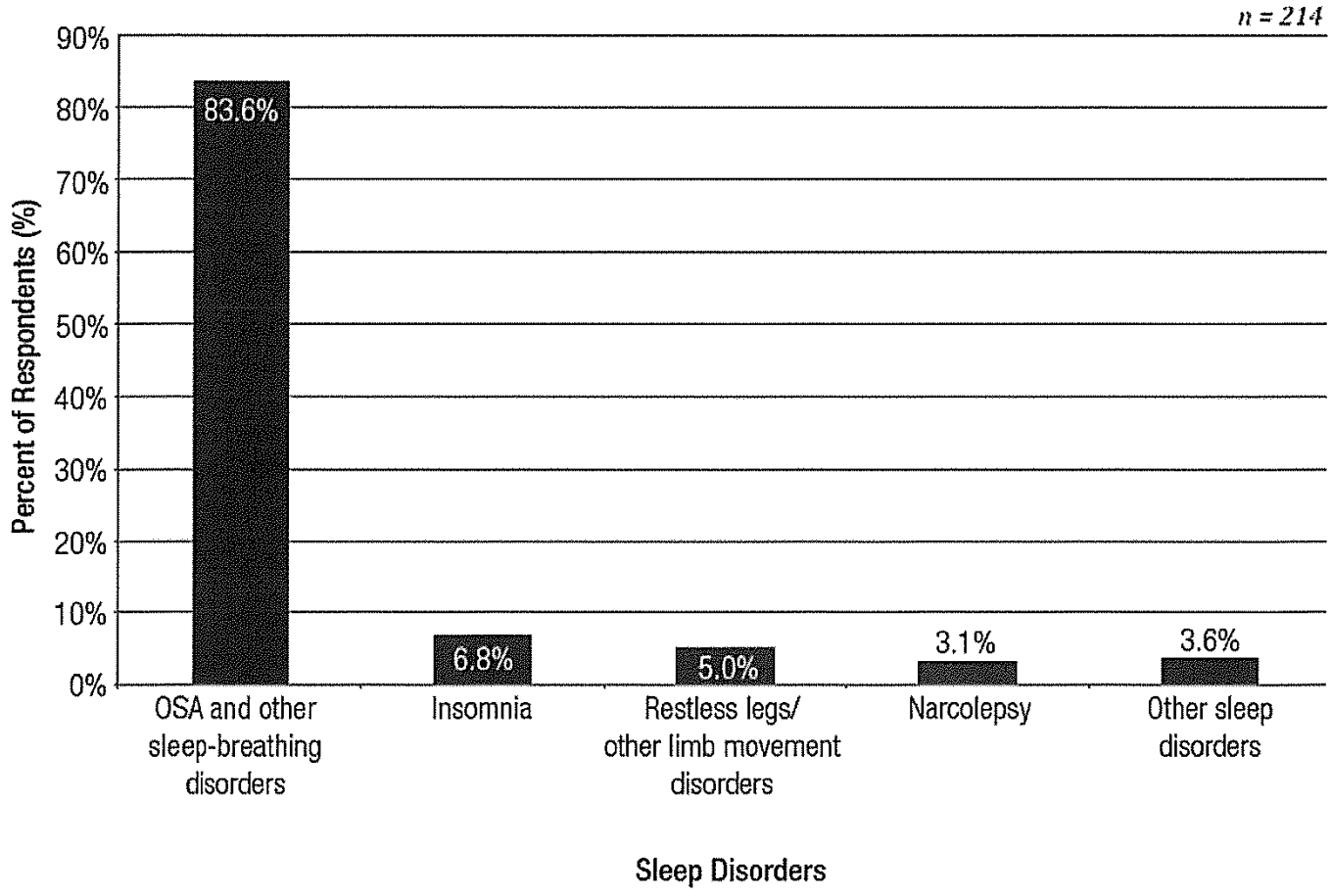
FINANCIAL MANAGEMENT

15% of OSA Testing Done with HSTs (and Growing)

Published on February 27, 2014

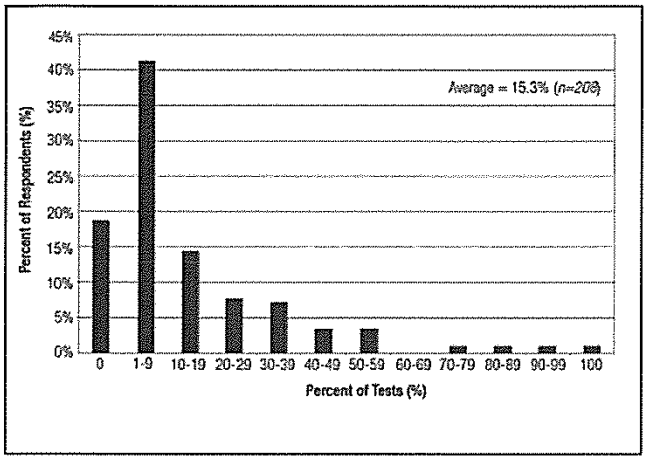
Sleep Review and Needham & Co's first quarter survey reveals that HST and APAP use grows, while sleep center bed numbers decline.

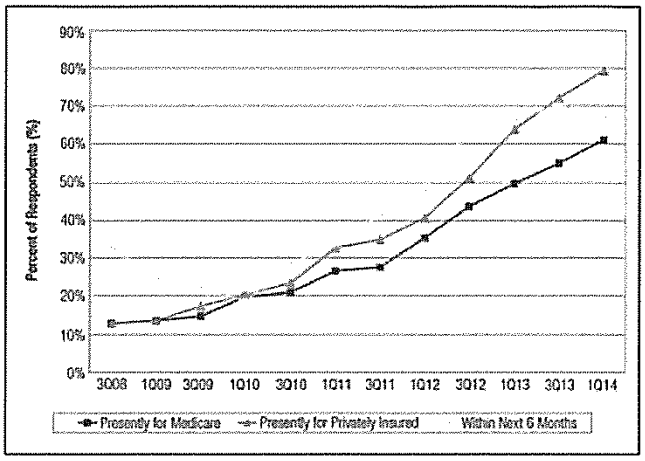
By Mike Matson, CFA

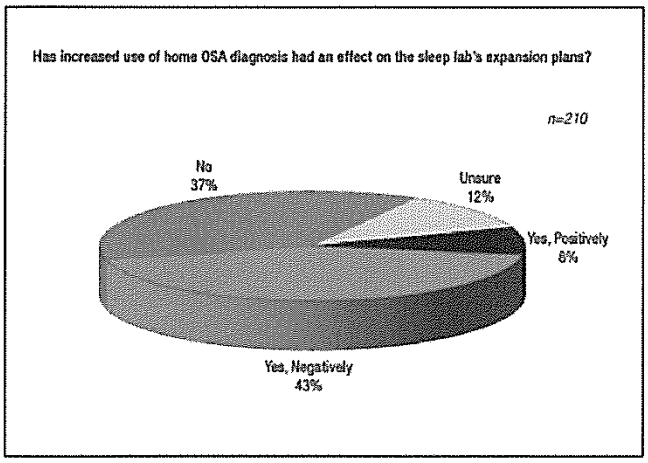


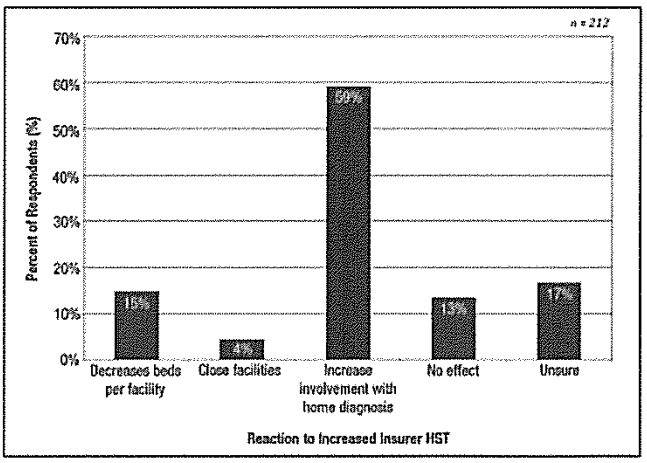
Sleep Disorders Evaluated

The vast majority of sleep center patients are being evaluated primarily for obstructive sleep apnea (OSA) and other sleep-breathing disorders (84%), while 7% were evaluated for insomnia, and 5% evaluated for restless leg syndrome and other limb movement disorders, according to the survey. Narcolepsy and other sleep disorders both accounted for less than 4% of the patients.









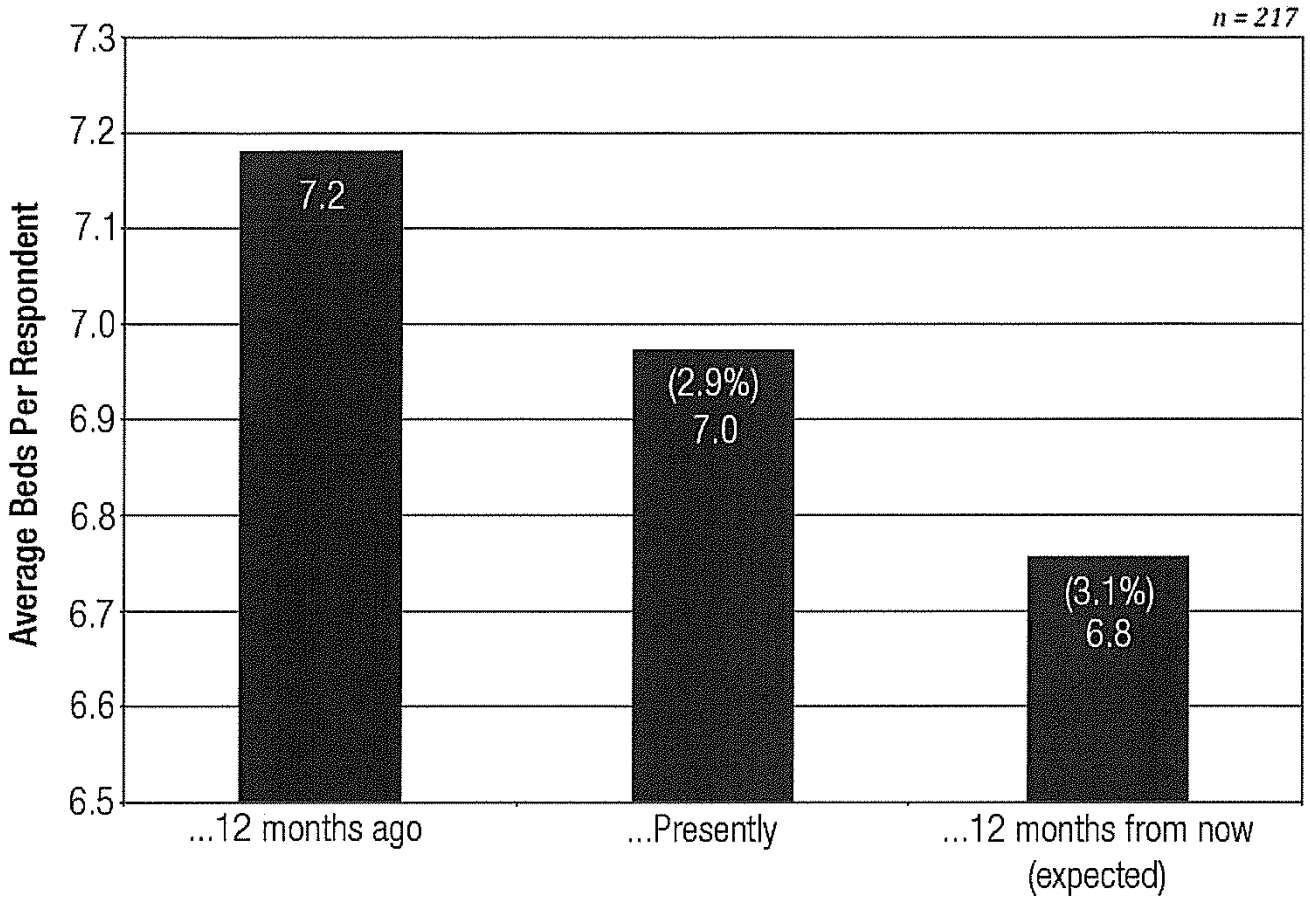
Home Sleep Testing (HST)

On average, 15% of OSA tests are done with HSTs rather than in-lab tests. Over time, we expect this to grow, although we did not ask respondents about their future expectations.

Currently, 79% of sleep centers offer HST for patients with commercial insurance compared to 61% that offer HST for patients with Medicare. In two other HST questions, 59% of respondents indicated that they expect to increase involvement in home testing, while 43% of respondents have reduced their expansion plans as a result of home testing. We think that increased use of HST is the primary factor behind the declining number of beds at sleep centers.

Beds and Patient Volume

Sleep centers continued to contract as patient volume declined. Sleep centers reduced beds by 3% in the last 12 months, and expect to reduce beds by another 3% in the next 12 months. Patient volumes declined by 2% in the last 12 months, although the surveyed sleep centers expect volumes to increase by about 4% in the next 12 months. However, both of these measures may understate volume growth given the increased use of home sleep testing. We forecast 1%-4% growth for the US sleep market during 2014, consisting of 3%-4% volume growth, 4%-5% mix growth, and price declines of 5%-6%.



Automatic Positive Airway Pressure (APAP) Devices

On average, respondents report that 14.8% of their patients use auto-setting flow generators, while only 13.0% of their patients use bilevel flow generators. Over the longer term, use of auto-setting flow generators has steadily climbed, while use of bilevel flow generators has been relatively stable. Increased use of auto-setting flow generators is probably the result of increased use of HST, since auto-setting flow generators do not require the patients to be titrated to determine the proper pressure setting.

Oral Appliances

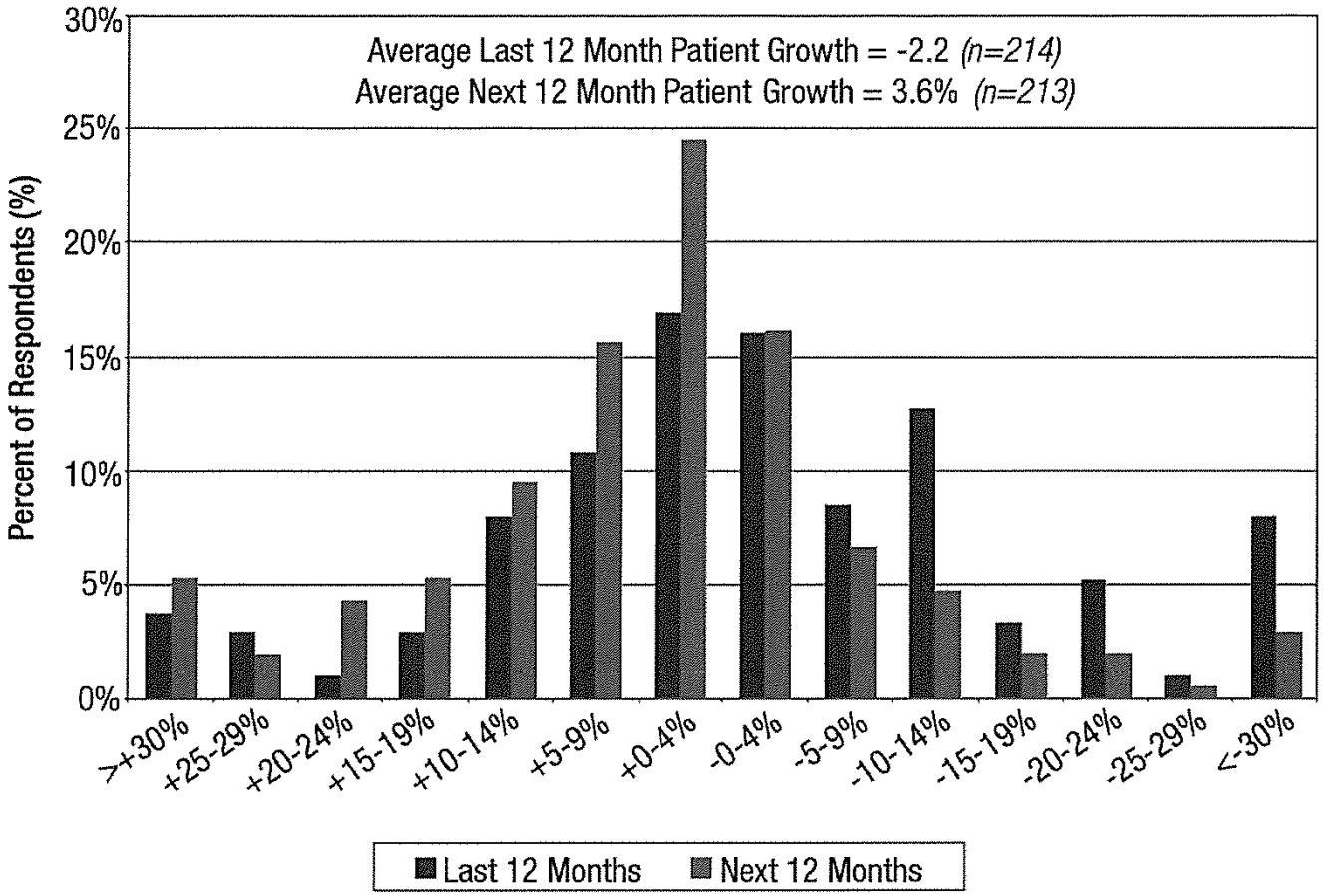
For the first time, we asked respondents about patients who start their OSA treatment with oral appliances (without first trying a PAP device); 49.5% indicated that between 1% and 9% of their patients took the oral appliance-first route, and 45.6% said 0% of their patients fall into this category. Only small percentages indicated that 10% or more of patients started with an oral appliance.

Branded Prescriptions

For the first time, we asked the respondents if home medical equipment companies (HMEs) were asking for changes to branded prescriptions as a result of competitive bidding. Only 13% of respondents said that they have been asked to switch to branded prescriptions, while 58% said they have not been asked. On average, respondents indicated that about 9% of the HMEs they are in contact with have asked for changes to branded prescriptions. On average, sleep centers reported writing brand-specific prescriptions for 62% of mask prescriptions and for 47% of flow generator prescriptions. While the rate of branded prescriptions has been relatively stable in recent years, this quarter's decline may have been driven by push-back from HMEs, since 13% of respondents indicated that HMEs had asked them to change branded prescriptions.

About the Survey

Needham & Company LLC and *Sleep Review* worked together to survey sleep centers around the United States about the current state of the



domestic sleep market. The survey was emailed to around 12,000 sleep professionals, with 226 responses resulting in a response rate of about 2%. We note that response rates varied for each question since respondents were not required to answer every question. Of the respondents, 186 (82%) completed the entire survey. The responses were collected between January 17 and February 10, 2014. Sleep center directors/supervisors/managers (39% of respondents) and registered polysomnography technicians (29% of respondents) were the most common types of respondents. Every geographic region and 44 US states were represented, with the Midwest (28% of respondents) and Southeast (28% of respondents) most heavily represented. Click here to see how this year's survey results compare to past years.

***Mike Matson, CFA**, is a senior research analyst, medical technologies & diagnostics, at Needham & Company LLC. Questions about the survey may be sent to sleepeditor@allied360.com.*

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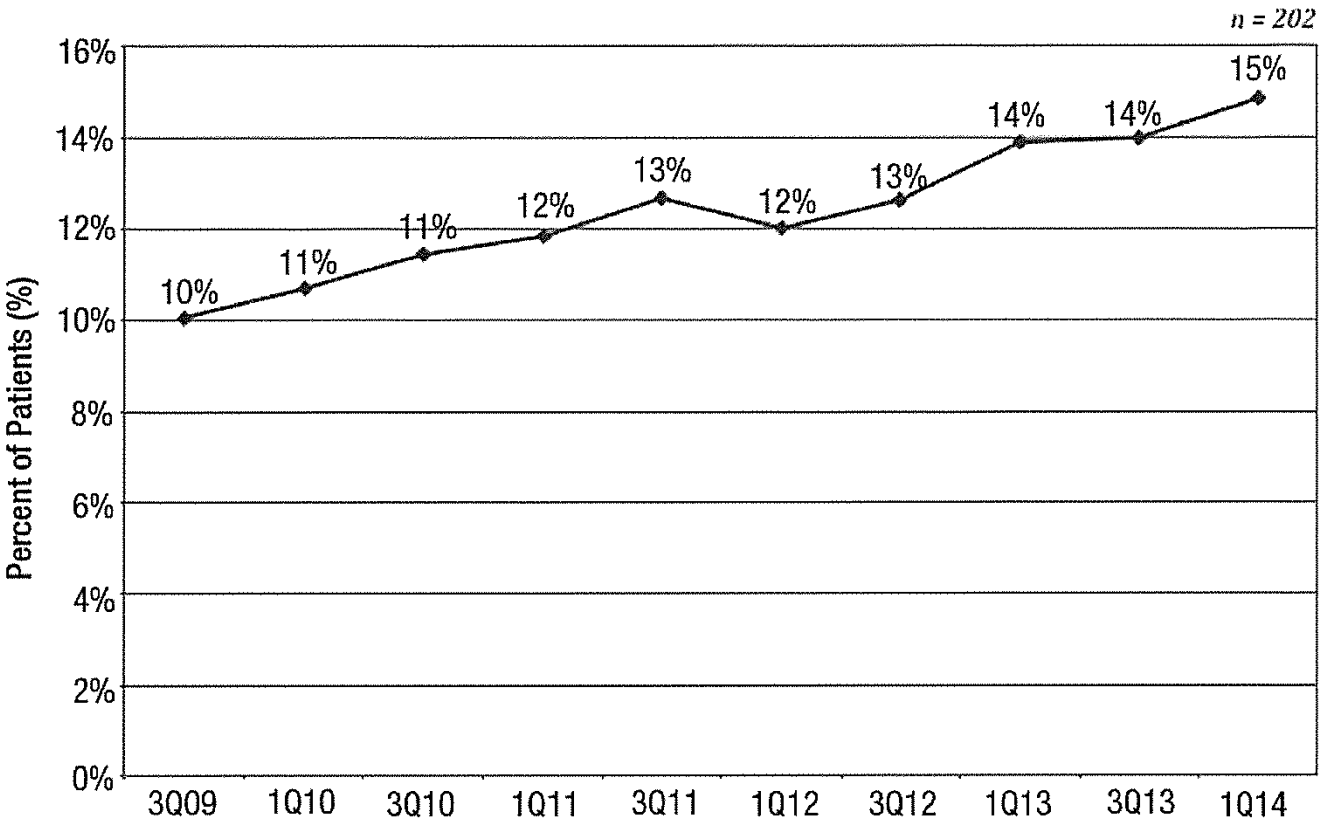
n = 202
Percent of Patients (%)
16%
14%
12%
10%
8%
6%
4%
2%
0%
10%
11%
11%
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13%
12%
13%
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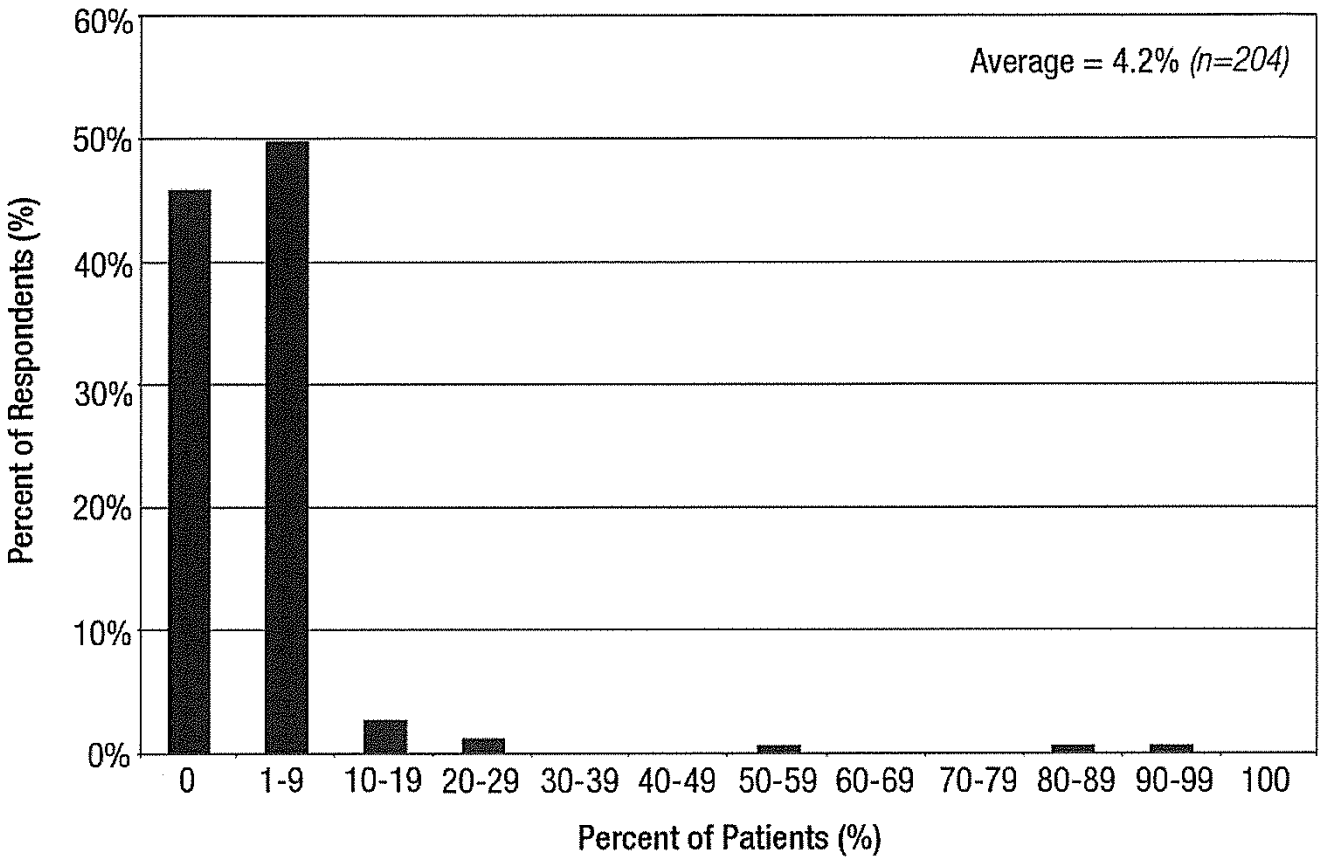
Average = 4.2% (n=204)
Percent of Respondents (%)
60%
50%
40%
30%
20%
10%
0%
0
1-9
10-19
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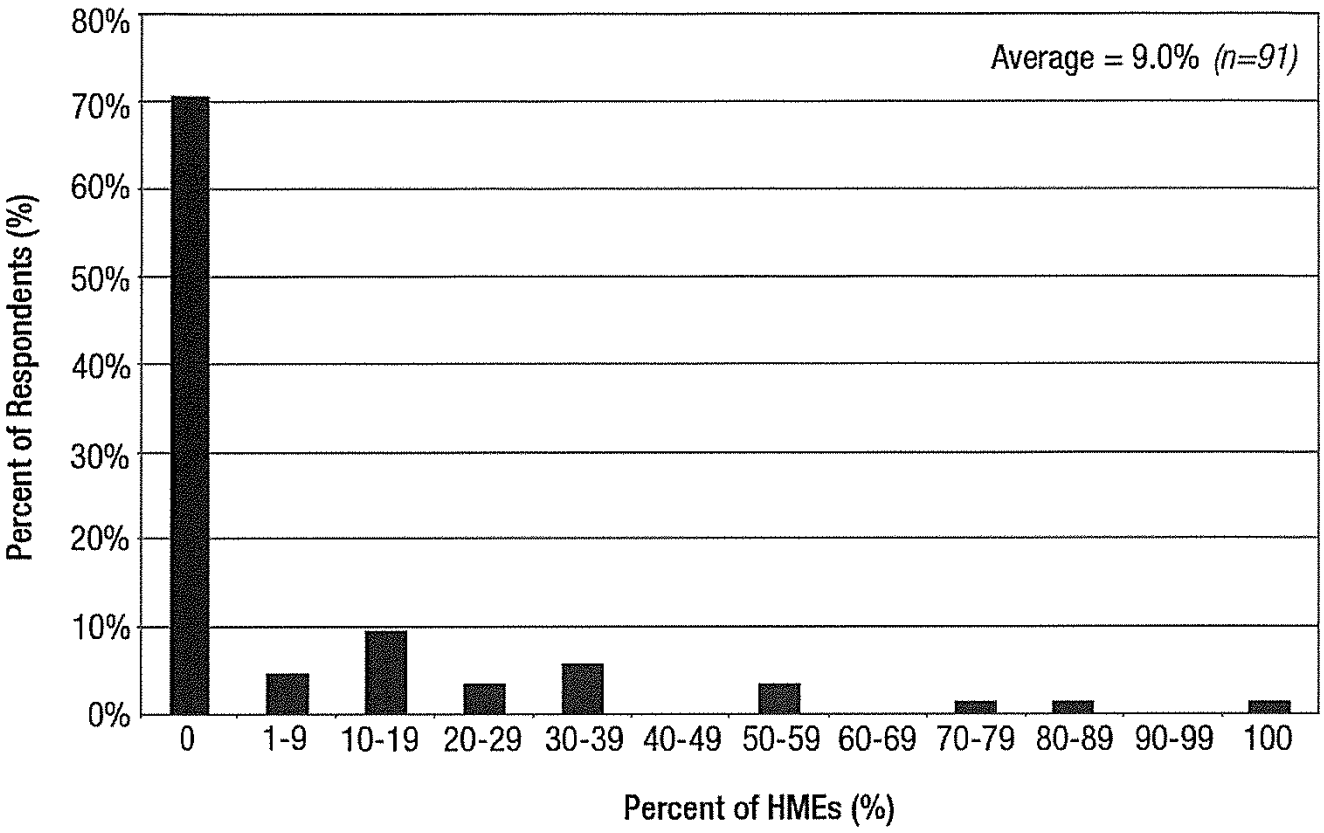
30-39
40-49
50-59
60-69
70-79
80-89
90-99
100
Percent of Patients (%)

SLP 092


Average = 9.0% (n=91)
Percent of Respondents (%)
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70%
60%
50%
40%
30%
20%
10%
0%
0
1-9
10-19
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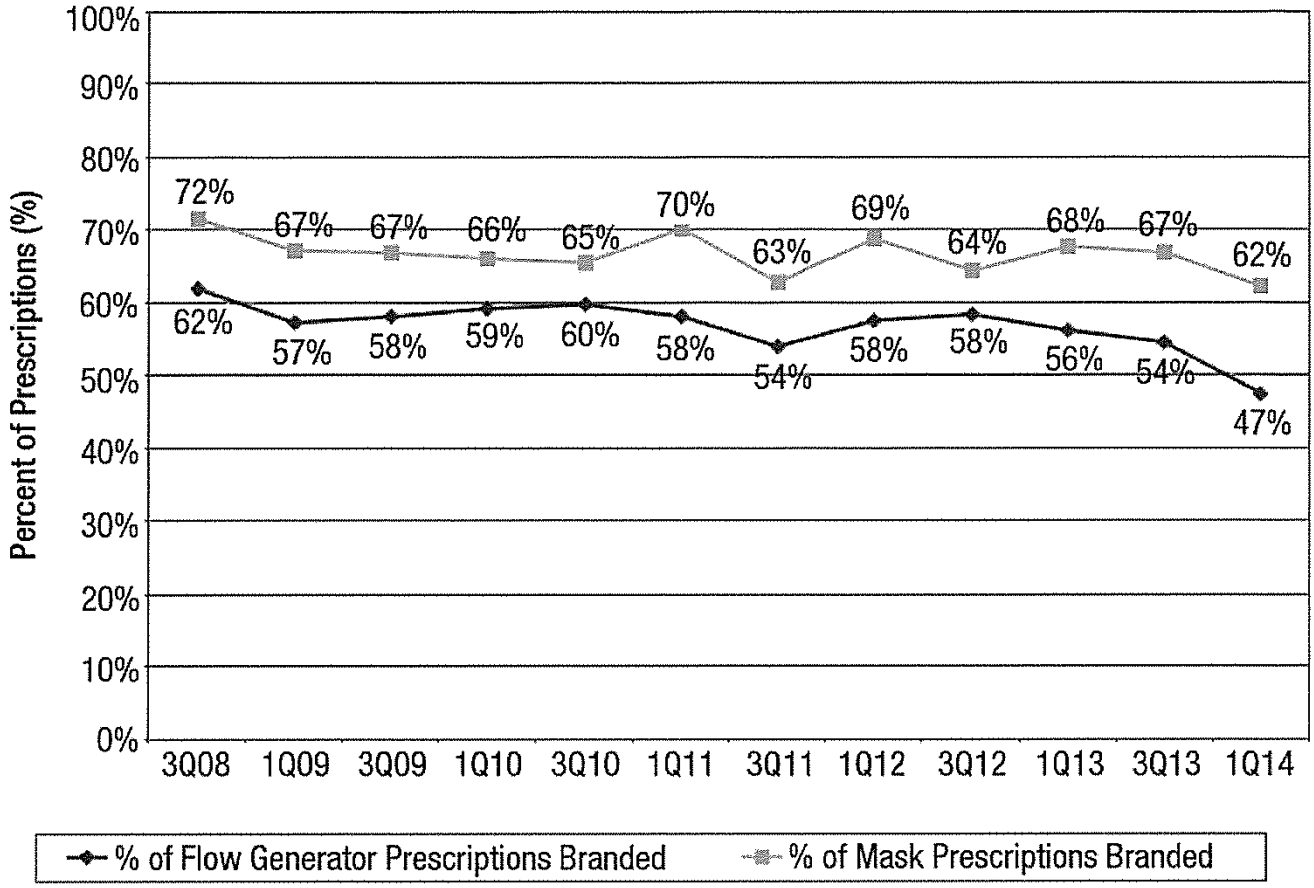
40-49
50-59
60-69
70-79
80-89
90-99
100
Percent of HMEs (%)

SLP 093

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Special Articles

The Future of Sleep Technology: Report from an American Association of Sleep Technologists Summit Meeting

http://dx.doi.org/10.5664/jcsm.3720

Rita Brooks, M.Ed.; Melinda Trimble

American Association of Sleep Technologists, Darien, IL

ABSTRACT

The American Association of Sleep Technologists (AAST) Board of Directors hosted a Sleep Technology Summit on September 21, 2013 with the goals of identifying changes in the delivery of diagnostic and treatment services to sleep disorders patients, predicting the impact on sleep technologists, identifying new roles for sleep technologists, and determining appropriate education to prepare technologists for the future. A carefully chosen panel of speakers focused on the business skills necessary to provide care cost effectively and the clinical skills that will be essential for the technologist of the future to help care for patients with sleep disorders. A group of selected leaders, educators, and industry professionals reviewed the current state of affairs and examined opportunities to sustain the profession and define the role of the sleep technologist of the future. Facilitated group discussions of these critical topics followed each session.

There was a clear consensus that regulatory and economic pressures are changing the way sleep disorders patients are diagnosed and treated. Private insurers are requiring pre-authorization for laboratory sleep studies and are incentivizing home sleep testing for most patients suspected of obstructive sleep apnea. Reimbursement for home testing will be lower than for laboratory testing, and further reductions in overall reimbursement are anticipated. These factors will almost certainly reduce the need for technologists to perform laboratory diagnostic studies and pressure sleep centers to reduce payrolls. Remaining laboratory patients will have more complicated sleep disorders, have more comorbidity, and require a higher level of care than most of the patients currently tested in sleep centers. Testing these patients will require technologists with a higher level of training, experience, and sophistication.

A second area of consensus was that the focus in medicine is changing from diagnosis to outcomes. New models of integrated care will include an increased focus on patient education, monitoring, and follow-up. The most effective treatments will require an individualized, patient-centered approach. A workforce analysis shows that the number of trained physician specialists will be inadequate to provide this care. Well-trained sleep medicine practitioners at many levels will be needed to meet treatment goals, including some roles appropriate for sleep technologists.

These factors provide challenges and opportunities for sleep technologists. In order to maintain viability as an allied health profession, the majority of sleep technologists will need to be better educated and demonstrate competency in more roles than overnight monitoring and record scoring. Models for this transition already exist, with several programs moving technologists from night work to days and from diagnosis to patient education, provision of treatment, and monitoring of adherence. The challenge for the professional association is to define new roles for sleep technologists and provide the education that the membership will require to flourish in those new roles.

meeting. *J Clin Sleep Med* 2014;10(5):589-593.

The diagnosis of sleep disorders, especially obstructive sleep apnea, is expected to increase in coming years due to increases in rates of obesity[1] and other risk factors. Despite this trend, many surveys of sleep businesses indicate a decreasing need for sleep technologists.[2] The cause of this apparent paradox is a shift from traditional laboratory testing to home sleep testing using portable monitoring devices. Home testing is now reimbursed by Medicare, and an increasing number of private payers and is recognized as an alternative for diagnosis by the National Institutes of Health.[3] Some estimates predict that as many as 70% of patients with obstructive sleep apnea could be accurately diagnosed using home portable monitoring devices.

The impact of this shift is expected to be a dramatic increase in patient throughput per technologist. Compared to American Academy of Sleep Medicine (AASM) requirements of 2 patients per technologist for laboratory testing,[4] a single technologist can prepare and record 3 or 4 times more home sleep testing patients per night. Home sleep testing devices use limited channels and many systems use computer-assisted scoring, making preparation of studies for physician interpretation less labor intensive. Both factors will reduce demand for sleep technologists.

An additional trend in medicine is a shift from diagnostic testing to "integrated care." At present, reimbursement incentivizes diagnostic testing and procedures. Regulatory and market forces are changing the focus to outcomes. An accountable-care model is developing that will shift incentives to promotion of adherence to treatment and long-term follow-up. As a result of these shifts, a reasonable prediction based on workload and reimbursement is that in the near future there will be a true integration of pre-test evaluation, diagnostic testing, provision of care, follow-up, and long-term care.

Will these trends result in a progressive shrinking of the sleep technologist workforce, or will there be new opportunities for technologists in the integrated sleep center of the future? What skills and knowledge will make a technologist a valuable member of the sleep medicine patient care team? In an effort to answer these questions, the American Association of Sleep Technologists (AAST), which represents more than 4,200 members, hosted a Sleep Technology Summit on September 21, 2013, at the national office in Darien, Illinois. Key opinion leaders were invited to speak on the fluid business environment and the clinical activities that will be essential for the technologist of the future. A group of selected leaders, educators, and industry professionals reviewed the current state of affairs and examined opportunities to sustain the profession and define the role of the sleep technologist of the future.

ECONOMIC AND REGULATORY FACTORS

Dr. Stephen Plenzler, Senior Director of Program Operations of the Sleep Management Program at Care Core National, LLC, summarized the financial pressures on the business of sleep medicine from an insurer's perspective. He noted that the demand for sleep disorders testing has increased dramatically in the past decade. Insurers will work to reduce costs by turning to less expensive diagnostic alternatives, such as home sleep testing. At the same time, insurers recognize that adequate treatment of sleep apnea is consistently reported to decrease health care expenditures and provide long-term cost savings.[5] Dr. Plenzler noted that, in comparison to other conditions, adherence with treatment of sleep apnea is considered to be low.[6] As a result, increased treatment adherence is an outcome that will be increasingly incentivized by insurers. At present, these two factors are not in balance; the majority of expense is currently for diagnosis of sleep apnea rather than treatment.

Carolyn Winter-Rosenberg, Director of Coding and Compliance for the AASM, reviewed sleep medicine in the public sphere, including coding and regulatory changes. Sleep testing faces decreasing reimbursement and will need to adapt to an increasing percentage of home sleep tests. In one scenario, maintaining the revenue stream of a typical sleep center would require a doubling of patient volume to compensate for the impact of these factors. The high volume of sleep tests being performed in sleep centers has already resulted in more frequent audits and fraud investigations. Sleep centers performing an increased volume of home sleep testing as a result of these changes will need to develop internal auditing and quality assurance programs in response. Center managers will need to keep current with changing regulations, including the anticipated change from ICD-9 to ICD-10. These changes present challenges and opportunities for sleep technologists who decide to maintain their viability in the center by moving to managerial roles.

CHANGING TREATMENT MODELS

Dr. Patrick J. Strollo, Professor of Medicine and Clinical and Translational Science and Medical Director of the University of Pittsburgh Medical Center Sleep Medicine Center and past president of the AASM, predicts that reimbursement for laboratory sleep studies will continue to decrease, and reimbursement for home sleep testing is likely to be "modest at best."[7] Like many of the speakers at the summit, Dr. Strollo also noted that the focus in medicine is shifting from procedures to outcomes. This will require that the sleep center team integrate with other medical professionals, including primary care physicians, otolaryngologists, behavioral specialists, and dentists. Technologists included in this integrated care model will require a basic understanding of medical terminology and physiology in order to participate. Dr. Strollo predicts that improved patient monitoring technology and alternative therapies will become standard treatment for sleep apnea in the future. This, too, will require increased sophistication of all members of the sleep medicine team. Finally, development of an individualized, patient-centered

and an individualized program of monitoring and intervention. The participation of a trained and educated sleep medicine workforce is anticipated. Sleep technologists will have an opportunity to advance into these roles.

ENVISIONING NEW ROLES FOR SLEEP TECHNOLOGISTS

Is there a need for highly trained technologists, and would employers be willing to pay well-trained applicants a premium? At least one employer says he is already doing so. John Mathias, President of Sleep Services of America, told the group that he is currently offering a premium for flexible, qualified technologists. Core competencies are necessary but are no longer sufficient to be competitive in the job market. Mr. Mathias is willing to pay more for technologists who are knowledgeable about all aspects of sleep medicine and can easily be cross-trained for similar allied health positions. He also values advanced knowledge of medicine and an ability to care for complex patients. He has been forced to let go of some technologists who have failed to obtain appropriate credentials or meet licensure requirements. He noted that entry-level positions are declining but envisions a favorable future for technologists who have skills that exceed the minimum.

Dr. Dennis Hwang, Co-chair Sleep Medicine at Southern California Permanente Medical Group and Medical Director of the sleep center at Kaiser Permanente Fontana Medical Center, has a perspective that is unique at present but may provide a model for future sleep centers. The Kaiser system has a large number of covered lives. They have implemented a program that includes home sleep testing and regional facilities that provide laboratory testing for complex patients. All patients receive education and follow-up care. His clinic has approximately 1,700 patient encounters per month, yet it is staffed by only two physicians. He has turned to sleep professionals to provide a variety of different services, and many of these are drawn from staff formerly devoted to performing overnight studies or from respiratory care. These higher level sleep technologists provide diagnostic services and contribute to the care of patients with insomnia, restless legs syndrome, and narcolepsy, as well as obstructive sleep apnea. Specially trained sleep professionals manage the home sleep testing program and collect PAP downloads. Qualified personnel conduct individual and group education sessions, and participate in resolving individual treatment issues. The Kaiser system is a "closed" system, allowing Dr. Hwang access to comprehensive medical data for each patient, including costs. He is able to quantify the efficacy of changes to the treatment protocol not only in terms of adherence and outcomes, but also the cost of care to the insurer. Preliminary data have demonstrated a strong return on the investment of continuing contact with the patient after initiation of treatment.

A second aspect of Dr. Hwang's presentation was recognition that the patients that are sent for laboratory testing are increasingly complex and require a higher level of expertise for an adequate study. Technologists need to respond to CPAP failures by implementing treatment with more sophisticated PAP platforms or other alternatives. Technologists must understand complicated PAP devices and the effects of changes to the settings. This requires a working knowledge of respiratory physiology and pathology. A broader and more challenging task for the sleep technologist of the future is an understanding of comorbid disorders common to sleep center patients and how these comorbidities affect the sleep study and treatment options.

Kevin Asp, President of the Alaska Sleep Clinic, Inc., spoke to the group about including the provision of durable medical equipment, such as PAP machines and consumables, as an integral part of the sleep center of the future. Regulatory issues, primarily with Medicare, have caused many centers to shy away from this aspect of sleep medicine. He argued that therapeutic issues are best resolved by competent sleep center staff. New technologies allow for accurate real time monitoring of patient adherence to treatment, which facilitates rapid intervention in patients who need it. In addition, internet, and cell phone communication with patients can provide timely intervention and support to improve patient adherence to treatment, reminders for replacement of disposables, and improve customer service. Mr. Asp feels that continuity of care will be a focus in the future, and well-trained sleep technologists who are adept at using new technologies will be at the center of that care.

OPTIONS FOR THE FIELD OF SLEEP TECHNOLOGY

A clear consensus at the conference was that maintaining the *status quo* is not a viable option. The technologist whose skill set begins and ends with performance of an adequate overnight sleep study will not be able to compete in the job market of the near future. Two options emerged from the presentations and discussion: broaden the skill set of the sleep technologist to include other allied health care tasks such as EEG, respiratory care, or ECG technology, or encourage technologists to become proficient in all aspects of sleep disorders care and become a valuable member of an integrated sleep care model. The first option is only possible in centers that offer a variety of diagnostic services, such as a hospital-based facility. Technologists following this pathway will need to seek training from allied health education programs. For those seeking to expand their skills in sleep medicine, few educational opportunities exist currently.

Integrated sleep medicine care includes pre-test evaluation, diagnostic testing, provision of care, follow-up, and long-term care. Today the typical sleep technologist focuses almost entirely on the diagnostic testing portion of this process. The future will almost certainly provide a more balanced approach to the care of patients with sleep disorders. Table 1 provides a list of potential roles for technologists in each of these areas. A common career pathway for sleep technologists has been to work nights for several years, become proficient in scoring, and then move to a day shift role. Some technologists progress into management roles and take a more diverse position in the sleep center. This diverse position will, in the estimation of many summit participants, become the entry point for many technologists in the future. The tasks are both technical and cognitive. Technologists will need to collect pre-test evaluation data, learn to monitor more complicated parameters during sleep studies, and become facile with data

Table 1

New opportunities and educational needs for sleep technologists

(more ...)

NEED FOR ADVANCED EDUCATION

Auburne Overton, President of the Board of Directors of the Committee on Accreditation of Polysomnographic Technologist Education (CoA PSG), argued that a higher level of education for all technologists is essential. Currently, most CoA PSG programs provide a certificate, with some providing an associate's degree. There was a consensus among the participants that the educational entry level for sleep technologists needs to move to an associate's degree level in the near future. There is also now growing support for a requirement that entry-level sleep technologists hold a bachelor's degree. In a recent survey of educators, 83% of responders endorsed "agree" or "strongly agree" for the statement, "Education requirements for sleep technologists will increase in the next 5-10 years."[8] In addition, 83% endorsed, "An advanced educational degree in sleep technology will increase professional competence." In order to expand the educational opportunities available for new and current sleep technologists, there is a great demand for the development of more Associate Degree programs at institutes of higher education nationwide. The CoA PSG is dedicated to assisting sleep technologists when speaking to the administration of their local colleges about developing those programs, as well as assuring that those programs provide the quality and content necessary for the future of sleep medicine through participating in the program accreditation process.

Cindra Altman, President of the Board of Registered Polysomnographic Technologists, concurred with a corresponding need to increase educational requirements for eligibility for registration examinations. There was support at the conference for a joint committee of all stakeholders to begin work on a plan of action that would require professional level training of sleep technologists to meet the needs of physicians, employers, and educators.

Summit participants also agreed on the need to offer practicing technologists an opportunity to build on their knowledge and experience to prepare for changing roles. This effort might include workshops, conferences, and continuing education programs that focus on several key areas:

1. **Core competencies** including medical terminology, basics of physiology, and pathophysiology of sleep disorders. The technologist of the future will need to interact on a professional level with physicians, other healthcare professionals and patients. Evidence-based research skills and written and oral communication skills will be essential in developing professionals prepared for interdisciplinary healthcare. Medical literacy, including an ability to explain complex medical issues to patients, will be part of the required skill set.
2. **Disease management** including pulmonary and cardiovascular comorbidities, endocrine disorders and obesity, and management of pediatric and elderly patients. Many sleep patients will follow critical pathways that include home sleep testing and PAP titration. Patients requiring laboratory testing will be complex, with multiple comorbidities or treatment failures. The sleep technologist will need to recognize and react to difficult situations and provide care that is more sophisticated than simple continuous PAP.
3. **Patient education** including individual and group sessions, self-directed care and motivational enhancement. As the focus in medicine shifts from diagnosis to adherence, technologists will need to become competent in health psychology methods. These methods have established efficacy and have been learned by a variety of health care professionals during relatively brief training sessions.
4. **Sleep center management** including billing and coding, quality assurance, and interaction with insurers. A technologist can bring valuable patient care experience to management positions. Acquiring skills in budgeting and development of business proposals will be important in this transition. Technologists will need to be trained to manage and motivate center personnel.

To this point, technologists who have developed expertise in these areas have relied, for the most part, on on-the-job training. Few training programs for sleep technologists currently offer an associate's degree, let alone a bachelor's degree. The key areas listed above may provide a road map for the development of higher education in sleep technology. As an intermediate step, the AAST and other stakeholders can fill the gap by broadening educational offerings. Rather than focus on electrode application and sleep study scoring, programs should focus on patient evaluation and long-term care. Diverse courses, seminars, workshops, and remote learning opportunities can focus on individual aspects of integrated sleep care; educational materials from these programs can provide the basis for a comprehensive curriculum.

CONFERENCE CONSENSUS

The AAST Board of Directors convened the Future of Sleep Technology Summit to explore the forces spurring change and provide participants with diverse views of the future of sleep medicine. There was a broad consensus that the technologist of the future will need a higher level of education and skills to provide value to potential employers and be competitive in the job market. As a result of the Summit, the AAST Board has a better understanding of the market forces and probable future of sleep

technology. The Board hopes to serve its members by exploring new opportunities for education to help sleep technologists grow and adapt to new roles and realities.

DISCLOSURE STATEMENT

This was not an industry supported study. The authors have indicated no financial conflicts of interest.

ACKNOWLEDGMENTS

The authors appreciate the careful reading and helpful suggestions of Dr. Timothy Morgenthaler (President-elect, American Academy of Sleep Medicine), Ms. Auburne Overton (President of the Board of Directors of the Committee on Accreditation of Polysomnographic Technologist Education) and Ms. Cindra Altman (President of the Board of Registered Polysomnographic Technologists). Richard S. Rosenberg, PhD, provided editorial assistance in the development of this manuscript. Rita Brooks' professional credentials are RST, RPSGT and REEG/EPT. Melinda Trimble's professional credentials are RST, RPSGT and LRCP.

SUMMIT PARTICIPANTS

AAST Board of Directors:

Rita Brooks, MEd, RST, RPSGT, R.EEG/EPT - President
David Gregory, RST, RPSGT - Secretary
Cynthia Mattice, MS, RST, RPSGT - Treasurer
Marietta Bibbs, BA, RPSGT
Allen Boone, RPSGT, RST, CCRC
Joanne Hebding, RPSGT, CRTT
Laura Linley, RST, RPSGT, CRTT
Elise Maher, RPSGT
Bill Rivers, RPFT, RST, RPSGT

Speakers:

Kevin Asp, RPSGT, CRT
Dennis Hwang, MD
John Mathias, II
Steven Plenzler, PhD, D.ABSM
Patrick Strollo Jr., MD, FCCP, FAASM
Carolyn Winter-Rosenberg

Participants:

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Gail Demko, DMD
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Jane Perri, PhD, RPSGT
Beth Richey
Richard Rosenberg, PhD
Chad Whittlef, RPSGT
Harry Whitmore, RST, RPSGT
Rosa Woodrum, RRT

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Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Monday, September 12, 2016 2:38 PM
To: 'David S. Hardy'; User, OHCA
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie; 'dstromstad@wtbyhosp.org'
Subject: RE: Completeness Questions: 16-32113-CON

Hi Dave,
We have received your responses and will begin to review them shortly. Thank you much.

From: David S. Hardy [mailto:DHardy@carmodylaw.com]
Sent: Monday, September 12, 2016 1:59 PM
To: Schaeffer-Helmecki, Jessica; User, OHCA
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie; 'dstromstad@wtbyhosp.org'
Subject: RE: Completeness Questions: 16-32113-CON

Jessica,
Attached are the responses to the completeness letter in Docket Number 16-32113-CON (Southbury Sleep Lab) in PDF and Word formats. Please let me know if you have any questions. Thank you very much.
Dave

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From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Thursday, August 25, 2016 9:03 AM
To: 'dstromstad@wtbyhosp.org'; David S. Hardy
Cc: Michelle Volpe Esq. (mmv@bvmlaw.com); Riggott, Kaila; Greer, Leslie
Subject: Completeness Questions: 15-32113-CON

Good morning Ms. Stromstad and Mr. Hardy:

Attached please find a pdf and word version of completeness questions regarding your Certificate of Need application for the termination of Waterbury Hospital's sleep lab services at its Southbury site (docket number 15-32113-CON).

Please confirm receipt of this e-mail and feel free to contact me if you have any questions.

Jessica

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134

P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

HTML

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

October 6, 2016

Via Email Only

Ms. Darlene Stromstad
President & CEO, The Waterbury Hospital
64 Robbins Street
Waterbury, CT 06708
dstromstad@wtbyhosp.org

RE: Certificate of Need Application; Docket Number: 16-32113-CON
The Waterbury Hospital's Application to Terminate Sleep Lab Services in Southbury, CT

Dear Ms. Stromstad:

This letter is to inform you that, pursuant to Section 19a-639a (d) of the Connecticut General Statutes, the Office of Health Care Access has deemed the above-referenced application complete as of October 6, 2016.

If you have any questions concerning this letter, please feel free to contact me at (860) 509-8075.

Sincerely,

J Schaeffer-Helmecki

Jessica Schaeffer-Helmecki
Planning Analyst

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From: Schaeffer-Helmecki, Jessica
Sent: Friday, October 07, 2016 9:00 AM
To: 'dstromstad@wtbyhosp.org'
Cc: Riggott, Kaila; User, OHCA; Greer, Leslie
Subject: Deemed Complete: Application 16-32113-CON
Attachments: 16-32113-CON Notification of Application Deemed Complete.pdf

Dear Ms. Stromstad,

The attached letter is to notify you that The Waterbury Hospital's application to terminate its Southbury sleep lab (docket number 16-32113-CON) has been deemed complete. If you have any questions please do not hesitate to contact me.

Thank you,

Jessica

Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
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