Polysomnography & Sleep Medicine

A Jurisdictional Scan

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Contents

EXECUTIVE SUMMARY 4

INTRODUCTION 8

THIS REPORT 8

RESEARCH QUESTIONS 8

METHODOLOGY 9

STRUCTURE OF THE REPORT 10

PART 1: CANADIAN JURISDICTIONS 11

1. Public Coverage and Rates 12
2. Role of Private Clinics in Service Delivery 16
3. Ordering Sleep Tests 20
4. Accreditation 24
5. Service Planning and Capacity 28
6. Measuring Wait Times 34
7. CPAP Funding and Regulation 39

KEY FINDINGS: CANADIAN JURISDICTIONS 44

PART 2: INTERNATIONAL JURISDICTIONS 47

USA – MEDICARE 48

COMMONWEALTH GOVERNMENT OF AUSTRALIA 58

NHS ENGLAND 68

KEY FINDINGS: INTERNATIONAL JURISDICTIONS 83

WORKS CITED 85

Executive Summary

BACKGROUND

The Surgical and Diagnostic Services Branch (SDSB) of the BC Ministry of Health engaged InsideOut Policy Research to conduct a jurisdictional scan of sleep testing provision in selected Canadian and international jurisdictions.

Canadian jurisdictions examined were: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, and Nova Scotia. International jurisdictions studied were: NHS England, the Commonwealth Government of Australia, and the United States (Medicare Program).

METHODOLOGY

The SDSB developed a questionnaire that included a range of questions on policy, payment, and the regulatory environment related to the provision of Level I and Level III sleep testing.

Subject Matter Experts (SMEs) were engaged for all of the Canadian provinces in scope, with the exception of Québec and Nova Scotia. The SMEs completed the questionnaire and participated in a follow-up telephone discussion with researchers and SDSB representatives. Information for Québec and Nova Scotia was sourced from publicly-available materials. Likewise, information on sleep testing provision in the international jurisdictions was gathered from public documents.

CANADIAN JURISDICTIONS: KEY FINDINGS

Public Coverage and Rates

All Canadian jurisdictions examined publicly cover Level I sleep testing when the test is performed in a public facility or in a provincially-approved sleep centre.

With respect to Level III testing, Ontario appears to be unique in not providing public coverage.

Jurisdictions differ with respect to billing models. In some provinces, testing is covered through fee-for-service, and in others it is covered through the global budget.

Role of Private Clinics in Service Delivery

Alberta is unique in having private (patient-pay) provision of Level I sleep testing. Patient-pay through private sleep clinics is considered an essential component of access to sleep medicine in the province.

Private sleep clinics that offer Level III testing are operating in all of the Canadian jurisdictions examined. In many cases, these tests are performed free of charge under the assumption that a proportion of patients will purchase CPAP equipment or other sleep medicine supplies from the clinic.

BC and Ontario are distinct in accrediting (BC) or licensing (Ontario) privately-owned facilities to bill the provincial public healthcare plan for the provision of Level I sleep tests.

In BC, private sleep clinics that are accredited and have received provincial approval may also bill the public plan for Level III sleep testing. BC is the only province where patients may access publicly-funded Level III testing in privately-owned facilities.

Accreditation

In the provinces examined, all public facilities providing Level I sleep testing are subject to accreditation.

However, private sleep clinics (that are not approved to bill a provincial public healthcare plan) are generally unregulated and unaccredited. SMEs recognized that this is an area of concern that requires attention.

To date, Alberta is the only province to have developed and implemented a mandatory accreditation process for all public and private, Level I and Level III sleep study facilities. This initiative, which is in its early stages, pertains only to diagnosis of sleep disorders.

Service Planning and Capacity

The number of publicly-funded sleep testing facilities (and beds) in relation to the population varies considerably from one province to another. For instance, Ontario has more than ten times the number of publicly-funded beds (roughly 690) compared to BC (71), even though its population is only three times higher.

Ontario and BC have formal approval processes in place for sleep medicine facilities. Ontario also has a methodology for determining the appropriate number of sleep study facilities in a specific geographical area; BC's primary assessment criterion is the 'reasonable utilization of existing facilities'.

Measuring Wait Times

While some of the Canadian jurisdictions examined are taking steps towards tracking, monitoring, and reporting wait times for sleep studies (and other diagnostic tests), this work is emergent. Where benchmarks exist, few (if any) jurisdictions are meeting them.

CPAP Funding

Half of the Canadian jurisdictions reviewed (Saskatchewan, Manitoba, and Ontario) cover some portion of the cost of CPAP equipment for patients.

When the same sleep facility provides diagnosis of sleep disorders and also sells therapeutic equipment, a conflict of interests arises. SMEs recognized this conflict of interest, but only Ontario appears to have gone some way to addressing it (i.e. through the policies guiding its coverage of CPAP equipment).

CANADIAN JURISDICTIONS: NOTABLE ISSUES

Public Benefit and Private Provision

When a province publicly covers a medical service i.e. deems it a 'benefit', it is recognized that the service is medically necessary. This, in principle, should prohibit private patient-pay provision of the same service.

All Canadian provinces examined for this scan have a thriving private home sleep apnea sector offering Level III sleep testing.

To avoid contravening the Canada Health Act, while still generating revenue, many private sleep clinics offer patients a 'complimentary' Level III test, on the basis that they will sell CPAP equipment and supplies to some proportion of patients. In some provinces that publicly cover Level III sleep tests, private sleep clinics may be charging patients for the test.

Conflict of Interest

In all Canadian jurisdictions examined there are private sleep testing facilities that both diagnose OSA and directly sell CPAP equipment. This creates a conflict of interest, in that the relationship between the practitioner and the patient may be compromised by commercial interests.

While many SMEs acknowledged this conflict, only Ontario has taken specific steps to address it.

Regulation of Private Sleep Clinics

Among the Canadian jurisdictions studied, Alberta is unique in having established a mandatory accreditation process for all public and private sleep testing facilities. This accreditation process applies only to diagnostic testing and not to clinical decision making and treatment.

Alberta's experience with developing and implementing mandatory accreditation offers a number of important "lessons-learned." There is an opportunity for BC to benefit from Alberta's experience by further engaging with the relevant Alberta SMEs.

INTERNATIONAL JURISDICTIONS: SUMMARY OF KEY FINDINGS

The scan of selected international jurisdictions (NHS England, Australia, and U.S. – Medicare) identified a number of effective practices that may inform and enhance the provision of sleep testing in BC going forward. Particular strengths of provision in these jurisdictions include:

- **Service Planning and Capacity:** In England, the British Lung Foundation has produced a *Toolkit* for commissioning and planning services for the diagnosis and treatment of obstructive sleep apnea. The *Toolkit*, which is comprehensive and robust, is designed to help audit existing services, understand local needs, and plan future provision.
- **Authorization to Order Sleep Tests:** In the interest of system efficiency and equity of access, Australia and NHS England have models in place that allow GPs to directly refer patients for sleep studies without assessment by a sleep or respiratory physician. In Australia this includes Level I and Level III (equivalent) sleep testing; In NHS England, it is confined to home sleep testing (Level III equivalent).
- **Measuring and Reducing Wait Times:** NHS England has a guaranteed maximum waiting time for sleep testing of 6 weeks from referral. NHS England is the only jurisdiction among all those examined (Canadian and international) to have a robust system in place to track, analyze, and report out on diagnostic wait time data, and to use wait time indicators to monitor and drive service efficiency.
- **CPAP Funding:** US Medicare and NHS England provide much more comprehensive CPAP funding than most of the Canadian provinces examined for this report. For instance, Medicare pays 80% of the Medicare-approved amount for the rental of a CPAP machine and purchase of related supplies, and in England, provision and maintenance of a standard CPAP machine is fully covered by the NHS. Of note, studies conducted in the UK indicate that public coverage of CPAP therapy is cost effective.
- **Home Sleep Testing as the New Gold Standard?** NHS England is promoting multi-channel home sleep testing as the new gold standard for diagnosing obstructive sleep apnea. This is based on research evidence indicating that polysomnography is required only for complex cases. Since 2017/2018, the NHS England *Tariff* has set the same rate for multi-channel sleep studies and polysomnography, potentially to encourage practitioners towards ordering a home test as the standard procedure.

Introduction

THIS REPORT

This report, commissioned by the BC Ministry of Health (Surgical and Diagnostic Services Branch), documents the findings of a jurisdictional scan on the topic of polysomnography and related sleep medicine studies. The scan was guided by a series of questions on a range of topics associated with the provision of sleep testing, including: public/private coverage; compensation; policy; service delivery; and regulation.

The following jurisdictions were included in the scan:

- In Canada – the provinces of British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, and Nova Scotia; and
- Internationally – NHS England; the Commonwealth Government of Australia; and the United States (Medicare Program).

RESEARCH QUESTIONS

The research questions were developed by the Ministry of Health and presented in the form of a questionnaire. The following questions were included:

Does the jurisdiction:

- Cover/publicly insure sleep studies, and if so at what rate?
- Differentiate between publicly-owned and privately-owned facilities in terms of where a sleep study may be performed and/or where it must be performed to qualify for public coverage?
- Allow patient-pay sleep testing?
- Use a priority wait time system and/or wait time benchmarks?
- Use any framework or guiding principles concerning the number of sleep study facilities in the jurisdiction and/or their location?
- Allow the operation of stand-alone, Level III home sleep testing facilities?
- Allow sleep testing facilities to also sell CPAP machines or other sleep-related treatment devices?

In the jurisdiction:

- Who is authorized to order sleep testing?
- Are sleep clinics subject to regulation/accreditation?
- Do sleep clinics require any formal approval in order to open/operate?
- How is the need for sleep testing facilities identified?

- What is the (estimated) number of sleep study facilities?

METHODOLOGY

For the Canadian jurisdictions, the Ministry engaged the intergovernmental relations (IGR) team to identify appropriate Subject Matter Experts (SMEs) in each of the selected provinces. The SMEs were asked to complete the questionnaire and participate in a follow-up telephone interview to discuss key elements of the jurisdiction's approach to sleep medicine. SMEs from the provinces of Alberta, Saskatchewan, Manitoba, and Ontario completed the questionnaire and engaged in a follow-up telephone call with the InsideOut team and BC Ministry of Health representatives.

The IGR team was unable to establish contact with suitable SMEs for the provinces of Québec or Nova Scotia. For these jurisdictions, the InsideOut team completed the questionnaire using publicly-available information (with some information gaps).

For the international jurisdictions (NHS England, the Commonwealth Government of Australia, and the United States), the InsideOut team also relied on publicly-available information to complete the questionnaire. The types of documents and resources reviewed for the international jurisdictions (and the provinces of Québec and Nova Scotia) included:

- Medical fee schedules;
- Policies, standards, and guidelines;
- Health services clinic websites (public and private);
- Overviews / outlines of insurance programs, coverage strategies; and
- Government reports and reviews.

Note on the focus of the U.S. scan:

Due to the complexity of the U.S. healthcare and medical insurance system, as well as the significant degree of variability across the individual states with respect to sleep testing policy, levels of coverage, costs, payment options, and regulation, it was not viable to produce a general synthesis of the United States' approach to sleep testing based on publicly-available information. It was, therefore, determined that this report would focus specifically on the federally-sponsored "Medicare" benefits program, which offers the closest equivalent to the Canadian healthcare system, and which includes varying levels of sleep testing coverage for its program participants.

Research Scope

The original scope of the jurisdictional scan included Levels I, II, III, and IV sleep testing. However, early on in the research process, it was observed that most of the jurisdictions selected do *not* currently offer Level II or Level IV sleep testing, and there was limited information from publicly-available sources on either type of test. Consequently, the InsideOut team (in agreement with the Ministry of Health client) determined that the final report would focus

primarily on Level I and Level III sleep studies.[1]

STRUCTURE OF THE REPORT

The report is organized into two sections:

- Part 1 provides detailed findings for the seven Canadian jurisdictions examined, organized according to topic areas that reflect the foci of the original survey. Notable issues and themes across the Canadian jurisdictions are also identified.
- Part 2 presents detailed findings for the three international jurisdictions examined. These findings are presented as individual jurisdictional snapshots. The order in which information is presented follows the original survey. Key findings for the international jurisdictional are also provided.

Definition of "Patient Pay"

In this report, the term "patient pay" is used in connection with privately-owned, unregulated / unaccredited, Level III sleep testing facilities, which may charge patients for a test, but which more commonly provide testing at no charge and then generate revenue by selling CPAP equipment to a proportion of patients tested.

Sleep Testing Definitions:

Level 1: Overnight Polysomnography in a monitored setting with the technologist supervising the patient during the night, a complete set of biological signals is acquired including EEG recordings, EOG, EMG, oxygen saturation, thoracic effort, abdominal effort, body position and leg twitches. Assessment of sleep itself is derived from examining the brainwaves

Level III: 3 to 14 multichannel home sleep testing. Measures respiratory airflow through the nose and mouth while patients are sleep. Also measures oxygen saturation and respiratory effort.

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[1] Note: SMEs from Alberta reported that there is currently one private provider interested in offering Level II sleep studies, but provision has not yet begun. The SME also noted that they were not "convinced" by Level II testing, and they saw "no real need for it" in the public context.

PART 1:
CANADIAN JURISDICTIONS

1. Public Coverage & Rates
2. Role of Private Clinics in Service Delivery
3. Patient Pay
4. Ordering Sleep Tests
5. Accreditation
6. Service Planning & Capacity
7. Measuring Wait Times
8. CPAP Funding & Regulation

1. Public Coverage and Rates

Key Points

- All Canadian jurisdictions examined publicly cover Level I sleep testing, and all but Ontario cover Level III testing.
- Jurisdictions differ with respect to billing models – i.e. in some cases professional fees are funded through the global budget, and in other cases they are funded through fee-for-service.
- The majority of jurisdictions – with the exception of BC and Ontario – do not have a "technical fee" for Level I and III testing.
- In all jurisdictions, public coverage for both Level I and Level III sleep testing is restricted to studies performed in a public facility or in a privately-owned, provincially-approved sleep centre.

Table 1. Public coverage and associated rates for Levels I and III sleep studies

Note: GB = Global Budget; and FFS = Fee-for-Service. These are indicated when the information was available.

Public Coverage & Rates for Sleep Testing							
Level & Rates	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Level I – Public Coverage	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Professional Fee	$167.40	$100.00 *(GB)*	$298.30/ $268.40*	*Not specified (FFS)*	$97.50 *(GB)*	*n/a*	*n/a*
Technical Fee	$387.02	*n/a*	*n/a*	*Not specified (GB)*	$370.75 *(FFS)*	*n/a*	*n/a*
Total Fee	$544.42	$100.00	$298.30/ $268.40*	$216.50	$468.25	$105.55	$148.80
Level III – Public Coverage	Yes	Yes	Yes	Yes	No	*Not specified*	Yes
Professional Fee	$83.61	$30.00 *(GB)*	$55.70/ $50.20*	$142.40 *(FFS)*	*n/a*	*n/a*	*n/a*
Technical Fee	$83.86	*n/a*	*n/a*	*Not specified (GB)*	*n/a*	*n/a*	*n/a*
Total Fee	$167.47	$30.00	$55.70/ $50.20*	$142.40	*n/a*	*Not specified*	$62.00

** The Saskatchewan SMEs provided two different fee rates – one for "referred / sleep specialist" testing and the other for "not referred / GP" testing. (See jurisdictional highlights below.)*

Public Coverage and Rates: Jurisdictional Highlights

British Columbia

BC provides public funding for sleep testing Levels I, III, and IV, as long as the facilities are accredited and approved to bill the Medical Services Plan.

Alberta

Alberta does not currently have fee-for-service billing codes for sleep studies.

Public hospital-based facilities offer Level I and Level III sleep testing funded from their global budget for sleep services. There is an internal negotiated rate for Level I and Level III interpretation:

- Level I – approximately $100.00 for interpretation (no technical fee);
- Level III – approximately $30.00 for interpretation (no technical fee).

These rates have remained the same for a considerable period of time.

Consultation with a sleep specialist (to determine whether a Level I test is required) is publicly covered regardless of whether the consultation is with a specialist at a public hospital-based facility or with a specialist in a private sleep clinic.

Ontario

Currently, Ontario only publicly covers Level I sleep testing. The fees are the same for public hospitals and Independent Health Facilities (IHFs).

Level III testing is not publicly covered.

In public hospitals, the technical fee for a Level I sleep study comes from the global budget, and the professional fee is charged as a fee-for-service payment. Within Independent Health Facilities (IHFs), both the technical and professional fees are billed as fee-for-service payments (the former claimed by the IHF and the latter by the physician).

Manitoba

Manitoba publicly covers Level I and Level III sleep studies for all provincial residents. The interpretation/professional fee is covered through fee-for-service, and the technical fee is covered through the hospital global budget.

Saskatchewan

The province of Saskatchewan publicly covers Level I and Level III sleep studies, provided that the tests are conducted at one of the two public regional sleep testing facilities (in Saskatoon and Regina).

Services occurring within a provincially-designated sleep laboratory are not eligible for technical fees.

The table below (provided by the SME) details the current fee structure (presumably reflecting professional fees).

Table 2. Billing codes for Level I and Level III sleep studies in Saskatchewan

Code	Description	Referred/ Specialist	Not referred/ GP
Codes 281D to 291D are limited to physicians with regional health authority sleep lab privileges			
281D	Diagnostic (includes visit)	$298.30	$268.40
284D	Portable sleep study	$55.70	$50.20

Québec

In Québec, the relevant billing codes are presented as a single fee (rather than "technical" or "professional" fees). The publicly-available information does not indicate whether the fees are covered through a global budget or fee-for-service model.

The Québec Billing Schedule presents (what appear to be) baseline fees for sleep testing, determined by the number of hours required to complete the test (e.g. 2-4 hours, 4-8 hours, or 8+ hours). The Schedule also lists the billing codes and fees for a number of "supplementary" tests that presumably may be added-on to the baseline test (e.g. additional EMG or EEG monitoring).

Table 3. Québec Billing Schedule billing codes and fees for sleep testing

Insurance Coverage by Type of Test		
Billing Code	**Type of Test**	**Total Fee**
08472	Cardio-Pulmonary Sleep Study (Polysomnography)	$105.55
08489	Oximetry Testing	$26.40
08473	Test (2-4 hours)	$101.20
08474	Test (4-8 hours)	$158.35
08475	Test (8+ hours)	$158.35

Insurance Coverage by Type of Test		
08483	EEG Supplement	$63.35
08495	EMG Supplement	$31.65
08452	Additional Monitoring	$42.20
08494	OSLER Vigilance Test	$31.65
08490	Sleep Latency Test	$95.00
08491	Awake Test	$95.00

Nova Scotia

In Nova Scotia, Level I and Level III sleep studies are covered by the public plan.[2] The Health Service Codes for sleep testing are not divided into "professional" and "technical" fees. Instead, each service is assigned a certain number of Medical Service Units (MSUs), which represent the total fee for service. As of April 1, 2018, each MSU is valued at $2.48.[3]

Table 4. Fee Schedule (based on MSU system) in Nova Scotia

Insurance Coverage by Type of Test				
Level of Test	**Professional Fee**	**Technical Fee**	**Base Units (1 MSU = $2.48)**	**Total Fee**
Level I	*n/a*	*n/a*	60 MSU	$148.80
Level III	*n/a*	*n/a*	25 MSU	$62.00

[2] Nova Scotia, Medical Services Insurance (MSI) Program. (May 2016). "MSI Physician's Bulletin," p. 4.
[3] Ibid., p. 1.

2. Role of Private Clinics in Service Delivery

Key Points

- Stand-alone Level III Home Sleep Apneal Testing (HSAT) facilities exist in all Canadian provinces examined. These privately-owned clinics generally provide Level III testing free of charge to the patient, under the assumption that some portion will later purchase CPAP equipment or other sleep medicine supplies. This business model allows private companies to avoid violating the Canada Health Act in jurisdictions where Level III testing is recognized as a publicly-insured benefit.
- In Ontario and BC, approved/accredited privately-owned sleep clinics may bill the public plan (Level I in Ontario; Level I and III in BC.
- In Alberta, the private sector offers both Level I and Level III patient-pay testing services. Alberta is unique among the Canadian provinces examined in having private patient-pay provision of Level I sleep studies. Patient-pay through private sleep clinics is considered an essential component of access to sleep medicine in the province, as there is relatively little public coverage.
- Ontario appears to be unique in offering a patient-pay option in the public system for Level I testing that exceeds what is covered by the public healthcare plan (OHIP).

Table 5. Privately-owned, publicly-funded provision of sleep testing

Privately-Owned, Publicly-Funded Sleep Testing							
Level I	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Privately-owned, publicly-funded	Yes *(accredited facilities only)*	No	No	No	Yes *(licensed IHFs only)*	No	No
Level III	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Privately-owned, publicly-funded	Yes *(accredited facilities only)*	No	No	No	No	No	*Not specified*

*Table 6. Privately-owned, **not** publicly-funded provision of sleep testing*

Privately-Owned, **Not** Publicly-Funded Sleep Testing							
Level I	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Privately-owned, NOT publicly-funded	No	Yes	No	No	No	No	No
Fee to patient	*n/a*	$500-$1000	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*
Level III	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Privately-owned, NOT publicly-funded	Yes *(unaccredited facilities)*	Yes	Yes	Yes	Yes	Yes	Yes
Fee to patient	$0*	$0-$250	$0*	$195	$0-$250	$395	$0*

** Many private clinics provide testing for free on the assumption that they will sell CPAP equipment to some proportion of patients.*

Role of Private Clinics: Jurisdictional Highlights

British Columbia

In BC, only those facilities that have received provincial approval and are accredited through the College of Physicians and Surgeons of BC may bill the Medical Services Plan (MSP). There is currently a mixture of publicly-owned and privately-owned facilities that are approved to bill the MSP. There are also a number of private, unaccredited Level III HSAT companies that operate beyond the auspices of the Ministry.

Patient-pay is prohibited in all MSP-approved facilities in BC. However, patient-pay is available in privately-owned facilities that are not regulated or accredited. These facilities do not typically charge a fee for a Level III test; their business model relies on selling CPAP therapy to some portion of their patients.

Alberta

Public funding for sleep studies in Alberta – and therefore the capacity to provide publicly-insured sleep testing – has not increased in many years (in spite of a significant increase in demand). Since there is very little insured coverage in Alberta for sleep testing, private provision is considered "necessary."

Private sleep testing clinics typically do not charge patients for Level III testing. Their business model relies on selling CPAP therapy to some portion of their patients. (Note, however, that

because the public system does not underwrite the cost of CPAP therapy, from the patient's perspective, there is no real monetary difference between private and public provision – this could also be said for BC.)

Ontario

In Ontario, Level I sleep testing is covered under the provincial plan with some restrictions. For individuals who would like a further assessment beyond what is covered by the province, "patient-pay" through the public system is permitted. According to the 2019 Ontario Medical Association's Schedule of Fees for uninsured services (2019), a Level I sleep test costs $1,128.25.

The following from ACCQ Sleep Labs (authorized IHF) sets out in plain language the extent of Ontario Health Insurance Program (OHIP) coverage for sleep studies and a patient's ability to pay privately if they want assessment(s) beyond what is covered:

> *Each patient is allowed 1 initial diagnostic study per lifetime and 1 repeat diagnostic study every 12 months. Should you develop another sleep disorder in the time after your first sleep study, you may be eligible for another diagnostic study after 12 months. In addition to your diagnostic study, patients are eligible for a therapeutic study if deemed necessary by your sleep physician. If you are prescribed CPAP therapy, you are eligible for a repeat titration study every 2 years if clinically required. If you do not have a valid Ontario Health Card and would like to have a sleep study you may pay privately for your sleep study (current OHIP rates apply). If you have a valid Ontario Health Care and you would like a further assessment beyond what is covered by OHIP, you also have the option to pay privately.*[4]

Ontario SMEs stated that they were unaware of any private Level III HSAT facilities operating in the province. However, an internet search on "home sleep apnea testing Ontario" found a number of private entities operating in the province (some building-based, some internet-based). Such companies offer at-home sleep testing of various degrees of sophistication and for a range of fees, including, in some instances, for free. Several of the organizations identified are also selling CPAP equipment and other "sleep solutions."

Manitoba

There are a number of private companies that offer Level III HSATs in Manitoba. Patients may pay out-of-pocket for a private Level III HSAT. One private company (RANA) quoted the price of $195.00 for the take-home test.

Saskatchewan

In Saskatchewan, there are numerous privately-operated facilities offering Level III HSATs.

[4] ACCQ Sleep Labs. (n.d.). "Get Referred for a Sleep Study."

These facilities do not typically charge a fee for a Level III test. Their business model relies on selling CPAP therapy to some portion of their patients.

However, one of the Saskatchewan SMEs observed that some private sleep clinics have been known to charge patients a fee for a Level III test. This has occurred (apparently without government intervention/objection) even though Level III testing is covered by the public plan.

In 2018, the Saskatchewan Aids to Independent Living (SAIL) program – which provides CPAP equipment on "loan" to eligible patients for a fee of $275.00 – changed its guidelines so that all Level I and Level III tests must be reviewed by a sleep specialist (with privileges at a Saskatchewan Sleep Disorder Centre) in order for patients to qualify for the program.[5] The SME contact noted that, with these changes now in place, it is possible that private facilities will start charging for Level III testing, as patients would be unlikely to purchase non-subsidized CPAP equipment from a private clinic.

Québec

It is not clear from public sources if patient-pay is available for Level I sleep testing in Québec.

There are a number of private companies in Québec offering Level III home sleep testing. The *Centre du Sommeil de Montréal* (private clinic), for example, charges $395.00 per Level III HSAT. Patients who pay out-of-pocket for Level III sleep testing may be eligible for an income tax refund, though this would depend on each individual's income tax situation.[6]

Nova Scotia

In Nova Scotia, Level III testing may be performed in a private facility. In most (if not all) cases, private clinics offering Level III testing do so free of charge to the patient.[7] It is not clear, however, if the private clinics are billing the Level III test to the province (using the MSI Health Service Codes) or whether they simply do not charge a fee for the test (assuming that the patient will purchase CPAP equipment at a later date).

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[5] Government of Saskatchewan. (2018). "Saskatchewan Aids to Independent Living Program (SAIL) – General Policies." Note: The SAIL program issues approximately 2,500 CPAP's per year in SK. Unfortunately, SME contacts were not able to quantify this figure as a percentage of the whole as it is not known how many CPAPs are provided solely through private providers.

[6] Centre du Sommeil de Montréal. (2017). "FAQs."

[7] See for example, MedSleep Atlantic – Halifax, and Sleep Therapeutics. Note that MedSleep Atlantic – Halifax advertises overnight Level I testing in a private sleep lab. However, following a brief discussion with a representative from the Halifax sleep lab, it was made clear that private Level I testing is no longer available in NS because "there was no insurance that would cover it."

3. Ordering Sleep Tests

Key Points

- With respect to Level I sleep testing:
  - In all of the provinces examined, **sleep specialists** are authorized to order a Level I sleep test directly.
  - In BC (in certain Health Authorities), Alberta (at the Edmonton sleep centre only), Manitoba, Ontario (with additional qualifications), and Nova Scotia, **respirologists** are also authorized to order a Level I sleep test directly.
- With respect to Level III testing:
  - In all of the provinces examined (for which there was information about Level III testing), **sleep specialists** and **respirologists** are authorized to order a Level III sleep test directly.
  - In Alberta, and Manitoba, GPs are also permitted to order a Level III test; however, in Manitoba, the GP must be designated by the Sleep Program Director in order to authorize the test. In BC, many referring physicians, including GPs appear to refer to unregulated HSAT facilities.
- Alberta SMEs noted considerable variation across the province with respect to who can order a Level I or Level III sleep test directly. It is anticipated that the new provincial Sleep Medicine Diagnostic (SMD) accreditation standards will reduce this variation.
- Few SMEs were able to provide a comment with respect to who is authorized to order sleep tests in the private sector.

Table 7. Ordering sleep testing – authorized individuals

Authorized to Order Sleep Tests Directly							
Level I	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Sleep Specialist	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Respirologist	Yes *(designated HAs only)*	*Calgary*: No *Edmonton*: Yes	No	Yes	Yes *(additional qualifications required)*	*Not specified*	Yes
GP	No	No	No	No	No	No	*Not specified*
Other	No	No	No	No	No	No	*Not specified*

Authorized to Order Sleep Tests Directly							
Level III	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Sleep Specialist	Yes	Yes	Yes	Yes	*n/a*	*Not specified*	Yes
Respirologist	Yes *(designated HAs only)*	Yes	Yes	Yes	*n/a*	*Not specified*	*Not specified*
GP	No (except to HSAT facilities)	Yes	No	Yes *(must be designated by HA)*	*n/a*	*Not specified*	No
Other	No	Yes	No	No	*n/a*	*Not specified*	No

Ordering Sleep Tests: Jurisdictional Highlights

British Columbia

In BC, respirologists are only authorized to order Level I and Level III sleep tests in certain designated Health Authorities.

The BC Ministry of Health is unaware of the referral requirements/practices for sleep testing facilities that are unregulated/unaccredited. Anecdotally, the Ministry is aware that many referring physicians, including GPs are referring patients to unaccredited HSAT facilities.

Alberta

There is considerable variation across Alberta with respect to who is able to order a Level I or Level III sleep test directly. One of the aims of the recently introduced provincial Sleep Medicine Diagnostic (SMD) accreditation standards, which require clinics to be regulated and accredited with the CPSA, is to reduce this variation.

Public testing:

- ***Level I:*** Generally speaking, a consultation with a sleep specialist is required before a Level I sleep test can be ordered. However, as noted above, there is variation across the province and models differ. For example, at the Edmonton clinic, respirologists can order a Level I sleep test directly; no consultation with a sleep specialist is required. However, at the Calgary clinic, a Level I test must be ordered by a sleep specialist.
- ***Level III:*** Any medical practitioner can order Level III testing. (There is no need for a sleep specialist to order the test.)

Private testing:

- ***Level I:*** The patient is referred to the clinic by their GP. At the clinic, the patient is assessed by a sleep specialist who will order a Level I test, if appropriate.
- ***Level III:*** Publicly-available information suggests that private clinics do not necessarily require a GP referral to access Level III sleep testing services. According to the *Centre for Sleep & Human Performance*, for example, "you do *not* require a doctor's referral, but it is beneficial for us if you provide the name of your family physician so that we can forward a copy of the initial consultation."[8]

Ontario

For sleep studies performed in an IHF, patients must undergo a pre-study assessment by a sleep specialist.

For repeat diagnostic or therapeutic sleep studies, a pre-study assessment by a physician practising sleep medicine is required (with some exceptions, which are outlined in the Ontario Schedule of Benefits, Physician Services).

Respirologists that have acquired "additional qualifications" may order a Level I test.

Manitoba

In Manitoba, only specialists with training in sleep medicine may directly order a Level I sleep test. Level III tests must be ordered by qualified physicians who have been designated by the Winnipeg Regional Health Authority Sleep Program Director. These restrictions only pertain to publicly-insured services.

The only restriction applicable to the private provision of sleep studies is that, under the Regulated Health Professionals Act (RHPA), a sleep test must be conducted by a physician who is trained and competent to do so.

Saskatchewan

Within the public system, GPs may refer patients into one of Saskatchewan's two regional sleep facilities. The facility's sleep specialist will assess the referral and determine which type of sleep test is appropriate (Level I or III). In addition, all respirologists are authorized to order publicly-covered Level III testing; no additional training is required. (It was noted that allowing respirologists to order Level III tests can help with waitlists and speed up access to Level I testing.)

GPs may also refer patients to private facilities (and may choose to do this because of wait times for the two public sleep clinics).

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[8] Centre for Sleep and Human Performance. (2019). "Frequently Asked Questions."

Québec

According to the *Mount Sinai Hospital, Sleep Apnea Clinic* website, patients are typically referred to the sleep centre by a physician (e.g. family GP), where they will then be evaluated by a "pulmonary physician specialized in the diagnosis and treatment of sleep disorders."[9]

Nova Scotia

Patients require a GP referral to book an appointment at the publicly-funded Sleep Disorders Clinic in Halifax. Although the clinic website does not indicate who is authorized to order the sleep test, there are four "sleep specialty physicians" currently listed on the website, each with a different specialty, including: Respirology, Psychiatry, Sleep Medicine, and Neurology.[10]

According to a representative from the private sector MedSleep Atlantic – Halifax sleep clinic, "no referral is necessary" to book an appointment with the clinic, though patients must be assessed by one of the clinic's sleep specialists before a Level III HSAT can be ordered.

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[9] Mount Sinai Hospital Montreal. (2017). "Sleep Apnea Clinic." See also: L'association pulmonaire – Québec. (2019). "Diagnostic"; Center for Advanced Research in Sleep Medicine. (n.d.). "How to Get a Consultation"; Clinique sommeil et santé. (2019). "Diagnostic Lab"; Sleep Apnea Solutions; and Clinique SomnoMed.
[10] Sleep Disorders Clinic. (n.d.). "The Sleep Clinic Team."

4. Accreditation

Key Points

- In the provinces examined, all public facilities providing Level I sleep testing are subject to accreditation.
- Alberta is the only province examined with an accreditation process in place for **all public and private, Level I and Level III** sleep study facilities:
  - The accreditation process in Alberta applies to the diagnostic process only (and does not pertain to clinical decision-making related to treatment).
- In BC, all facilities that bill the MSP must be accredited (including publicly-owned and privately-owned facilities); however, there are still a number of private, stand-alone Level III HSAT facilities that are unaccredited and operate "outside the auspices of the Ministry."
- Ontario has a licensing system in place for all Independent Health Facilities providing publicly-funded services.

Table 8. Accreditation of sleep study facilities[11]

Accreditation of Sleep Study Facilities – Levels I and III							
Publicly-owned, publicly-funded facilities	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Accreditation of facilities	Yes	Yes	Yes	Yes	Yes Level I only	Yes	Yes
Credentialing / Clinical standards for practitioners	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Training requirements for technical staff	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[11] The data gathered did not indicate differences in Level I and Level III accreditation processes.

Accreditation of Sleep Study Facilities – Levels I and III							
Privately-owned, publicly-funded facilities	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Accreditation of facilities	Yes	*n/a*	*n/a*	*n/a*	Yes	*n/a*	*Not specified*
Credentialing / Clinical standards for practitioners	Yes	*n/a*	*n/a*	*n/a*	Yes	*n/a*	*Not specified*
Training requirements for technical staff	Yes	*n/a*	*n/a*	*n/a*	Yes	*n/a*	*Not specified*
Privately-owned, NOT publicly-funded facilities	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Accreditation of facilities	No	Yes	No	No	No	No	*Not specified*
Credentialing / Clinical standards for practitioners	No	Yes	No	No	No	No	*Not specified*
Training requirements for technical staff	No	Yes	No	No	No	No	*Not specified*

Accreditation: Jurisdictional Highlights

British Columbia

In BC, both public and privately-owned facilities that wish to bill the MSP must be approved and accredited through the College of Physicians and Surgeons of BC's Diagnostic Accreditation Program (DAP).

Credential/clinical standards and training requirements for technical staff is required for accreditation under the DAP, which is a necessary condition to bill the public plan.

The Advisory Committee on Diagnostic Facilities approval for Level I sleep testing also includes the ability to conduct Level III sleep testing.

Alberta

Alberta appears to be the only jurisdiction examined to have implemented a diagnostic accreditation process for all public and private sleep study facilities offering Level I and III sleep tests. The provincial Sleep Medicine Diagnostic (SMD) accreditation standards were developed in 2018 with the goal of ensuring patient safety and quality of care in the full range of sleep medicine facilities operating in the province. However, there are no standards covering clinical decision-making related to treatment (e.g. CPAP), and this was noted by SMEs as something of a gap in the current regulatory landscape.

Ontario

Independent Health Facilities (IHFs) providing sleep studies in Ontario are licensed by the Ministry, and the College of Physicians & Surgeons of Ontario (CPSO) conducts quality assurance assessments. The process is described at CPSO – Independent Health Facilities.

The CPSO has prepared the "Clinical Practice Parameters and Facility Standards" guideline document for IHFs, which include topics such as: service provision; staffing and training requirements; facility standards; and other relevant policies and procedures.

Manitoba

Publicly-funded hospitals in Manitoba are subject to accreditation at the regional health authority level.

There are no government-established regulations or requirements related to sleep testing in private centres. However:

- Private practitioners must adhere to existing legislation, such as the regulated Health Professionals Act and associated "reserved acts"; and
- Physicians practising at private sleep clinics are regulated by the College of Physicians and Surgeons of Manitoba.

Québec

According to the Mount Sinai Hospital Montréal website, it is mandatory under Québec law for public healthcare organizations to be evaluated by an independent third party to assess the

quality of the organization's practices and services.[12] Accreditation appears to be voluntary for private facilities in Québec.

The *Collège des médecins du Québec* sets out the standards for the public provision of sleep testing in Québec, including the requirement for all sleep labs to have a medical director (trained in sleep medicine).[13]

Other Jurisdictions Examined

There was limited information, other than that represented in the table at the beginning of this section, on the topic of accreditation for the provinces of Saskatchewan and Nova Scotia.

[12] Mount Sinai Hospital Montreal. (n.d.). "Accreditation." Accreditation Canada – an independent, not-for-profit organization – appears to be one of the primary accrediting bodies for public and private sleep testing facilities in the province. See for example, Mount Sinai Hospital Montreal. (n.d.). "Accreditation"; Clinique sommeil et santé; and Medigas. (n.d.). "Maintaining Quality Standards." The *Institut de médecine du sommeil* advertises that it is the only medical sleep centre in Québec currently accredited by the American Academy of Sleep Medicine. Institut médecine du sommeil. (n.d.). "Pourquoi choisir un laboratoire accrédité par l'American Academy of Sleep Medicine, AASM?"

[13] Collège des médecins du Québec. (2014). "Apnée obstructive du sommeil et autres troubles respiratoires du sommeil," p. 4.

5. Service Planning and Capacity

FORMAL APPROVAL TO OPEN/OPERATE

Key Points:

- Broadly, few of the provinces examined have specific approval processes in place with respect to the opening and operation of sleep clinics.
- Ontario and BC are the only provinces examined that have formal approval processes in place for sleep medicine facilities, including those that are privately-owned and publicly-funded.

Jurisdictional Highlights

British Columbia

Facilities must receive approval from the Advisory Committee on Diagnostic Facilities, the advising body to the Medical Services Commission. All approvals are subject to the Diagnostics Accreditation Program (DAP), which is overseen by the College of Physicians and Surgeons of BC.

There is no approval process in place for those facilities operating outside the MSP.

Alberta

Until recently, there were no restrictions with respect to who can open a sleep study clinic in Alberta. However, involved physicians and RTs are now expected to be registered with their provincial regulatory college and to be practising in a facility accredited by the College of Physicians and Surgeons of Alberta.

Ontario

The Ministry of Health and Long-Term Care (MOHLTC) issues a licence to an Independent Health Facility. The conditions and limitations of the license allow the submission of claims to the Ministry for operating costs associated with providing insured sleep studies.

Sleep laboratories in public hospitals do not require a license from the Ministry.

Approval process: The process of approval as an IHF is outlined in the Independent Health Facilities Act (2014) (available here). The key components are:

- When services are to be moved to IHFs, or when it is determined that new services will be provided in IHFs, a call for applications will be made by the MOHLTC; and

- If successful as the result of the call for application process, an operator will be issued a licence to perform services specified in the licence, at the site specified in the licence, for **up to five years**.[14]

(There is also a process for unsolicited proposals; however, according to the Ontario SMEs, this has never resulted in a licence being granted.)

Withdrawal or non-renewal of licence: An IHF licence may be suspended, revoked or not renewed by the Director, based on considerations such as poor service, contravention of legislation or licence condition, dishonesty or discontinued operation. Licences may be transferred, or a licensed facility may move from one location to another, but only with prior consent of the Director of Independent Health Facilities and in conformity with applicable policies.[15]

Quality assessment and inspection: MOHLTC uses a "continuous quality improvement approach" in the monitoring of services provided in IHFs. The IHF Act requires every licensed facility to have an established method of monitoring the care and treatment it provides. In support of this, the CPSO has developed "clinical practice parameters and facility standards" for each type of licensed IHF. It is expected that each IHF will be assessed at least once per licence term. The CPSO acts as the principal assessor.

Manitoba

Publicly funded (hospital-based) facilities require approval through the "normal health care system proposal and funding process." There is no separate process specific to sleep disorder testing.

In the private sector, there is no provincial approval process specific to private sleep testing clinics. (However, "the normal medical clinic accreditation process through the College of Physicians and Surgeons of Manitoba" applies.)

Saskatchewan

No formal approval or regulatory process is required with regard to the provision of Level III sleep testing and the sale of CPAP equipment in Saskatchewan.

Private facilities also do not have to apply to the Ministry of Health/Health Authority to be able to refer patients to the SAIL program. However, they must be an SK-based facility.

[14] *Independent Health Facilities Act*. (June 2014).
[15] Ibid.

Other Jurisdictions Examined

There was limited publicly-available information for the provinces of Québec and Nova Scotia with respect to the approval process to open/operate a sleep testing facility.

DETERMINING NEED FOR/NUMBER OF SERVICES

Key Points:

- Of the provinces for which SME interviews were conducted, Ontario emerged as the only jurisdiction with guiding principles in place concerning the number of sleep study facilities in a specific geographical area.
- Regarding the approach to determining the need for additional sleep testing services, only Ontario provided a specific process.
- Several SMEs noted that the number of private sleep clinics in their province was (presumably) driven by market demand.

Jurisdictional Highlights

British Columbia

BC accepts applications from both public and privately-owned facilities seeking approval to bill MSP for provision of Polysomnography services. The primary assessment criterion is 'reasonable utilization of existing facilities'.

Ontario

Guiding principles concerning the number of sleep study facilities and/or their location:

For Independent Health Facilities, the Ministry of Health and Long Term Care (MOHLTC) uses service-to-population data to determine relative access to services in order to recommend to the Director whether to approve the relocation of an existing licenced facility. No facility will be approved to move into a "Catchment Zone" (geographic area) that is either adequately or over-serviced compared to the province of Ontario as a whole, based on population and average service levels.

For the purpose of IHFs, a Catchment Zone is:

- An Ontario town or city with a population greater than 100,000; or
- For a town with a population of 100,000 or less, the township/municipality in which the town is located; or
- For a township/municipality with a population of 100,000 or less, the county in which the township/municipality is located.

Determining the need for additional sleep testing services:

For IHFs, access is currently modelled statistically through a comparison of the level of service in a defined geographic catchment area to the level of service available to the province as a whole. Service-to-population ratios within a catchment that is 70% or below the provincial average is considered under-serviced. Catchment areas with a service-to-population ratio of 150% or above the provincial average are considered over-serviced. In between these two rates is considered adequately serviced.

Ontario SMEs observed that few or no new licenses of sleep study facilities have been issued "in decades." They referenced a 2014 IHF policy that prevents current IHF licensees from operating more than a certain number of beds. The consensus among SMEs was that there has been no change in the number of publicly-insured sleep clinics in Ontario in "quite a long time."

Other Jurisdictions Examined

Guiding principles concerning the number of sleep study facilities and/or their location:

The jurisdictions of BC, Alberta, Saskatchewan, and Manitoba do not currently have guidelines in place concerning the number of sleep facilities. There was no information available publicly on such guidelines for the provinces of Québec and Nova Scotia.

Determining the need for additional sleep testing services:

In Manitoba, the need for publicly-funded sleep testing facilities is identified by the individual health authorities, and the need for private sleep testing facilities is identified by the individual (private) facility operator.

In BC and Alberta, there are no formal processes in either public healthcare system to identify the need for sleep testing. The SME from Alberta commented that the number of hospital-based facilities in that province has been static, although small changes in capacity have been allowed based on demand from local providers within those facilities.

Participating SMEs from a number of provinces observed that market demand likely informs the supply of private sleep clinics.

There was no publicly available information for Saskatchewan, Québec, and Nova Scotia on the issue of determining the need for additional sleep testing services.

NUMBER OF FACILITIES AND BEDS

The original survey asked provincial SMEs if they could estimate the number of sleep facilities in their jurisdiction. During telephone interviews, SMEs were also asked if they could provide the number of Level I beds. The numbers that SMEs provided are shown in the table below.

There was little to no publicly-available information on the number of facilities and beds in the provinces of Québec and Nova Scotia.

Table 9. Number of sleep testing facilities and beds

Number of Sleep Testing Facilities and Beds							
Level I	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Public facilities	7	5	2	1	49	*Not specified*	1
Public beds	32	18	10	10	*200 (estimate)*	*Not specified*	*Not specified*
Privately-owned, publicly-funded facilities	10	*n/a*	*n/a*	*n/a*	62 *(licensed IHFs)*	*Not specified*	*n/a*
Privately-owned, publicly-funded beds	39	*n/a*	*n/a*	*n/a*	490 *(licensed IHFs)*	*Not specified*	*n/a*
Privately-owned, NOT publicly-funded facilities	*n/a*	6	*n/a*	*n/a*	*n/a*	*Not specified*	*n/a*
Privately-owned, NOT publicly-funded beds	*n/a*	12	*n/a*	*n/a*	*n/a*	*Not specified*	*n/a*
Level III	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Public facilities	7	3	2	2	*n/a*	*Not specified*	*Not specified*
Privately-owned, publicly-funded facilities	8	*n/a*	*n/a*	*n/a*	*n/a*	*Not specified*	*n/a*
Privately-owned, NOT publicly-funded facilities	*Number unknown*	175	16	3	*Number unknown*	*Not specified*	5 *(at least)*

Notes on the data provided:

- In several of the jurisdictions, there are an undetermined number of private HSAT facilities in operation that are not accredited.
- The 16 private facilities providing Level III testing noted by the Saskatchewan SME are operated by six different companies.
- Alberta provided the following additional information regarding the number of sleep facilities and beds in the province:

Number of Sleep Study Beds				
Location	**Public**	**Private**	**Public Total** *(Whole Province)*	**Private Total** *(Whole Province)*
Calgary	6	4	18	12
Edmonton	6	4		
Lethbridge	6	*n/a*		
Sherwood Park	*n/a*	2		
Red Deer	*n/a*	2		

6. Measuring Wait Times

Key Points:

- BC, Saskatchewan, Manitoba, and Nova Scotia currently use a priority system to triage patients who require a sleep study.
- Although some provinces have wait time benchmarks in place, because they do not publish wait times (except for Nova Scotia), it is difficult to determine if the benchmarks are being met:
  - Nova Scotia is the only province examined that publicly reports wait times on a regular basis; however, based on the data published by the Nova Scotia Health Authority, these benchmarks are not currently being met.
- Manitoba and Saskatchewan track wait times for sleep studies; however, they do not publish these wait times data.
- SMEs from a number of provinces commented that long wait times for sleep testing are an issue that they are working to address. Some SMEs reported that efforts to reduce wait times implemented to date have not been successful.
- It is worth noting that private companies often advertise significantly shorter wait times than the public healthcare system.

Table 10. Measuring sleep testing wait times

Measuring Wait Times							
	BC	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Priority System	Yes	No	Yes	Yes	No	*Not specified*	Yes
Benchmarks	Yes	No	Yes	No	No	*Not specified*	Yes

Wait Times: Jurisdictional Highlights

British Columbia

BC has adopted the priority system and wait time benchmarks recommended by the Canadian Thoracic Society (CTS). The benchmarks, which apply to level I testing only, are:

- **Priority I (urgent):** 2-4 weeks;
- **Priority II:** 2 months; and

- **Priority III:** 6 months.

It is unknown if the current wait time measures include the time from initial GP referral to sleep specialist. The benchmark measurements and wait times are part of the BC Ministry's current review of sleep medicine in the province.

Alberta

There is no priority system used at the provincial level in Alberta. However, individual sleep clinics may decide to track wait times for their facility. For example, the sleep centre in Calgary currently tracks wait times through its EMR system. The following wait times information for this centre was provided:

- Wait One (i.e. from referral to specialist assessment):
  - **Urgent**: 2 ½ – 3 months for assessment with sleep specialist; and
  - **Routine**: 12 – 18 months (though many "routine" patients may wait longer than this).
- Wait Two (i.e. from specialist assessment to test):
  - **Level I**: 2 – 3 months; and
  - **Level III**: no wait following assessment.

Ontario

Ontario does not use a priority system or wait time benchmarks at the system level for sleep testing. SMEs reported that there are no plans (as far as they are aware) to bring in wait time measurements or standards for sleep studies.

Note: A study on *Clinical pathways and wait times for OSA Care in Ontario*, published in 2018, but using data from 2006 – 2013, found that the median diagnostic time exceeded six months, the median treatment time exceeded three months, and the median overall wait exceeded one year.[16]

Manitoba

Median wait times for the publicly-funded sleep program in Manitoba are provided to the Ministry of Health, Seniors and Active Living for performance indicator monitoring. No provincial wait time target has been established.

[16] Povitz, M., et al. (2018). "Clinical pathways and wait times for OSA care in Ontario, Canada: A population cohort study." *Canadian Journal of Respiratory, Critical Care, and Sleep Medicine*. DOI: 10.1080/24745332.2018.1512841, p. 5.

Tracking Wait Times:

In 2007, Manitoba started to collect wait times data (for adults) via the EMR system ("Accuro" – which has a built-in algorithm to collect data). The algorithm is based on the Canadian Thoracic Society (CTS) guidelines for obstructive sleep apnea.

The Accuro system collects wait times data for Level I and Level III testing. It measures the time from initial GP referral to the appointment with a sleep specialist, and the time from the sleep specialist consultation to the actual sleep test.

The Manitoba wait times for sleep testing have never been published. However, SMEs noted that the wait list typically hovers around 2,500 patients (at a constant rate), and occasionally rises to 5,000 patients. Despite Manitoba's efforts to reduce wait times, the wait list has remained relatively constant.

Saskatchewan

Saskatchewan uses a four-level priority system to triage patients. Depending on the patient's priority, wait times can be anywhere from 4-6 weeks (for urgent cases) and up to 2 years (for non-urgent cases, i.e. snoring only and no co-morbidities). The wait time benchmarks follow the CTS guidelines.

Tracking Wait Times:

According to SMEs, Saskatchewan is tracking wait times for sleep studies, although these are not currently published.

Québec

No publicly-available information could be located regarding Québec's approach to tracking wait times for sleep studies.

However, there are a number of references in the public domain to "long wait times" for sleep testing in the province. Some of the private clinics advertise shorter wait times as a reason for patients to seek testing in the private sector. The Montréal Sleep Centre, for example, states that, "the wait time for a sleep test in the Montreal area can be one to three years. Once the test is completed it is common for patients to wait 3-4 months for results. Sleep tests at our clinic can often be scheduled on the same day or next day and detailed results are ready 7-10 days later."[17]

[17] Centre du sommeil de Montréal, Montreal Sleep Center. (n.d.). "FAQs."

Nova Scotia

The Sleep Disorders Clinic (operated through a partnership between the NS Health Authority and the Dalhousie University Division of Respirology) uses a priority system. The triage categories and associated benchmarks are as follows:[18]

Table 11. Nova Scotia priority system for sleep testing

Priority Level	Description	Benchmark
Urgent	• Nocturnal hypoventilation disorders with impending respiratory failure • Severe daytime sleepiness leading to an urgent public safety issue	14 days
Semi-Urgent	• Severe sleep apnea in the setting of significant medical illness – i.e. congestive heart failure, pulmonary hypertension, poorly controlled hypertension, recent stroke, etc. • Sleep disorders with severe daytime symptoms	84 days
Non-Urgent	• All other sleep apnea • Periodic limb movements and restless leg syndrome • Narcolepsy – if criteria is not met for urgent and semi-urgent categories • Other adult sleep disorders – REM behaviour disorder, unusual parasomnias, etc. • Insomnia – referrals of patient with known psychiatric diagnoses are discouraged, with request for patients to be assessed by their psychiatrist	365 days

Meeting the Benchmarks:

Although Nova Scotia has benchmarks in place (for urgent, semi-urgent, and non-urgent patients), according to the NS Health Care Wait Times website the Sleep Disorders Clinic is not currently meeting these benchmarks. For example, data for October 1 – December 31, 2018, indicates that the Respirology Sleep Clinic (QEII Health Sciences Centre) met the established standards for only 9% of urgent patients and 11% of semi-urgent patients.[19]

Measuring Wait Times:

Although the Sleep Disorders Clinic has established benchmarks (as noted above), it is not clear what time frame these benchmarks cover (i.e. referral to initial consult or consult to test).

[18] Dalhousie University, Division of Respirology. (January 2019). "Sleep Clinic & Laboratory." See also, Dalhousie University. (2019). "Respirology Sleep Clinic – Ambulatory Care Clinic Average Wait Time (Days) – QEII Health Sciences Centre."
[19] Ibid.

The Nova Scotia Healthcare Wait Times website, however, notes that for "Diagnostic Imaging and Tests," the wait time starts when the hospital receives the request from the doctor that referred the patient, and the wait time ends when the patient's exam or test is completed.[20]

[20] Nova Scotia, Healthcare Wait Times. (n.d.). "How Wait Times are Measured."

7. CPAP Funding and Regulation

Key Points:

- Saskatchewan, Manitoba, and Ontario contribute funding towards the cost of CPAP equipment for all patients.
- Alberta, Manitoba, and Saskatchewan have programs/program components in place to assist with/cover the cost of CPAP for patients on low incomes.
- Nova Scotia covers the cost of CPAP for individuals residing in public long-term care facilities that do not have the means to cover the costs themselves.
- Saskatchewan's funding program policy (SAIL) stipulates that CPAP funding is *only* available to patients whose test results have been reviewed by a sleep specialist from one of the public regional sleep study facilities.
- When the same sleep facility provides diagnosis of OSA and also sells CPAP equipment, a conflict of interest arises. Broadly, SMEs from across the provinces examined recognized this conflict of interest, though only Ontario appears to have gone some way to addressing it. For instance:
    - In Ontario, funding for CPAP is provided through the Assistive Devices Program (ADP). The ADP will not register a sleep testing facility as a registered vendor of CPAP equipment.
    - Note, however, that a Google search for entities providing Level III at-home sleep testing in Ontario found that some of the private (unregulated) companies are also selling CPAP machines and other "sleep solutions."

Table 12. CPAP provision, funding and regulation

CPAP Funding and Regulation							
	BC	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Public funding for all patients	No	No	Yes	Yes	Yes *(75% of ADP price)*	No	No
Co-payment for all patients	*n/a*	*n/a*	$275.00	$500.00	25% of ADP price	*n/a*	*n/a*
Public funding for low-income patients	No	Yes	Yes	Yes	*Not specified*	No	Yes
Co-payment for low-income patients	*n/a*	*Not specified*	$0.00	$0.00	*Not specified*	*n/a*	$0.00

CPAP Funding and Regulation							
	BC	**AB**	**SK**	**MB**	**ON**	**QC**	**NS**
Sleep facilities permitted to sell CPAP	Yes	Yes	Yes	Yes	No	Yes	Yes

CPAP: Jurisdictional Highlights

British Columbia

BC does not currently contribute to the funding of CPAP machines and other sleep related devices.

The province does not block sleep testing facilities from selling CPAP machines, which potentially creates a conflict of interest. All HSAT facilities and some approved, accredited privately-owned sleep clinics (approved to bill MSP) sell CPAP and other therapeutic devices.

Alberta

In Alberta, public funding for CPAP equipment is provided to low-income individuals only, through a number of government programs. Some of these programs are provincial (e.g. Seniors Assistance Program, Assured Income for the Severely Handicapped, Alberta Works) and some are federal (e.g. Non-insured Health Benefits Program).[21]

Conflicts of Interest:

Private sleep clinics typically do not charge for Level III testing because they are looking to sell CPAP equipment to patients. The potential conflict of interest created by this situation was acknowledged by SMEs. This conflict of interest is covered in a general clause in the physicians' general standards of practice, but it is not enforced (unless complaints are made and specifics with proof are available).

SMEs acknowledged that there are issues of concern when the same private clinic/company is conducting testing *and* offering (selling) treatment options (e.g. CPAP equipment), and that this is not currently adequately addressed in Alberta. One SME noted that these issues would largely be mitigated if CPAP provision were designated as a "restricted activity" under the Health Professions Act.

SMEs noted that patients may not be aware of the financial implications of the treatment being recommended to them, because private clinics are not being clear about this. In response,

[21] Government of Alberta. (2019). "Buyer's Information – Continuous Positive Airway Pressure (CPAP) Therapy Equipment."

Alberta Health Services has developed a "consumer information handout" on patients' options and rights with respect to sleep tests, and the costs associated with therapy.

Ontario

Ontario residents may receive funding assistance for CPAP, APAP, and BPAP devices through the Assistive Devices Program (ADP). The following criteria apply:

- Patients must meet the program's medical eligibility criteria for a CPAP/APAP/BPAP device, confirmed through a Level I sleep study; and
- The device must have been prescribed by a physician who is listed as an ADP-registered prescriber for CPAP/APAP/BPAP devices.

To be an ADP-registered prescriber the physician must meet the College of Physicians and Surgeons of Ontario's clinical practice guidelines for physicians practising in sleep medicine.

To receive ADP funding assistance for a CPAP, APAP, or BPAP device, the individual must purchase their device from an ADP-registered vendor. The program covers 75% of the ADP price for respiratory equipment and supplies; patients must pay 25% of the ADP price.[22] The current ADP price is set at $860.00.

In Fiscal 2017/18, a total of 64,707 CPAP devices were issued to Ontarians through the Assistive Devices Program.

Conflicts of Interest:

The ADP will not register a sleep testing facility as an ADP-registered vendor. This means that the conflict of interest associated with a testing facility also selling therapeutic devices does not exist within the regulated provision of sleep medicine.

Note, however, that a Google search for entities providing Level III at-home sleep testing in Ontario found that some of the private (unregulated) companies are also selling CPAP machines and other "sleep solutions."

Saskatchewan

In Saskatchewan, CPAP therapy is partially covered by the public healthcare plan, through the *Saskatchewan Aids to Independent Living* (SAIL) program.

If a patient is diagnosed with sleep apnea, and CPAP therapy is recommended, the SAIL program provides the CPAP machine "on loan" for a fee of $275.00. If the patient qualifies for social assistance, they do not have to pay this fee.

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[22] See Government of Ontario. (2019). "Respiratory Equipment and Supplies." The ADP price is based on the manufacturers'/distributors' cost, and the complexity of the device. For more information on funding assistance for CPAP devices see the Government of Ontario. (2019). "Assistive Devices Program."

Although the CPAP machine is *loaned*, there are no absolute limits on how long an individual can keep the machine. After 5 years, the patient may get a new machine for another payment of $275.00 (unless the patient qualifies for social assistance, in which case the fee is waived). Returned machines are cleaned and serviced, and put back into the inventory.

Results of Level III tests provided by private facilities must be reviewed by a sleep specialist from one of the public regional facilities for a patient to be eligible for the SAIL program.

Manitoba

Manitoba provides partial funding of a CPAP machine when the machine is prescribed through the Manitoba Sleep Disorder Centre (MSDC). Manitoba does *not* provide any funding for CPAP machines prescribed by private sleep clinics.

When prescribed through MSDC, the province covers $700.00 and the patient pays $500.00 of the total $1200.00 cost of a basic (new or replacement) CPAP machine. The patient also pays for the cost of all CPAP supplies. If any patient wishes to purchase an upgraded CPAP machine model, they are responsible for covering the entire cost.

Low-income patients may acquire a basic CPAP machine at no cost through the Employment and Income Assistance (EIA) program.

Manitoba provides BiPAP machines at no cost to the patient when prescribed through the MSDC.

Both CPAP and BiPAP machines are provided through private vendors on contract with the MSDC.

Manitoba does not prohibit private sleep testing facilities from selling CPAP machines or other sleep-related treatment devices.

Québec

The *Régie de l'assurance maladie du Québec* (RAMQ) does not currently contribute to CPAP equipment or other sleep-related devices.[23]

Québec does allow private facilities that offer Level III HSATs to sell CPAP machines and other sleep-related equipment.[24]

It is not clear if there are any regulations prohibiting public facilities from selling CPAP equipment. However, none of the public hospitals that offer Level I sleep testing (e.g. Mount Sinai Hospital, Hôpital Rivière-des-Prairies, etc.) appear to sell CPAP devices, and patients are typically directed to the private sector for the purchase of any necessary equipment.

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[23] See Amélie St-Yves. (February 2018). Actualité santé. "Dévoué pour aider ses patients à dormir."

[24] See: Sleep Apnea Solutions; Centre du sommeil de Montréal; and Apnée santé.

Nova Scotia

CPAP machines are not currently publicly-funded in Nova Scotia, unless the patient qualifies for coverage under the *Long Term Care – Special Needs Policy*.[25] To be eligible for special needs funding, the individual must:

- Reside in a Department of Health facility;
- Be unable to cover the cost themselves; and
- Be ineligible for assistance through any other program or source of funding. [26]

To support low-income patients (without private insurance coverage) to access CPAP equipment, the Lung Association of Nova Scotia offers a "Sleep Apnea Refurbishment Program." The association collects "gently-used" newer models of CPAP and BiPAP machines, and students from the Dalhousie University of Health Sciences refurbish the machines for (free) distribution to patients who could otherwise not afford therapy.[27]

The Sleep Disorders Clinic in Halifax (the only publicly-funded facility in Nova Scotia) does not appear to sell CPAP equipment. The Nova Scotia Health Authority has published an information brochure to help patients navigate the purchase of a CPAP machine from the private sector.[28]

All of the private companies offering Level III testing in Nova Scotia also sell CPAP equipment.

[25] CBC. (September 2018). "Hefty Price of Sleep Apnea Machines Tying Up Hospital Beds." Nova Scotia Department of Health Continuing Care Branch. (2008). "Special Needs Policy – Long Term Care."
[26] Nova Scotia Department of Health Continuing Care Branch. (2008). "Special Needs Policy – Long Term Care," p. 3.
[27] Lung Association of Nova Scotia. (2019). "Sleep Apnea Refurbishment Program."
[28] Nova Scotia Health Authority. (2016). "Choosing a CPAP Provider."

Key Findings: Canadian Jurisdictions

The following key findings represent notable issues and themes that have emerged from an analysis of the Canadian jurisdictional data, in concert with discussions between the InsideOut research team and the BC Ministry of Health client.

Healthcare Legislation and Public / Private Provision

When a province publicly covers a medical service i.e. deems it a 'benefit', it is recognized that the service is medically necessary. This, in principle, should prohibit private patient-pay provision of the same service.

An important issue under consideration through this research is the challenge, for Canadian jurisdictions, that arises from the stipulations of "medically necessary" diagnosis and treatment, and the private provision of home sleep apnea testing. In principle, when a province publicly covers a medical service a patient should not be charged a fee for that service, wherever it may be delivered.

All Canadian jurisdictions examined publicly cover Level I sleep testing (either through fee-for-service or global budget), and all but Ontario publicly cover Level III sleep testing. While public coverage is in place, the capacity may not be there to address all patients in a timely fashion. Wait times are an issue in most provinces examined for this scan and likely have been a factor in the growing number of private, unregulated HSAT facilities in every province reviewed.

When a province publicly insures Level III testing, this creates a challenge with respect to enforcing the terms of the Canada Health Act. To avoid contravening the Act, while still generating revenue, many private HSAT facilities offer patients a 'complimentary' Level III test, on the basis that they will sell CPAP equipment and supplies to some proportion of the patients.

In some provinces where Level III testing is publicly covered, private sleep clinics may be charging patients for the test.

Noted Conflict of Interest

In all of the Canadian jurisdictions examined, there are private HSAT facilities that both diagnose Obstructive Sleep Apnea **and** directly sell CPAP equipment. This creates a conflict of interest in that the relationship between the practitioner and the patient may be compromised by commercial interests.

Ontario has explicitly recognized this conflict of interest and has taken some steps to address it. Public funding for CPAP, for instance, is provided through the Assistive Devices Program, and the program will not register a sleep testing facility as a vendor of CPAP.

However, the ADP program only applies to the public funding of CPAP equipment, and there are still a number of unregulated private companies operating across the province of Ontario that offer Level III HSATs and also sell CPAP equipment.

Service Planning and Capacity

Except for Ontario, none of the Canadian jurisdictions examined have specific processes in place to determine the need for sleep medicine services and/or the appropriate extent of provision within a designated region or area.

Ontario uses service-to-population data to determine the need for additional services in a specific area, or "Catchment Zone." No facility will be approved to move into a Catchment Zone that is adequately serviced, or over-serviced, compared to the province of Ontario as a whole.

BC uses as assessment system based on 'reasonable use of existing facilities' but has no specific provision for determining the number of facilities in a given area.

Professional and Technical Fees for Sleep Testing

BC, Ontario, and Manitoba separate out the "professional" and "technical" components of the total fee for sleep testing services. The remaining Canadian jurisdictions either have a single (total) fee or a "professional" fee only.

In addition, there is variation among the Canadian provinces with respect to the funding streams for each fee, i.e. whether the professional/technical fee is funded through the global budget or a fee-for-service model.

Accreditation

Among the Canadian jurisdictions studied, Alberta is unique in having established a mandatory accreditation process for all public and private sleep testing facilities. This accreditation process applies only to diagnostic testing and not to clinical decision making and treatment.

In interview, Alberta SMEs offered the following lessons learned from the development and early implementation of their diagnostic accreditation standards:

- Private HSAT companies should be brought into the conversation about standards and accreditation early on in the process;
- Private HSAT companies may be sceptical about proposed/potential changes to their business context – it may be helpful for government to emphasize (from the beginning) that the process is about ensuring safety and quality of care, and not about closing down businesses; and
- The process should not be rushed – collaboration and co-operation takes time.

With the exception of Alberta, and BC's accreditation of private clinics approved to bill the MSP, private sleep clinics in Canada are largely unregulated and unaccredited. This was regarded by SMEs as an issue that requires attention.

Measuring Wait Times

While some of the Canadian jurisdictions examined are taking steps towards tracking, monitoring and reporting wait times for sleep studies (and other diagnostic tests), this work is emergent. Where benchmarks exist, few (if any) jurisdictions are meeting them.

CPAP Funding

Half of the Canadian jurisdictions examined cover some portion of the cost of CPAP for patients.

Of note, in April 2014, Québec's Ministry of Health and Social Services engaged the *Institut national d'excellence en santé et services sociaux* (INESSS) to produce a jurisdictional study examining public policies on the coverage of CPAP for the treatment of OSA. The final report provides a summary of the different management models in place in Canada and select international jurisdictions, and estimates the direct costs of instituting public coverage of CPAP for OSA. A copy of the report (in French) may be accessed here.

PART 2:

INTERNATIONAL JURISDICTIONS

USA – Medicare

The Centers for Medicare & Medicaid Services (CMS) is the federal agency that administers the single-payer national insurance program "Medicare." Medicare provides medical insurance coverage for U.S. residents who are 65 years of age or older, as well as for residents of all ages with certain disabilities.[29] Its status as a publicly-funded insurance program makes it somewhat comparable to the Canadian system. However, Medicare offers numerous different plans, ranging from "Original Medicare" (which is divided into "Part A" and "Part B" coverage plans) to various different "Medicare Advantage Plans," which are offered by Medicare-approved private companies. For the sake of efficiency, this scan focuses primarily on "Original Medicare – Plan B" in its review of sleep testing in the U.S.

TYPES OF SLEEP TESTING

There are four "types" of sleep testing in the U.S., as outlined in the following table: [30]

Table 13. Types of Sleep Testing in the U.S.

Types of Sleep Testing in the U.S.		
Study Type	**Format**	**Description**
Type I	Polysomnography (overnight sleep study)	This sleep study takes place in a certified lab and is most often used to diagnose sleep apnea. During a PSG, the individual is connected to monitors that measure brain activity, eye movement, amount of oxygen in the blood, blood pressure, and heart rate. If the study shows evidence of sleep apnea, the patient may be connected to a CPAP machine to see if it improves sleep patterns.
Type II	Home Sleep Test	A Type II device measures **seven** different channels, including heart rate, air flow and oxygen levels.
Type III	Home Sleep Test	A Type III device measures **four** different channels.
Type IV	Home Sleep Test	A Type IV device measures **three** channels, one of which is airflow.

[29] Medicare also covers "people of all ages with end-stage renal disease." American Academy of Sleep Medicine. (n.d.). "Medicare Policies."
[30] Mike Olmos. Medicare.com. (2018). "Does Medicare Cover Sleep Studies?"

PUBLIC COVERAGE OF SLEEP STUDIES

Medicare will cover sleep testing (types I, II, III, and IV) only when used to aid in the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms of OSA. Medicare will *not* cover sleep tests when they are used to aid in the diagnosis of chronic insomnia.[31]

The Centers for Medicare & Medicaid (CMS) annually publishes its fee schedule for medical services, including fees for different kinds of diagnostic sleep testing.[32] Each specific service or test is identified via a "Current Procedural Terminology" (CPT) code.[33] The CPT codes do not directly correspond to the four types of sleep testing (described above), though they may be generally categorized into "attended sleep study" (equivalent to Type I) or "unattended sleep study" (equivalent to Types II-IV). The following tables provide the fee schedule for both kinds of sleep testing:

Table 14. Fee schedule (2019) for sleep studies – attended by a technologist

** Note: All amounts shown are in US dollars.*

2019 Fee Schedule – Sleep studies attended by a technologist				
CPT Code	**Description**	**Professional Fee**	**Technical Fee**	**Total Fee**
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist	$63.43	$374.45	$437.88
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist	$124.33	$500.94	$625.28
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist	$90.10	$593.20	$683.30

[31] As noted in the Nationally Covered Indications – Guidelines, "the use of polysomnography (PSG or HST) for diagnosis for patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under section 1862(a)(1)(A) of the Act." See: UnitedHealthcare. (July 2018). "Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1)."

[32] Center for Medicare & Medicaid Services. (2019). "Physician Fee Schedule Search." The American Academy for Sleep Medicine (AASM) also publishes the fee schedule in a centralized table. See, for example, AASM. (2019). "Sleep Services – 2018 vs. 2019 National Payment Comparison." Note: The American Academy of Sleep Medicine also publishes a national payment comparison of sleep studies for the previous and current calendar years (e.g. 2018 vs. 2019). For the most recent comparison of fees, click here.

[33] Correct Code Check. (2019). "Code Search."

2019 Fee Schedule – Sleep studies attended by a technologist				
CPT Code	**Description**	**Professional Fee**	**Technical Fee**	**Total Fee**
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist	$129.02	$526.53	$655.55

Table 15. Fee schedule (2019) for sleep studies – unattended by a technologist (Home Sleep Tests)

2019 Fee Schedule – Sleep studies unattended by a technologist				
CPT Code	**Description**	**Professional Fee**	**Technical Fee**	**Total Fee**
95800	Sleep Study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g. by airflow or peripheral arterial tone), and sleep time	$43.25	$129.38	$172.63
95801	Sleep Study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g. by airflow or peripheral arterial tone)	$42.89	$49.73	$92.62
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g. thoracoabdominal movement)	$50.82	$89.74	$140.55

Note: Once a certain deductible is met, Medicare pays for the majority of the medical service, although the beneficiary is still typically required to pay 20% of the Medicare-approved amount.[34]

PUBLICLY / PRIVATELY OWNED FACILITIES AND PUBLIC COVERAGE

In the U.S., sleep testing can be performed in both publicly-owned and privately-owned facilities. Medicare places some restrictions on where certain tests may be performed in order to qualify for coverage, and all sleep lab facilities must accept "assignment" for the test to be

[34] Center for Medicare & Medicaid Services. (2019). "Medicare & You: The Official U.S. Government Medicare Handbook," p. 29.

covered. Assignment is an agreement by the doctor, provider, or supplier to be paid directly by Medicare, to accept the payment amount Medicare approves for the service, and not to bill the patient for any more than the Medicare deductible and coinsurance.[35]

Medicare places the following restrictions on sleep testing:[36]

- **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***.
- **Type II or Type III** sleep testing is covered when used to aid the diagnosis of 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***.
- **Type IV** sleep testing device is covered when used to aid the diagnosis of 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***.
- **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 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***.

PRACTITIONERS AUTHORIZED TO ORDER SLEEP TESTING

A Polysomnography – Type I sleep test must be ordered by the "beneficiary's physician" if it is to be covered by Medicare.[37] It is unclear to which specific healthcare practitioner "physician" refers (e.g. sleep specialist, respirologist. GP, etc.).

The CMS website does not comment on whether a referral is required (and if so, by whom) for a Home Sleep Apnea Test (HSAT) to qualify for coverage. However, given that Medicare only pays for HSATs that are used in the diagnosis of sleep apnea in patients who have clinical signs and symptoms of sleep apnea, it is likely that a doctor's referral may be necessary to prove the patient's eligibility for coverage.

Patient-Pay Sleep Testing

It appears that some form of medical prescription from a family doctor or a board certified sleep specialist is required for those who wish to pay out-of-pocket for a sleep test. Although the

[35] Ibid., p. 113.
[36] Centers for Medicare & Medicaid Services. (2009). "Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N)." See also, Medicare.gov. (n.d.). "Your Medicare Coverage."
[37] Medicare Regulation 42 CFR 410.32(a). Centers for Medicare & Medicaid Services. (2009). "Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N)." See also: CMS. (n.d.). "Your Medicare Coverage."

InsideOut research team was unable to locate any specific guidance on the rules for patient-pay referral scenarios, there are a number of private sleep lab facilities that articulate a need for some kind of medical referral to access their services. The SleepQuest clinic, for example, notes that a "prescription from a licensed medical doctor is required for all services," while the Alaska Sleep Education Center similarly states that individuals must either visit their family doctor *or* a board certified sleep specialist prior to making an appointment with the clinic.

Table 16. Ordering Practitioner Type – private sector

Ordering Practitioner Type – Private Clinics / Companies				
	PSG – Type I	**HSAT – Type II**	**HSAT – Type III**	**HSAT – Type IV**
Sleep Specialist (Board Certified)	Yes	Yes	Yes	Yes
Respirologist	*Unknown*	*Unknown*	*Unknown*	*Unknown*
General/Family Practitioner	Yes	Yes	Yes	Yes

WAIT TIME MEASUREMENTS

There does not appear to be any kind of universal priority system in place with respect to sleep testing in the U.S. Broadly speaking, Medicare beneficiaries may choose where they would like to have their sleep test performed, as long as the sleep lab facility accepts Medicare assignment. As such, patients may choose the fastest available option. In most cases, sleep lab facilities do not advertise how long it will take to book an appointment.

REGULATION AND ACCREDITATION OF SLEEP FACILITIES

The Social Security Act mandates the establishment of minimum health and safety and Clinical Laboratory Improvement Amendments (CLIA) standards that must be met by providers and suppliers participating in the Medicare program.[38]

To qualify for reimbursement, Medicare-participating healthcare providers and suppliers are surveyed either by "State Survey Agencies" or by "Accrediting Organizations" (AOs) to ensure that they adequately meet CMS quality and safety standards.[39] If the healthcare

[38] CMS. (2018). "Quality, Safety, and Oversight – Certification & Compliance." See also, CMS. (2018). "Research Testing and Clinical Laboratory Improvement Amendments of 1998 (CLIA) Regulations."
[39] For details on the "State Survey" certification process, see CMS. (n.d.). "Certification Process."

provider/supplier (voluntarily) chooses to be accredited by an AO, they will be exempt from routine surveys by State survey agencies.[40]

The three AOs that offer accreditation for sleep clinics in the U.S. are the American Academy of Sleep Medicine (AASM), The Joint Commission (TJC), and the Accreditation Commission for Health Care, Inc. (ACHC).[41]

The AASM *Standards for Accreditation of Sleep Disorders Centers* also provides details with respect to the credentialing requirements for healthcare practitioners and technologists. These include, for example, the designation of a qualified medical director, a board-certified sleep specialist, and the staffing of "appropriately trained, supervised, and required by state law, licensed sleep technologists."[42]

In the U.S., sleep technologists are credentialed by the Board of Registered Polysomnographic Technologists (BRPT), the American Board of Sleep Medicine (ABSM), or the National Board for Respiratory Care (NBRC).[43]

Private Clinics

Private or "independent" sleep clinics may also seek accreditation on a voluntary basis. The AASM, for example, offers an Accreditation program specifically for "independent sleep practices" (i.e. a practice that manages all sleep patients, performs home sleep testing, and is overseen by a Board-Certified sleep medicine physician).[44] Accredited-independent clinics are also subject to similar staff credentialing and training requirements, as demonstrated by the AASM's *Independent Sleep Practice Standards for Accreditation*.[45]

Table 17. Accreditation for sleep lab facilities

Subject to Regulation / Accreditation – to be eligible for Medicare		
	Medicare-participating Clinics	**"Independent" Clinics**
Accreditation of facilities	Yes	Yes (*voluntary*)
Credentialing/clinical standards for practitioners	Yes	Yes
Training requirements for technical staff	Yes	Yes

[40] See Section 1865(a)(a) of the Social Security Act. Details available at: Center for Medicare and Medicaid Services. (n.d.) "Accreditation."
[41] Debbie Rubio. Medical Management Plus. (April 2018). "New Credential Requirements for Hospital Sleep Centers."
[42] AASM. (n.d.). "Standards for Accreditation of Sleep Disorders Centers," pp. 6-10.
[43] American Association of Sleep Technologists. (2017). "What Credentials are Required to Become a Sleep Technologist?"
[44] AASM. (2019). "Independent Sleep Practice Accreditation."
[45] AASM. (2018). "Independent Sleep Practice Standards for Accreditation."

PATIENT-PAY SLEEP TESTING

In the U.S., patients may choose to pay out-of-pocket for all levels of sleep testing.

Table 18. Patient-Pay sleep testing, U.S.

Patient Pay				
	Type I (PSG)	**Home Sleep Study – Type II**	**Home Sleep Study – Type III**	**Home Sleep Study – Type IV**
Is patient pay allowed?	Yes	Yes	Yes	Yes
What is the standard fee? (provide $ amount)	*See comments below for fee structures*	*Prices vary depending on supplier*	*Prices vary depending on supplier*	*Prices vary depending on supplier*

Patient-Pay Fees for Sleep Testing

The cost for "patient-pay" sleep testing in the U.S. varies according to the individual sleep lab facility or private company. The New Choice Health – Sleep Study Cost Comparison website, however, provides the *average* cost for Type I – Polysomnography sleep studies that consumers will pay in most major U.S. cities. The average prices are based on the median price-range offered by a selection of private sleep study clinics in each city. Some examples are as follows:

Table 19. Patient-Pay costs for PSG – Type I
** All prices listed in US dollars.*

Type I – Polysomnography Patient Pay Costs			
City	**Number of medical providers**	**Price Range**	**Average Cost**
Seattle, WA	27	$800 – 2,100	$1,114
Omaha, NB	12	$775 – 2,000	$1,087
Detroit, MI	38	$725 – 1,900	$1,012
Orlando, FL	12	$675 – 1,750	$933
New York, NY	106	$850 – 2,250	$1,200

The cost of a Home Sleep Test (without insurance) will vary depending on the supplier. Although most private suppliers do not publicize their price lists online, according to the American Sleep Association the cost of an HSAT in the U.S. typically falls between $150 and

$500 (USD).[46] One of the few suppliers that advertises their prices online (SleepQuest) charges $380 (USD) for an HSAT that measures heart rate, oxygen saturation, EEG, EOG, EMG, body position, respiratory effort, airflow, snoring, body movement, sleep states / REM and actigraphy. (This test appears to be equivalent to a Level II sleep study in BC.)

FUNDING OF CPAP

Medicare will cover a 3-month trial of CPAP therapy if the beneficiary has been diagnosed with obstructive sleep apnea (OSA). Medicare may cover the therapy for a longer period if the beneficiary meets with their doctor in person, and the doctor documents in the patient's medical record that the CPAP therapy is helping.[47]

If it is determined that the CPAP machine is necessary beyond the 3-month trial, the beneficiary will pay 20% of the Medicare-approved amount for the rental of the machine and purchase of related supplies (e.g. masks, tubing); a deductible also applies. Medicare will pay the supplier to rent the machine for 13 months if the beneficiary uses it without interruption. After the beneficiary has rented the machine for 13 months, they own it.[48]

APPROVAL FOR SLEEP FACILITIES TO OPEN/ OPERATE

In the U.S., all medical practices must obtain (and maintain) a valid state license to provide any kind of healthcare service. If a valid state license is not required (by applicable law), then a practice may submit a "certificate of occupancy" and/or a "permit to provide healthcare services."[49]

DETERMINING NUMBER OF AND NEED FOR SLEEP FACILITIES

The InsideOut team was unable to identify any frameworks or guiding principles concerning the number of sleep study facilities operating, and/or their location, in the U.S. However, the number of sleep study clinics operating in any given geographic area appears to vary dramatically. For example, based on the AASM-sponsored "Sleep Education – Find a Facility Near You, Search Portal," there are 175 accredited sleep clinics in the New York City area, while the city of Las Vegas only has three.[50]

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[46] American Sleep Association. (2018). "Home Sleep Test and Sleep Apnea Sleep Study Testing."
[47] Center for Medicare & Medicaid Services. (2019). "Medicare & You: The Official U.S. Government Medicare Handbook," p. 35.
[48] Ibid.
[49] AASM. (2018). "Independent Sleep Practice Standards for Accreditation," p. 8.
[50] AASM. Sleep Education. (2019). "Find a Sleep Facility Near You."

The available source material does not explicitly indicate how the need for sleep testing facilities is identified, nor by whom. In 2012, the American Academy for Sleep Medicine (AASM) noted a rise in the number of sleep testing facilities seeking accreditation in the U.S., though there was no further information with respect to the development of further testing facilities. [51]

STAND-ALONE HOME SLEEP APNEA TESTING FACILITIES

There are multiple private suppliers that offer Home Sleep Apnea Tests (HSATs), but do *not* provide overnight sleep testing services. The following table offers a select number of private suppliers that offer stand-alone HSATs in the U.S.

Table 20. Private suppliers in the U.S. that offer HSATs

Private Suppliers that Offer Stand-Alone HSATs	
Company	**Website**
Shasta Sleep Services	https://www.shastasleepservices.com/home-sleep-testing
Home Sleep, LLC	http://www.homesleepllc.com/
Cerebra Health	https://cerebrahealth.com/sleep_service
Blackstone Medical Services	https://www.blackstonemedicalservices.com/

SLEEP STUDY FACILITIES AND THE SALE OF CPAP MACHINES

There are a number of private respiratory supply companies operating in the U.S. that sell CPAP machines and other sleep-related treatment devices, and that also offer Level III home sleep testing services.[52] This suggests that the practice of selling equipment and providing home sleep testing is not currently prohibited in the U.S.

While private CPAP suppliers appear to be authorized to offer Level III home sleep tests, there do not seem to be any that also offer Level I overnight sleep testing. It is not clear, however,

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[51] AASM. (2012). "Demand for treatment of sleep illness is up as drowsy Americans seek help for potentially dangerous conditions."

[52] See, for example: Americare – Respiratory Services; Get Snooze; and iSleep Home Testing.

whether this a result of regulation/policy, or whether private medical suppliers are not typically equipped to conduct more complex sleep testing (Level I) in an overnight sleep lab facility.

NUMBER OF SLEEP STUDY FACILITIES

No publicly available estimate of the number of sleep study facilities in the U.S could be located. However, one research study noted that, as of 2013, the American Academy of Sleep Medicine (AASM) had accredited 2,600 "full-service" sleep facilities, and nearly 1,000 "out-of-center sleep test" (OCST) providers.[53]

[53] Sam A. Fleishman et al. (2013). CHEST Journal. "Point: Should Board Certification Be Required for Sleep Test Interpretation? Yes."

Commonwealth Government of Australia

Medical services in Australia are provided by both the public and private healthcare sectors. Citizens may choose to enroll as a "public patient" in the publicly-funded universal healthcare system (Medicare); they may decide to purchase private insurance and be treated as a "private patient"; or they may use a combination of both public and private coverage.[54] Broadly speaking, Medicare pays for "public patients" to be treated in public hospitals/facilities, and private insurance pays for "private patients" to be treated in private hospitals/facilities.[55] However, the barriers between the public and private system are somewhat permeable: public patients may be eligible for some Medicare coverage when accessing private health services; and private patients (who are also enrolled in Medicare) may also access certain public health services.

TYPES OF SLEEP TESTING

According to the Australian Sleep Association (ASA) *Guidelines for Sleep Studies in Adults* (2014), sleep studies are categorized into four "types."[56] Like the B.C. system, Type I refers to an "attended" polysomnography sleep study, and Types II-IV represent various levels of "unattended" home sleep studies.[57] (Note: Type IV sleep studies are rarely mentioned in the jurisdictional source material for Australia.)

Table 21. Four types of sleep testing, Australia

Types of Sleep Testing	
Study Type	**Description**
Type I	Polysomnography Study (PSG) is a lab-based (i.e. attended) study that requires the continuous recording of multiple physiological variables to measure sleep architecture and cardio-respiratory function during sleep. Signals recorded typically include: Two electroencephalogram (EEG) signals; Bilateral electro-oculograms (EOGs); Submental electromyography (EMG); Electrocardiography (ECG); Bilateral anterior tibial muscle activity; Arterial O2 saturation; Sound; Respiratory thoraco-abdominal movements; Airflow (nasal pressure and oronasal themocouples); and Body position.

[54] Most taxpayers pay a Medicare levy of 2% of their taxable income to fund Medicare. See, HealthDirect. (n.d.). "What is Medicare?"
[55] William Jolly. CanStar. (2018). "What's the Difference Between Medicare and Private Health Insurance?"
[56] For details see, "Ching Li Chai-Coetzer et al. (2014). Prepared for the Australasian Sleep Association. "Guidelines for Sleep Studies in Adults," pp. 5-11.
[57] Ibid.

Types of Sleep Testing	
Study Type	**Description**
Type II	A Level II study refers to a portable PSG device that is unattended by trained sleep laboratory staff. It records a minimum of **7 channels**, including: EEG; EOG; Chin EMG: ECG or heart rate; Airflow; Respiratory effort; and Oxygen saturation.
Type III	A Level III study is referred to as a "limited channel sleep study." It usually measures at least **4 channels**, and may include: Oximetry; Respiratory effort (chest, abdominal, or both); Airflow (nasal or oral by pressure or thermistor); Head or body position, Jaw movement; ECG; Tonometry (a marker of autonomic control); Actigraphy; and Sound.
Type IV	A Level IV study measures only **1 or 2 channels**, which may include: Oxygen saturation; Heart rate; and/or Airflow.

PUBLIC COVERAGE OF SLEEP STUDIES

The Australian Medicare system publicly insures both "lab-based" (i.e. attended) diagnostic sleep studies, as well as "unattended" diagnostic sleep studies. The Medicare Benefits Schedule (MBS) provides a list of all health services that are covered or eligible for a benefit payment under Medicare, and the list includes two relevant items:[58]

- **Item 12203** – Lab-Based Diagnostic Sleep Study (equivalent to Type I); and
- **Item 12250** – Unattended Sleep Study (equivalent to Type II).

Note: Although the MBS does not include any explicit fee information for sleep studies Types III or IV, it is possible that MBS Item 12250 may also cover Type III, which measures *at least* 4 channels.

Table 22. Australia Medicare fees for sleep studies

2019 MBS Fee Schedule					
MBS Item	**MBS Service**	**Description**	**Professional Fee**	**Technical Fee**	**MBS Fee**
12203	Lab-based diagnostic sleep study (9 channels)	Overnight diagnostic assessment of sleep, for a period of at least 8 hours duration, for a patient age 18 years or more, to confirm the diagnosis of a sleep disorder.[59]	N/A	N/A	$588.00 (AUD)

[58] Australian Government, Department of Health. (2019). "Medicare Benefits Schedule – Item 12203" and "Medicare Benefits Schedule – Item 12250."
[59] For further details for each test (including specific requirements for coverage), see: Australian Government, Department of Health. (2019). "Medicare Benefits Schedule – Item 12203."

2019 MBS Fee Schedule					
MBS Item	**MBS Service**	**Description**	**Professional Fee**	**Technical Fee**	**MBS Fee**
12250	Unattended sleep study (7 channels)	Overnight diagnostic sleep study to confirm the diagnosis of Obstructive Sleep Apnea (OSA).	N/A	N/A	$335.30 (AUD)

PUBLICLY / PRIVATELY OWNED FACILITIES AND PUBLIC COVERAGE

The amount that Medicare pays towards a medical service is based on where the service is provided. Although "sleep studies" are not explicitly mentioned in the Medicare coverage scheme, diagnostic testing may be conducted at a public hospital, private hospital, or outpatient clinic, and testing typically requires a visit with a GP or specialist. The following list outlines what medical services are covered in each location: [60]

- **Public hospital** – Medicare will pay 100% of the cost of the treatment itself, anesthesia, all diagnostic work, and all fees (e.g. theatre fees, accommodation fees, and doctor's fees);
- **Private hospital** – Medicare will pay 75% of the public rate for treatment, anesthesia, and all diagnostic work. The individual and the private health insurer are responsible for the rest, including 100% of the cost of all fees such as theatre fees, accommodation fees, and doctor's fees;
- **Outpatient clinic** – This refers to diagnostic work. Medicare will pay 85% of the public rate and the individual will be responsible for the rest. Private health insurance usually does not cover outpatient services;
- **GP Visit** – Medicare will pay 100% of the cost if the GP "bulk bills" (i.e. the GP or specialist accepts the Medicare fee as the full fee for their service, and there is no additional fee to the patient). If they do not bulk bill, Medicare will pay 100% of the public rate and the individual will pay any extra if the doctor charges more; and
- **Specialist Visit** – Medicare will pay 100% of the cost if the provider bulk bills. If they do not bulk bill, Medicare will pay 85% of the public rate and the individual will have to pay the additional 15% plus any extra if the doctor charges more.

[60] Richard Laycock. Finder. (n.d.) "What does Medicare Cover?"

Table 23. Where a sleep study may be performed, Australia

Where a Sleep Study may be Performed				
	Level I	**Level II**	**Level III**	**Level IV**
May be performed in a publicly-owned facility (hospital)	Yes	Yes	Yes	Yes
May be performed in a privately-owned sleep lab/clinic	Yes	Yes	Yes	Yes

Table 24. Where a sleep study must be performed in Australia to receive public funding

Where Sleep Studies Must Be Performed to Receive Public Funding				
	Level I	**Level II**	**Level III**	**Level IV**
Publicly-funded if performed in a publicly-owned facility (hospital)	Yes	Yes	Yes	Yes
Publicly-funded if performed in a privately-owned sleep lab/clinic	Yes, partially	Yes, partially	Yes, partially	Yes, partially

Note: According to the Australian Institute of Health and Welfare "Admitted Patient Care Report," a total of 72,524 patients had a sleep study performed between 2016 and 2017. Of this number, 56,726 patients (78.2%) were seen in a private hospital, and only 15,798 patients (21.8%) were seen in a public hospital.[61]

PRACTITIONERS AUTHORIZED TO ORDER SLEEP TESTING

The MBS website provides a breakdown of the referral requirements for diagnostic sleep studies (attended and unattended – items 12203 to 12250). According to MBS, a general practitioner (GP) may directly refer a patient for either an attended or unattended sleep study (MBS items 12204 and 12250) *without* a personal assessment by a sleep or respiratory physician, when validated screening questionnaires suggest a high pre-test probability for a diagnosis of symptomatic,

[61] Australian Government, Australian Institute of Health and Welfare. (2018). "Admitted Patient Care 2016-2017 – Australian Hospital Statistics," p. 170.

moderate to severe OSA.[62] The need for testing can also be determined by a sleep or respiratory physician following direct clinical assessment (either in-person or by video conference).[63]

The source material does not articulate a distinct set of referral guidelines for "patient-pay" scenarios.

Table 25. Ordering practitioner type to be eligible for public coverage, Australia

Ordering Practitioner Type – To be eligible for public coverage				
	Level I	**Level II**	**Level III**	**Level IV**
Sleep Specialist	Yes	Yes	Yes	*Unknown*
Respirologist	Yes	Yes	Yes	*Unknown*
General/Family Practitioner	Yes	Yes	Yes	*Unknown*
Other	N/A	N/A	N/A	*Unknown*

WAIT TIME MEASUREMENTS

In Australia, public hospitals use a priority system to triage patients' access to care. As stated in the Australian Health Care Agreements (AHCAs), "access to public hospital services must be on the basis of clinical need and within a clinically appropriate time period."[64]

The "urgency categories" and specific referral triage protocols, however, are set by each State in accordance with their own policies and practices.[65]

Publicly available sources do not address the use of a priority system in the specific context of sleep testing, though it is likely that sleep testing referrals are triaged according to the State-level policies and practices for other kinds of diagnostic services.

The Commonwealth Government of Australia does not currently track wait times for diagnostic services (including sleep testing) at the national level.

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[62] Australian Government, Department of Health. (n.d.). "Medicare Benefits Schedule – Item 12203." The use of "approved screening questionnaires before referring patients to a sleep test" were only recently added to the MBS coverage requirements in November 2018. See Australian Government, Department of Health. (2018). "MBS Review Recommendations: Adult Laboratory-Based (Level I) Sleep Studies."

[63] Australian Government, Department of Health. (n.d.). "Medicare Benefits Schedule – Item 12203." Note: Medicare will *not* cover Sleep Testing – Types I or II (12203 to 12250) when the interpretation and preparation of a permanent report is provided by a technician or supervised staff rather than by a qualified adult sleep medicine practitioner. See Australian Government, Department of Health. (n.d.). "Medicare Benefits Schedule – Item 12203."

[64] Parliament of Australia. (2003). "Hospitals in Australia."

[65] Stephen Duckett. The Conversation. (July 2018). "Getting an Initial Specialists' Appointment is the Hidden Waitlist."

Some State governments, however, provide information with respect to wait times for sleep studies. The Government of Queensland, for example, notes that "current routine waiting times" for sleep studies in the state are "six to eight months."[66] It is not clear how these wait times are calculated / measured or if specific benchmarks are being used.

REGULATION AND ACCREDITATION OF SLEEP FACILITIES

Since 1997, an accreditation process for sleep services has been available in Australia to "foster excellence in the approach to management of sleep disorders."[67] The accreditation program appears to be voluntary in nature, and is run jointly by the National Association for Testing Authorities (NATA) and the Australasian Sleep Association (ASA). (Note: NATA has been recognized by the Australian Commonwealth Government as the sole national accreditation body for establishing and maintaining competent laboratory practice in Australia.)[68]

The ASA *Standard for Sleep Disorder Services* (2016) sets the minimum standards by which NATA-accredited sleep disorder clinics must operate.[69] The *Standard* not only describes all of the mandatory requirements with which accredited clinics must comply, it also incorporates the quality management principles from the Standard for Medical Laboratories (ISO 1589:2012), as well as other ASA standards and relevant statutory requirements.[70] The *Standard* also includes training requirements for technical staff.[71]

Table 26. Accreditation and regulation, Australia

Subject to Regulation / Accreditation & Types of Regulation				
	Level I	**Level II**	**Level III**	**Level IV**
Accreditation of facilities	Yes - *Voluntary*	Yes - *Voluntary*	Yes - *Voluntary*	Yes - *Voluntary*
Credentialing/clinical standards for practitioners	Yes	Yes	Yes	Yes
Training requirements for technical staff	Yes	Yes	Yes	Yes

[66] Queensland Government. (2019). "Sleep Studies."
[67] NATA and ASA. (2016). "ASA/NATA Sleep Disorders Services."
[68] NATA and ASA. (2018). "About NATA and the ASA/NATA Sleep Disorders Services Accreditation Program," p. 4.
[69] Ibid., p. 5.
[70] Australasian Sleep Association. (2016). ASA Standard for Sleep Disorders Services, p. 6.
[71] Ibid., p. 20.

PATIENT-PAY SLEEP TESTING

Source material specific to "patient-pay sleep testing" in Australia is limited. In many cases, if a "public patient" (i.e. covered by Medicare) chooses to use a private facility, they will initially pay out-of-pocket and then will seek reimbursement through Medicare. Therefore, it may be assumed that those who do *not* have Medicare or private insurance may be able to pay for testing themselves.

A standard patient-pay fee for each type of sleep test could not be found.

Table 27. Patient-pay, Australia

Patient Pay				
	Level I	**Level II**	**Level III**	**Level IV**
Is patient pay allowed?	Yes	Yes	Yes	Yes
What is the standard fee?	*Information not available*	*Information not available*	*Information not available*	*Information not available*

FUNDING OF CPAP

According to the MBS website, it appears that Medicare does *not* contribute any funding to CPAP machines or other devices.

A number of public and private clinics in Australia sell CPAP equipment, without any mention of Medicare coverage or direct MBS billing. The Sleep Health Foundation of Australia similarly provides extensive information about how to access a CPAP machine (from CPAP suppliers) without providing any information with respect to Medicare coverage.

APPROVAL FOR SLEEP FACILITIES TO OPEN/ OPERATE

Under Australia's federal system, the provision of public hospital services in each jurisdiction is governed by State and Territory legislation.[72] The licensing and approval of private hospitals are also the responsibilities of State and Territory governments.[73]

However, the Commonwealth Government still plays a role in the regulation of private hospitals (through the National Health Act 1953 and the Health Insurance Act 1973), including

[72] Parliament of Australia. (2003). "Hospitals in Australia."
[73] Ibid.

the requirement that a hospital be "declared" by the Commonwealth before it can receive health insurance benefits.[74]

Generally speaking, hospitals must be licensed in order to operate. The following table provides some select examples of State requirements for private hospital licensing:[75]

Table 28. Private facility regulation, selects states, Australia

Private Facility Regulation – by State	
State	**Details**
New South Wales	Private hospitals and day procedure centres must be licensed under the *Private Health Facilities Act 2007* and the *Private Health Facilities Regulation 2010.* Schedule 1 of the *Private Health Facilities Regulation* outlines the standards with which private hospitals must comply.
Victoria	The Department of Health is responsible for the regulation of private hospitals and day procedure centres under the *Health Services Act 1988* and the *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002* A private hospital or day procedure centre cannot commence or continue operation and admission of patients unless the premises are registered under this legislation.
Queensland	Private hospitals within Queensland are licensed under the *Private Health Facilities Act 1999* which empowers the Chief Health Officer to make standards *for the protection of the health and wellbeing of patients receiving health services at private health facilities.*
Australian Capital Territory	In the ACT, private hospitals are licensed under the *Public Health Act 1997*. Under that Act, the operation of a private hospital is classified as a public health risk activity, requiring licensing. Private hospital licences are issued under the *ACT Healthcare Facilities Code of Practice 2001*, which is an enforceable code of practice under the *Public Health Act 1997*.

DETERMINING NUMBER OF AND NEED FOR SLEEP FACILITIES

The Australian Government, Department of Health website provides few details with respect to how the need for sleep testing facilities is identified. However, there have been calls from the independent (not-for-profit) research sector to increase federal funding for sleep disorder research and testing facilities.

In 2018, for example, Professor Danny Eckert, Director of the Sleep Program with the independent research association "NeuRA" (Neuroscience Research Australia) called for a $200

[74] Ibid.
[75] Australian Government, Department of Health. (2012). "Private Hospital Licensing and Data Collection."

million strategic investment into sleep health over the next 5-10 years to be funded by Australian Government, Department of Health.[76] Professor Eckert claims that as a result of "limited treatment options, and lack of sleep health services available in the current healthcare system, wait times to see a sleep health professional can be more than a year, limiting Australians' access to high-quality sleep services."[77]

STAND-ALONE HOME SLEEP APNEA TESTING FACILITIES

The Commonwealth Government website does not provide explicit guidance on the operation of stand-alone, Level III home sleep apnea testing facilities. However, there are number of private clinics/companies that offer home sleep tests, without advertising additional overnight sleep testing services. The following table provides select examples:

Table 29. Private suppliers offering stand-alone HSATs, select examples, Australia

Private Suppliers that Offer Stand-Alone HSATs	
Company	**Website**
CPAP Australia	https://www.cpapaustralia.com.au/home-sleep-test/
Home Sleep Studies Australia	https://www.homesleep.com.au/
Sleep Clinic Services	https://www.sleepclinicservices.com/home-sleep-study

SLEEP STUDY FACILITIES AND THE SALE OF CPAP MACHINES

In 2009, the Australasian Sleep Association released the *Best Practice Guidelines for Provision of CPAP Therapy*, which recognizes a potential conflict of interest with respect to the diagnosis of sleep disorders and the sale of equipment by the same practitioner/supplier. The authors of the *Guidelines* note that "where an individual has financial interests in both activities" (i.e. the provision of diagnostic services *and* the provision of CPAP devices) "there is a clear duality of interest and must be recognised as such."[78] The Australasian College of Physicians *Code of Professional Behaviour* also states:

[76] NeuRA. (November 2018). "Australia needs to prioritise sleep to improve health and productivity of the nation."
[77] Ibid.
[78] Australasian Sleep Association. (2009). "Best Practice Guidelines for Provision of CPAP Therapy," p. 6.

> *The principle guiding the responses to dualities of interests relating to the clinical setting is that the relationship between clinician and patient should not be compromised by commercial or other interests that could subvert the principle that the interests of the patient should be primary.*[79]

The authors of the *Guidelines* therefore conclude that it is "not desirable for an individual clinician engaged in the diagnosis of OSA to derive income from the business of CPAP provision. Nor is it desirable for an organisation engaged in CPAP provision to provide diagnostic services with a view to profit from subsequently selling CPAP to a patient."[80]

However, the ASA *Guidelines* do not appear to be strictly enforced, nor does they appear to be backed by legislation, and there are numerous private companies currently operating in Australia that sell both CPAP equipment *and* home sleep testing services.[81] While Level I sleep lab facilities do not typically appear to sell CPAP equipment, there are some private sleep lab facilities that explicitly endorse certain private CPAP vendors. For example, SNORE Australia states that their "preferred supplier" of CPAP therapy equipment is *Air Liquide Healthcare*, which operates CPAP clinics out of many of the SNORE Australia premises.[82]

NUMBER OF SLEEP STUDY FACILITIES

Sleep Disorders Australia (SDA) provides a list of approximately 160 public and private sleep clinics in operation in Australia (2016). However, it is unlikely that this is an exhaustive list, and it is not clear which levels of sleep testing each clinic currently offers.

The Australasian Sleep Association (ASA) also provides a service directory for "Sleep Labs" in Australia, which includes the details for approximately 100 public and private facilities across the country.

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[79] Ibid.
[80] Ibid., pp. 6-7.
[81] See, for example: CPAP Australia and Sleep Right.
[82] SNORE Australia. (2019). "CPAP Information."

NHS England

TYPES OF SLEEP TESTING

In its *Standards of Care – Sleep Apnoea* (2018), the UK Association for Respiratory Technology and Physiology (ARTP) states that sleep studies in the United Kingdom (which includes NHS England) are categorized into four levels (1 through 4) depending on the number of recording channels used. Descriptions are provided below:

(Note that: the UK classification of sleep studies runs in the reverse order to the AASM.)

Table 30. Types of sleep testing, UK Association for Respiratory Technology and Physiology

Types of Sleep Testing	
Study Type	**Description**
Level 1 Sleep Study: Overnight Pulse Oximetry	Usually consists of 2 channels measuring a respiratory signal (oxygen saturation) and an arousal signal (pulse rate). Often used as a screening tool, with a progression to a more advanced sleep investigation if results are equivocal or negative when a screening questionnaire score is high and/or if significant clinical symptoms are present.
Level 2 Sleep Study: Limited Channel cardio-Pulmonary Sleep Study (Polygraphy)	Consists of at least 4 channels, measuring oxygen saturation, pulse rate, respiratory flow, respiratory effort, body position, snoring (vibration or audio channel) and leg movement. Does not measure sleep staging. Data from the different channels enable identification of apnoeas/hypopnoeas and differentiation between obstructive and central respiratory events. Often referred to in international guidelines as HSAT (Home Sleep Apnoea Testing).
Level 3 Sleep Study: Home Polysomnography	Consists of at least 7 channels, measuring oxygen saturation, pulse rate, respiratory flow, respiratory effort, body position, snoring, electroencephalography for sleep staging (EEG), electro-oculography (EOG), electrocardiography (ECG), electromyography (EMG), leg EMG, video and audio recording.
Level 4 Sleep Study: Standard Attended Polysomnography	As with a Level 3 study, consists of at least 7 channels, measuring oxygen saturation, pulse rate, respiratory flow, respiratory effort, body position, snoring, electroencephalography for sleep staging (EEG), electro oculography (EOG), electrocardiography (ECG), electromyography (EMG), leg EMG, video and audio recording. Usually takes place within a specialised sleep laboratory setting and may have a healthcare scientist in attendance throughout.

However, in its public material/communications, NHS England does not refer to the Level 1, 2, 3, 4 categorization system. Generally, publicly available source material distinguishes between polysomnography (PSG), which must be undertaken in a clinic/hospital setting, and home-based tests, such as pulse oximetry and multi-channel portable systems. The information on the patient-orientated NHS website, for example, describes two types of test:

- "Testing at home," using sensors that monitor oxygen levels, breathing movements, heart rate and snoring; and
- "Testing at a sleep centre" i.e. polysomnography.[83]

Sleep centres and other facilities providing sleep testing also do not use the terminology of the Level 1 through 4 categorization system. The table below details the range of sleep studies conducted at the Royal Papworth Hospital sleep centre (the largest sleep centre within NHS England), by way of an illustrative example of the types of testing provided and the language used.[84]

Table 31. Types of sleep testing, NHS Foundation Trust, England

Types of Sleep Testing	
Study Type	**Description**
Simple sleep study (oximetry)	Involves wearing an oxygen monitor on a finger during sleep. Can often be done at home. The monitor is collected from the sleep centre, worn overnight, then returned the next day for a recording of the patient's night's sleep to be downloaded.
Respiratory Polygraphy (multi-channel portable sleep study)	Performed in the patient's home. Involves a "fitting" session at the sleep centre and then the equipment is worn overnight at home and returned the next day. Equipment involves a band around the chest and abdomen to measure movement, a flow sensor in the nostrils and an oxygen monitor on the finger.
Polysomnogram (PSG)	Performed at the sleep centre. Uses sophisticated monitoring equipment to record patient's brain waves (electroencephalography or EEG) and other vital signs. Multiple sleep latency tests (MSLT) may be performed at the sleep centre the day after the PSG to assess sleepiness and look for easy lapsing into dream sleep (a feature of narcolepsy).
Actigraphy	Involves patient wearing a movement monitor on their arm or leg for a few days and nights at home. Used to assess sleep regularity or to look for Periodic Leg Movements (PLM). Equipment is mailed to the patient's home with operating instructions and then returned to the sleep centre for downloading of data.

Because sleep centres and clinics within NHS England tend to use the terminology/categories above, these are the categories used in this scan of sleep study provision in England.

[83] NHS. (2016). "Diagnosis: Obstructive Sleep Apnoea."
[84] NHS, Royal Papworth Hospital, NHS Foundation Trust. (n.d.). "Sleep Investigations at Royal Papworth Hospital."

PUBLIC COVERAGE OF SLEEP STUDIES

Upon referral to a specialist by a General Practitioner, patients may access an NHS sleep clinic for an overnight polysomnography assessment at the clinic or an at-home test (with take-home equipment). Both tests appear to be available under the NHS at no cost to the patient.

National prices and payment rules for providers of NHS care are published as the *National Tariff Payment System*. The *Payment System* makes reference only to a "Respiratory sleep study," which includes both outpatient and inpatient studies.

Table 32. Public coverage – fee for "respiratory sleep study", NHS England

Public Coverage by Type of Test			
Level of Test	**Professional Fee**	**Technical Fee**	**Total Fee**
Respiratory Sleep Study – ***includes multi-channel sleep study at home & full polysomnography***	n/a	n/a	408 GBP

For at home sleep studies, 408 GBP appears to be the total fee paid by the NHS to the sleep service. However, it is possible that when providing a clinic-based full polysomnography, the service may also be able to bill for the following tariffs:

Table 33. Public coverage – additional respiratory medicine tariffs, NHS England

Treatment function description	First Attendance - Single Professional	First Attendance - Multi Professional	Follow Up Attendance - Single Professional	Follow Up Attendance - Multi Professional
Respiratory Medicine	208 GBP	286 GBP	94 GBP	113 GBP
Respiratory Physiology	148 GBP	229 GBP	120 GBP	187 GBP

PUBLICLY / PRIVATELY OWNED FACILITIES AND PUBLIC COVERAGE

For sleep studies to be covered by the NHS, they must be conducted at an NHS sleep clinic (following referral by a GP).[85] The only exception to this is when the NHS is unable to provide a patient with a consultation and diagnostic test within the guaranteed maximum waiting time. (See "Wait Times" below.) In this instance, a patient's GP may seek approval for public funding for the patient to attend a private sleep clinic.

[85] See NHS. (2016). "Diagnosis: Obstructive Sleep Apnoea."

The NHS currently covers: multi-channel sleep studies at home; and hospital/clinic-based polysomnography.

However, the distinction between publicly-owned and privately-owned facilities is not clear-cut in England. In the UK, there are parallel public and private healthcare services. Hospitals, clinics and individual specialists may choose to provide both public (NHS covered) and private (private health insurance or patient-pay) care, and this is the common practice. Therefore, an NHS hospital or clinic may also provide a range of private healthcare services.

With respect to sleep testing, then, publicly-funded tests and patient-pay tests may be performed in the same facility.

Table 34. Where a sleep study may be performed, NHS England

Where a Sleep Study May Be Performed				
	Simple sleep study (oximetry)	*Multi-channel sleep study at home*	*Polysomnogram (PSG)*	*Actigraphy*
May be performed in an NHS facility	Yes	Yes	Yes	Yes
May be performed in a privately-owned sleep lab/clinic	Yes	Yes	Yes	Yes

Table 35. Where a sleep study may be performed to be publicly covered, NHS England

Where a Sleep Study May Be Performed to be Publicly Covered				
	Simple sleep study (oximetry)	*Multi-channel sleep study at home*	*Polysomnogram (PSG)*	*Actigraphy*
Publicly-funded if performed in an NHS facility	No	Yes	Yes	No
Publicly-funded if performed in a privately-owned sleep lab/clinic	No	No *(except when wait for NHS service exceeds maximum wait time)*	No *(except when wait for NHS service exceeds maximum wait time)*	No

PRACTITIONERS AUTHORIZED TO ORDER SLEEP TESTING

Publicly funded by the NHS:

Most commonly, sleep testing is ordered by a "sleep specialist" at an NHS sleep centre. This is the case for both take-home multi-channel portable systems and full polysomnography studies conducted at the sleep clinic.

The *Service Specification for Investigation and Treatment of Obstructive Sleep Apnoea Syndrome* (2009) (developed by the British Thoracic Society, the Association for Respiratory Technology and Physiology, the General Practice Airways Group and the Sleep Apnoea Trust Association) recommends that diagnosis requires "specialist clinical experience" and the availability of a "experienced specialist multidisciplinary team, comprising medical, nursing and scientific or technical specialists." The role of a "clinical lead" is seen as particularly important.[86]

However, models are developing in some regions within NHS England where GPs offer overnight at home sleep studies to patients. Development of such models is dependent on local expertise and interest.[87]

Table 36. Ordering practitioner types to be eligible for public coverage, NHS England

Ordering Practitioner Type – To be eligible for NHS coverage		
	Take-home multi-channel portable system	**Full polysomnography**
Sleep Specialist	Yes	Yes
Respirologist	Yes	Yes
General/Family Practitioner	Yes *(in some regions)*	No

Patient-pay:

Patient-pay scenarios in England include private health insurance and self-funding.

- ***Private health insurance:*** Depending on the individual's level of coverage, a private health insurance company *may* approve diagnosis and treatment at a private sleep centre (or a hospital/clinic that offers both NHS and private services). A referral from a GP or other medical specialist is required and the patient is seen by a clinician, such as a sleep specialist, respiratory physician, or neurologist, who orders the appropriate sleep test.

[86] As cited in British Lung Association. (2015). "Obstructive Sleep Apnoea (OSA): Toolkit for Commissioning and Planning Local NHS Services in the UK," p. 16. See also, The British Thoracic Society, et al. (2009). *Service Specification for Investigation and Treatment of Obstructive Sleep Apnoea Syndrome*.
[87] British Lung Association. (2015). "Obstructive Sleep Apnoea (OSA)," p. 14.

- ***Self-funding:*** Individuals who choose to pay for their own diagnosis and treatment may self-refer to a private sleep centre. Broadly, patients are assessed by a clinician specializing in sleep medicine and/or respiratory medicine, who orders the appropriate sleep study (in-patient or home-based).

  However, at least one private sleep centre in England (The London Sleep Centre) offers a patient-pay online service for home-based diagnosis of OSA. For a fee of 450 GBP, an individual may order a "Home Sleep Study" that comprises:

  - **Assessment** via "a comprehensive sleep diagnosis questionnaire";
  - **Home sleep study** – mailed to the individual after the centre receives the completed questionnaire; and
  - **Results appointment** – via phone or Skype with a "Consultant Sleep Physician."

WAIT TIME MEASUREMENTS

Sleep studies are one of the "15 key diagnostic tests" for which NHS England has established a maximum waiting time guarantee of **six weeks**. Consequently, waiting times for sleep studies are tracked, monitored and reported out on.

Diagnostic wait times form part of the NHS Constitution. The Constitution includes the pledge that "patients should not be required to wait 6 weeks or longer for a diagnostic test."[88] There is some debate over whether or not this "pledge" constitutes a **legal right** to have a diagnostic test within six weeks of the request being sent.[89]

Note that waiting time guarantees, and the mandated tracking and reporting of waiting time data, pertain only to NHS services. Private services frequently advertise their low or no waiting times (as part of their marketing), but actual waits for private care are not measured or monitored by government.

Priority system:

NHS England uses a two-classification priority system in which a patient's condition is assessed as being clinically "routine" or clinically "urgent."[90] With respect to waiting list management, patients are seen by clinical priority and in the order in which they were added to the waiting list.

[88] NHS England. (2015). "NHS Diagnostic Waiting Times and Activity Data: May 2015 Monthly Report," p. 4.
[89] See, for example, Nuffield Trust. (2018). "Diagnostic Test Waiting Times."
[90] There is also a classification of "Two Week Wait," which is used for suspected cancer. This classification does not apply to referrals for sleep studies. See the online NHS Data Dictionary for details.

Wait time benchmarks:

In England, NHS patients have the right to have a sleep study (as one of the guaranteed diagnostic tests) within six weeks of the referral being sent to an NHS sleep clinic.

NHS England tracks, analyzes and reports out on diagnostic wait time data and uses a number of indicators that are designed to monitor and to support service effectiveness and efficiency. Indicators that are routinely tracked and reported with regard to diagnostic tests (including sleep studies) are:

- The total number of patients waiting six weeks or longer from referral at the end of the month;
- In the last 12 months, the proportion of patients waiting six weeks or longer at the end of a month;
- Average (median) waiting time; and
- Number of tests undertaken in a particular period (month/year).

These indicators, plus some additional measures, are reported monthly. The most recently reported data (at the time of writing) is for December 2018. Key statistics for December 2018 with respect to sleep studies include:

- The number of sleep studies conducted by NHS England during the month was 8,912, a decrease of 0.4% compared to December 2017;
- The proportion of patients waiting six weeks or longer for a sleep study was 5.8% of the total number of patients waiting at the end of the month, down from 6.5% in the previous December;
- At the end of December 2018, there was a total of 9,144 patients still waiting for a sleep study; this was an increase of 6.6% over December 2017;
- The median waiting time for a sleep study was 2.75 weeks;
- The total number of sleep studies conducted by NHS England in YTD 2018/19 was 99,811, down from 101,849 in YTD 2017/18 (a drop of 4.8%).

Waiting time start and stop:

The waiting time starts from the point at which the referral is sent and ends when the patient receives the test.

However, it is worth noting that the six-week maximum waiting time for a diagnostic test is also a key milestone to support the achievement of the **18 week referral to treatment (RTT) target** introduced by NHS England in 2010. In the case of a test for an ultimate diagnosis of OSA, for instance, an NHS patient in England would expect to begin treatment for OSA within 18 weeks of a GP referral to a sleep specialist.

REGULATION AND ACCREDITATION OF SLEEP FACILITIES

In England, accreditation of sleep centres and sleep apnoea services, and adherence to clinical standards/credentialing for sleep centre practitioners appear to be voluntary, and are, therefore, somewhat ad hoc.

Accreditation of Facilities

British Sleep Society Accreditation

According to the European Sleep Research Society (ESRS), an accreditation process for sleep centres providing polysomnography was developed by the British Sleep Society (BSS). Under this process, the Sleep Centre at Papworth Hospital (in Cambridge) received accreditation in 2011, followed by the Sleep Disorders Centre at Guy's and St Thomas' Hospital in 2012.

The ESRS states that the BSS accreditation process was suspended "with the advent of other accreditation processes within the wider National Health Service."[91] However, evidence of the existence of these "other accreditation processes" is lacking – at least within publicly available sources.

A 2016 publication by Guy's and St. Thomas' Hospital (detailing their "Sleep Visiting Professional Programme"), describes the Hospital's Sleep Disorders Centre as:

> *[…] one of only two British Sleep Society accredited sleep centres providing diagnosis and treatment for any sleep condition.*[92]

This claim suggests that little to no progress was actually made to develop "other accreditation processes" within the wider NHS and that, currently, the sleep centres at Papworth and at Guy's and St. Thomas' remain the only accredited centres within NHS England.

The ESRS notes that a "relaunch" of the British Sleep Society's accreditation process is "currently under consideration."[93] However, no publicly available evidence of this could be located.

European Sleep Research Society Accreditation

In the apparent absence of a current national accreditation process, sleep centres in England that wish to become accredited may elect to do so under the European Accreditation process developed by the European Sleep Research Society (ESRS). This voluntary accreditation process (set out in the *European Guidelines for the Accreditation of Sleep Medicine Centres*) involves two components:

- Completion of a comprehensive questionnaire; and

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[91] ESRS. (2016). "The British Sleep Society (BSS)."
[92] Guy's and St. Thomas' NHS Foundation Trust. (2016). "Sleep Visiting Professional Programme," p. 3.
[93] ESRS. (2016). "The British Sleep Society (BSS)."

- A site inspection visit conducted by a panel of "independent specialists experienced in sleep medicine.[94]

The requirements for the ESRS accreditation process cover:

- *Staffing* – including the complement and broad skill levels of management and medical staff, technical staff, and administrative staff;
- *Facilities* – including bedrooms, recording and examination rooms, and sanitary facilities; and
- *Recording techniques and criteria* – for polysomnography, polygraphy, MSLT, and Maintenance of Wakefulness Tests (MWT).

Certification for Practitioners

European Sleep Research Society Certification

The ESRS has also developed a set of *European Guidelines for the Certification of Professionals in Sleep Medicine*. The *Guidelines* "introduce a qualification" for professionals "whose main occupation is to practice sleep medicine in the setting of a sleep medicine centre." They cover:

- The object of specific competencies;
- The scope of sleep medicine; and
- The qualification procedures that pertain to: medical specialists, non-medical professionals with a master's degree (e.g. psychologists, biologists), and nurses and technologists.

Certification is voluntary and is achieved by successfully completing a theoretical and practical examination. "The certification confirms successful education in the science, practical clinical work, and technical skills as well as sufficient experience in the area of sleep medicine."[95]

UK Association for Respiratory Technology and Physiology Certification

The UK Association for Respiratory Technology and Physiology (ARTP) offers the following practitioner certification programs:

- "Overnight Pulse Oximetry Certificate" – to provide a competence based assessment for the performance and analyses of Overnight Pulse Oximetry;
- "Overnight and Polygraphy Practitioner" – covers: referral pathways; equipment; advantages/disadvantages of the investigation; quality assurance; interpreting results; and causes/mechanisms of sleep apnoea; and

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[94] Pevernagie, D. et al. (2006). "European guidelines for the accreditation of Sleep Medicine Centres." Steering committee of the European Sleep Research Society. *J Sleep Res.*, *15*, pp. 231- 238.
[95] Ibid., p. 137.

- CPAP Accreditation Certificate – to provide a competence-based assessment for the initiation, monitoring and ongoing support of patients treated with CPAP.

All of these programs appear to be voluntary.

National Standards of Care for Sleep Apnoea Services

In addition to its practitioner certification programs, the UK's Association for Respiratory Technology and Physiology has developed and published *Standards of Care for Sleep Apnoea Services (Diagnostics)*. The latest version of standards is dated July 2018.

According to the introduction, the ARTP standards document, "outlines minimum standards together with a code of conduct that will protect patients and maintain high standards of sleep diagnostic services across the United Kingdom."[96] The standards apply to equipment (e.g. sleep monitoring devices) and to general services, including diagnostic assessments, staffing, staff qualifications and staff training.

However, it is not clear whether or how these standards are enforced. Since the document also states that "the standards have been compiled to *recommend* a minimum standard for service delivery" (emphasis added), it is reasonable to conclude that adherence is purely voluntary.

PATIENT-PAY SLEEP TESTING

Patient-pay sleep testing is allowed in England, where there is a parallel system of public and private healthcare. Individuals who are willing and able to pay for a sleep study may self-refer to a private sleep centre for assessment and testing. They may also be able to pay for a sleep test at an NHS hospital that offers both public and private services.

In general, private facilities (and NHS hospitals offering private services) do not publish the fees charged to the patient for sleep studies. Also, there appears to be no "standard fee," as individuals who are interested in accessing a sleep study as a self-paying patient are required to contact the specific facility to request a quote for the service. In the table below, fees charged by the London Sleep Centre (obtained by email inquiry to the Centre) are provided as an example.

[96] Association for Respiratory Technology and Physiology. (2018). *ARTP Standards of Care for Sleep Apnoea Services (Diagnostics)*, p. 2.

Table 37. Patient-pay, England

Patient Pay				
	Simple sleep study (oximetry)	*Multi-channel sleep study at home*	*Polysomnogram (PSG)*	*Actigraphy*
Is the patient allowed to pay?	Yes	Yes	Yes	Yes
What is the standard fee?	No "standard fee" – varies by facility and location	No "standard fee" Example: • London Sleep Centre charges 450 GBP for a test ordered online	No "standard fee" – varies by facility and location Example: • London Sleep Centre charges 1500 GBP for an in-patient overnight polysomnography and 2,000 GBP for an in-patient overnight polysomnography and multiple sleep latency test	No "standard fee" – varies by facility and location

FUNDING OF CPAP

When diagnosis and treatment are provided by the NHS, provision of a "standard CPAP machine" is fully covered by the NHS. Coverage includes a yearly maintenance check of the equipment at the prescribing NHS sleep clinic. Worn out or faulty equipment is replaced as required at no cost to the patient.[97]

Cost-effectiveness studies conducted in the UK have concluded that coverage of CPAP is a cost-effective strategy for the NHS after a minimum of two years of treatment.[98]

NHS England recommends use of a custom made mandibular advancement device (MAD) for treatment of mild OSA. The NHS patient information website notes that MADs "aren't always available on the NHS" and that patients may therefore "need to pay for the device privately

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[97] See NHS. (2016). "Diagnosis: Obstructive Sleep Apnoea," and Oxford Radcliffe Hospitals, NHS Trust. (n.d.). "Information for CPAP Users." Note that it is not clear whether someone paying privately (private health insurance/self-pay) for a sleep test would then qualify for NHS-covered CPAP treatment.

[98] See, for example: Guest, J.F., Helter, M.T., Morga, A. and Stradling, J.R. (2008). "Cost-effectiveness of using continuous positive airway pressure in the treatment of severe obstructive sleep apnoea/hypopnoea syndrome in the UK." *Thorax, 63*, pp. 860-865. Of note, The British Lung Association estimates that only 330,000 adults are currently being treated out of an OSA population of 1.5 million and contends that, "Treating OSA [with CPAP] would save the NHS millions of pounds." (For further details click here.)

through a dentist or orthodontist." This suggests, however, that some local health trusts within the NHS may cover the cost of MADs and/or that some patients may qualify for coverage.[99]

APPROVAL FOR SLEEP FACILITIES TO OPEN/ OPERATE

For NHS health services, a formal commissioning process for new sleep clinics would be undertaken at the local level by the area Clinical Commissioning Group (CCG).

CCGs are "clinically-led statutory NHS bodies" responsible for the planning and commissioning of healthcare services for their local area. CCGs are led by an elected governing body made up of GPs, other clinicians and lay members. They are independent entities, accountable to the Secretary of State for Health through NHS England.[100]

No evidence could be found suggesting that private sleep centres require "approval" (i.e. from a public health body or other government authority) to open or operate.

DETERMINING NUMBER OF AND NEED FOR SLEEP FACILITIES

The British Lung Foundation has produced a *Toolkit for Commissioning and Planning Local NHS Services in the UK* (2015) for the diagnosis and treatment of OSA.[101] The *Toolkit*:

> *[…] aims to support the planning of the sleep services which are needed to manage the country's burgeoning sleep apnoea work load. […] It is designed to help audit existing services, understand local needs and plan future provision.*[102]

The *Toolkit* includes an information booklet, an audit checklist, and an "online OSA calculator tool" to support the commissioning of sleep services.

The booklet address the following topics:

- Burden of OSA in the UK (including OSA risk);
- Geographical differences in current service provision;
- Economic case for treating OSA; and
- Recommendations for service provision for a "typical" area, based on existing guidelines and research.

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[99] NHS. (2016). "Diagnosis: Obstructive Sleep Apnoea."
[100] NHS Clinical Commissioners. (2019). "About CCGS."
[101] See British Lung Association. (2015). "Obstructive Sleep Apnoea (OSA)."
[102] Ibid., p. 4.

The audit checklist enables health areas to benchmark themselves against recommended provision.

The OSA service calculator tool generates a report for any named local health area, which provides area-specific information on:

- The adult population;
- The estimated OSA prevalence;
- Recommended service provision for a population of this size;
- Cost avoidance for treating OSA; and
- Information about the local prevalence of OSA risk factors to consider when making decisions about service provision.

The online calculator tool is freely available to anyone and can be accessed (and used) here.

Note that use of the British Lung Association *Toolkit* appears to be voluntary.

The information in the British Lung Association *Toolkit* suggests that the need for sleep testing facilities is identified at local health "area" level. In England, "local area" maps to the 195 "Clinical Commissioning Groups" (CCGs) that are responsible for commissioning most of the hospital and community services within NHS England.

STAND-ALONE HOME SLEEP APNEA TESTING FACILITIES

A web search using the key words "home sleep apnoea test" + "England" identified a small number of private entities that are offering 4 or more channel home sleep apnoea testing services and that are not affiliated with a facility that provides overnight testing. (See the table below for details.)

Such private suppliers do not appear to be particularly numerous. More common are companies offering simple oximetry home testing services.

Interestingly, one of the suppliers identified (Philips) states that their service is "NHS approved." It is unclear exactly what this means, unless it is simply that the individual's results (as the website claims) "are analysed by [a] team of sleep specialists, according to the NHS process."

Table 38. Private suppliers offering stand-alone HSATs, England

Private Suppliers that Offer Stand-Alone HSATs	
Company	**Website**
Philips	https://homesleepapneadiagnosisservice.co.uk/#philips_home_sleep_test
Online Sleep Clinic	http://www.onlinesleepclinic.co.uk/testing_at_home.html
SleepTest (by Intus Healthcare)	https://www.sleeptest.co.uk
ResMed	https://www.resmed.com/uk/en/healthcare-professional.html

Of note, all of these suppliers are providing a web-based service. An individual orders the home test online (sometimes following completion of an online sleep survey/quiz purporting to indicate whether or not they are at high or low risk of having OSA); the home test is delivered to the individual (by mail or other parcel delivery service); the test is returned to the supplier (by mail or other parcel service); results are analyzed; and a diagnosis report is emailed to the individual.

SLEEP STUDY FACILITIES AND THE SALE OF CPAP MACHINES

A review of the websites of private sleep clinics in England, and of organizations offering online home sleep testing services, indicates that some of these facilities do advertise and sell CPAP machines and other sleep-related treatment devices. Therefore, there appears to be no prohibition against this.

With regard to public care within an NHS sleep centre, a "standard" CPAP machine is provided (and maintained) at no cost to the patient. However, if a patient wishes to purchase their own machine, staff at NHS sleep centres may offer advice on the alternative machines that are available.[103]

NUMBER OF SLEEP STUDY FACILITIES

The Sleep Apnoea Trust Association (UK) maintains a list of NHS sleep clinics in England on its website (http://www.sleep-apnoea-trust.org/sleep-apnoea-trust-list-nhs-sleep-clinics-uk/). There are currently 211 sleep clinics on the list (which was last updated and verified on 2 February 2018). All but a very small number of the clinics are located in hospitals.

[103] See for example, Oxford Radcliffe Hospitals, NHS Trust. (n.d.). "Information for CPAP Users," p. 7.

Private clinics are not included on the list (although, as noted above, most NHS facilities offer private as well as publicly funded services).

The list is organized by county (the largest unit of local government in England) and it is apparent from a review of the list that provision of sleep services is highly variable across England, with some counties being very well supplied and others having very few (and sometimes only one) sleep clinic.

In its 2015 *Toolkit*, the British Lung Association states that there are 289 sleep units in the UK as a whole (England, Wales, Scotland and Northern Ireland). This source also notes the "large differences in the number of available sleep centres per health area."[104]

To provide some sense of clinic/patient ratio: the population of England is just under 55 million people (2015 data); the population of the UK is just over 66 million (2017 data); and the British Lung Association estimates that around 1.5 million people in the UK have OSA.

[104] British Lung Association. (2015). "Obstructive Sleep Apnoea (OSA)," p. 10.

Key Findings: International Jurisdictions

The following key findings represent notable issues and themes from the international data that offer pertinent comparisons with the Canadian context.

Healthcare Legislation and Public / Private Provision

All of the international jurisdictions studied have parallel public and private systems of healthcare, and there are no comparable legislative constraints upon the provision of private healthcare.

Service Planning and Capacity

With respect to NHS England, the British Lung Foundation has produced a *Toolkit* for commissioning and planning services for the diagnosis and treatment of OSA. The *Toolkit* "is designed to help audit existing services, understand local needs and plan future provision." It includes an information booklet, an audit checklist, and an "online OSA calculator tool" to support the commissioning of sleep services.

Authorization to Order Sleep Tests

In Australia, a GP may directly refer a patient for either an attended or unattended sleep study *without* a personal assessment by a sleep or respiratory physician, when validated screening questionnaires suggest a high pre-test probability for a diagnosis of symptomatic, moderate to severe OSA.

In some regions within NHS England, models are being explored in which GPs offer overnight (at home) sleep studies directly to patients. Development of such models is dependent on local expertise and interest.

Measuring Wait Times

NHS England is the only international jurisdiction examined that has established guaranteed maximum waiting times for a number of "key diagnostic tests," including sleep studies. This guarantee gives NHS patients the right to have a sleep study within six weeks of the referral being sent to an NHS sleep clinic.

NHS England tracks, analyzes and reports out on diagnostic wait time data and uses a number of indicators that are designed to monitor and to drive service effectiveness and efficiency.

CPAP Funding

Of the international jurisdictions studied, US Medicare and NHS England have public coverage arrangements in place:

- In the US, Medicare pays 80% of the Medicare-approved amount for the rental of a CPAP machine and purchase of related supplies.

- In England, when diagnosis and treatment are provided by the NHS, provision of a "standard CPAP machine" is fully covered by the NHS. Coverage includes a yearly maintenance check of the equipment at the prescribing NHS sleep clinic. Worn out or faulty equipment is replaced as required at no cost to the patient.

Cost-effectiveness studies conducted in the UK have concluded that coverage of CPAP is a cost-effective strategy for the NHS after a minimum of two years of treatment.

Home Sleep Testing – the New "Gold Standard"?

In Canada, the US and Australia, clinic-based polysomnography is considered the "gold standard" for the diagnosis of Obstructive Sleep Apnea (OSA).

By contrast, NHS England appears to be promoting multi-channel home sleep testing as the new gold standard for diagnosing OSA. The British Lung Foundation (2015) has noted that polysomnography is required only for more complex cases (or where simpler tests have proved inconclusive). With the introduction of its 2017/18 *Tariff*, NHS England made the decision to set the same rate, of 408 GBP, for multi-channel sleep study at home and full clinic-based polysomnography. This appears to be a deliberate policy on the part of NHS England to "nudge" practitioners towards ordering a home test as the default procedure, except for complex cases.

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