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Title 29-A §1258 Medical Advisory Board

- 2. B. The board shall advise the Secretary of State on written medical and vision standards related to operator's licensing. Standards may only be adopted as rules.
- 6. Immunity. A member of the board or other person making an examination and report of opinion, recommendation or advice to the Secretary of State in good faith is immune

NOTES: Are these rules considered Major Substantive rules requiring the review and approval of the legislative committee with oversight? I do not believe the rule in play was properly adopted as Major Substantive, but should have been.

What is the objective of this and the other Medical Review Board "rules"? Medical treatment, or safe driving.

Sleep Apneas and related Diagnoses

- Obstructive Sleep Apnea - OSA - failure of muscles in throat to relax to let air in.
- Central Sleep Apnea - CSA - failure of autonomous CNS to send signal to breathe.
- Mixed Sleep Apnea
- Treatment Emergent CSA - TECSA is CSA triggered by PAP device usage
- Oxygen Deprivation/Saturation - SaO2 - failure of respiration to provide enough oxygen
- Excessive Daytime Sleepiness - EDS
  - Inability to maintain wakefulness and alertness
  - Irrepressible need for sleep or unintended lapses into drowsiness or sleep
  - Changes in neurocognitive function
  - EDS may persist despite optimal CPAP use
  - associated with neurocognitive and functional impairment
  - Inattentiveness
  - delayed reaction times

Medical Specializations

- Neurology - best for CNS
- Pulmonology - best for OSA
- ENT - good for OSA
- Psychiatrists

Diagnostic Methods/Measures

- Sleep Studies (Polysomnography or PSG) - Diagnostic; Therapeutic; positional
- AHI (apnea/hypopnea index) - measures severity (frequency) of OSA: an AHI of 15 or fewer obstructive events [stop breathing] per hour is considered mild [Who established this guideline?]
- Home Sleep Studies (HST)
- Epworth Sleepiness Scale (ESS) - widely used measure of subjective daytime sleepiness; somewhere between 7 and 12 out of 24 on the ESS is favorable [FAILS to differentiate between intentional dozing and unintentional catnaps]
- Informal questioning about actual sleepiness experienced
- Maintenance of Wakefulness Tests (MWT) @
- Multiple Sleep Latency Tests (MSLT) @
- Clinician must use subjective reports [from patient] … such as the ESS

@ … best objective measures of daytime sleepiness; expensive and time consuming; they are not routinely used to assess daytime sleepiness in drivers.

Treatments#

- CPAP - Continuous positive airway pressure
- BiPAP - Bi-level positive airway pressure
- APAP - auto-titrating positive airway pressure
- ASV - adaptive servo-ventilation
- Oxygen Therapy
- bariatric surgery for morbid obesity
- oral mandibular advancement devices
- upper airway surgery craniofacial surgery
- hypoglossal nerve stimulators
- Pharmacotherapy is an option for unresolved EDS in OSA
  - Wake-promoting agents (dopamine)
  - CNS stimulants are not indicated to treat patients with EDS in OSA.
- Diet and weight management
- Exercise
- Treatments directly related to driving with EDS
  - Anti-fatigue alarm device
  - Driving Fatigue Monitoring System
  - Caffeine (coffee, soda, etc.)
  - Alertness aids - like No Doze

Medicare guidelines are the standard for adherence to treatment and require an average of 4 hours PAP use per night 70% of the time. = 19.6 hours per week.

Statutes and Rules

- Rule #250c003
  - SECTION (2)(4)(B)(1)(b) The Secretary of State may suspend the license of such person, allow person to retain a license, or issue a license subject to any conditions or restrictions deemed advisable, having in mind the safety of the public and the person.
  - SECTION (2)(4)(B)(1)(d) Without preliminary hearing, suspend any operator's license, operating privilege, or privilege to apply for and obtain a license in the State of Maine if the Secretary of State determines that the person's continued operation of a motor vehicle presents a potential danger to the person or other persons or property.
  - SECTION (3) [**general**] levels or degrees of impairment:
    - 3. Active impairment
      - C. Severe. This section deals with conditions that preclude safe operation of a motor vehicle. This may be due to the severity of the condition; because the condition is not controlled; or because of a new condition which requires further testing and follow-up to determine safety to operate.

NOTES: Are these rules considered Major Substantive rules requiring the review and approval of the committee with oversight? I do not believe the rule in play was not adopted as a Major Substantive but should have been.

- **SECTION 3: FUNCTIONAL ABILITY PROFILES**

Section on Narcolepsy - Medium - Predictable mild **cataplexy** controlled with behavioral strategies and medication, ESS 8 or more, consistent use of medications and behavioral strategies for sleepiness, and avoidance of driving if sleepy.

- OBSTRUCTIVE SLEEP APNEA
  - Driver sleepiness is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with obstructive sleep apnea (OSA) are at increased risk for car accidents.
  - OSA (and possibly central sleep apnea) can cause impairment in daytime performance. It is associated with increased risk of motor vehicle crashes, with estimates ranging from 2% to 7% in those with OSA compared to those without. [A] [B] The condition is common (2-8% in older literature, with more recent estimates suggesting that 25% of adult men in the US are affected [25% of 517,826 in Maine], and the frequency of occurrence increases with age, BMI (body mass index) and comorbid conditions such as diabetes.
  - People with sleep apnea may have delayed reaction times and inattentiveness in addition to frank sleepiness. Some are unaware of their sleepiness and cognitive impairment. It is important to recognize that excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea. A recent study demonstrated that increased risk of motor vehicle crashes is present in those with **mild OSA** as well as those with severe disease [C]. The diagnosis of OSA is made through polysomnography (PSG), with insurers increasingly insisting upon Home Sleep Studies (HST) although the gold standard is still in lab polysomnography.
  - Treatment of OSA generally improves daytime sleepiness. Use of continuous positive airway pressure (CPAP) is a highly effective treatment with studies suggesting that daytime symptoms improve within two weeks of positive airway pressure (PAP) treatment. [D] It is the only **treatment** modality **demonstrated** to reduce crash risk [E]. Not using CPAP for as little as one night may cause daytime impairment [F].
  - Other treatment options for OSA include bariatric surgery for morbid obesity, use of oral mandibular advancement devices, upper airway surgery and craniofacial surgery. Hypoglossal nerve stimulators have been approved by the FDA for treatment of OSA.[G] Assessment of treatment efficacy with PSG after surgery or with use of an oral device is recommended.
  - It is difficult for clinicians to assess sleepiness (and possible impairment while driving) in a patient with OSA. Sleepiness cannot be measured easily by objective testing. Maintenance of Wakefulness Tests (MWT) and Multiple Sleep Latency Tests (MSLT) are the best objective measures of daytime sleepiness in those with OSA, but are performed only in Sleep Centers, are expensive and time consuming. They are not routinely used to assess daytime sleepiness in drivers. The clinician must use subjective reports as well as objective data from CPAP downloads to assess adherence to treatment and level of daytime sleepiness.
  - The diagnosis of obstructive sleep apnea should only be made by a physician or NP/PA with specialized training in Sleep Medicine. Those with OSA are frequently followed by a sleep specialist or a neurologist.
  - The Epworth Sleepiness Scale is a widely used measure of subjective daytime sleepiness although the sensitivity and specificity of the scale is less than ideal. A score of 7 or less out of 24 is considered normal (not sleepy) [H]. The acceptable range cutoff value is subject to debate, with some researchers suggesting that 7 or less is normal (not sleepy): others suggesting 12 or less).

- Patients on PAP therapy should have data downloaded from their device to measure adherence with therapy. Medicare guidelines [i] are the standard for adherence to treatment and require an average of 4 hours PAP use per night 70% of the time.
- PAP devices also calculate an AHI (apnea/hypopnea index). The AHI determines the severity of OSA: an AHI of 15 or fewer obstructive events per hour is considered mild.
- The clinician must educate patients that driving safety is ultimately the individual's responsibility. Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy.

Profile Levels	**Degree of Impairment[2]/ Potential for At Risk Driving**	**Condition Definition / Example**	**Interval for Review and Other Actions**
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Recovered after Treatment(s) other than CPAP, such as surgical intervention, weight loss or dental device[3]. Polysomnogram (PSG) demonstrates an AHI[4] (apnea/ hypopnea index) of less than 15. ESS (Epworth Sleepiness Scale)[5] score of less than 8. No report of accident or near miss.	N/A
3.	Active impairment	See footnote regarding PAP therapy.[6] This diagnosis should be made only after a sleep study. Neurology or sleep med specialists are often the clinicians to provide follow-up.	
	a. Mild	AHI[4] < 15 on diagnostic PSG and not sleepy, ESS less than 8. Not on treatment.	Three years
	b. Moderate	PAP download demonstrates adherence to treatment.[6 7] AHI[4] less than 15 on download. ESS less than 8. No crashes or near misses.	Yearly
	c. Severe	• History of falling asleep while driving or near miss, or • strong suspicion of OSA with concern for unsafe driving; and/or • Non-responsive or non-adherent[7] to therapy.	**No driving**

My record -

- **I refuse to wear a PAP device; 15+ years of apnea**
- **I have no history of driving while tired; 50+ years of driving**
- **I have no accidents or violations related to drowsiness; only 2 accidents lifetime**
- **I have driven just over 4000 miles a year in the last two ears.** I don't travel far nor often.
- I emphasize important factors from **my PSGs** that should be considered
    1. high sleep latency (hard time falling asleep
    2. extended periods of wakefulness after arousals
    3. low levels of SaO2 desaturation
    4. mild score on Epworth Sleepiness Scale
    5. My sleep efficiency scores indicate hard time falling asleep (Normal sleep efficiency is considered to be 80% or greater.)
    6. Non-supine AHI = 1.2
- **I developed a Personal Safe Driving Plan**

1. I never drive when I know I am tired.
2. If I start to lose concentration, I pull over and take a short refreshing roadside nap.
3. I never drive more than one hour in any direction. That is about the limit of my concentration.
4. I drink PEPSI plus two cups of coffee every day.
5. I usually have the radio or CD player going in the car.
6. Always wear sunglasses to prevent retinal fatigue.
7. I am intentionally aware of my problem and pay good attention.
8. I have a good driving record which is an indication that I have not had prior problems with driving.
9. I have driven just over 4000 miles a year in the last two ears. I don't travel far nor often.
10. I do not drink.
11. I do not smoke.
12. I do not own a cell phone.
13. I manage my meds so they won't affect me when I will be driving.
14. I use Melatonin to sleep better at night and be more alert during the day.
15. I rarely/never drive after sunset.
16. I rarely if ever have passengers nor let them distract me.
17. I have an anti-drowsiness device I wear for non-local ventures.
18. I am ADHD with an emphasis on Hyper-attentive if you know what that means.

29 DEPARTMENT OF SECRETARY OF STATE

250 BUREAU OF MOTOR VEHICLES

Chapter 3: PHYSICAL, EMOTIONAL AND MENTAL COMPETENCE TO OPERATE A MOTOR VEHICLE

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29 DEPARTMENT OF SECRETARY OF STATE

250 BUREAU OF MOTOR VEHICLES

Chapter 3: PHYSICAL, EMOTIONAL AND MENTAL COMPETENCE TO OPERATE A MOTOR VEHICLE

SUMMARY: These rules describe the standards to be used by the Secretary of State in determining physical, emotional and mental competence of persons to operate motor vehicles. The rules establish a reporting system that requires persons to submit medical information to the Secretary of State. Persons found incompetent to operate a motor vehicle in accordance with procedures outlined in these rules may have their driving privileges suspended, revoked or restricted.

SECTION 1: STANDARDS

1. **Secretary of State**. The Secretary of State shall determine the physical, emotional, and mental competence of a person to operate a motor vehicle with the advice of the Medical Advisory Board and on the basis of the Functional Ability Profiles.

2. **Functional Ability Profiles**. Standards to determine the competence of a person to operate a motor vehicle are those contained in the "Functional Ability Profiles" adopted by the Secretary of State with the assistance of the Medical Advisory Board.

SECTION 2: REPORTING SYSTEM

1. **Medical conditions requiring report**. Conditions which may result in functional limitations and increase risk of unsafe operation of a motor vehicle should be reported. Conditions for which a person is required to submit a report to the Secretary of State include, but are not limited to, alterations/loss of consciousness, cardiovascular, chronic pulmonary, hypoglycemia, musculoskeletal, neurological (including dementia, epilepsy/seizures, narcolepsy, sleep apnea), substance use, mental/emotional, and visual disorders.

2. **Sources of information**. Sources of information concerning medical conditions include, but are not limited to:

   A. Permits, licenses, renewal applications, and accident reports;

   B. Written reports from family, physicians, law enforcement personnel and other government agencies; and

   C. Signed statements from citizens.

3. **Nature of medical report**. Upon receipt of information concerning the existence of a medical condition for which a report is required or which may affect a person's ability to operate a motor vehicle, the Secretary of State shall request the person involved to submit a medical report from a physician or from other qualified treatment personnel who may be specified. Other treatment personnel may include but are not limited, to licensed or certified professionals as follows: Physicians, nurse practitioners (NP), physician’s assistants (PA), optometrists, psychologists, chiropractors (only for musculoskeletal issues), licensed clinical social workers (LCSW) trained in substance abuse or mental health, physical or occupational therapists (PT or OT), and any other medical personnel as deemed appropriate by the Secretary of State or his/her designee.

A. To be acceptable, the medical report must be made on forms supplied or approved by the Secretary of State and must contain the physician's or other treatment personnel's diagnosis of the patient's condition(s) and any prescribed medication(s).

B. The Secretary of State may specify the clinician qualifications in certain situations, e.g. narcolepsy or obstructive sleep apnea.

C. The Secretary of State may require an individual to certify in writing the date of the person's last seizure, or alteration of consciousness.

4. **Action by the Secretary of State**

A. Upon receipt of a medical report indicating that a person is competent to operate a motor vehicle, the Secretary of State may approve the person's competence to operate a motor vehicle, with or without restrictions, taking into consideration the safety of the public and the welfare of the driver.

B. Upon receipt of a medical report indicating that a person is not competent to operate a motor vehicle, or upon the failure or refusal of a person to submit the requested information, the Secretary of State shall follow one or more of the following procedures:

(1) If, from records or other sufficient evidence, the Secretary of State has cause to believe that a person is not physically, emotionally, or mentally competent to operate a motor vehicle, the Secretary of State may:

(a) Obtain the advice of any member of the Medical Advisory Board or the Board collectively. The Board, or any member may formulate advice from the existing records and reports, or may request that an examination and report be made by the Board or any other qualified person so designated. The licensed driver or applicant may present a written report from a physician or other qualified treatment personnel of the person's choice, to the Board or the member reviewing the matter and such report must be given due consideration. Members of the Board and other persons making examinations and reports are not liable for their opinions and recommendations pursuant to this subsection.

(b) Require a person to submit to a driving evaluation. Upon the conclusion of such an evaluation, the Secretary of State shall take action as may be appropriate. The Secretary of State may suspend the license of such person, allow person to retain a license, or issue a license subject to any conditions or restrictions deemed advisable, having in mind the safety of the public and the person.

(c) After hearing, suspend any operator's license, operating privileges, or privilege to apply for and obtain a license in the State of Maine.

(d) Without preliminary hearing, suspend any operator's license, operating privilege, or privilege to apply for and obtain a license in the State of Maine if the Secretary of State determines that the person's continued operation of a motor vehicle presents a potential danger to the person or other persons or property. The Secretary of State shall notify the person that a hearing will be provided without undue delay.

5. **Confidentiality of reports**. Reports received under this rule are confidential in accordance with the Maine Motor Vehicle Statutes.

SECTION 3: FUNCTIONAL ABILITY PROFILES

Functional ability to operate a vehicle safely may be affected by a wide range of physical, mental or emotional impairments. To simplify reporting and to make possible a comparison of relative risks and limitations, the Medical Advisory Board has developed Functional Ability Profiles for twelve categories, with multiple levels under each profile. Conditions that may affect the safety of a person to operate a motor vehicle but are not included in the specified categories, may be reported using the general definitions listed below. Clinician recommendations to limit or expand driving privileges, shorten or extend intervals for review, add or delete restrictions will be given due consideration. However, the Secretary of State will make the final determination.

Each profile follows the same format and describes levels or degrees of impairment:

1. **No diagnosed condition.** This section is used for a patient who has indicated to the Bureau of Motor Vehicles a problem for which no evidence is found, or for which no ongoing condition can be identified. For example, this category might apply to a person with a heart murmur as a young child who indicates heart trouble, or to a teenager who fainted in gym class once on a hot day who indicates blackouts.

2. **Condition, fully recovered/compensated.** This category includes history of a condition that has been resolved or does not warrant review. Guidance for the use of this section is provided in each profile.

3. **Active impairment**

   A. **Mild.** This section deals with conditions which warrant periodic medical review because of an ongoing condition that could deteriorate, and/or conditions that may impair ability to drive but which are controlled so that a person can still operate a motor vehicle safely.

   B. **Moderate.** This section deals with conditions that require more frequent medical review, or may necessitate use of personal medical devices, orthotics, adaptive equipment for the car, or restrictions to safely operate a motor vehicle. Some conditions may require a driving test to determine fitness to drive, or may preclude driving, but with potential for recovery allowing safe operation of a motor vehicle.

   C. **Severe.** This section deals with conditions that preclude safe operation of a motor vehicle. This may be due to the severity of the condition; because the condition is not controlled; or because of a new condition which requires further testing and follow-up to determine safety to operate.

   In all cases, periodic review may result in a different profile level as the condition improves or deteriorates.

   When the circumstances of an individual driver do not clearly fit within the guidelines presented in these rules, the Medical Advisory Board or any Member may be consulted for review, on a case by case basis.

   Reporting of temporary conditions is not required. However, a person experiencing a condition or taking medications that may impair their ability to safely operate a motor vehicle should refrain from operating a motor vehicle until their condition improves or they are no longer taking the medication.

CARDIOVASCULAR DISORDERS

Cardiovascular disease may affect a driver's ability in a variety of ways, most particularly being the possibility of cardiac syncope or near syncope, due to either dysrhythmia or medications/devices used to treat the cardiac disorder. Guidelines are provided for two important categories of diagnoses that may require driving restriction or periodic review.

Supraventricular Arrhythmia and Cardiac Syncope

In general, the first two levels of this profile apply to individuals whose arrhythmia has been of a minor nature or so remote and well controlled that the patient is expected to drive without his/her condition presenting a risk to the public. In other cases, such as Supraventricular Tachycardia, Atrial Fibrillation, or bradydysrhythmias, the risk is related to the likelihood of recurrence, and the likelihood that recurrence may result in alteration or loss of consciousness.

Ventricular Tachycardia and Ventricular Fibrillation (VT and VF)

Implantable Cardioverter-Defibrillators (ICD) present special circumstances and problems. Generally, a patient who receives such a device for a presenting rhythm that resulted in loss of consciousness (e.g., for secondary prevention[i], following syncope or sudden death), or a person who experiences Loss of Consciousness(LOC) associated with discharge of the device for an abnormal rhythm, should not drive for 6 months. Driving may be resumed after 6 months without an event. Patients, who have a device implanted for primary prevention[1] due to non-syncopal rhythms may be allowed to resume driving within a week. It is important to note that each of these is a discrete decision by the treating clinician and must be considered individually.

Other Cardiac Conditions

Any other cardiac condition which could cause syncope or near syncope so that a person might not be safe to drive, may be profiled using the generic profile levels described in SECTION 3 of the FAP. Vasovagal syncope is excluded from this FAP. The clinician may make recommendations about driving or the interval for review. A person with generalized deconditioning which reduces functional capacity should be evaluated using the "Miscellaneous Musculoskeletal and Neurological Conditions" FAP.

Footnotes:

[i]Primary prevention refers to placement of an ICD in a person that has not experienced a sudden cardiac arrest, but is at high risk for such an event. Placement in a person that has already experienced a cardiac event such as syncope or cardiac arrest is referred to as secondary prevention.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE

Cardiovascular Disorders[1]: Ventricular Tachycardia/Ventricular Fibrillation

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Arrhythmia by history, not documented, asymptomatic	N/A
3.	Active impairment		
	a. Minimal	Non-syncopal, non-sustained ventricular tachycardia.	4 years
	b. Moderate	Sustained VT without syncope under treatment; and/or VT or VF, treated with medication or ICD[3], greater than 6 months without syncope or LOC. If driver has ICD - no pre or post shock syncope, alteration of consciousness, or interference with ability to control a motor vehicle, within past 6 months.	2 years
	c. Severe	Same as Profile 3.b., but under treatment less than 6 months, or syncope pre or post ICD[3] discharge, or syncopal arrhythmia not responding to treatment; or New conditions under investigation to determine potential risk for unsafe driving.	No driving

[1] For further discussion regarding CARDIOVASCULAR DISORDERS, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] ICD includes implantable cardioverter defibrillators

FUNCTIONAL ABILITY PROFILE
Cardiovascular Disorders[1]: Supraventricular Arrhythmias[2]/Cardiac Syncope/Bradyarrhythmias

Profile Levels	Degree of Impairment[3]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Arrhythmias by history, not documented, asymptomatic; or Documented arrhythmias (excluding VT/VF[4]) with none in the last 18 months and no other identified heart disease.	N/A
3.	Active impairment	Excluding VT or VF[4]	
	a. Minimal	Documented arrhythmias associated with syncope more than 18 months ago, asymptomatic; and/or A-fib or supraventricular tachycardia without syncope, only mildly symptomatic (e.g., dyspnea, mild lightheadedness).	6 years
	b. Moderate	Documented arrhythmias associated with syncope within the past 6-18 months, mildly symptomatic (e.g., dyspnea, mild lightheadedness).	2 years
	c. Severe	Documented arrhythmias associated with syncope within the past 6 months or symptoms that interfere with normal functioning; or History of syncope of unknown cause less than 6 months ago, with underlying heart disease(For exception see[5]); or New conditions under investigation to determine potential risk for unsafe driving.	No driving

[1]For further discussion regarding CARDIOVASCULAR DISORDERS, please refer to NARRATIVE found at the beginning of this section.
[2]Excludes transient arrhythmias or conduction defects associated with acute myocardial infarction.
[3] For further explanation of circumstances, please refer to SECTION 3.
[4] For Ventricular Tachycardia or Ventricular Fibrillation, see appropriate FAP Table.
[5] Definitive therapy for prevention of syncope may allow driving in <6months on an individual basis.

CHRONIC PULMONARY DISEASE

Chronic obstructive pulmonary disease (COPD) refers to those pulmonary diseases characterized by obstruction to the outflow of breath, as measured by expiratory flow rates, and includes emphysema, chronic bronchitis, and some forms of chronic asthma. Restrictive pulmonary diseases are distinct in limitation of expansion of the lung and include any type of pulmonary fibrosis, chronic infection with scarring, dust deposition, etc. Although the pathology is different, a final common pathway for both major types of pulmonary disease will be breathlessness or dyspnea, hypoxia, frequent exacerbations and infections, eventual pulmonary insufficiency, and finally respiratory failure.

Most COPD in U.S. is the result of chronic tobacco use and its sequelae. It is the fourth leading cause of death nationally, counts 16 million sufferers in the U.S., is the major cause of hospitalization in Medicare recipients in Maine, and is the source of many reports of disease in license applications to Maine Bureau of Motor Vehicles. Chronic restrictive disease is much less common.

Currently the Global Initiative for Chronic Obstructive Lung Disease (GOLD)[A] guidelines as developed by World Health Organization and the National Institutes of Health define the diagnosis and severity of COPD using pulmonary function testing measuring FVC and FEV1. COPD is confirmed if the FEV1/FVC is < 0.70.

Severity of disease is divided into Classes A-D in the following way:

A MILD: FEV1 ≥ 0.80 (of predicted normal for age and sex)

B MODERATE: FEV1 ≥ 0.50 and <0.80

C SEVERE: FEV1 ≥ 0.30 and < 0.50

D VERY SEVERE: FEV1< 0.30

These categories were developed to define treatment and prognosis but can also be used to predict severity of symptoms and hypoxia. There are other systems for defining severity. For example, the previously used American Thoracic Society chart[B] uses two parameters (PFT and DLCO) and divides classes of disease slightly differently. However, none of these systems are based on oxygen saturation or PO2.

In contrast, most studies of driving ability and COPD have focused on the neuropsychological effects of hypoxia. Classic studies in the 1980's found difficulties in COPD patients on complex cognitive testing. Grant and colleagues (1982)[C] studied 203 severely hypoxic patients (mean PO2 of 51) and matched controls, and found 42% with cognitive difficulties in the study group compared to 14% in the controls. These did not correlate well with standard pulmonary function tests (PFT's). A second study by Prigatano (1983)[D] confirmed the same type of cognitive limits in slightly less hypoxic patients, mean PO2 of 66. A meta-analysis[E] done by several of these researchers in 1987 found that neuropsychological effects were correlated with level of hypoxia.

More recent studies[F] [G] using driving simulators, done by European researchers, have confirmed that even mildly hypoxic patients have perceptual difficulties and perform less well than controls. At least one recent study[H] has correlated hypoxia with PFT and Gold classes. Few studies however have shown higher crash rates among COPD patients, although some Utah driver data[I] suggests that persons with any pulmonary condition are at higher risk of crashes.

Restrictive diseases could be scored by similar categories as the GOLD guidelines (mild, moderate, severe, very severe) based on percent FVC and could be subject to the same driving restrictions when hypoxic pulmonary insufficiency develops.

Based on the above research, shorter review periods are required in persons with higher class of disease or those requiring oxygen (even nocturnal or partial use) given that such persons are prone to exacerbations worsening their day to day status, prone to gradual decline, and prone to experience difficulty with stressful driving conditions. Those who cannot maintain adequate oxygenation with supplementation should not drive.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Chronic Pulmonary Disease[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Any pulmonary condition, recovered or cured; or Minimal, reversible, episodic, controlled pulmonary condition.	N/A
3.	Active impairment	Pulmonary disease	
	a. Mild	Gold A-B, mild dyspnea; or Gold C-D, maintains O2 sat 89% or greater on room air. Moderate dyspnea, no hypoxia less than 89%; or Restrictive or other pulmonary disease of mild severity, maintains O2 sat 89% or greater on room air.	4 years
	b. Moderate	Gold C-D, moderate dyspnea. O2 sat 88% or less, or PO2 55 or less on room air, but able to maintain O2 sat 89% or greater on oxygen supplementation; or Restrictive or other pulmonary disease of moderate severity, O2 sat 88% or less on room air but able to maintain O2 sat 89% or greater on oxygen supplementation; or Exercise or sleep induced O2 sat 88% or less.	2 year If O2 sat less than 88% (on room air) while at rest or driving must use O2 while driving. Note: Those with only sleep or exercise induced hypoxia are not required to use O2 while driving.
	c. Severe	Gold D, hypoxia cannot be controlled to maintain O2 sat 89% or greater, or PO2 56 or greater; or severe restrictive or other pulmonary disease, cannot maintain O2 sat 89% or greater; or new condition under investigation, unable to maintain O2 sat 89% or greater on room air.	No driving

[1] For further discussion regarding PULMONARY DISORDER, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.

DEMENTIA

Many disease processes can cause dementia, most commonly Alzheimer's Dementia, stroke, and Parkinson's Disease. Less common causes include Lewy Body and fronto-temporal dementias, HIV and other chronic viral CNS infections, B12 deficiency, chronic alcohol damage, and multiple sclerosis. All dementias cause some mixture of permanent, often progressive, loss or impairment of cognitive skills like memory, visuo-spatial perception, language, abstraction, prosody and/or praxis impairments, and/or executive function (complex reasoning, planning and judgment).

Memory loss is usually the first to occur in Alzheimer's Dementia, but alone is insufficient to make that diagnosis without other cognitive deficits. Memory loss may be absent or at least occur later in several other types of dementia. Dementias must also be differentiated from other cognitive impairments like congenital mental retardation, transient impairments from delirium-producing conditions, or "mild cognitive impairment" (MCI) which entails mild memory or other cognitive deficits but no functional impairment. MCI carries no increased crash risk, nor may mild dementia. However, the potential for progression in both justifies more frequent physician re-evaluations.

The cognitive changes associated with dementia often affect drivers' ability to drive competently and increase crash risks. Those risks are elevated, especially in emergencies and in complicated traffic patterns, such as at intersections, with lane changes, while merging and making left-hand turns. Drivers with a screening Mini Mental Status Examination (MMSE) score of <24 fail road tests 70% of the time, but 30% pass; those with scores of <19 fail 95% of the time, and only 5% pass.[A]

Unfortunately, there are no tests of driving competence with 100% sensitivity/specificity. Current evidence does show several potentially useful clinical associations between specific cognitive test results and driving outcomes, although scoring cut-points for safe/unsafe driving often vary among studies. Nevertheless, office tests of attention, executive function, visuo-spatial skills, and memory are useful in assessments of drivers with dementia. These include Trails B, Useful Field of View, clock drawing, and several others.[A B]

The MMSE is commonly used clinically as a screening evaluation instrument and to classify the severity of Alzheimer's or mixed vascular dementias. Although MMSE copyrights have slowed its use, it still has the longest track record in driving/dementia research. An abnormal score alone is not sufficient to diagnose dementia without further clinical and functional evaluation because it has a 10-20% false positive rate.[C] A normal score alone is insufficient to clear a person suspected of having dementia to drive since it has a false negative rate as well, especially because it measures insight and executive functions poorly. The MMSE particularly may correlate poorly with driving competence in non-Alzheimer dementias like fronto-temporal types.

Though MMSE scores are used as partial guidelines for driving competence, other more available cognitive tests, especially the Clinical Dementia Rating (CDR) scale, the Montreal Cognitive Assessment Test (20-25 = mild), or the Short Blessed Test (8-15 = mild) may serve equally well.

Although not all experts agree, the Driver Fitness Working Group[A] states that the presence of two or more of the following factors may indicate the need for a cognitive assessment by a health care professional. Applicants with greater numbers of risk factors should be considered at greater risk, although the relative risks are not necessarily additive.

1. Age 80 years or older
2. History of a recent crash or moving violations
3. Applicant self-report or caregiver report of impaired skills
4. Use of psychoactive medications such as benzodiazepines, neuroleptics, antidepressants, or use of medications for Alzheimer's Disease
5. History of active alcohol abuse
6. History of falls
7. Inability to understand or hear instructions during interactions with the health professional
8. Scores with simple screening tools that indicate the possibility of a cognitive deficit

Online programs intended to assist older drivers self-evaluate driving skills may help them to an appropriate decision to retire from driving. Road tests with a driving rehabilitation instructor, occupational therapist or driver educator may also be useful. Family members may also provide useful information about an elder's ability to drive safely.

Online medical textbooks maintain useful reviews of all these issues.[D]

When BMV is notified that a licensed driver is diagnosed with dementia[D], the driver will usually be required to submit a "Driver Medical Evaluation" (CR-24) form, completed by an appropriate clinician. Depending on the outcome of the Evaluation, the driver may also be required to take a road test, which must be administered by a BMV Driver's License Examiner.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Diagnosed Dementia[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Cognitive impairment recovered. (Rare, usually within 6 months of identification. Example: recovery following a stroke.)	N/A
3.	Active impairment	Diagnosed progressive dementias with 2 or more functional impairments lasting >6 months, and other causes having been ruled out. For Lewy Body Dementia, see[3].	
	a. Mild	Dementia without concern for unsafe driving in clinician's judgment. Supporting evidence should be submitted and could include documentation of MMSE 24-26+, CDR< 1, or MoCA≥22, without evidence of executive dysfunction or visuo-spatial impairment.	2 years[4]
	b. Moderate	Dementia with risk factors for unsafe driving in clinician's judgment, but limited driving may be possible & safe. Supported by documentation i.e., MMSE 20-23, CDR 1-1.5, or MoCA 19-21, without evidence of executive dysfunction or visuo-spatial impairment.	Annually ROAD TEST
	c. Severe	Dementia with history of unsafe driving, or driving is not safe in judgment of clinician. Supporting evidence should be submitted and could include: MMSE ≤19, CDR 2 or greater, or MoCA≤18, or deficits in visuo-spatial or executive function; or new cognitive impairment under investigation, with concern for potentially unsafe driving.	No driving

[1] For further discussion regarding DEMENTIA, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] Lewy Body Dementia exhibiting significant movement disorder manifestations should also be reviewed using the Parkinson's FAP.
[4] If clinician documentation supports stability over several years and they make a recommendation, the interval for review may be extended. If clinician documents progression of disease and recommends more frequent review and road testing, the interval may be shortened.

HYPOGLYCEMIA WITH OR WITHOUT DIABETES MELLITUS

Hypoglycemia can cause altered consciousness, weakness, fatigue, lethargy, motor abnormalities, visual disturbances, tremors or psychiatric disorders. Hypoglycemia requiring the assistance of a third party is incompatible with driving, especially when accompanied by hypoglycemia unawareness.

Other complications of diabetes should be assessed under the appropriate guidelines, e.g. diabetic retinopathy should be referred to the visual acuity profile.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Hypoglycemia (With or Without Diabetes Mellitus)[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Condition which caused hypoglycemic episode is fully recovered; or No hypoglycemic episodes within past 3 years and/or low risk for recurrence.	N/A
3.	Active impairment		
	a. Mild	Single episode of hypoglycemia within the past 12 months readily explained by one-time event that is not likely to recur (e.g. accidental overdose of insulin); or History of hypoglycemic episodes, more than 12 months ago, and condition is stable.	3 years
	b. Moderate	One or more hypoglycemic episodes requiring third party assistance 3-12 months ago and condition is stable. Clinician should indicate if person has hypoglycemic unawareness.	1 year Note: Review drivers with hypoglycemic unawareness every 3 months until profile level 3a.
	c. Severe	One or more hypoglycemic episodes requiring third party assistance, with or without hypoglycemic unawareness, within the past 3 months.	No driving

[1] For further discussion regarding HYPOGLYCEMIA, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.

MENTAL DISORDERS

There is no certain way of predicting which persons with mental disorders (the American Psychiatric Association's preferred term for psychiatric illness) will have accidents, but many high risk drivers are such because of symptoms from psychiatric conditions. In a review of medical literature spanning 1960-2000, the National Highway Traffic Safety Administration noted that people with schizophrenia, personality disorders and chronic alcohol abuse are at highest risk for unsafe driving.[A] (Refer to Substance Use Disorders FAP for guidelines)

Given that many mental disorders wax and wane in severity, this FAP attempts to provide guidelines that protect public safety but allow driving when possible. Recommendations are drawn from a review of medical literature, a review of recommendations from other states, and from the experiences of physicians in Maine.

Diagnosis of a mental disorder is important, but clinicians should also focus on a patient's function, in particular attention and concentration, executive function (or other cognitive changes related to psychiatric diagnosis), psychosis, psychomotor retardation, response disinhibition or impulsivity, intent for dangerousness to self or others, and on whether or not the patient has the insight to recognize limitations or the judgment to stop driving if the limiting symptoms occur.

When assessing safety and stability, clinicians may also consider patient histories and collateral information about motor vehicle crashes, driving citations, relapses in substance use disorder, patient compliance with treatment, and relapses in the mental disorder for which the patient is being treated in order to gain a fuller picture of the patient's ability to drive safely. One episode of poor judgment does not necessarily mean a patient should stop driving. There should be a pattern of concerning behaviors or symptoms.

Many individuals with psychiatric illness are maintained on medications on an outpatient basis. These drugs have varying degrees of sedative side effects and can potentiate other central nervous system depressants. Persons receiving such medications should be screened in terms of severity of side effects incident to medication and the adequacy of the remission of symptoms related to the mental disorder.

Normally, BMV will not require reporting of prescribed medications used as ordered. However, in cases where proper use of prescription medications have resulted in driver impairment, such as OUI, crashes, reports of unsafe driving, or when a clinician is concerned that a patient may be non-compliant with driving recommendations, use of the Opiate Replacement and Prescription Medication FAP is appropriate. Please note that clinicians are responsible to assess their patients for potential risk and advise them whether to drive or not based on their medications and medical conditions.

Medications that are of particular concern for sedation, especially if patients are prescribed more than two or are concurrently prescribed opioids or are abusing drugs or alcohol, include the tricyclic antidepressants, sedative hypnotics, some antipsychotics, and benzodiazepines. Methadone and benzodiazepines are a particularly troubling combination for risk of sedation. (See Substance Use Disorder FAP if that is primary diagnosis).

Special Circumstances

Electroconvulsive Therapy (ECT): A seizure induced by ECT treatment is not considered a Seizure Disorder for purposes of driving a motor vehicle. Transient confusion or cognitive changes would be expected to clear in a day or two after treatment, during which the patient should not drive. However, it is possible for ECT treatments to result in long-lasting cognitive changes that impair the ability to drive safely, usually in the context of evolving dementia. Under these circumstances evaluate according to the Dementia FAP.

Psychogenic Non-epileptic Seizures (PNES): PNES are considered to be a form of Conversion Disorder in DSM-V (the most recent DSM at the time this FAP was written) .[BC] Until a formal diagnosis of PNES has been made (consultation with Neurology and EEG Video Monitoring are especially helpful in this regard), clinicians should use the FAP for Seizures even if PNES is suspected. Once PNES is formally diagnosed, the evaluation of driver safety should be individualized but patients with PNES are very likely to fall in to category 3b or 3c on this FAP. There is no clear consensus in the medical literature about driving limitations for PNES , but in a study in the United Kingdom, 50% of neurologists who specialize in diagnosing PNES felt that driving restrictions should be similar to that for epilepsy. There are reports of motor vehicle crashes related to PNES.[D] Prognosis for cessation of psychogenic seizures is better if PNES resolves spontaneously in the first year or two, but poor if the symptoms have gone on for 10 or more years.

Novel treatments or treatment in development: Transcranial Magnetic Stimulation[E] and intravenous ketamine are examples of new or novel treatments at the time of this FAP preparation that have no track record in the medical literature as far as driver safety is concerned (but are not meant to be the only treatments considered here). Practitioners using any new or novel treatments are strongly urged to consider a patient's ability to drive safely as part of their post-treatment assessment protocols.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Mental Disorders[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Past history of a psychiatric disorder in sustained remission 2 years or more. No impairment in driving abilities from medication/treatment side effects, and does not meet listed criteria below.	N/A
3.	Active impairment	Please refer to narrative section "Special Circumstances" regarding PNES & ECT. On-going symptoms that meet current DSM criteria for a mental disorder[3]; and	
	a. Mild	Condition stable but less than 2 years; no cognitive impairment; minimal functional impairment from symptoms or medications or other treatments; or Occasional recurrence of mild to moderate symptoms without suicidal or homicidal intent and with insight and judgment adequate to stop driving if functional limitations or medication side effects occur	1 year
	b. Moderate	History of symptoms such as suicidal or homicidal intent, aggressive or violent behaviors, impulsivity, psychosis, inattentiveness, or cognitive changes; with poor insight into limitations that create a risk for driving that occur only during recurrence of the psychiatric disorder. Symptoms have improved with treatment and have been stable for at least 3 months. Cleared by clinician to drive. Clinician should recommend ROAD TEST if, driver is returning to	6 months ROAD TEST if recommended by clinician

		driving after 6 months or more of no driving; or if they are transitioning from Severe Profile Level 3c to Moderate 3b.	
	c. Severe	Persistent or progressive psychiatric symptoms that are not expected to improve despite adequate treatment or due to chronic patient non-compliance, AND 1 or more of the following: Chronic dangerous behaviors toward self or others; chronic suicidal or homicidal intent; chronic delusions or hallucinations that impair driving ability; severe anger, impulsivity or irritability that create a driving hazard; chronic poor insight and judgment about driving limitations leading to dangerous behaviors; significant executive function or cognitive changes related to psychiatric condition; chronic medication or treatment side effects such as sedation, blurred vision or tardive dyskinesia that impair safe vehicle operation; or New condition or onset of symptoms, under investigation **and** that may pose risk to safe operation of a motor vehicle.	No driving

[1] For further discussion regarding PSYCHIATRIC DISORDERS, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] For substance use or withdrawal disorders, please see FAP for Substance Use Disorders.

MUSCULOSKELETAL AND NEUROLOGICAL DISORDERS

There are a wide variety of Neurologic and Musculoskeletal disorders which can impact driving safety. Impairment may be the result of altered muscular, skeletal, neurologic, and/or cognitive function. Motor, sensory, and/or cognitive deficits may adversely affect strength, coordination, reaction time, range of motion, visual perception, processing speed, judgment, problem solving, attention, memory, and/or awareness, in terms of a driver's ability to perform the actions necessary to safely operate a motor vehicle.

Disorders affecting cognition such as epilepsy, stroke, traumatic brain injury, Parkinson's disease, dementia, and encephalopathy as well as disorders affecting neuromuscular function such as multiple sclerosis, Parkinson's disease, muscular dystrophy, cerebral palsy, myasthenia gravis, amyotrophic lateral sclerosis, spinocerebellar ataxia, foot drop, neuropathy, and spinal cord disorders all may present their own unique barriers to safe motor vehicle operation. What's more, there is considerable overlap in the clinical manifestations of these disorders. A driver with these conditions may have chronic functional limitations that have the potential to affect safe operation of a motor vehicle and should be evaluated. When functional abilities are in question, a road test may be recommended by the clinician or required by BMV.

Many of these conditions may result in symptoms or impairments that fall under more than one Functional Ability Profile (FAP) and will need to be evaluated using more than one FAP. For example, following a stroke a driver may experience a visual field or acuity disturbance and may also need adaptive equipment. This person would need to be evaluated using both the Stroke and the Visual Disorders FAP's. A person with Parkinson's Disease may have cognitive or psychiatric deficits as well as the neurological and motor deficits. They would need to be evaluated using the Parkinson's, as well as the Dementia or Mental Disorders FAP. BMV will use the most restrictive FAP to determine the fitness of a person to drive.

Neurological disorders may have an unpredictable, episodic, or progressive course and require periodic evaluation by a qualified medical practitioner. The treating clinician shall determine the timing of evaluation but should have a working knowledge of a driver's current condition when filling out the Driver Medical Evaluation (CR-24) form. When completing the CR-24 the driver must have been seen within the past 12 months or less.

Individuals with any number of neurological and musculoskeletal conditions may use adaptive equipment when driving. Person's that use adaptive equipment when driving must take a road test. Although referral to a driving rehabilitation specialist may be indicated in some cases, it is not required by BMV. When BMV requires a road test, it will be administered by a BMV Driver's License Examiner. The road test will determine whether the person is allowed to drive and if there are driving restrictions.

Conditions which require review include but are not limited to the following:

Amputation or Limb Deficiency

Amputation or limb deficiencies may be either congenital or acquired of the upper or lower extremities, with functional implications to safe driving being the decreased ability to operate one or more of the vehicle controls. Adaptive driving equipment will require consideration depending on the specific limb deficiency, use of prosthesis and overall functional abilities of the person. Evaluation by a driving rehabilitation specialist may be appropriate depending on the extent of impairment. However, it is not required and does not take the place of the BMV road test. The Miscellaneous Musculoskeletal and Neurological Functional Ability Profile should be used to assess potential for driving impairment.

Arthritis or Joint Disorders

This category would include related conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and spinal stenosis, among others. Affected structures include joints of axial and appendicular skeleton, and/or spinal nerves. These conditions can cause pain, decreased strength and range of motion, and impaired functional mobility, potentially altering the ability to safely operate motor vehicle controls. In assessing these persons for potential driving impairment, overall functional performance of the person in terms of ability to perform activities of daily living should be taken into consideration to help determine if adaptive equipment or strategies may be needed. Miscellaneous Musculoskeletal and Neurological Conditions Functional Ability Profile should be used to assess driving impairment.

Cerebrovascular Accident (CVA or Stroke)

Stroke may have a complicated and variable presentation. Residual impairments may include altered strength, mobility, coordination, motor planning, sensation, spatial planning, body or environmental awareness, vision, communication, judgment, and cognition. Motor deficits or contractures may require upper or lower extremity adaptive equipment for driving. Due to the possibility of multiple potential deficits, a comprehensive evaluation by a driving rehabilitation specialist may be indicated but is not required. Use the TBI/Stroke Functional Ability Profile to assess impairment. Other medical issues following a stroke may include seizures, cognitive impairment, and/or visual disorders which need to be evaluated separately using the proper Functional Ability Profile for those conditions. Please note that a transient ischemic attack (TIA) by definition has no residual deficit and is therefore not subject to the Stroke FAP.

Miscellaneous Musculoskeletal and Neurological Conditions

Neurologic and musculoskeletal conditions with the potential to impair a person's ability to safely operate a motor vehicle are numerous, and therefore have not all been specifically listed. Even if these conditions have not been adequately identified in any of the other categories, they still should be evaluated. Examples of neuromuscular conditions which would be appropriately evaluated using the Miscellaneous Musculoskeletal and Neurological Conditions FAP include but are not limited to muscular dystrophy, cerebral palsy, amyotrophic lateral sclerosis, peripheral/other neuropathies, syringomyelia, as well as any generalized deconditioning syndrome due to any etiology which reduces functional capacity to drive. These conditions may require personal medical equipment or adaptive accessories to operate a motor vehicle, cause deficits in mobility, sensation, strength, coordination, reaction time, range of motion, and/or other abilities needed to safely operate a motor vehicle. Referral to a driving rehabilitation specialist, although not required, may be indicated in some cases. Also, persons who have an implanted spinal cord/dorsal column stimulator are advised to turn off the device prior to driving due to the potential for unexpected changes in stimulation with activity that could possibly be unsafe. When visual, cognitive, psychiatric or other conditions also exist, they should be evaluated separately using the appropriate profile.

Multiple Sclerosis (MS)

Multiple Sclerosis is a highly variable disorder. Some people may have few if any perceptible symptoms associated with the disorder, while others may be significantly impaired. MS may cause visual impairment, cognitive impairment, alterations in sensation, muscle weakness, incoordination, spasticity, joint contracture. Upper and/or lower extremity orthotics may be required, and a person may also be operating an adapted vehicle from a mobility device (such as a wheelchair). These deficits may cause difficulties with manipulation of vehicle controls, and driver performance in complex driving environments. Comprehensive evaluation for adaptive equipment and an evaluation by a driving rehabilitation specialist may be beneficial but is not required. The progressive nature of MS warrants periodic reassessment of driving risk using the MS Functional Ability Profile. Psychiatric, cognitive, or visual deficits should be evaluated separately using the appropriate Functional Ability Profile.

Parkinson's or Parkinsonian Syndromes

Parkinson's Disease and Parkinsonism physical signs include tremor, bradykinesia, postural instability, and rigidity, along with complex cognitive issues such as dementia and mood disturbance. These deficits may cause slowed reaction times, difficulties with vehicle controls, and impaired performance in complex driving environments. Evaluation by a driving rehabilitation specialist may be indicated. The progressive nature of the disorder warrants periodic reassessment using the Parkinson's Functional Ability Profile. Psychiatric or cognitive issues should be evaluated separately using the appropriate Functional Ability Profile.

For the purpose of this FAP, Progressive Supranuclear Palsy, Multisystem Atrophy, Corticobasal Ganglionic Degenerations, Medication Induced Parkinsonism and Lewy Body Dementia are considered Parkinsonian Syndromes. The cognitive implications of Lewy Body Dementia should be reviewed using the Dementia FAP.

Spinal Cord Injury (SCI)

SCI of the cervical, thoracic, or lumbosacral regions is the result of a medical condition, lesion or trauma to the neural elements within the spinal canal. This causes impairment of motor and sensory function to the upper or lower limbs and trunk which is variable and depends on the level of injury. Although common terms to describe spinal cord injury are paraplegia and tetraplegia (quadriplegia), The American Spinal Injury Association (ASIA) Impairment Scale more precisely grades the degree of impairment according to the spinal level of preserved motor and sensory function. Safe driving after SCI may be impaired due the altered ability to operate vehicle controls; so the use of orthotics, adaptive driving equipment, and an adapted motor vehicle for use with mobility device/wheelchair are often required. Comprehensive evaluation by a driving rehabilitation specialist should be considered. Miscellaneous Musculoskeletal and Neurological Conditions Functional Ability Profile should be used to assess driving impairment.

Traumatic Brain Injury (TBI)

TBI causes dysfunction of the central nervous system resulting from trauma or forces to the head significant enough to alter brain function. Cognitive changes after TBI can affect mood, memory, executive function, judgment, initiation, attention, and problem-solving. In addition, because self-awareness and judgment may be affected, a person may not be able recognize their impairments. Depending on the extent of the injury, other deficits may include altered gait, balance and sensation, as well as impaired muscle and joint function due to weakness, spasticity, and contracture. These persons may require ankle-foot orthoses or upper extremity orthotics to improve mobility and use of extremities. Factors that impact on ability to drive safely after TBI can be extensive, and a comprehensive driving evaluation by a driving rehabilitation specialist should be considered. Use the Stroke/TBI Functional Ability Profile to assess impairment. Other medical impairments following TBI may include seizures, cognitive, and visual disorders, which need evaluation separately using the proper Functional Ability Profile for those conditions.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Cerebrovascular Accident (CVA/Stroke) or Traumatic Brain Injury (TBI)[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	History of Stroke or TBI without residual physical or cognitive deficits or impairments.	N/A
3.	Active impairment	History of Stroke or TBI with residual[3] cognitive and/or physical impairments or deficits. For TIA, see.[4]	Please document residual deficits on Driver Medical form.
	a. Mild	Residual[3] cognitive or physical deficits, but unlikely risk to safely operating a motor vehicle and does not require assistive medical equipment or nonstandard accessory driving devices.[5]	N/A Clinician may request ROAD TEST if unsure[5]
	b. Moderate	Residual[3] cognitive or physical deficits that could potentially impair ability to safely drive, and/or requires assistive medical equipment or nonstandard accessory driving device(s).	4 years ROAD TEST
	c. Severe	Residual[3] cognitive and/or physical deficits that are significant enough to impair ability to safely drive. Or, a person with physical or cognitive changes when stroke is suspected and condition is being investigated.	No driving

[1] For further discussion regarding CEREBROVASCULAR ACCIDENT OR TRAUMATIC BRAIN INJURY, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] Stroke and TBI may lead to other cognitive or physical impairments such as seizures, visual deficits such as hemianopsia or diplopia, or cognitive deficits, such as dementia, impairment to reasoning or judgment, these need to be evaluated using the appropriate FAP. The most restrictive Profile will determine the driving privileges.
[4] Please note that a transient ischemic attack (TIA) by definition has no residual deficit and is therefore not subject to this FAP.
[5] If a provider has concerns regarding an individual's ability to operate a vehicle safely that are not captured in this FAP then a road test may be requested. Include documentation of all pertinent medical concerns, and rationale for requesting road test.

FUNCTIONAL ABILITY PROFILE
Miscellaneous Musculoskeletal and Neurological Disorders[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	History of injury, deficiency, disorder, or other condition recovered, no longer requires treatment and maintains normal function.	N/A
3.	Active impairment	Chronic condition such as amputation or limitation of limb, arthritis, joint dis-orders, spinal cord injury, or others which may affect neuromuscular function; and currently require treatment or cause impairments, restrictions, or deficits.	For spinal cord/dorsal column stimulator see[3].
	a. Mild	Chronic condition that does not pose risk for safe driving and does not require use of assistive medical equipment or nonstandard accessory driving devices; or Clinician documents stable condition that is unlikely to deteriorate and driver has already passed road test.	N/A
	b. Moderate	Chronic condition, which may impair ability to drive safely and/or requires personal assistive medical equipment (such as prosthesis, orthosis, or any type of nonstandard accessory driving device such as hand/foot controls).	4 years[4] ROAD TEST
	c. Severe	Chronic condition, which causes impairments that interfere with the ability to drive safely despite use of personal assistive medical equipment, or any nonstandard accessory driving devices.	No driving

[1] For further discussion regarding MISCELLANEOUS MUSCULOSKELETAL AND NEUROLOGICAL DISORDERS, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] Persons who have an implanted spinal cord/dorsal column stimulator are advised turn off the device prior to driving due to the potential for unexpected changes in stimulation with activity that could possibly be unsafe.
[4] Interval for review may be more frequent if recommended by clinician.

FUNCTIONAL ABILITY PROFILE
Multiple Sclerosis[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	There is no recovery from multiple sclerosis	N/A
3.	Active impairment	Multiple sclerosis may affect many domains of the nervous system including cognition, vision, motor skills, coordination etc. In addition it may cause fatigue and/or psychiatric symptoms.[3]	
	a. Mild	Symptoms well controlled, or condition is quiescent. No side effects from medications that could potentially impair driving.	4 years
	b. Moderate	Symptoms or medication side effects that may potentially impair safe driving.	2 years ROAD TEST
	c. Severe	Symptoms or side effects of medication severe enough to preclude safe driving.	No driving

[1] For further discussion regarding MULTIPLE SCLEROSIS, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] Multiple Sclerosis is a highly variable disorder. Some people may have few if any perceptible symptoms associated with the disorder, while others may be significantly physically or cognitively impaired. Symptoms may fall under more than one FAP and all appropriate FAP's should be used. For example, a driver may require adaptive equipment or have a significant visual field or acuity disturbance. The most restrictive FAP will determine driving privileges or restrictions.

FUNCTIONAL ABILITY PROFILE

Parkinson's and Parkinsonian Syndromes[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder[3]	N/A
2.	Condition fully recovered	Parkinson's Disease[3] is a lifelong condition and there is no recovery. Drug induced Parkinsonism may be considered recovered when symptoms resolve after the causative medication is stopped.	N/A
3.	Active impairment	Parkinson's Disease[3] may cause tremor, autonomic instability, rigidity, bradykinesia and/or dyskinesia, cognitive or psychiatric symptoms.[4]	
	a. Mild	Mild physical symptoms that do not pose risk for safe operation of a vehicle. No cognitive or psychiatric symptoms. Medications do not cause drowsiness.	2 years[5]
	b. Moderate	Physical symptoms and/or side effects of medication may potentially interfere with the safe operation of a motor vehicle. May have early cognitive or psychiatric symptoms[4].	1 year ROAD TEST
	c. Severe	Physical symptoms or side effects of medications are incompatible with safe operation of a motor vehicle. For cognitive or psychiatric symptoms, see[4].	No driving

[1] For further discussion regarding PARKINSON'S OR PARKINSONIAN SYNDROMES, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] For the purpose of this FAP, Lewy Body Dementia, Multisystem Atrophy, Corticobasal Ganglionic Degenerations, medication induced Parkinsonism, Vascular Parkinsonism, and Progressive Supranuclear Palsy are considered Parkinsonian Syndromes.

[4] Cognitive or Psychiatric symptoms should be evaluated using the Dementia or Mental Disorders FAP.

[5] When Parkinsonian Syndrome is caused by medications and patient is stable, the clinician may recommend extending the review interval up to 4 years.

NARCOLEPSY

Narcolepsy is a chronic disorder of the central nervous system characterized by the brain's inability to control sleep-wake cycles. The prevalence is not clear, but estimated at .02 to .1 % of the US population. At various times throughout the day, people with narcolepsy can experience irresistible and sudden bouts of sleep: the onset of sleep is usually heralded by awareness of sleepiness which usually becomes more predictable over time and with experience. In addition to daytime sleepiness, other symptoms can include cataplexy (70%) which is the sudden loss of voluntary muscle tone triggered by strong emotions, sleep paralysis (25-50%), sleep hallucinations (20-40%), and disturbed night sleep (70-80%). Symptoms commonly begin in the teen years through the mid-twenties or early thirties, with the first symptom generally that of excessive daytime sleepiness.

There are significant implications for driving safety given the core symptoms of this disorder but there is a paucity of data regarding narcolepsy and driving safety. People with untreated symptoms of narcolepsy have three to four fold risk of crashes compared to the general population (self-reported data). [A B C] The few studies that examined crash risk and narcolepsy were performed in untreated individuals and utilized driving simulators: the applicability to real world driving is not known. [D] Narcolepsy is a treatable condition, and both behavioral interventions and medications are used. Medications used to treat sleepiness include stimulants (amphetamine/ methylphenidate), modafinil, and Xyrem (sodium oxybate). Patients are counseled to take planned naps, and a brief (20 minute) nap generally significantly improves sleepiness. Cataplexy is treated with SNRI/SSRI's[i], tricyclic antidepressant medications, and/or sodium oxybate.

Narcolepsy is a lifetime condition that requires ongoing monitoring and assessment, as response to medications may wane over time, or cataplexy may develop years after other symptoms. Given that daytime sleepiness can be profound, careful monitoring for increasing levels of sleepiness and emergence of cataplexy are essential. Practice parameters recommend regular follow up to determine adherence and response to treatment; a patient stabilized on medications should be seen regularly; at least once per year, and ideally twice yearly.[E] Further testing for residual sleepiness with an in lab study (MSLT[ii] or MWT[iii]) may be appropriate, in some circumstances. These tests are not routinely performed, but may be used to assess an individual's ability to remain awake (or propensity to fall asleep) if sleepiness poses a risk for public or personal safely.[F]

Those with narcolepsy are frequently followed by specialists(neurologists or sleep medicine specialists).

Given the risk for crashes if symptoms are not effectively treated, additional information regarding current symptoms must be included in the narrative section of the Driver Medical Evaluation and specifically address presence or absence and severity of cataplexy, degree of residual daytime sleepiness, and adherence to medications and behavioral strategies.

Footnotes:

[i] Serotonin and Norepinephrine Reuptake Inhibitor/Selective Serotonin Reuptake Inhibitor medications.

[ii] Multiple Sleep Latency Test: performed in Sleep Centers. Objective determination of an individual's underlying sleepiness by measuring latency to sleep in 5 trials of 20 minutes each after documentation of adequate sleep the night prior to testing. Pathologic sleepiness is defined as a mean sleep latency of less than 5 or 6 minutes. May be used to assess efficacy of treatment.[G]

[iii] Maintenance of Wakefulness Test: performed in Sleep Centers. Objective assessment of ability to stay awake while passive and sedentary in a non-stimulating environment. The strongest evidence for an individual's ability to maintain wakefulness is provided by a capacity to remain awake through 4 trials of 40 minutes each. AASM standards state that MWT testing is indicated when assessing individuals whose inability to remain alert constitutes a safety hazard and in patients with Narcolepsy. May be used to assess efficacy of treatment.[H]

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Narcolepsy[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	This is a chronic lifelong condition. Do not use this profile level.	N/A
3.	Active impairment	This diagnosis must be made by a physician, (preferably a sleep specialist or neurologist), and applies to patients who have a confirmed diagnosis of narcolepsy. Clinician assessment recommended at least every 6 months.	A physician must complete the Driver Medical Evaluation with narrative that includes items in[3].
	a. Mild	No cataplexy, minimal or no subjective sleepiness (Epworth Sleepiness Scale[4] of 7 or less), and consistent use of medications and behavioral strategies.	2 year
	b. Moderate	Predictable mild cataplexy controlled with behavioral strategies and medication, ESS[4] 8 or more, consistent use of medications and behavioral strategies for sleepiness, and avoidance of driving if sleepy.	1 year
	c. Severe	Unpredictable cataplexy, inconsistent use of medications or no effective medication yet found, and ESS[4] 8 or more; or Suspected narcolepsy under investigation with concern for safety.	No driving

[1] For further discussion regarding NARCOLEPSY, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] Brief narrative to include: presence/absence of cataplexy (type of symptoms and frequency), degree of residual sleepiness, description of treatment, effectiveness of treatment, and adherence to treatment.
[4] Epworth Sleepiness Scale: validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and 17 or greater is severe. (Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249).

OBSTRUCTIVE SLEEP APNEA

Driver sleepiness is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with obstructive sleep apnea (OSA) are at increased risk for car accidents.

OSA (and possibly central sleep apnea) can cause impairment in daytime performance. It is associated with increased risk of motor vehicle crashes, with estimates ranging from 2% to 7% in those with OSA compared to those without. [A B] The condition is common (2-8% in older literature, with more recent estimates suggesting that 25% of adult men in the US are affected), and the frequency of occurrence increases with age, BMI (body mass index) and comorbid conditions such as diabetes.

People with sleep apnea may have delayed reaction times and inattentiveness in addition to frank sleepiness. Some are unaware of their sleepiness and cognitive impairment. It is important to recognize that excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea. A recent study demonstrated that increased risk of motor vehicle crashes is present in those with mild OSA as well as those with severe disease. [C] The diagnosis of OSA is made through polysomnography (PSG), with insurers increasingly insisting upon Home Sleep Studies (HST) although the gold standard is still in lab polysomnography.

Treatment of OSA generally improves daytime sleepiness. Use of continuous positive airway pressure (CPAP) is a highly effective treatment with studies suggesting that daytime symptoms improve within two weeks of positive airway pressure (PAP) treatment. [D] It is the only treatment modality demonstrated to reduce crash risk.[E] Not using CPAP for as little as one night may cause daytime impairment.[F]

Other treatment options for OSA include bariatric surgery for morbid obesity, use of oral mandibular advancement devices, upper airway surgery and craniofacial surgery. Hypoglossal nerve stimulators have been approved by the FDA for treatment of OSA.[G] Assessment of treatment efficacy with PSG after surgery or with use of an oral device is recommended.

It is difficult for clinicians to assess sleepiness (and possible impairment while driving) in a patient with OSA. Sleepiness cannot be measured easily by objective testing. Maintenance of Wakefulness Tests (MWT) and Multiple Sleep Latency Tests (MSLT) are the best objective measures of daytime sleepiness in those with OSA, but are performed only in Sleep Centers, are expensive and time consuming. They are not routinely used to assess daytime sleepiness in drivers. The clinician must use subjective reports as well as objective data from CPAP downloads to assess adherence to treatment and level of daytime sleepiness.

The diagnosis of obstructive sleep apnea should only be made by a physician or NP/PA with specialized training in Sleep Medicine. Those with OSA are frequently followed by a sleep specialist or a neurologist.

The Epworth Sleepiness Scale[i] is a widely used measure of subjective daytime sleepiness although the sensitivity and specificity of the scale is less than ideal. A score of 7 or less out of 24 is considered normal (not sleepy).[H] The acceptable range cutoff value is subject to debate, with some researchers suggesting that 7 or less is normal (not sleepy): others suggesting 12 or less).

Patients on PAP therapy should have data downloaded from their device to measure adherence with therapy. Medicare guidelines[I] are the standard for adherence to treatment and require an average of 4 hours PAP use per night 70% of the time.

PAP devices also calculate an AHI (apnea/hypopnea index). The AHI determines the severity of OSA: an AHI of 15 or fewer obstructive events per hour is considered mild.

The clinician must educate patients that driving safety is ultimately the individual's responsibility. Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy.

Footnotes:

[i]Epworth Sleepiness Scale: A validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and greater than 16 is severe. (*Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249*)

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Obstructive Sleep Apnea[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Recovered after Treatment(s) other than CPAP, such as surgical intervention, weight loss or dental device[3]. Polysomnogram (PSG) demonstrates an AHI[4] (apnea/ hypopnea index) of less than 15. ESS (Epworth Sleepiness Scale)[5] score of less than 8. No report of accident or near miss.	N/A
3.	Active impairment	See footnote regarding PAP therapy.[6] This diagnosis should be made only after a sleep study. Neurology or sleep med specialists are often the clinicians to provide follow-up.	
	a. Mild	AHI[4] < 15 on diagnostic PSG and not sleepy, ESS less than 8. Not on treatment.	Three years
	b. Moderate	PAP download demonstrates adherence to treatment.[6] [7] AHI[4] less than 15 on download. ESS less than 8. No crashes or near misses.	Yearly
	c. Severe	History of falling asleep while driving or near miss, or strong suspicion of OSA with concern for unsafe driving; and/or Non-responsive or non-adherent[7] to therapy.	No driving

[1] For further discussion regarding OBSTRUCTIVE SLEEP APNEA, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] For those with dental device, repeat PSG must be done with device in place.
[4] AHI: apnea/hypopnea index: number of obstructive events per hour of sleep.
[5] Epworth Sleepiness Scale: validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and 17 or greater is severe. (Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249).
[6] Treatment with positive airway pressure therapy. PAP devices include but are not limited to, CPAP (continuous positive airway pressure), BiPAP (bi-level positive airway pressure), and ASV (adaptive servo-ventilation).
[7] Adherence to or compliance with CPAP treatment derived from Medicare guidelines: use of PAP an average of four or more hours per night at least 70% of the time.

SEIZURES & EPILEPSY

Epilepsy is defined as a disorder in which a person has had two or more unprovoked seizures. A seizure is a disruption in the normal electrical activity in the brain resulting in temporary cerebral dysfunction. Epilepsy excludes people with provoked (otherwise known as symptomatic) seizures such as from eclampsia, central nervous system infection, secondary to an adverse drug reaction, acute stroke, metabolic derangement, or alcohol withdrawal. Seizures and epilepsy shall be evaluated using this FAP. The disorders causing provoked seizures as well as many other physiological processes may cause an alteration in consciousness sufficient to preclude the safe operation of a motor vehicle and shall abide by the FAP in the appropriate section, if known, or that entitled, "Unexplained Alteration or Loss of Consciousness".

Guidelines for special circumstances

1. First ever unprovoked seizures, will be no driving for 6 months off medication or no driving until a minimum of 3 months seizure free on medication. Then follow the rules for epilepsy.
2. If a person has a provoked seizure that is that is very *unlikely to recur* such as a seizure caused by a medication that is subsequently stopped, then driving may resume when the treating clinician feels it is reasonable. If the *likelihood of recurrence of a provoked seizure is not known,* e.g., a head injury or brain infection, no driving is allowed until seizure free for at least 6 months. *If the reason for the seizure is captured in a different FAP, such as substance use disorder, a profile level for the other FAP should also be submitted* and the more restrictive FAP will determine driving restrictions.
3. Suspected psychogenic non-epileptic seizures (PNES) should be evaluated using this FAP. However, once a diagnosis of PNES is confirmed, the mental disorders FAP should be used.
4. Seizures caused by Electroconvulsive Therapy are excluded from this FAP.
5. Seizures occurring in the setting of medically supervised medication changes are not to drive until the treating clinician believes the person is medically stable. Generally, at least one month on a new medication regimen. When *medication is tapered,* with the intention to stop anti-seizure medications, no driving allowed while tapering and for 3 months after the medication has been stopped. The person will then be considered profile 3a until profile 2 is appropriate.
6. If there is a pattern of at least one year of nocturnal only seizures then driving is permitted and the person shall be considered profile 3a. This diagnosis should be made by a neurologist or other appropriately qualified clinician.
7. If there is an established pattern (6 months or longer) of only simple partial seizures, without any alteration of consciousness *and* do not affect the ability to operate a motor vehicle, then driving is permitted and the person shall be considered profile 3a. Example: Arm parasthesias without weakness or alteration of consciousness after brain tumor resection. This diagnosis should be made by a neurologist or other appropriately qualified clinician.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Seizures and Epilepsy[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	History of epilepsy: 2 years seizure free, off medications (e.g., after resolution of a childhood epilepsy syndrome or successful tapering off of seizure medications when a person has been free of seizures for an extended period of time.); or, Seizure provoked by known cause, with very low risk for reoccurrence (e.g., resolution of a subdural hematoma or resection of a meningioma that had caused seizures). Refer to "Guidelines" #2, in the narrative section.	N/A
3.	Active impairment	For special circumstances such as provoked seizures, medication changes, nocturnal or partial seizures only and first unprovoked seizure, refer to "Guidelines" in narrative section.	
	a. Mild (controlled)	History of epilepsy: On or off medication. Seizure free 3 months or more.	2 years
	b. Moderate	N/A	N/A
	c. Severe (uncontrolled)	Seizure[1] within previous 3 months, refractory epilepsy or medication non-adherence.	No driving

[1] For further discussion regarding SEIZURES AND EPILEPSY, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.

SUBSTANCE USE DISORDER / PRESCRIPTION MEDICATIONS

Driving while impaired by drugs or alcohol is an obvious public safety hazard. In Maine, close to a quarter of fatal motor vehicle accidents involve alcohol. 2012 OUI records in Maine (the most recent available at the time of this writing) indicate that although younger age groups drink and drive at higher rates, alcohol-related driving episodes occur in all driver age groups.[A] Prescription medications, even when taken as prescribed, also have the potential for side effects, dependence, or interactions which may alter the ability to drive, or exacerbate a decline in function related to an underlying medical condition. It is important for clinicians to know that a driver who is impaired due to prescribed medication use can also be charged with OUI.

Clinicians are responsible to assess their patients for potential risks and advise them whether to drive or not based on their medications and medical conditions. Being alert to other medical or social history information that points to drug or alcohol abuse, such as gastrointestinal symptoms, falls or injuries, muscle or neurologic symptoms, infections, and social or work problems is part of that process. With this in mind, the clinician's role is to recognize high-risk individuals from a medical perspective, and assess their physical and mental fitness to drive safely. Compliance with treatment and recovery is also a critical factor in determining whether a patient is stable and fit to return to safe driving. In addition, criteria for defining use versus abuse may be different in a community setting compared to use when in a treatment/recovery program where abstinence is a criteria.

Substance Use Disorder

A diagnosis of Substance Use Disorder[B] can involve either substance abuse or dependence, and is diagnosed when a patient continues to use a substance or combination of substances at the expense of significant medical, social or legal consequences. Physical dependence occurs when a person develops a physiologic tolerance to a substance or substances. Physical dependence on a prescribed medication when taken as ordered does not constitute a Substance Use Disorder in and of itself. In addition, be aware that many patients who exhibit "drug-seeking" behaviors are likely exhibiting physical dependence (which may be iatrogenic from legitimate treatment by the medical provider), but this is not necessarily the result of a Substance Use Disorder. Since there is almost no research data or medical literature available regarding the length of time necessary for a person to demonstrate lasting recovery, or any definitive marker indicating the ability to drive safely, the recommendations that follow take into account guidelines from other states and the experience of physicians in Maine who treat these illnesses. *Please note that the descriptions of "mild, moderate or severe" under "Degree of Impairment/Potential for at Risk Driving" in the FAP for Substance Use Disorder, **do NOT** correspond to the similarly named categories in current DSM.*

In order to evaluate a patient for Substance Use-related fitness to drive safely, the clinician must take into account many factors. These include the substance/substances being used (e.g. alcohol, benzodiazepines, opiates, sedative-hypnotics, marijuana/cannabis, stimulants, heroin, cocaine, methamphetamine, and/or other street drugs), interactions of the abused substance with any prescribed medications, the patient's insight into his/her abuse behaviors, his/her judgment about driving when intoxicated or impaired, the risk for polysubstance use and abuse, and the patient's ability or motivation to comply or participate in rehabilitation and recovery. In the context of alcohol or drug use this can be particularly challenging given the intermittent and/or relapsing nature of Substance Use Disorders

Other medical risks or side effects related to Substance Use Disorder also need to be taken into account. For example, a person may have difficulty driving safely during periods of withdrawal from substances, especially alcohol and benzodiazepines where delirium and seizures are a risk. Opiates or heavy marijuana use can cause physical symptoms that would impair muscle control, concentration and attention. Chronic heavy alcohol abuse also puts a person at increasing risk for cognitive impairment and neuromuscular decline, both of which mean

potentially unsafe vehicle operation. **Please note that a driver who suffers a convulsive seizure caused by abuse of or withdrawal from street drugs, prescription medications or alcohol is unfit to drive for a minimum of 6 months per NHTSA Driver Fitness Medical Guidelines.**[C] Clinicians also need to be aware of the risks to public safety by drivers that combine substances of abuse, and/or mix them with legitimately prescribed medications. Epidemiologic studies show that in 20-25% of fatal crashes, drivers were found to have used a combination of two or more drugs/alcohol.[D] Among the most significant substance mixtures are alcohol in combination with either marijuana or a stimulant such as cocaine; marijuana used along with either a stimulant, benzodiazepine or an opiate; and benzodiazepines combined with opiates. Methadone and benzodiazepines are an especially worrisome combination due to a greatly increased risk of sedation.

Currently, the legal environment surrounding marijuana/cannabis has seen several changes, and clinicians will need to be more aware of related safety risks. Over a 10-year study period, cannabis has been detected in the blood in an increasing numbers of drivers involved in fatal accidents (from 4.2% in 1999 to 12.2% in 2010 in one study[E] of 23,591 fatal accidents). Another study found that there was a dose-response relationship to urine concentrations of 11-nor-9-carboxy-delta-9-tetrahydrocannabinol (psychoactive compound in cannabis) and motor vehicle accidents.[F]

Opioid Replacement Therapy and Prescription Medications

This FAP may be used when a person is prescribed opioid medications for replacement therapy or pain management, or any other medications that may potentially impair driving. Medications of particular concern for driving include the tricyclic antidepressants, sedative hypnotics, some antipsychotics, and benzodiazepines, especially if patients are prescribed more than two or are concurrently prescribed opioids, using medical marijuana, or are abusing drugs or alcohol. Methadone and benzodiazepines are a particularly troubling combination for risk of sedation. Data on buprenorphine and driving indicate that once established on a dose and in stable recovery, most people can safely drive, although this must be assessed on an individual basis.[G] Medical Marijuana, although not a prescription medication, is included here due to its' potential to produce side effects that could impair driving.

Normally, BMV does not require reporting when prescribed medications are used as ordered. However, in cases where proper use of prescription medications has resulted in driver impairment, leading to OUI, crashes, reports of unsafe driving, or when a clinician is concerned that a patient may be non-compliant with driving recommendations, use of the Opioid Replacement and Prescription Medications FAP is appropriate.

Statistically, once a patient is on an established dose of methadone, the risk for sedation or at-risk driving is minimal (barring any other polysubstance abuse or polypharmacy).[H] However, on an individual basis, in the period of time immediately following an opiate replacement dose, there may be an increased risk for sedation to the point that the patient should be counseled not to drive. This is particularly pertinent in the case of methadone, since patients may have to drive to receive a dose at a methadone clinic and then drive home, and is especially worrisome if the patient is also on a benzodiazepine.

***Resources and Tools for Clinicians**:*

(These resources are not part of rules. They are provided for informational purposes only.)

- *Maine's Prescription Monitoring Program. As of April, 2015, the link to sign up as a PMP "data requester" is http://www.maine.gov/pmp.*
- *Screening tools for alcohol risk exist, such as CAGE[I] and AUDIT.[J]*
- *Laboratory assessment may give objective evidence for substance use or compliance with a recovery program. However, urine drug testing is fraught with pitfalls. Medical providers are strongly encouraged to educate themselves before interpreting drug test data (for example via the paper on rational urine drug testing cited here [K]). Medical providers need to be aware of the parameters for detection of the laboratory they use.[L]*
- *Biomarkers for Alcohol[L]—see Appendix*

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Substance Use Disorder[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	History of substance-use disorder, in sustained recovery for 2 or more years, and must not fit any of the profile level descriptions below.	N/A
3.	Active impairment	Substance use at any point in the past two years that meets current DSM Criteria for a Substance Use Disorder; and	
	a. Mild	No motor, judgment or intellectual impairment with NO history of medical detox, drug or alcohol related seizure[3], adverse driving or legal consequences of substance use for the past 12 months, & no more than 1consequence in last 5 years.	1 year Until criteria met for fully recovered.
	b. Moderate	History of substance abuse significant enough to cause motor, judgment, or intellectual impairment. History may include drug or alcohol related events such as motor vehicle crash, OUI or serious medical consequences. (E.g. medical detoxification or seizure[3] from use or withdrawal) Must be **abstinent at least 3 months** with **up to one** event in one year or two events in 5 years, EXCEPT in case of convulsive seizure[3] related to abuse of or withdrawal from alcohol or drugs. Such cases must be **abstinent at least 6 months;** or History of **two or more** events in 1 year, three or more in 5 years, must be **abstinent at least 1 year.**	6 months (To resume driving after specified period of abstinence, driver must be medically cleared and pass a ROAD TEST.)
	c. Severe	Substance abuse significant enough to cause permanent motor, judgment, or intellectual impairment. For dementia related to substance use, see footnote[4]; or	No driving

		History of drug or alcohol related event(s) including motor vehicle crash, OUI, or medical consequences (including medical detoxification or seizure[3] from use or withdrawal). Driver has not been abstinent long enough to meet criteria for Moderate Profile Level 3.b.	

[1] For further discussion regarding SUBSTANCE USE DISORDER, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] For other types of seizures, refer to Seizure /Epilepsy FAP.

[4] If patient has dementia related to substance use, use Dementia FAP.

FUNCTIONAL ABILITY PROFILE
Opioid Replacement Therapy and Prescription Medications[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	No longer on opiate replacement therapy, with no relapses and no evidence of prescription abuse for at least 2 years; or No longer prescribed the medication that caused impairment or no on-going side effects that could impair driving x 1 year.[3]	N/A
3.	Active impairment[3]	On prescription medication of concern[4]; or On opiate replacement therapy, (e.g., suboxone or methadone or similar prescription); and	
	a. Mild	Stable and functioning well with no other Substance Use Disorder issues[3] and no sedation or unsafe side effects. No impairment of motor, judgment or intellectual functions from prescription medications; or Off prescription medications but not long enough to meet criteria for "Condition fully recovered".	1 year
	b. Moderate	Experiences sedating side effects from medication, but with judgment to avoid driving while having these side effects, and no other Substance Use Disorder issues[3]. NOTE: If there is a history of poor judgment about driving under these circumstances, leading to OUI, crashes, or reports of unsafe driving, must demonstrate they have the judgment to avoid driving while having these side effects or be off medication for at least 3 months, AND pass ROAD TEST to resume driving.	1 year ROAD TEST

	c. Severe	i. Experiences sedation or side effects from medication, with poor judgment about driving under these circumstances, leading to OUI, crashes or reports of unsafe driving; or	No driving
		ii. Has problems with substances of abuse that increase the risk for dangerous driving in combination with prescription medications[3].	Comply with appropriate profile level on Substance Use Disorder FAP

[1] For further discussion regarding OPIOID REPLACEMENT THERAPY AND PRESCRIPTION MEDICATIONS, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, please refer to SECTION 3.

[3] Comply with "Substance Use Disorders" FAP when patient misuses prescription medications or non-prescribed drugs.

[4] Normally, prescribed medications used as ordered do not need to be reported to BMV. Clinicians are responsible to assess their patients for potential risk, and advise them whether to drive or not based on their medications and medical conditions. However, in cases where proper use of prescription medications has resulted in driver impairment, such as OUI, crashes, reports of unsafe driving, or when a clinician is concerned that a patient may be non-compliant with driving recommendations, use of this FAP is appropriate.

UNEXPLAINED ALTERATION / LOSS OF CONSCIOUSNESS

The Functional Ability Profile (FAP) for alteration/loss of consciousness shall pertain to drivers who have an **unexplained** alteration in their thought process that would preclude safe operation of a motor vehicle. This is a relatively common occurrence. Through medical investigation the cause may be identified or **explained** and the person should then be categorized under the appropriate FAP. Medical work up should evaluate possible cardiac and/or neurologic causes. An explained alteration of consciousness (AOC) with low to no likelihood of recurrence is not generally subject to the FAP rules. Examples of this include concussion with recovery, adverse drug reaction, or medical illness with recovery such as pneumonia, sepsis, vasovagal episode, cough syncope, or anaphylactic reactions.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Unexplained Alteration of Consciousness (AOC)[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	History of unexplained AOC but none in 4 years	N/A
3.	Active impairment		
	a. Mild	History of AOC greater than 1 year ago.	2 years
	b. Moderate	History of any unexplained AOC within 6 months – 1 year ago.	1 year
	c. Severe	Any unexplained AOC within the past 6 months	No driving

[1] For further discussion regarding UNEXPLAINED ALTERATION OF CONSCIOUSNESS, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.

VISUAL DISORDERS

The main elements of vision necessary for safe driving are visual acuity, peripheral vision and freedom from double vision (diplopia). These three items are elaborated in the following pages as Functional Ability Profile charts on visual parameters. Other, not so easily measured visual factors are discussed below:

Defects in color vision, important in distinguishing traffic signals, are usually compensated for by learning traffic light positions and are not in themselves reasons to deny driving and are usually tested adequately by the road evaluation.

Night vision, contrast sensitivity, and glare recovery may be impaired in the presence of corneal scars, cataracts, and retinal aging or disease. Evidence is inconclusive that testing these parameters of visual function can determine which drivers are safe.

Sometimes an ocular defect or disease does not cause the applicant to fail the eye examination. If the examining clinician suspects that the condition may affect driving, it is reasonable to ask that a road test be given by a BMV driver examiner to look at specific aspects of driving. For example, a patient with retinitis pigmentosa who wants to drive at night may pass all the office eye exams but the disease's effect on the patient’s night driving remains uncertain. The clinician might recommend a night road test evaluation.

Drivers with hemianopsia must meet standard vision requirements described in this Functional Ability Profile. They must also pass the Esterman field test as described in the Peripheral Vision Profile Table. Individuals with a history of traumatic brain injury or stroke should be evaluated using both the Visual Disorders and the Cerebrovascular Accident (CVA/Stroke) or Traumatic Brain Injury(TBI) FAP’s.

Individuals with deficits in useful field of view and visual processing speed, as well as other visuo-spatial deficits, should be assessed for other cognitive impairments using the Dementia FAP.

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Visual Disorders[1]: Visual Acuity

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	Sees 20/40 or better in best eye without correction.	N/A
2.	Condition fully recovered	Visual acuity correctable to 20/40 or better in best eye. Restrict to corrective lenses.	N/A
3.	Active impairment	Those needing corrective lenses to meet visual acuity requirements will be restricted to wearing them when they drive. See note[3] below re: telescopic or bioptic lenses.	
	a. Mild	Vision correctable to 20/40 in best eye but could deteriorate due to glaucoma, diabetic retinopathy, macular degeneration, or other potentially progressive diseases.	2 years or interval recommended by vision examiner
	b. Moderate	Vision correctable to at least 20/100 in best eye; restrict to daytime driving (See note[4] below).	1 year or interval recommended by vision examiner
	c. Severe	Best corrected vision currently less than 20/100 in each eye.	No driving

[1] For further discussion regarding VISUAL DISORDERS, please refer to NARRATIVE found at beginning of this section.

[2] For further explanation of degree of impairment, refer to SECTION 3.

[3] Telescopic or bioptic lenses (BTL's) may not be used for purposes of meeting any of the visual acuity requirements. Drivers who meet the Visual Acuity requirements without BTL's may use them for taking the road test and for driving.

[4] The daytime only restriction may be changed based on:

- A recommendation from an optometrist or ophthalmologist advising that the individual's vision is adequate to permit the safe operation of a motor vehicle; and
- A BMV night time driver's examination that demonstrates the driver's ability to operate a motor vehicle safely; and
- A review of the individual's driving record shows the ability to operate a motor vehicle safely and in accordance with all applicable laws, rules, and regulations governing the operation of motor vehicles.

FUNCTIONAL ABILITY PROFILE
Visual Disorders[1]: Peripheral Vision

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	Binocular total visual field of at least 120° & a minimum of 50° to left and 50° to right of fixation.	N/A
2.	Condition fully recovered	Past history of visual field defect but current total is 120° or more with at least 50° to left and 50° to right of fixation.	N/A
3.	Active impairment	See notes [3] [4] [5] & [6] re: testing. For hemianopsia, see note[6] below.	
	a. Mild	Binocular or monocular visual field total 120° or better with minimum of 50° to left and 50° to right of fixation, with potential for deterioration.	4 years
	b. Moderate	i. Binocular or monocular visual field total less than 120° but at least 110° and at least 50° to left and 50° to right of fixation. Must pass Esterman. See note[5].	1 year or as recommended by vision examiner. Road Test depends on Esterman.
		ii. Binocular or monocular visual field total at least 110°, but less than 50° to left or 50° right of fixation. Must pass Esterman[5], and road test required.	1 year or as recommended by vision examiner. ROAD TEST.
	c. Severe	Binocular or monocular visual field total less than 110°.	No driving

[1] For further discussion regarding VISUAL DISORDERS, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] Testing of peripheral vision must be done without the use of Fresnel paste on prism lenses. Prisms incorporated into correction are allowed.
[4] Peripheral vision should be measured with a 10 mm white test object at 330 mm, preferably without corrective lenses, in the horizontal meridian. Contacts or permanent prism lenses may be used. Confrontational visual fields or alternate field tests other than the 10 mm white at 330 mm are acceptable. The minimum peripheral visual field must be 120°, with at least 50° to left and 50° to right of fixation. For exception, see note[5] below.
[5] The binocular Esterman test may be used for drivers with at least 110˚ but less than 120°. If test passed without missing any points, no road test will be required. Missing one to three points on the Esterman test requires passing a road test. Missing four points on the Esterman test will disqualify for driving.
[6] If hemianopsia is present driver will also need evaluation using the TBI/Stroke profile and must pass the Esterman field test as stated above.

FUNCTIONAL ABILITY PROFILE
Visual Disorders[1]: Double Vision

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	Never sees double.	N/A
2.	Condition fully recovered	History of diplopia that has recovered or eyes crossed but no diplopia without patch.	N/A
3.	Active impairment	If diplopia is due to a head injury or stroke, also require an evaluation using that profile.	
	a. Mild	Intermittent diplopia or constant double vision correctable by patching one eye.	4 years
	b. Moderate	Monocular diplopia in the only eye meeting visual acuity requirements, with potential for correction.	No driving
	c. Severe	Monocular diplopia in the only eye meeting visual acuity requirements, without potential for correction.	No driving

[1] For further discussion regarding VISUAL DISORDERS, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.

APPENDIX

Potential Biomarkers of Alcohol Use[1]

Note: Medical providers are strongly encouraged to read the information in this reference to get more details about the appropriate use of these lab tests. The tests are listed here as a basic introduction. Medical providers need to understand the subtleties of these lab tests and the potential for false positives and false negatives when using these tests clinically.

Biomarker	Screens for Heavy Drinking	Identifies Relapse to Heavy Drinking	Monitors Abstinence	Time to return to normal Range with abstinence
CDT	yes	yes		2-3 weeks
Ethyl Glucuronide (urine)		yes	yes	1-3 days
EtS		yes	yes	1-3 days
GGT	yes			2-4 weeks
MCV	yes			several months
Phosphatidyl ethanol		yes		2-4 weeks
AST, ALT	yes			2-4 weeks

[1] *The role of Biomarkers in the Treatment of Alcohol use Disorder, Revision Spring 2012. Volume 11, Issue 2.* *www.samhsa.gov*

This reference is available free, online, and is included for information only. It is not a part of rules.

APPENDIX

BIBLIOGRAPHY
(References are included for information only, and are not a part of rules.)

CARDIOVASCULAR

Epstein, A.E., et al. Personal and Public Safety Issues related to Arrythmias that may affect Consciousness: Implications for Regulation and Physician Recommendations. Circulation 1996;94: 1147-1166.

CHRONIC PULMONARY DISEASE

[A]*From the* Global Strategy for the Diagnosis, Management and Prevention of COPD, *Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015. Available from: http://www.goldcopd.org/.*

[B]*American Thoracic Society. (1986). Evaluation of impairment/disability secondary to respiratory disorders. American Review of Respiratory Disorders, 133, 1205-1209.*

[C]*Grant, I., Heaton, R.K., McSweeny, A.J., Adams, K.M., & Timms, R.M. (1982). Neuropsychologic findings in hyoxemic chronic obstructive pulmonary disease. Archives of Internal Medicine, 142, 1470-1476.*

[D]*Prigatono, G.P., Parsons, G.A., Wright, E., et al. (1983). Neuropsychologic test performance in mildly hypoxemic patients with chronic obstructive pulmonary disease. Journal of Clinical and Consulting Psychology, 51, 108-116.*

[E]*Grant, I., Prigatano, G.P., Heaton, R.K., McSweeny, A.J., Wright, E. C., & Adams, K.M. (1987). Progressive neuropsychologic impairment and hypoxemia. Annals of General Psychiatry, 44, 999-1006.*

[F]*Karakontaki, F., Gennimata, S., et al. Driving-Related Neuropsychological Performance in Stable COPD Patients(2013). Pulmonary Medicine, 2013, 1-10.*

[G]*Orth, M., Diekmann, C., et al, Driving Performance in Patients with Chronic Obstructive Pulmonary Disease(2008). Journal of Physiology and Pharmacology, 59, Suppl 6, 539-547.*

[H]*Karakontaki, F., Gennimata, S., et al. Driving-Related Neuropsychological Performance in Stable COPD Patients(2013). Pulmonary Medicine, 2013, 1-10.*

[I]*Diller, E., Cook, L., Leonard, D., Dean, J.M., Reading, J., & Vernon, D. (1998). Evaluating drivers licensed with medical conditions in Utah, 1992-1996. NHTSA Technical Report 1992-1996. Washington, DC.*

DEMENTIA

[A] *Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration. www.nhtsa.gov*

[B]*Physician's Guide to Assessing and Counseling Older Drivers developed by the American Medical Association/National Highway Traffic Safety Administration, September 2010, Chapter 3. (http://geriatricscareonline.org/ProductAbstract/physicians-guide-to-assessing-and-counseling-older-drivers/B013) Accessed July 16, 2015*

[C]*Anthony JC, LeResche L, Niaz U, von Korff MR, Folstein MF.Limits of the 'Mini-Mental State' as a screening test for dementia and delirium among hospital patients. Psychol Med. 1982 May;12(2):397-408.*

[D]*Ladden MD. Approach to the evaluation of older drivers In: UpToDate, Schmader KE (Ed), UpToDate, Waltham, MA. (Accessed July 16, 2015.)*

HYPOGLYCEMIA WITH OR WITHOUT DIABETES

Medical Conditions and Driving – A Review of Literature (1960-2000), September 2005, DOT HS 809 690; US Dept. of Transportation National Highway Traffic Safety Administration

Assessing Fitness to Drive for Commercial and Private Vehicle Drivers, Medical Standards to Drive and Clinical Management Guidelines, March 2012 as amended up to 16 March 2013, NTC Australia

Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration www.nhtsa.gov

MENTAL DISORDERS

[A]Medical Conditions and Driving – A Review of Literature (1960-2000), September 2005, DOT HS 809 690; US Dept of Transportation National Highway Traffic Safety Administration

[B]American Psychiatric Association (2013). Diagnostic and Statistical Manual (5th ed). Washington DC.

[C]Benbadis, S, Lutsep, H, et al. Psychogenic Nonepileptic Seizures. Medscape News and Perspective. Updated: Oct 09, 2015. emedicine.medscape.com/article/1184694-overview

[D]Morrison I and Razvi S. Driving regulations and psychogenic non-epileptic seizures: Perspectives from the United Kingdom. Seizure European Journal of Epilepsy. March 2011. 20(2):177-180. DOI:http://dx.doi.org//10/1016/j.seizure.2010.11.011

[E]Rossi S, Hallett M, Rossini Ret al. Safety, ethical considerations and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. Clin Neurophysiol 2009. 120(12):2008-2039. Doi: 10.1016/jclinph.2009.08.016.

MUSCULOSKELETAL AND NEUROLOGICAL DISORDERS

Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration www.nhtsa.gov

NARCOLEPSY

[A] Aldrich, M.S. Automobile accidents in patients with sleep disorders. Sleep 1989; 12(6), 487-494.

[B] Broughton R, Ghanem Q, Hishikawa Y, Sugita Y, Nevsimalova S, Roth B. Life effects of narcolepsy in 180 patients from North America, Asia and Europe compared to matched controls. Can J Neurol Sci 1981; 8(4):299–304.

[C] Aldrich, M.S. Narcolepsy. The New England Journal of Medicine (1990), 323, 389-394.

[D]Findley, L., Unverzagt, M., Guchu, R., Gabrizio, M., Buckner, J., & Suratt, P. (1995). Vigilance and automobile accidents in patients with sleep apnea or narcolepsy. Chest (1995); 108(3), 619-624

[E]T. Morgenthaler, V Kapur, T. Brown, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. Sleep, 2007, Dec 1; 30 (12): 1705-1711

[F]M. Littner, C. Kushida, M. Wise, et al. Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test. Sleep, 2005; 28 (1):113-121

[G] Carskadon MA, Dement WC: Daytime sleepiness: Quantification of behavioral state. Neurosci Bio Rev 1987; 11:307-317.

[H] Review by the MSLT and MWT Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine: The clinical use of the MSLT and MWT. Sleep, 2005; 28: 123-144.

OBSTRUCTIVE SLEEP APNEA

[A]*Vorona RD, Ware JC: Sleep disordered breathing and driving risk. Curr Opin Pulm Med 2002; 8: 506-510*

[B]*Tregear,S Reston J, Phillips B: Continuous positive airway pressure reduces risk of motor vehicle crash among drivers with obstructive sleep apnea: systematic review and meta-analysis. Sleep, 2010; 33(10): 1373-1380.*

[C]*Weaver TE, Mancini C, Maislin G, Cater J, Staley B, Landis JR, Ferguson KA, George CF, Schulman DA, Greenberg H, Rapoport DM, Walsleben JA, Continuous positive airway pressure treatment of sleepy patients with milder obstructive sleep apnea: results of the CPAP Apnea Trial North American Program (CATNAP) randomized clinical trial. AM J Resp Critical Care Med, 2012 Oct 1;186(7):677-83.*

[D]*George CF: Reduction in motor vehicle collisions following treatment of sleep apnea with nasal CPAP. Thorax 2001; 56:508-512*

[E]*Sassani A, Findley LJ, Kryger M, et al: Reducing motor vehicle collisions, costs, and fatalities by treating obstructive sleep apnea. Sleep, 2004; 27(3): 453-458.*

[F]*Kribbs NB, NB, Pack AI, Kline LR, et al: Effects of one night without nasal CPAP treatment on sleep and sleepiness in patients with obstructive sleep apnea. AM Rev Respir Dis, 1993; 147-:1162-1168*

[G]*Malhotra, Atul. Hypoglossal-nerve stimulation for obstructive sleep apnea. N Engl J Med, 2014 Jan 9; 370(2):170-1.*

[H]*Johns MW: Sleepiness in different situations measured by the Epworth Sleepiness Scale. Sleep 1994; 17(8):703-710.*

[I]*Centers for Medicare and Medicaid Services, Medicare Learning Network, MLN Matters, SE1238, p.6 http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1238.pdf*

SEIZURES AND EPILEPSY

Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration. www.nhtsa.gov

SUBSTANCE USE DISORDER / PRESCRIPTION MEDICATION

[A]*Substance Abuse Trends in Maine, State Epidemiological Profile 2014. Hornby Zeller Associates, Inc. May 2014. www.maine.gove/dhhs/samhs/osa/pub/data/2014.pdf*

[B]*American Psychiatric Association (2013). Diagnostic and Statistical Manual (5th ed). Washington DC.*

[C] *Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration. www.nhtsa.gov*

[D]*Brady JE, Li G. Prevalence of alcohol and other drugs in fatally injured drivers. Addiction, 2013; 108(1):104-11*

[E]*Brady JE, Li G., Trends in Alcohol and Other Drugs Detected in Fatally Injured Drivers in the United States. 1999-2010. Am J Epidemiology 2014; 179(6):692-9. Epub Jan 29, 2014: doi 10.1093/aje/kwt327*

[F]*Li MC et al. Marijuana Use and motor vehicle crashes. Epidemiol Rev 2012; 34(1): 65-72.*

[G]*Soyka M et al. Less impairment in one portion of a driving-relevant psychomotor battery in buprenorphine-maintained than in methadone maintenance patients. Results of a randomized clinical trial. J of Clin Psychopharm 2005; 25(5), 490-493.*

[H]*National Highway Traffic Safety Administration: Drug and Human Performance Fact Sheets. Methadone. http://www.nhtsa.gov/people/injury/research/job185drugs/methadone.htm*

[I]*JA Ewing. Detecting Alcoholism: The CAGE Questionnaire. JAMA 252: 1905-1907; 1984.*

[J] *Babor TF, et al. The Alcohol Use Disorders Identification Test Guidelines for Use in Primary Care, 2nd Ed. http://apps.who.int/iris/bitstream/handle/10665/67205/WHO_MSD_MSB_01.6a.pdf?sequence=1&isAllowed=y*

[K]*Reisfield GM, Salazar E, Bertholf RL. Review: Rational Use and Interpretation of Urine Drug Testing in Chronic Opioid Therapy. An Clin Lab Sci Autumn 37(4), 301-314, 2007. www.annclinlabsci.org/content/37/4/301.full*

[L]*The role of Biomarkers in the Treatment of Alcohol use Disorder. Spring 2012. Volume 11, Issue 2. www.samhsa.gov*

UNEXPLAINED ALTERARIONS/LOSS OF CONSCIOUSNESS

Weisberg, LA., Garcia, R Strub. "Episodic Loss of Consciousness." Essentials of Clinical Neurology: Neurology History and Examination. Chapter 8, pp. 1-13.

VISUAL DISORDERS

New standards for the visual function of drivers. Report of the Eyesight Working Group. Brussels. 2005. https://ec.europa.eu/transport/road_safety/sites/roadsafety/files/pdf/behavior/new_standards_final_version_en.pdf

Driver Fitness Medical Guidelines, September 2009, DOT HS 811 210; National Highway Traffic Safety Administration www.nhtsa.gov

Andrews, Elliott., Newman, Bill. Royal College of Ophthalmologists, Vision Standards for Driving. https://www.rcophth.ac.uk/patients/vision-standards/

*Colenbrander, August., Delaey, Jean. Report on Vision Requirements for Driving Safely, (2006) International Council of Ophthalmology, 30th World Ophthalmology Congress, Sao Paulo, Brazil www.icoph.org/pdf/**visionfordriving**.pdf Accessed December 10,2015.*

Jencke, Mary, Kazarian, Gregory., The Accident Record of Drivers with Bioptic Telescopic Lenses. (1983) State of California. Report #86. CAL-DMV-RSS-83-86.

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§1258. Medical Advisory Board

1. Board. The Medical Advisory Board, as established by Title 5, section 12004-I, subsection 84, consists of members appointed by the Secretary of State. Membership of the board is as follows.

A. The board must include licensed physicians representing the specialties of cardiology, gerontology, internal medicine, neurology or neurological surgery, ophthalmology, psychiatry, family practice and rehabilitative medicine and may include additional members who are professionals in relevant medical fields. [PL 1995, c. 482, Pt. B, §19 (AMD).]

B. The Secretary of State shall designate the chair of the board. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

C. Members of the board are entitled to compensation in accordance with Title 5, chapter 379. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

[PL 1995, c. 482, Pt. B, §19 (AMD).]

2. Duties. The duties of the board are as follows.

A. The board shall meet at least once every 2 years and may hold as many meetings as necessary. [PL 2005, c. 433, §17 (AMD); PL 2005, c. 433, §28 (AFF).]

B. The board shall advise the Secretary of State on written medical and vision standards related to operator's licensing. Standards may only be adopted as rules. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

C. The board shall coordinate efforts to educate health care providers and the public in the medical aspects of motor vehicle operator licensing. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

[PL 2005, c. 433, §17 (AMD); PL 2005, c. 433, §28 (AFF).]

3. Determination of competency. The Secretary of State may request written medical reports to determine who receives records, testimony, recommendations and reports of the board and determine the competency of a person to operate a motor vehicle.

[PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

4. Board review. The Secretary of State, having cause to believe that a licensed driver or applicant may not be physically or mentally qualified to be licensed, may obtain the advice of the board, a member of the board or another medical or paramedical professional licensed or certified in a medical specialty as follows.

A. The board may formulate advice from records and reports or may cause an examination and report to be made by a member or another qualified person. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

B. The person under review may deliver a written report to the board and the board must give due consideration to the report. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

C. The Secretary of State may request that the board interview in person someone whose ability to operate a motor vehicle safely is unascertainable through written reports or records. [PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

[PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

5. Suspension pending compliance. The license of a person under review who refuses to submit to an examination or to provide information as requested by the Secretary of State pursuant to this subchapter may be suspended until the individual complies with the request.

[PL 1993, c. 683, Pt. A, §2 (NEW); PL 1993, c. 683, Pt. B, §5 (AFF).]

6. Immunity. A member of the board or other person making an examination and report of opinion, recommendation or advice to the Secretary of State in good faith is immune from criminal or civil liability for so doing. A physician or other person who becomes aware of a physical, mental or emotional impairment that appears to present an imminent threat to driving safety and reports this information to the Secretary of State in good faith is immune from criminal or civil liability for so doing. The immunity for damages under this subsection applies only to the extent that this immunity is not in conflict with federal law or regulation.
[RR 1993, c. 2, §20 (COR).]

7. Confidentiality. A report received or made by the board, a member or the Secretary of State for the purpose of assisting the Secretary of State in determining whether a person is qualified to be licensed is confidential and only for the use of the board, the Secretary of State, medical personnel treating the person subject to review and the person subject to review.

These reports may not be divulged to another person unless the person subject to review gives written permission.
[PL 2015, c. 206, §5 (AMD).]

8. Reporting. Notwithstanding the provisions of Title 5, section 12005-A, the board is not required to file an annual report with the Secretary of State unless the board meets and exercises any of its powers and duties during a calendar year. In any calendar year in which the board meets and exercises any of its powers and duties, the board is subject to the provisions of Title 5, section 12005-A.
[PL 2005, c. 433, §16 (NEW); PL 2005, c. 433, §28 (AFF).]

SECTION HISTORY

RR 1993, c. 2, §20 (COR). PL 1993, c. 683, §A2 (NEW). PL 1993, c. 683, §B5 (AFF). PL 1995, c. 482, §§A21,B19 (AMD). PL 2005, c. 433, §§16,17 (AMD). PL 2005, c. 433, §28 (AFF). PL 2015, c. 206, §5 (AMD).

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Excessive daytime sleepiness (EDS) in OSA can affect many aspects of patients' lives

The American Academy of Sleep Medicine (AASM) defines EDS as:

- The **inability to maintain wakefulness and alertness** during the major waking episodes of the day[1]
- Resulting in periods of irrepressible need for sleep or **unintended lapses into drowsiness or sleep**[1]

While involuntary episodes of sleep are more likely to occur during relaxing or inactive situations, for some, they can also occur during those situations that require active participation.[1,2]

Changes in neurocognitive function are common and can make it difficult for patients to focus, remember, and complete day-to-day tasks[3,4]

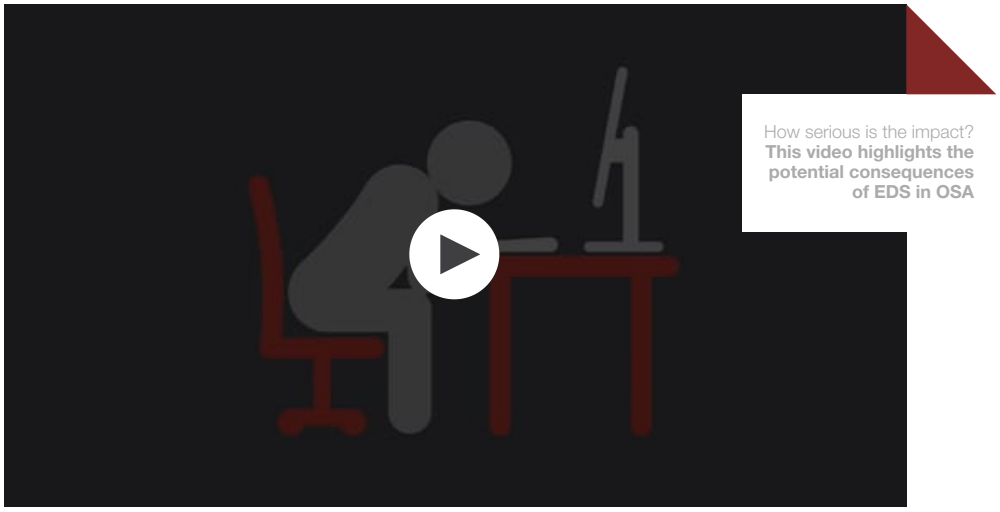
In an online survey, patients shared the real impact of EDS in OSA

reported falling asleep while working or during a meeting[5]*

felt that EDS negatively affected their romantic partnerships[6]*

said EDS impacted their ability to enjoy activities or hobbies[6]*

For US Healthcare Professionals



EDS in OSA: A public health burden?

Get the facts

Pharmacotherapy is an option for unresolved EDS in OSA

Learn more

References

US-SLE-2000215 Rev0520

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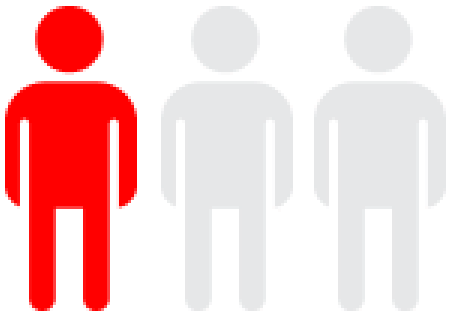
Excessive daytime sleepiness (EDS) in OSA is more common than you may think

- Animal and human studies indicate **a link between obstructive sleep apnea (OSA) and changes to the brain**—and these changes have been associated with a disruption in neurologic function[1-6]
- While CPAP is needed to address the airway issue in patients with OSA, it may not address all aspects of **compromised neuronal activity**, and **EDS may persist**[6,7]

In a study of patients with OSA

REPORTED FEELING SLEEPY DURING THE DAY DESPITE ANY AMOUNT OF CPAP USE[7*†]



1 IN 3 WHO USED THEIR CPAP ≥5 HOURS A NIGHT STILL REPORTED FEELING SLEEPY DURING THE DAY[7*]

*A study of 174 patients with moderate to severe OSA using continuous positive airway pressure (CPAP). Daytime sleepiness was assessed before and after 3 months of CPAP therapy using the Epworth Sleepiness Scale.[7]

†Includes average CPAP use of 2 or fewer hours per night, up to 7 or more hours per night.[7]

For US Healthcare Professionals

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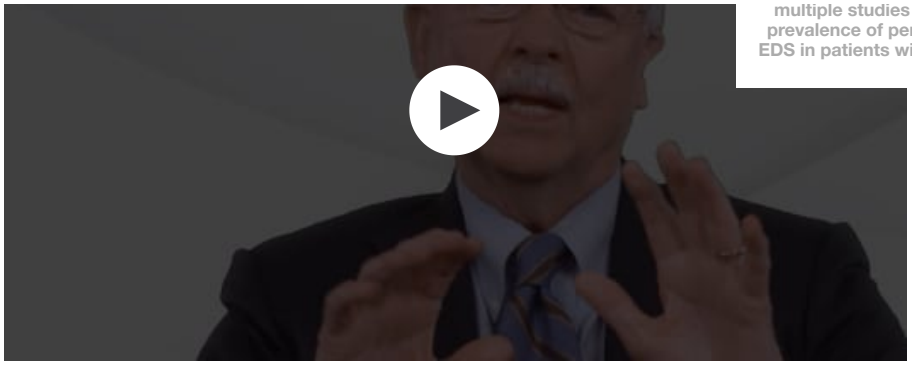


multiple studies on the prevalence of persistent EDS in patients with OSA

The real impact of EDS in OSA

See what patients had to say

Recognizing EDS in OSA

Learn about a tool that can help

References

Treatment considerations for excessive daytime sleepiness (EDS) in OSA

- While continuous positive airway pressure (CPAP) is considered the gold standard of treatment for obstructive sleep apnea (OSA), **EDS may persist despite optimal CPAP use**[1-3]*
- Sleep apnea treatments like CPAP have been proven to decrease symptoms such as apneas, hypopneas, and snoring, and improve sleep structure in patients with OSA[4,5]
- However, CPAP and **CPAP alternatives** + may not address the **brain alterations** and **subsequent neurologic dysfunction** that OSA can leave behind[6-9]

Pharmacotherapy should be considered for patients who have unresolved EDS despite optimal CPAP compliance[10]

*Always ensure patients are getting an adequate amount of sleep and that their primary airway therapy is optimized and working properly.[11]

Pharmacologic treatment options for EDS in OSA

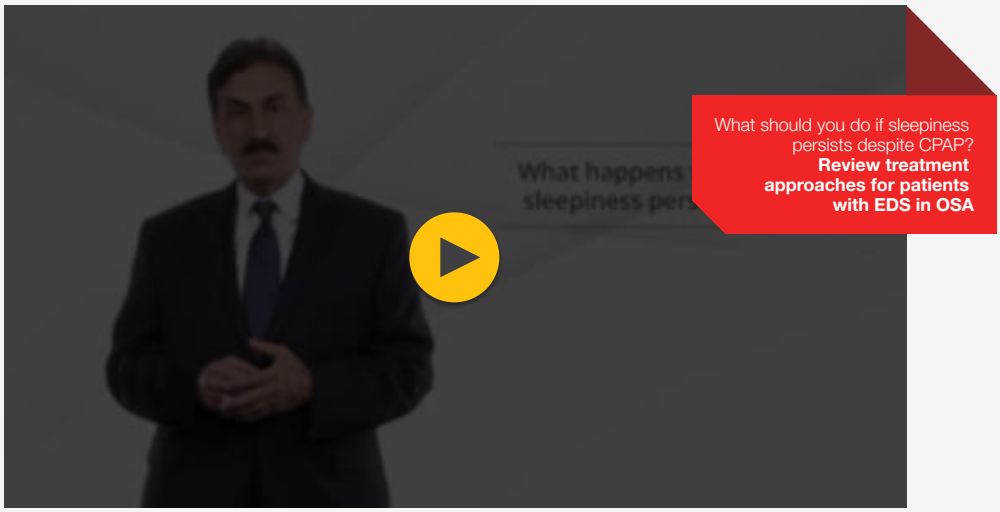
Wake-promoting agents[12-14]	CNS stimulants[15,16]

While not direct dopamine receptor agonists, most WPAs are thought to work in vitro by binding to the dopamine transporter and inhibiting dopamine reuptake.	CNS stimulants are thought to work by blocking the reuptake of dopamine and norepinephrine into the presynaptic neuron and increasing the release of these monoamines in the extraneuronal space.
Explore another option for adult patients with EDS in OSA. Learn more >>	CNS stimulants are not indicated to treat patients with EDS in OSA.

CNS=central nervous system.

Reinforce healthy lifestyle and behavioral modifications, and reexamine treatment objectives

- Educate patients about the importance of good sleep hygiene[17]
- Highlight the benefits of a proper diet and weight management[18]
- Encourage proper exercise and cardiovascular fitness[19]
- Evaluate EDS on an ongoing basis[10]



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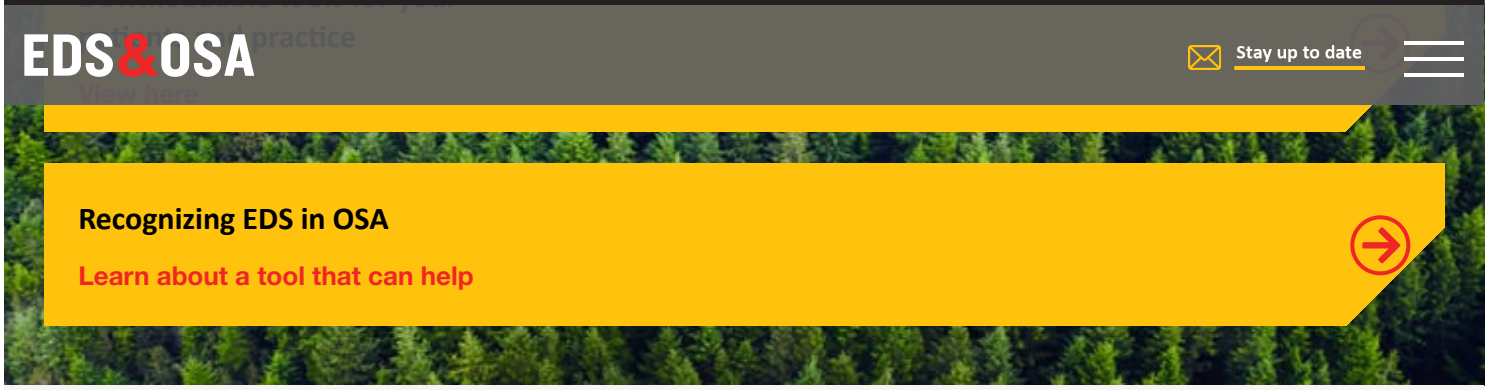
EDS&OSA

Stay up to date



References

Jazz Pharmaceuticals

US-SLE-2000215 Rev0520

SLEEPINESS SCALE

EPWORTH SLEEPINESS SCALE

Name: _____ **DOB:** _____ **Date:** _____

This questionnaire was developed to determine the level of daytime sleepiness in individuals. It has become one of the most frequently used methods for determining a person's average level of daytime sleepiness.

Please rate how likely you are to doze or fall asleep in the following situations by selecting the response that best applies. If you have not done some of these activities recently, select what would most likely happen if you were in that situation.

0 Would ***never*** doze

1 ***Slight*** chance of dozing

2 ***Moderate*** chance of dozing

3 ***High*** chance of dozing

	Chance of Dozing			
Sitting and reading	0	1	2	3
Watching television	0	1	2	3
Sitting inactive in a public place (eg, a theater or a meeting)	0	1	2	3
As a passenger in a car for an hour without a break	0	1	2	3
Lying down to rest in the afternoon when circumstances permit	0	1	2	3
Sitting and talking to someone	0	1	2	3
Sitting quietly after a lunch without alcohol	0	1	2	3
In a car, while stopped for a few minutes in traffic	0	1	2	3
			Total Score:	

Interpreting Epworth Sleepiness Scale Scores[1,2]		
Normal	EDS*	High Levels of EDS*
0-10	>10	>16

Sources: **1.** Johns M, Hocking B. Excessive daytime sleepiness: daytime sleepiness and sleep habits of Australian workers. *Sleep*. 1997;20(10):844-849. **2.** Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep*. 1991;14(6): 540-545.

*Excessive daytime sleepiness.

ES&OSA

For US Healthcare Professionals

&

Excessive daytime sleepiness (EDS) in OSA is often underrecognized and underreported

- Patients may be used to feeling tired all the time, not realizing that the level of sleepiness they're experiencing is more than normal[1]
- They may not be familiar with "excessive daytime sleepiness," instead using terms like "tired" or "fatigued" to describe how they're feeling[1,2]
- Screening every patient with obstructive sleep apnea (OSA) at every visit can help differentiate between fatigue and excessive sleepiness during the day[2]

The Epworth Sleepiness Scale (ESS) can be used with every patient for screening, identifying, and monitoring EDS in OSA[2]

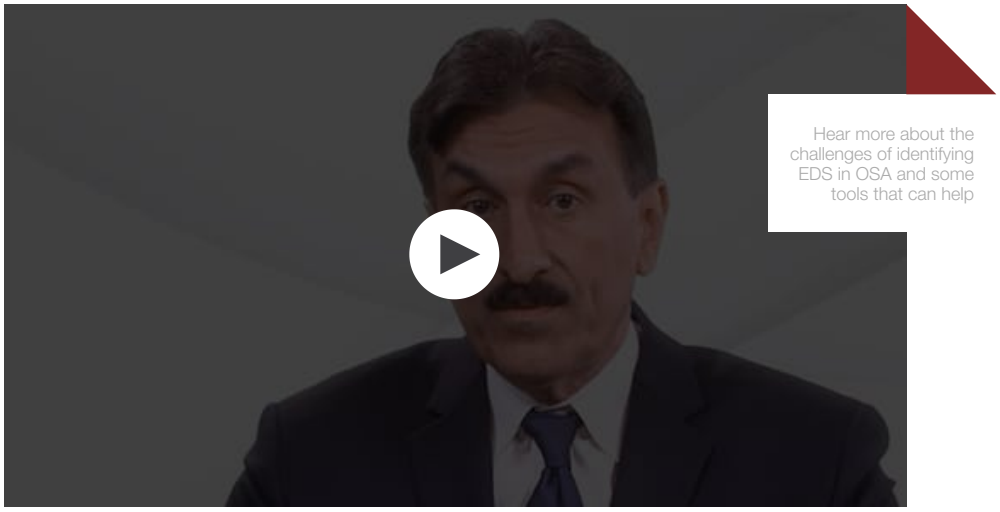
- A short questionnaire that takes only a few minutes to complete and patients can fill out in the waiting room[2]
- Patients are asked to rate (on a scale of 0 to 3) their likelihood of falling asleep during 8 daily activities, including reading, watching television, and driving[2]

Download the ESS

View the ESS

- A total ESS score of 10 or below falls within the normative range of sleepiness[2]

The American Thoracic Society (ATS) recommends routinely asking patients with OSA about their sleepiness.[3] After OSA diagnosis, you can use the ESS with every patient at every visit to assess their sleepiness over time.[2]



3 more tools that can help identify EDS in OSA:

+ **Functional Outcomes of Sleep Questionnaire (FOSQ)**

+ **Multiple Sleep Latency Test (MSLT)**

+ **Maintenance of Wakefulness Test (MWT)**

Diagnosis of persistent EDS in OSA is based on a clinical assessment, which must be made by the treating physician. The diagnosis must be made after airway treatment is implemented and all other causative disorders have been considered. These include other untreated sleep disorders, mental disorders, or the effects of medications.[6]

Downloadable tools for your patients and practice

View here

References

About the ESS

Dr Johns first developed the ESS for adults in 1990 and subsequently modified it slightly in 1997. He developed it so he could assess the 'daytime sleepiness' of the patients in his own private practice of Sleep Medicine. He named the questionnaire after Epworth Hospital in Melbourne, where he established the Epworth Sleep Centre in 1988.

The ESS is a self-administered questionnaire with 8 questions. Respondents are asked to rate, on a 4-point scale (0-3), their usual chances of dozing off or falling asleep while engaged in eight different activities. Most people engage in those activities at least occasionally, although not necessarily every day. The ESS score (the sum of 8 item scores, 0-3) can range from 0 to 24. The higher the ESS score, the higher that person's average sleep propensity in daily life (ASP), or their 'daytime sleepiness'. The questionnaire takes no more than 2 or 3 minutes to answer. It is available in many different languages.

The 1997 version of the ESS is the standard version that can be used by most adults. A license is needed to use it, whether or not license fees are payable.

See sample copy below

The following topics are canvassed in the sections below

- What the ESS measures
- Questions included in the ESS
- The 1997 version of the ESS
- Recall period for the ESS
- Format of the ESS questionnaire
- How to score the ESS
- Reference range of normal ESS scores
- Psychometrics of the ESS
- Language of the ESS and its translation
- Limitations of the ESS

What the ESS Measures

The ESS asks the respondent to rate on a 4-point scale (0-3) their usual chances of having dozed off or fallen asleep while engaged in eight different activities that differ widely in their somnificity. These ESS item-scores provide estimates of eight different SSPs for that person (Johns, 1994; 2010). The total ESS score (the sum of 8 item-scores) gives an estimate of a more general characteristic, the person's 'average sleep propensity' or ASP, across a wide range of activities in their daily lives (Johns, 2002). There is no other measure of ASP available at present with which to compare ESS scores directly.

The ESS does not ask about the person's subjective feelings of alertness/drowsiness at some particular time, as measured by the Karolinska Sleepiness Scale. Nor does it measure how often, or for how long, the respondent sleeps during the day. The ESS is not a check-list for identifying those situations in which the respondent most frequently dozes during the day. Nor can it measure a person's level of alertness/drowsiness continuously, as Optalert technology does (Johns, 2008; Anderson et al, 2013).

The ESS specifically distinguishes reports of dozing behaviour (and estimates of SSPs) from feelings of fatigue and drowsiness/sleepiness, in the sense of 'weariness from exertion'. Fatigue and drowsiness/sleepiness are related concepts that are often confused (Johns 2000(a), 2003, 2009; Mairesse et al, 2016).

Questions included in the ESS

The particular questions included in the ESS were chosen on a priori grounds to represent activities with a wide range of different somnificities. Their relative somnificities were later confirmed by analysis of variance (Johns, 2010) and also by Rasch analysis (Hagell et al 2007; Izci et al, 2008; Sargento, et al, 2015). Item 5 ('lying down to rest in the afternoon when circumstances permit') is an activity with a much higher somnificity than Item-6 ('sitting and talking to someone').

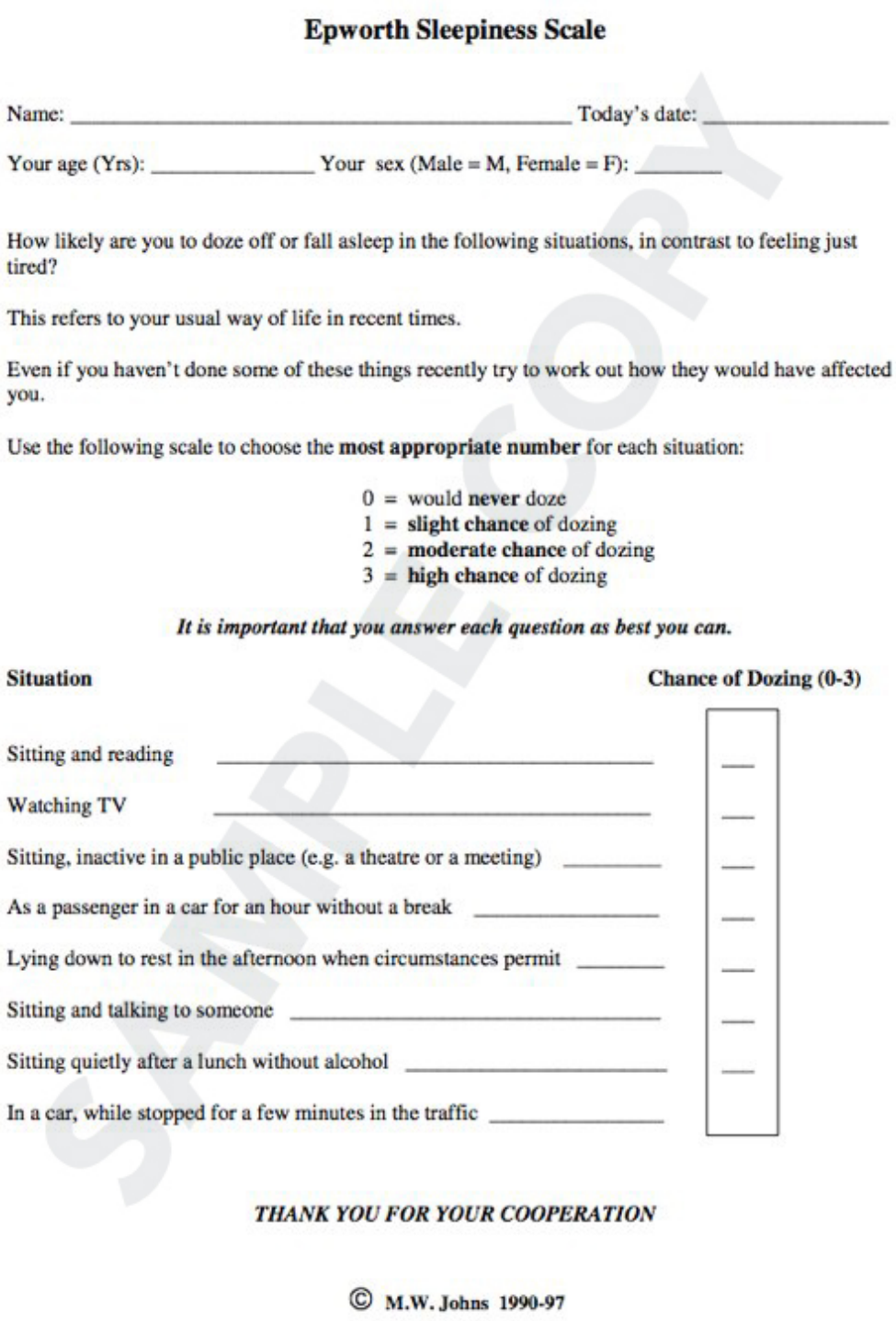
The relative somnificities of ESS activities are similar in different diagnostic groups and populations, regardless of their levels of ASP and the presence or absence of sleep disorders (Johns, 2002, 2010).
The ESS items were not selected from a list of related questions by principal components analysis, as is commonly done in the development of other questionnaires.

The 1997 version of the ESS

With the initial (1990) version of the ESS some respondents did not answer all the questions, for whatever reasons. Even if one question was not answered, their ESS score was not valid because it was not possible to interpolate item-scores. Up to 5% of ESS scores were invalid in some groups who used the 1990 version.

In 1997 the instructions to respondents were changed, with the addition of an extra sentence, 'It is important that you answer each question as best you can'. With this exhortation, nearly everyone answered all questions. The frequency of invalid ESS scores because of missed item-scores was reduced to less than 1%.

The 1997 version of the ESS is the standard version that can be used by most adults. It is available in many different languages as authorized translations.



Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation	Chance of Dozing (0-3)
Sitting and reading	
Watching TV	
Sitting, inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	

THANK YOU FOR YOUR COOPERATION

© M.W. Johns 1990-97

Recall period for the ESS

Respondents to the ESS rate their chances of having dozed off or fallen asleep in particular situations 'in recent times'. It was a deliberate decision not to specify this recall period more accurately. It was intended to be long enough for the respondent to have experienced at least most of the activities, so they could estimate in retrospect their chances of dozing in each. Thus, 'in recent times' was intended to mean a few weeks to a few months, not a few hours or days.

There may be circumstances in which this recall period needs to be specified more accurately. For example, clinicians may want to compare ESS scores before

and after instigating some particular treatment for a sleep disorder, such as nasal continuous airway pressure treatment for obstructive sleep apnea. Under those circumstances it is possible, with permission, to use a specific version of the ESS which specifies, for example, an interval such as ‘over the last month’ (Broderick JE et al, 2013).

Format of answers to ESS questions

In the usual format, each ESS item-score is recorded as one number (0-3), written in a box. Alternatively 4 boxes, labelled 0 to 3, may be presented for each question, and the respondent then ticks the most appropriate box. Electronic versions are possible too, by arrangement. The ESS scores derived from interviews, whether by phone or personally, may be valid, but that needs confirmation.

How to score the ESS

All ESS item-scores are intended to be integers (0-3). However, some people cannot decide on one number and report half-values. It is recommended that these scores be taken at face value. If, after adding them up, the total ESS score includes a half, it should be rounded up to the next whole number. If one or more item-scores are missing, that ESS is invalid because it is not feasible to interpolate missing item-scores. The ESS score (the sum of 8 item-scores) is the only number required under most circumstances.
Respondents should not be given an ‘interpretation’ of particular ESS scores when they answer the questionnaire because that may influence their responses.

Reference range of normal ESS scores

It was initially reported in 1991 that the ‘normal’ range of ESS scores was 2 to 10 (Johns, 1991). With more data, that proved to be incorrect. Adults in Australia who have no evidence of a chronic sleep disorder (including frequent snoring) had a mean ESS score of 4.6 (95% confidence intervals of 3.9-5.3) with a standard deviation of 2.8 and a range from zero to 10 (Johns and Hocking, 2004). By this criterion, the reference range of ‘normal’ ESS scores is zero to 10. That is the same as the range defined by the 2.5 and 97.5 percentiles.

A similar ‘normal’ range has been reported from the United Kingdom (mean = 4.5 +/- 3.3 (SD), n= 188) (Chen at al, 1995), Italy (4.4+/- 2.8, n=54) (Manni et al, 1999), and Turkey (3.6 +/- 3.0, n= 60) (Izci et al, 2008). However, more evidence is needed to be sure that a similar reference range applies to other populations.

Many ESS scores reported from the general community, disregarding the presence or absence of sleep disorders, are higher than this ‘normal’ range. That is presumably because sleep disorders that increase ASPs, especially the different forms of sleep disordered breathing, are common in the community (Mihăicută et al, 2013). However, it should not be assumed that sleep disordered breathing is the only factor affecting ESS scores. Other causes, including depression, are also important. Gender and age have little effect on ESS scores

among adults, but ethnicity does. African-Americans have significantly higher ESS scores than Caucasian Americans (Mihăicută et al, 2013; Sanford et al, 2006).

ESS scores of 11-24 represent increasing levels of 'excessive daytime sleepiness' (EDS). The percentage of people with EDS varies widely between different groups, from about 10 to 40% or more (Johns and Hocking, 1997; Sanford et al, 2006). Almost all patients suffering from narcolepsy have severe or moderate EDS by these ESS criteria, as expected (Parkes et al, 1998; Johns, 2000; van der Heide et al, 2015).

In general ESS scores can be interpreted as follows:

0-5 Lower Normal Daytime Sleepiness

6-10 Higher Normal Daytime Sleepiness

11-12 Mild Excessive Daytime Sleepiness

13-15 Moderate Excessive Daytime Sleepiness

16-24 Severe Excessive Daytime Sleepiness

For practical purposes, the ESS is a unitary scale that is reliable and valid for measuring a person's ASP. It is very cheap and easy to use for individuals and large groups.

Psychometrics of the ESS

The psychometric properties of the ESS have been investigated widely. The internal consistency of responses to the eight questions has been tested by Cronbach's alpha, which has varied between 0.73 and 0.90 (mean = 0.82) in ten separate investigations (eg. Johns,1992; Hagell et al, 2007). The test-retest reliability of ESS scores (measured over a few weeks to a few months) has been tested by the intraclass correlation coefficient which has varied between 0.81 and 0.93 in five separate investigations (eg. Gibson et al. 2006; Izci et al. 2007; Cho et al 2011; van der Heide et al. 2015).

Principal components analysis of ESS item-scores has yielded variable results, with a single factor in some investigations, but more than one factor in others. In the latter investigations there has been one dominant factor, as well as one or two minor factors with Eigenvalues not much above 1.0, the assumed cut-off point (eg. Johns, 1992; Sargento et al, 2013). We might conclude that there is one

dominant factor, with high loadings on all scales, but sometimes there are additional minor factors that vary between groups.

Rasch analysis of ESS item-scores has enabled differences between the items to be assessed at the same time as differences between people, based on Item Response Theory. This analysis has confirmed that the ESS involves an ordinal sequence of Items, from Item 5 (the least 'difficult') to Item 6 (the most 'difficult'), which can be interpreted in this context as differences of somnificity. The evidence from several different Rasch analyses of the ESS indicates that it has a unitary structure (Hagell, et al, 2007; Izci et al, 2008; Sargento et al, 2015).

External Criterion Validity of the ESS

Strong evidence for the external criterion validity of the ESS has come from investigations of the sensitivity and specificity of ESS scores for distinguishing narcoleptic patients from normal controls, who have very different ASPs by definition (Parkes et al, 1998; Johns, 2000(b).

A functional MRI study of 'normal' adults has shown that those with higher ESS scores (even within the 'normal' range) have lower connectivity between the bilateral thalamus and cortical regions involved in somatosensory and motor functions in the resting awake state (Kilgore et al, 2015).

The external criterion validity of the ESS has also been tested, less conclusively, by the correlation between ESS scores and mean sleep latencies in the Multiple Sleep Latency Test (MSLT). It has been shown repeatedly that this is not a close relationship, statistically significant in some but not all reports (eg. Johns, 1992; Sangal et al, 1997; Chervin, et al, 1999).

The external criterion validity of the ESS has also been tested by examining the relationship between ESS scores and the severity of obstructive sleep apnea, measured by the apnea-hypopnea index (AHI). That too is not a very close relationship, usually but not always statistically significant (Manni et al 1999; MihÄƒicutÄƒ et al, 2013). That is also true for the relationship between the severity of OSA and measures of daytime sleepiness other than the ESS, such as the MSLT (Guilleminault et al, 1988). We might conclude that such relationships are of limited use for testing the validity of any method for measuring daytime sleepiness, whether subjective or objective.

The responsiveness of ESS scores to treatment effects has been demonstrated by their reduction after nasal continuous positive airway pressure treatment for obstructive sleep apnea (Standard Response Mean >0.8) (Chen et al, 2002; Hardinge et al, 1995), and also after the treatment of narcolepsy with stimulants (Broughton RJ, et al, 1997; van der Heide et al. 2015).

Translation of the ESS

The ESS was first developed in English for Australia, but has been translated into many other languages, especially by Mapi Research Trust who have used standardised procedures. For the ESS to remain useful internationally it is

important that it is standardised and not modified. In languages other than English, it is important that the meaning of the original (English) words be retained. The copyright prohibits any changes to the ESS, except under special circumstances and with written permission.

Limitations of the ESS

Because ESS item-scores are based on subjective reports, they can be influenced by the same sources of bias and inaccuracy as any other such reports. The ESS should not be used in isolation in circumstances where the scores could determine outcomes with potential legal implications, such as granting or withholding a driver's license. Confirmatory evidence of 'excessive daytime sleepiness' or an increased risk of a drowsy road-crash should be sought from other sources too.

The ESS does not usually enable accurate predictions to be made of a person's level of drowsiness, and hence their crash-risk, when driving a vehicle at some particular time. However, there may be an exception to this among people with very high ESS scores (>15), whose ASP is very high under most circumstances.

The ESS does not distinguish which factors, or which sleep disorders, have caused any particular level of ASP. The ESS is not a diagnostic tool by itself. Nor does it assess other aspects of a person's sleep habits, for which other methods are available.

The ESS is not suitable for use among people with serious cognitive impairment. Nor is it suitable for measuring rapid changes in sleep propensity over periods of hours, eg. to demonstrate the short-term sedative effects of a drug, or to assess the circadian rhythm of sleep propensity.

OBSTRUCTIVE SLEEP APNEA

Driver sleepiness is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with obstructive sleep apnea (OSA) are at increased risk for car accidents.

OSA (and possibly central sleep apnea) can cause impairment in daytime performance. It is associated with increased risk of motor vehicle crashes, with estimates ranging from 2% to 7% in those with OSA compared to those without. [A B] The condition is common (2-8% in older literature, with more recent estimates suggesting that 25% of adult men in the US are affected), and the frequency of occurrence increases with age, BMI (body mass index) and comorbid conditions such as diabetes.

People with sleep apnea may have delayed reaction times and inattentiveness in addition to frank sleepiness. Some are unaware of their sleepiness and cognitive impairment. It is important to recognize that excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea. A recent study demonstrated that increased risk of motor vehicle crashes is present in those with mild OSA as well as those with severe disease. [C] The diagnosis of OSA is made through polysomnography (PSG), with insurers increasingly insisting upon Home Sleep Studies (HST) although the gold standard is still in lab polysomnography.

Treatment of OSA generally improves daytime sleepiness. Use of continuous positive airway pressure (CPAP) is a highly effective treatment with studies suggesting that daytime symptoms improve within two weeks of positive airway pressure (PAP) treatment. [D] It is the only treatment modality demonstrated to reduce crash risk.[E] Not using CPAP for as little as one night may cause daytime impairment.[F]

Other treatment options for OSA include bariatric surgery for morbid obesity, use of oral mandibular advancement devices, upper airway surgery and craniofacial surgery. Hypoglossal nerve stimulators have been approved by the FDA for treatment of OSA.[G] Assessment of treatment efficacy with PSG after surgery or with use of an oral device is recommended.

It is difficult for clinicians to assess sleepiness (and possible impairment while driving) in a patient with OSA. Sleepiness cannot be measured easily by objective testing. Maintenance of Wakefulness Tests (MWT) and Multiple Sleep Latency Tests (MSLT) are the best objective measures of daytime sleepiness in those with OSA, but are performed only in Sleep Centers, are expensive and time consuming. They are not routinely used to assess daytime sleepiness in drivers. The clinician must use subjective reports as well as objective data from CPAP downloads to assess adherence to treatment and level of daytime sleepiness.

The diagnosis of obstructive sleep apnea should only be made by a physician or NP/PA with specialized training in Sleep Medicine. Those with OSA are frequently followed by a sleep specialist or a neurologist.

The Epworth Sleepiness Scale[I] is a widely used measure of subjective daytime sleepiness although the sensitivity and specificity of the scale is less than ideal. A score of 7 or less out of 24 is considered normal (not sleepy).[H] The acceptable range cutoff value is subject to debate, with some researchers suggesting that 7 or less is normal (not sleepy): others suggesting 12 or less).

Patients on PAP therapy should have data downloaded from their device to measure adherence with therapy. Medicare guidelines[I] are the standard for adherence to treatment and require an average of 4 hours PAP use per night 70% of the time.

PAP devices also calculate an AHI (apnea/hypopnea index). The AHI determines the severity of OSA: an AHI of 15 or fewer obstructive events per hour is considered mild.

The clinician must educate patients that driving safety is ultimately the individual's responsibility. Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy.

Footnotes:

[i]Epworth Sleepiness Scale: A validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and greater than 16 is severe. (*Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249*)

FOR REFERENCES, SEE BIBLIOGRAPHY AT END OF DOCUMENT.

FUNCTIONAL ABILITY PROFILE
Obstructive Sleep Apnea[1]

Profile Levels	Degree of Impairment[2]/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Recovered after Treatment(s) other than CPAP, such as surgical intervention, weight loss or dental device[3]. Polysomnogram (PSG) demonstrates an AHI[4] (apnea/ hypopnea index) of less than 15. ESS (Epworth Sleepiness Scale)[5] score of less than 8. No report of accident or near miss.	N/A
3.	Active impairment	See footnote regarding PAP therapy.[6] This diagnosis should be made only after a sleep study. Neurology or sleep med specialists are often the clinicians to provide follow-up.	
	a. Mild	AHI[4] < 15 on diagnostic PSG and not sleepy, ESS less than 8. Not on treatment.	Three years
	b. Moderate	PAP download demonstrates adherence to treatment.[6 7] AHI[4] less than 15 on download. ESS less than 8. No crashes or near misses.	Yearly
	c. Severe	History of falling asleep while driving or near miss, or strong suspicion of OSA with concern for unsafe driving; and/or Non-responsive or non-adherent[7] to therapy.	No driving

[1] For further discussion regarding OBSTRUCTIVE SLEEP APNEA, please refer to NARRATIVE found at beginning of this section.
[2] For further explanation of degree of impairment, please refer to SECTION 3.
[3] For those with dental device, repeat PSG must be done with device in place.
[4] AHI: apnea/hypopnea index: number of obstructive events per hour of sleep.
[5] Epworth Sleepiness Scale: validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and 17 or greater is severe. (Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249).
[6] Treatment with positive airway pressure therapy. PAP devices include but are not limited to, CPAP (continuous positive airway pressure), BiPAP (bi-level positive airway pressure), and ASV (adaptive servo-ventilation).
[7] Adherence to or compliance with CPAP treatment derived from Medicare guidelines: use of PAP an average of four or more hours per night at least 70% of the time.

Journal Pre-proof

Treatment-Emergent Central Apnea

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Treatment-Emergent Central Apnea

Physiologic Mechanisms informing clinical practice.

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Keywords: central sleep apnea, continuous positive airway pressure, treatment-emergent central sleep apnea, sleep-disordered breathing, sleep apnea, adaptive servo ventilation

Abbreviations: AHI (apnea-hypopnea index), TECSA (Treatment-Emergent Central Sleep Apnea), CPAP (continuous positive airway pressure), ASV (Adaptive Servo Ventilation), BPAP (Bi-level Positive Airway Pressure), OSA (obstructive sleep apnea), SDB (sleep-disordered breathing).

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ABSTRACT

The purpose of this review is to describe our management approach to patients with treatment-emergent central sleep apnea (TECSA).

The emergence of central sleep apnea during positive airway pressure therapy occurs in approximately 8% of titration studies for obstructive sleep apnea, and has been associated with several demographic, clinical and polysomnographic factors, as well as factors related to the titration study itself. TECSA shares similar pathophysiology with central sleep apnea. In fact, central and obstrcutive sleep apnea pathophysiologic mechanisms are inextricably intertwined, with ventilatory instability and upper airway narrowing occurring in both entities. TECSA is a “dynamic” process, with spontaneous resolution with ongoing positive airway pressure therapy in most patients, persistence in some, or appearing de novo in a minority of patients. Management strategy for TECSA aims to eliminate abnormal respiratory events, stabilize sleep architecture, and improve the underlying contributing medical comorbidities. Continuous positive airway pressure therapy remains a standard therapy for TECSA. Expectant management is appropriate given its transient nature in most cases, while select patients would benefit from an early switch to an alternative positive airway pressure modality. Other treatment options include supplemental oxygen, and pharmacologic therapy.

I. Introduction

Treatment-emergent central sleep apnea (TECSA) -previously called complex sleep apnea - refers to the development of central apnea after the initiation of positive pressure therapy for obstructive sleep apnea (OSA). The ICSD-3 diagnostic criteria for this condition include: 1) the presence of predominantly OSA on diagnostic polysomnography (PSG), 2) resolution of obstructive events with positive airway pressure (PAP) therapy without a backup rate, and 3) the emergence or persistence of central apneas or hypopneas on PAP therapy with central apnea index (CAI>5) events/hour of sleep, and the number of central events is ≥50% of the total events.[1].

The presence of central apnea upon initiation of PAP therapy underscores the pathophysiologic overlap between OSA and CSA including instability of the ventilatory motor output, as expressed by high loop gain in patients with OSA and the occurrence of upper airway narrowing or occlusion during central apneas and hypopneas.[2-4]. Thus, TECSA is a “dynamic” process, with spontaneous resolution with ongoing PAP therapy in most patients, persistence in some, or appearing de novo in a minority of patients. [5-8] The AASM practice parameters for treatment of CSA syndromes in adults did not specifically address TECSA. More recently, TECSA has been briefly included in a European Respiratory Society Task Force document on nocturnal central breathing disturbances. Therefore, TESCA treatment remains a gray area as caution is mandated when therapeutic approach is extrapolated from other forms of central apnea.

In this review, we will describe common clinical scenarios where TECSA is encountered, discuss our management approach in the context of current guidelines and the relevant literature, and present our approach to the treatment of TECSA in the clinical setting.

II. Case Scenarios

Case # 1

A 53-year-old healthy male referred in consultation for evaluation of snoring and hypersomnia. PSG revealed OSA with an apnea-hypopnea index (AHI) of 56/hr. Auto-PAP was prescribed at 5 to15cm H2O. Wireless monitoring data during a follow-up visit at 4 weeks of therapy revealed full PAP adherence. Residual AHI was elevated at 23/hr due to the emergence of central events. The patient was asymptomatic and sleeping well.

Case # 2

An obese, but otherwise healthy 28-year-old male was referred in consultation after being involved in a motor vehicle accident when he fell asleep while driving. A split-night PSG revealed mostly obstructive respiratory events with an AHI of 42.6 events/hr. CPAP therapy was titrated to 14 cm H2O. Obstructive apneas and hypopneas were eliminated at CPAP of 12cm H2O. Central apneas appeared at CPAP of 8 cm H2O and were reduced but not eliminated at CPAP of 14 cmH2O. Wireless monitoring data after 2 weeks of therapy at CPAP of 14 cm H2O revealed a suboptimal adherence of 48.5% use > 4hrs and a residual AHI of 17.4/hr mainly due to central apneas. The patient complained of PAP intolerance and significant sleep fragmentation.

III. Review of current literature

A. Determinants of breathing instability during sleep: Lessons from physiologic studies

Respiration during NREM sleep is critically dependent on P_aCO_2 ; the susceptibility to central apnea manifests by unmasking the hypocapnic apneic threshold.[9] Interestingly, central apnea rarely occurs as a single event; instead, it occurs in cycles of apneas or hypopneas, alternating with hyperpnea, a reflection of the negative feedback closed-loop cycle that characterizes ventilatory control. This is often described using the engineering concept of “loop gain”[10]

combining mainly two factors including: 1) chemoreflex sensitivity, (controller gain) reflecting the response of the ventilatory system to changing $P_{ET}CO_2$, (the controller), and 2) the effectiveness of the lung/respiratory system in lowering $P_{ET}CO_2$ in response to hyperventilation (the plant). The overall loop gain is the multiplicative result of several distinct and interactive mechanisms (chemosensitivity, plant gain, and circulatory delay).[10]

The "loop gain" is a valuable construct to understand the contribution of breathing instability to the pathogenesis of sleep-disordered breathing (SDB), especially Cheyne-Stokes respiration. However, SDB includes a multitude of physiologic derangements that defy the assumed rhythmic periodicity of loop gain including high peripheral chemoreflex gain,[11] frequent transient arousals from sleep, and abnormal cerebrovascular responsiveness, [12] factors that promote further breathing instability during sleep.

The propensity to develop central apnea during sleep could be determined experimentally by inducing central apnea using nasal mechanical ventilation. [13] The requisite magnitude hypocapnia to induce central apnea is referred to as the CO_2 reserve. A narrow reserve CO_2 indicate a high propensity to develop central apnea and vice versa. This experimental paradigm also allows for determination of the plant gain and chemoreflex sensitivity (controller gain).

Findings from experimental studies of induced central apnea have provided significant insight regarding the determinants of CSA and may inform our understanding of TECSA, as well as potential therapeutic approaches. For example, increased controller gain may explain increased propensity to central apnea in men versus pre-menopausal women,[14] and in older adults compared to young and middle-aged adults.[15] Likewise, patients with OSA also demonstrate higher propensity to induced central apnea, and higher loop gain, compared to healthy matched adults.[13] Interestingly, PAP therapy for 4 weeks is associated with decreased controller gain and

widening of the CO_2 reserve.[13] This observation may provide the physiologic explanation for the noted resolution of TECSA in many patients following PAP therapy for 3 months.

Plasticity is a fundamental property of the ventilatory control system. Controller gain/chemoreflex sensitivity displays substantial plasticity in response to physiologic interventions or pharmacologic manipulations. For example, acute intermittent hypoxia, mimicking recurrent respiratory events on oxygenation, results in increased controller gain and subsequent narrowing of the CO_2 reserve.[16] In contrast, administration of a hyperoxic gas mixture results in decreased controller gain and widening of the CO_2 reserve. [17] Finally, manipulation of male sex hormones exerts a predictable effect on the controller gain and the CO2 reserve. Specifically, administration of testosterone[18] to premenopausal women was associated with increased hypocapnic chemoreflex sensitivity (controller gain), whereas administration of leuprolide [19]or finasteride [20] to young men exerts the opposite effect. The mutability of the controller gain can be utilized therapeutically in the treatment of central apnea including TECSA.

The propensity to central apnea is also influenced by the changes in the background drive to breathe. Increased ventilatory drive and ensuring low alveolar pressure of CO2 (PaCO2), for a given metabolic rate, promotes stability by decreasing the magnitude of hypocapnia for a given change in alveolar ventilation, whereas reduced drive and elevated PaCO2 increases the magnitude of hypocapnia for a given change in alveolar ventilation. For example, background hypoventilation, which may occur in response to opioid analgesics, increases the propensity to develop central apnea. In contrast, administration of acetazolamide is associated with decreased plant gain and mitigation of the risk for central apnea. [21]

Central apnea may also influence the development of OSA. Patients with unfavorable upper airway anatomy are dependent on ventilatory motor output to preserve upper airway patency.

Studies using upper airway imaging have shown that central apnea [2] and hypopnea [4] result in pharyngeal narrowing or occlusion in normal individuals and SDB patients. Pharyngeal closure combined with mucosal and gravitational factors may impede pharyngeal opening and necessitate a substantial increase in a drive that perpetuates breathing instability. Thus, investigating determinants of central apnea may be relevant to understanding the pathogenesis of upper airway obstruction in susceptible individuals.

B. Prevalence and risk factors

The prevalence of TECSA is uncertain given the variability in applying the diagnostic criteria. A systematic review estimated a prevalence of 8% (range 5% to-20%). [22] One limitation is the identification and classification of hypopnea on PSG in most clinical sleep laboratories under "obstructive" events, given the limited value of precise classification in terms of management decisions. Therefore, pre-PAP central SDB cannot be excluded in a substantial proportion of patients seen in clinical practice. TECSA risk factors are summarized in Table 1.

C. Natural history: Spontaneous resolution vs. persistence

TECSA is a dynamic condition that appears to resolve after several weeks of PAP therapy, [6-8] with a spontaneous resolution rate between 54% - 86 %. [23] One caveat is the tendency to aggregate PAP-persistent CSA and PAP-emergent CSA under the rubric TECSA. While the occurrence of TECSA may implicate PAP or the relief of upper airway obstruction as the "triggers", persistent CSA –after a period of PAP therapy- may indicate PAP failure and the need for an alternative treatment of CSA. A recent study used PAP telemonitoring to assess CSA trajectories during PAP therapy at weeks 1 and 13 after initiating therapy in a large number of patients (n=133,006).[8] Overall, TECSA was noted in 3.5% of the patients, resolved in over a half, persisted in about a quarter of affected patients, and was associated with higher rate of therapy termination. Similar findings were demonstrated in a recent systematic review of 5

studies analyzing the natural evolution of TECSA (n= 135,283). [23] Of note, all studies except one allowed inclusion of patients with CSA at baseline. Patients affected by TECSA may be less adherent to therapy and are at higher risk of PAP intolerance, manifesting as dyspnea, air hunger, and involuntary CPAP mask removal during the night.[6,24] Moreover, delayed TECSA is another distinct form of TECSA that insidiously manifests on a subsequent titration study despite the absence of TECSA on the first titration study. In summary, TECSA has a dynamic nature; being transient (weeks to months) in most patients, persistent over the long run, or delayed, appearing on a subsequent titration study after being absent on baseline assessment.

IV. Review of guidelines

The 2012 AASM CSA treatment guidelines did not specifically address TECSA.[25] In contrast, the European Respiratory Society 2017 guidelines defined TECSA as CSA that emerges and persists under CPAP use and excluded pre-existing CSA and transient CSA that resolves with ongoing PAP use as well as CSA in patients with underlying cardiovascular, endocrine, renal or neurological diseases.[26]They suggested a switch to ASV in patients with TECSA who have a residual AHI > 15/h on CPAP.

V. Management Strategy

a. Goals of Therapy

Management options for TECSA parallel those used for the treatment of CSA. In addition, several factors must be considered for appropriate management of TECSA. Table 2. is a summary of different treatment modalities and their mechanism(s) of action.

First, the overall aim of treatment of TECSA is to reduce the AHI and improve residual symptoms. However, The ICSD-3 diagnostic criteria do not include clinical features among the diagnostic criteria, and studies investigating treatment options have used the frequency of

respiratory events as the outcome variable. Thus, management strategy should be individualized based on the underlying etiology and co-morbid conditions.

Second, the appearance of TECSA on polysomnography may reflect one or more pathophysiologic mechanisms:

- Unmasking of central apnea: patients with central SDB and an unfavorable upper airway anatomy may develop pharyngeal narrowing and obstrcutive apneas during periods of central apnea or reduced ventilatory motor output,[2] such as during hypocapnic central hypopnea. Relief of upper airway obstruction with PAP therapy may unmask the underlying central apnea.
- PAP-induced events: rapid changes in PAP level or mask leak may rapidly decrease arterial PCO_2 below the hypocapnic apneic threshold, leading to central apnea.
- Effect of intermittent hypoxia: exposure to chronic intermittent hypoxia is associated with enhanced peripheral chemoreceptor activity. Likewise, acute intermittent hypoxia, as seen in OSA, is associated with increased propensity to central apnea.[16]

Third, the etiologic variability of TECSA may explain the variability in treatment response, as many published studies include those with PAP-refractory CSA.[6,27] In addition, most patients with CSA have comorbid OSA.[28] The lack of randomized controlled studies investigating the treatment of TECSA renders estimates of treatment response and natural history imprecise.

The presence of recurrent central apnea indicates elevated loop gain via one of its two components: plant gain or controller gain. Patients with persistent TECSA may be those with the highest loop gain values.[29,30] Stanchina et al. documented in a pilot study that calculated loop gain was higher for patients with persistent TECSA after 1 month of CPAP therapy and that loop gain measurement may facilitate determination of patients who need alternative modes of PAP therapy.[30]Thus, identification of the underlying abnormality may be beneficial. For instance, CPAP

could decrease plant gain by increasing lung volume, whereas elevated chemosensitivity may respond to supplemental oxygen.[29,31] A combination of therapies may be necessary when several abnormalities exist in an individual patient, e.g. CPAP plus oxygen.

b. Proposed approach to treatment

Optimization and Watchful observation

This strategy is based on the premise that central apnea will resolve spontaneously in most patients after 2-3 months of PAP therapy. [6,23] We favor a cautious watchful waiting approach, informed by the overall clinical picture and the severity of residual AHI. This approach requires a careful assessment of co-morbid conditions, appropriate adjustments of opioid analgesics, and optimization of medical management, especially for patients with heart failure. Telemonitoring of device transmission data may obviate the need for repeat PSG in the majority of patients. Patients should be counseled to continue CPAP use pending reassessment, while addressing mask leak or adjusting pressure level if needed.[32] A combination of symptomatic improvement and low residual AHI (<15/hr) supports the continuation of CPAP therapy. Figure 1. outlines a proposed treatment algorithm that we use in our sleep center.

Bi-level therapy (BPAP or ASV)

Persistence of TECSA (AHI>15/hr) may require switching to an alternative PAP mode (ASV or BPAP with a backup rate), especially in the setting of residual symptoms. Both modes provide EPAP to eliminate OSA and an inspiratory pressure above EPAP to increase ventilation. BPAP delivers fixed IPAP and EPAP, the difference between both pressures is the magnitude of pressure support (PS). Accordingly, BPAP delivers fixed tidal volume for a given pressure support level. In contrast, ASV, which was originally introduced as a treatment for central apnea associated with heart failure, mitigates CSA by providing a variable magnitude of pressure support, above the amount of EPAP required to eliminate obstructive events, and a backup up

respiratory rate. The magnitude of the PS level is reciprocal to the observed respiratory effort over a 3-4 minutes window. In other words, ASV provides a higher PS level during low flow periods and less PS when flow is high; thus, dampening the magnitude of hyperventilation. Overall, ASV is more efficacious than CPAP or BPAP in eliminating respiratory events in patients with TECSA. [33,34] On potential limitation of the available literature is that the majority of studies investigating ASV have been sponsored by the device manufacturers, employing proprietary algorithms, and testing intermediate physiologic outcomes rather than clinical outcomes. In a direct comparison between ASV and CPAP, Morgenthaler et al [35]demonstrated a higher rate of CSA resolution 90 days after initiation of ASV compared to CPAP. However, the difference of 5.5 events per hour was lower than the *a priori* determined clinically relevant difference of 10 events per hour, and there was no difference in PAP adherence or patient-reported outcomes such as Epworth Sleepiness Scale, quality of life, and feeling refreshed. To our knowledge, Morgenthaler study was the only study that compared measures of symptomatic improvement between PAP modalities, and the first to evaluate quality of life measure in patients with TECSA.

The presence of co-morbid conditions may influence the response to CPAP therapy. For example, CSA associated with heart failure may be refractory to CPAP in up to 50% of patients, even with long-term use.[36,37] Select patients may need adequate care with early switch to alternative PAP modes.[38,39] However, ASV is contraindicated in patients with CSA associated with heart failure and reduced ejection fraction (HFrEF), based on the findings of the SERVE-HF, a randomized trial of ASV versus standard medical therapy in patients with predominantly CSA due to HFrEF (EF ≤45%) in which ASV was associated with a 6% absolute increase in all-cause mortality and cardiovascular mortality compared with standard medical therapy. [40]

The aforementioned considerations underpin our approach to use ASV in an individualized manner. Specifically, we use ASV, in the absence of a contraindication, if symptomatic TECSA persists despite the use of CPAP, alone or with supplemental oxygen (see below).

BPAP is another option for TECSA. Nevertheless, BPAP in the spontaneous mode may worsen central apneas.[41,42] In contrast, several studies have shown an improvement in AHI with the use of BPAP with a backup rate (BPAP in spontaneous timed mode or BPAP-ST).[33,34,41] One peculiar observation is the delayed emergence of TECSA 6 weeks after BPAP-ST was initiated.[33] This finding would not be expected to happen with ASV given the automated pressure support adjustment to ventilatory instability. Special care must be taken to use the least magnitude of effective PS to minimize hyperventilation and the risk of re-emergence of TECSA. Furthermore, clinicians must optimize patient-ventilator synchrony to minimize arousals and sleep state instability, as this also destabilizes ventilation.

Supplemental oxygen

Oxygen therapy had been proven to reduce CAI even in the absence of associated nocturnal hypoxemia.[43,44] Increased arterial PO_2 works by lowering carotid-body chemosensitivity, therefore buffering oscillations in ventilatory control.[45]The addition of oxygen to CPAP may result in better control of TECSA, via reduction of the hypoxic respiratory drive and increasing cerebral PCO_2 as CO_2 is displaced from hemoglobin by the increased oxygen level (Haldane effect).[46]

Nocturnal home oxygen therapy (HOT) has been extensively studied in patients with CSA and CHF. The CHF-HOT study group assessed the efficacy of HOT on SDB and other variables in 56 patients with stable CHF and CSA-CSB.[47] The study demonstrated that HOT significantly reduced AHI. A recent large network meta-analysis of 14 randomized controlled trials (n=919 patients) comparing the effect of any combination of CPAP, ASV, O_2 or inactive control on AHI in patients with CHF and CSA/CSB. [48] The authors found that ASV was the most efficacious therapy, (87.8%), followed by oxygen (12.2%). Therefore, oxygen is reserved for patients who do not tolerate PAP therapy or used in combination with PAP when response to PAP alone is unsatisfactory. [49] Oxygen is also beneficial in hypoxemic patients with cardiac or pulmonary

comorbidities requiring oxygen therapy independent of their TECSA. However, reimbursement for supplemental oxygen, in the absence of sustained hypoxia, is often a barrier.

Acetazolamide

Acetazolamide (ACZ), a mild diuretic, is associated with increased ventilatory motor output by inducing metabolic acidosis. Several studies have demonstrated efficacy of acetazolamide in reducing the severity of central apnea. There is empiric evidence that administration of acetazolamide is associated with widening of the CO_2 reserve, likely attributed to decreased plant gain and controller gain.[21] However, the effectiveness of acetazolamide after prolonged use is yet to be determined. We use acetazolamide on a case-by-case basis for in cases of persistent symptomatic TECSA as an adjunct to CPAP therapy.[21,50,51]

Positional therapy

Several studies have noted increased central apnea frequency in the supine position, likely attributed to passive upper airway collapse during CSA, lower lung volumes, and worsened pulmonary vascular congestion and associated hypoxia. New generation sleep position devices may be efficacious as salvage therapy for patients with CSA who are intolerant to PAP therapy.[52] We are cautious in utilizing this approach to treat TECSA pending outcome data.

VI. Case Scenarios Outcomes

The first patient had documented initial optimal adherence and reported substantial clinical improvement despite elevated residual AHI. Given the absence of TECSA risk factors and the overall favorable clinical picture, expectant management was an acceptable initial choice. Close telephone follow-up along with routine access to wireless monitoring data allowed for proper assessment of any potential symptomatologic worsening as well as the time course of TESCA evolution and guided the potential need for a repeat titration study. Residual AHI at 3 months was 14/hr. The patient remained asymptomatic. No further action was taken.

The second patient failed expectant management given significant discomfort with therapy and persistence of TECSA (residual AHI>15 events/hr). An ASV titration study was ordered and ASV was successful in eliminating both obstructive and central respiratory events. At 4 weeks follow up, patient had significantly improved adherence to therapy with 76% use >4 hrs and reported “quiet restful sleep”. PAP download data confirmed the absence of TECSA.

VII. Summary points

- TECSA is a complex process that combines central breathing instability and unfavorable upper airway structure and function.
- TECSA is a” dynamic process” with spontaneous resolution with ongoing PAP therapy in most patients (transient TECSA), persistence in some (persistent TECSA), or appearing de novo in a minority of patients (delayed TECSA).
- Expectant management is appropriate in asymptomatic patients with close follow-up.
- Switch to alternate PAP modalities (ASV, BPAP-ST) is appropriate in symptomatic patients, and when AHI>15/hr on follow-up.

Table 1. TECSA risk factors

1. Demographic factors[24,53-55]
   - male gender
   - older age
   - lower BMI

2. Medical comorbidities[56,54,6]
   - Congestive heart failure
   - Coronary artery disease
   - Opioids use

3. Baseline polysomnographic factors[6,27,53,54,57,23,58]
   - More severe OSA
   - Higher central apnea index
   - Higher mixed apnea index
   - Higher arousal index

4. Titration study factors[6,23,59]
   - Split-night study
   - Hasty/excessively high titration
   - Mask leak
   - Higher arousal index
   - Lower total sleep time
   - Lower sleep efficiency
   - Higher residual AHI
   - BPAP use

Table 2. Treatment of TECSA - Summary of different modalities

	Mechanism of action	Special considerations	Effectiveness	Cost
PAP therapy **1. CPAP**	*Fixed pressure eliminates obstruction (optimal pressure is a challenge as higher pressures may induce/worsen TECSA and lower pressures leave residual obstructive apneas and hypopneas)	*Close follow-up recommended *High rate of therapy discontinuation in symptomatic patients *Repeat titration required in select patients, may be associated with increased costs	*Spontaneous resolution of TECSA in 53.8-85.7% of patients after 4-28 weeks[23]	300-1000$
2. BPAP-ST	*EPAP is set to relieve obstruction *IPAP and back-up respiratory rate mitigate hypoventilation	*Avoid high IPAP-EPAP difference (PS) and back-up respiratory rate to prevent hyperventilation *Optimize patient-ventilator synchrony to improve comfort and adherence to therapy	*No direct comparative effectiveness with CPAP * Inferior to ASV[33] *Effectiveness is dependent on sleep technician proficiency for optimal titration results	2000-4000$
3. ASV	*EPAP is set to relieve obstruction * PS mirrors ventilation based on breath by breath analysis over 3-4 min window * Dampens the magnitude of hyperventilation	*Limited availability secondary to high cost *Contraindicated in heart failure patients with EF<45% (increased mortality)	*Superior to CPAP/BPAP-ST[33,34] * Effectiveness is dependent on sleep technician proficiency for optimal titration results	3000-5000$
Oxygen	*Decreased carotid body chemosensitivity, and dampens oscillations in ventilatory control	*Hypoxemic patients with cardio-pulmonary comorbidities may benefit from titration studies with O2	*Most effective in patients with CSA-CSB[47] *In our experience, O2 is mostly effective when added early on after TECSA appears and persists despite slow and careful upward titration and titrated to keep O2 saturation ≥94%	200$/month
Acetazolamide	Widens the CO2 reserve Decreased plant gain	*Limited evidence *Use is extrapolated from other CSA types (primary CSA, CSA secondary to spinal cord injury/disease)	*Evidence is limited	54-89$ / 30 days

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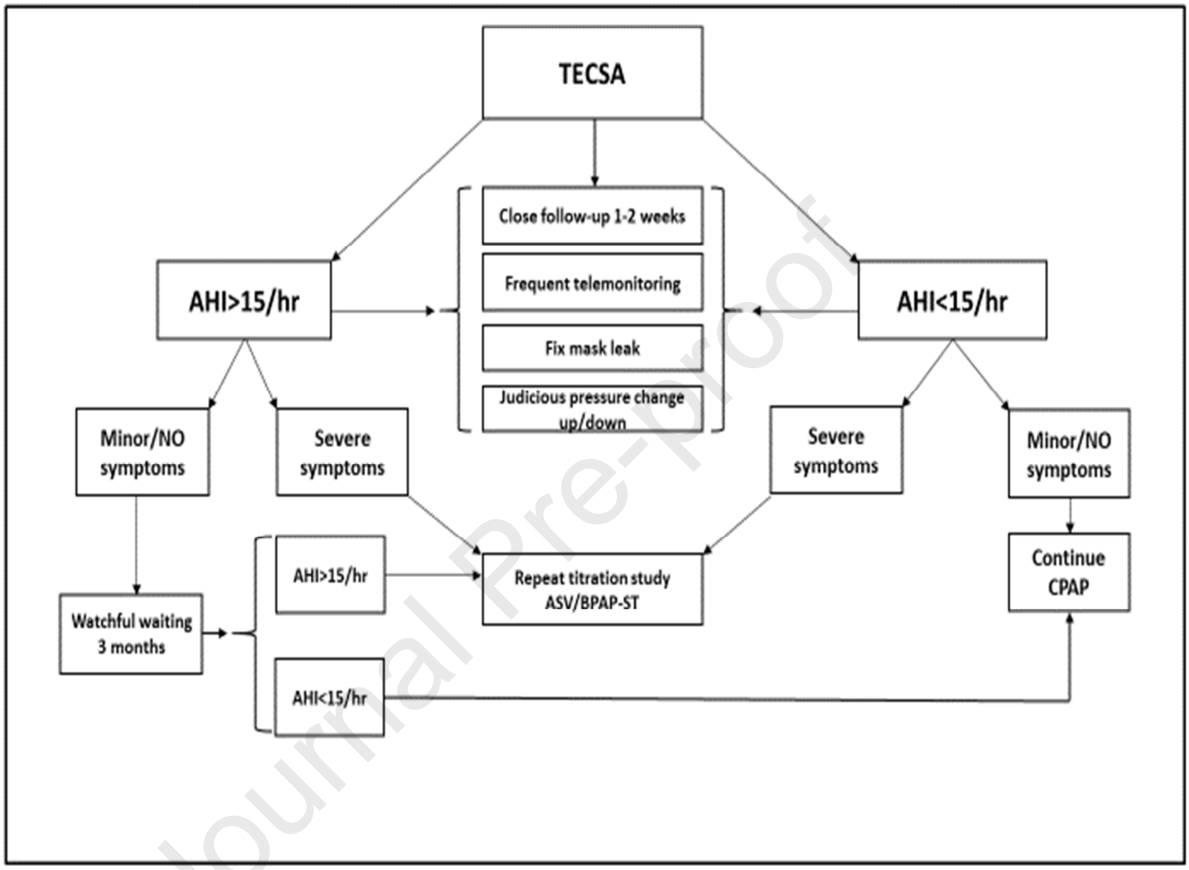
Figure 1. Proposed treatment algorithm



References

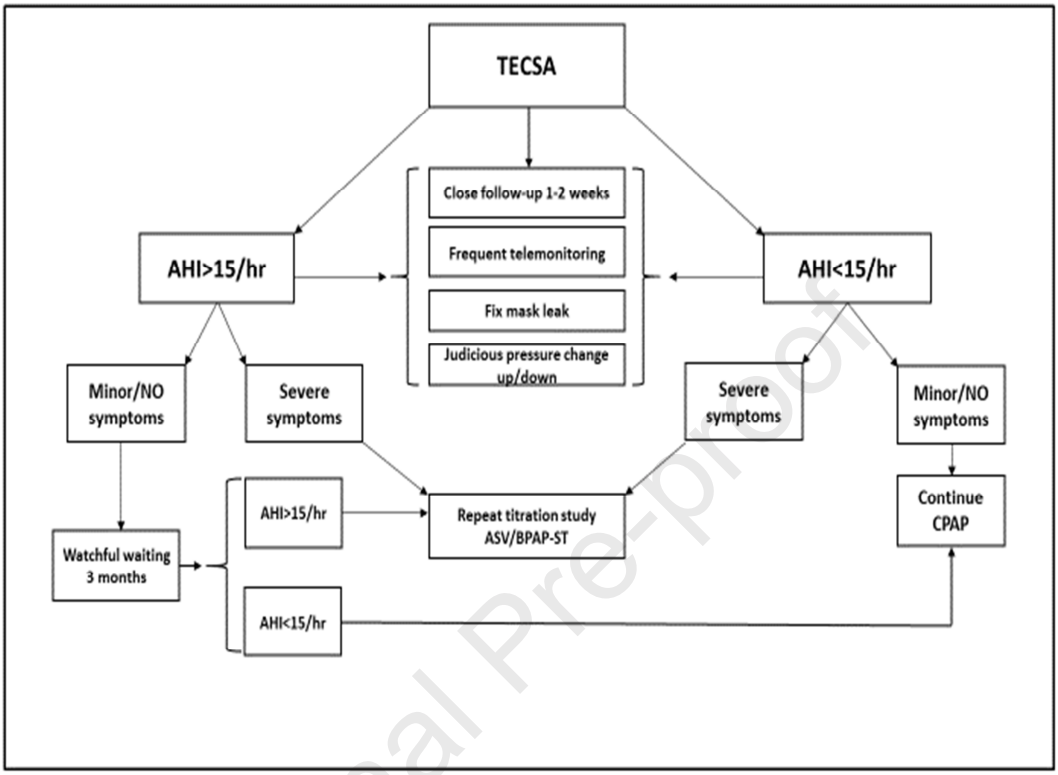
1. *International Classification of Sleep Disorders, 3rd edition.* Darien, IL: American Academy of Sleep Medicine; 2014.
2. Badr MS, Toiber F, Skatrud JB, Dempsey J. Pharyngeal narrowing/occlusion during central sleep apnea. *J Appl Physiol (1985).* 1995;78(5):1806-1815.
3. Younes M, Ostrowski M, Thompson W, Leslie C, Shewchuk W. Chemical control stability in patients with obstructive sleep apnea. *Am J Respir Crit Care Med.* 2001;163(5):1181-1190.
4. Sankri-Tarbichi AG, Rowley JA, Badr MS. Expiratory pharyngeal narrowing during central hypocapnic hypopnea. *Am J Respir Crit Care Med.* 2009;179(4):313-319.
5. Dernaika T, Tawk M, Nazir S, Younis W, Kinasewitz GT. The significance and outcome of continuous positive airway pressure-related central sleep apnea during split-night sleep studies. *Chest.* 2007;132(1):81-87.
6. Javaheri S, Smith J, Chung E. The prevalence and natural history of complex sleep apnea. *J Clin Sleep Med.* 2009;5(3):205-211.
7. Kuzniar TJ, Pusalavidyasagar S, Gay PC, Morgenthaler TI. Natural course of complex sleep apnea--a retrospective study. *Sleep Breath.* 2008;12(2):135-139.
8. Liu D, Armitstead J, Benjafield A, et al. Trajectories of Emergent Central Sleep Apnea During CPAP Therapy. *Chest.* 2017;152(4):751-760.
9. Skatrud JB, Dempsey JA. Interaction of sleep state and chemical stimuli in sustaining rhythmic ventilation. *J Appl Physiol Respir Environ Exerc Physiol.* 1983;55(3):813-822.
10. Khoo MC. Determinants of ventilatory instability and variability. *Respir Physiol.* 2000;122(2-3):167-182.
11. Narkiewicz K, van de Borne PJ, Pesek CA, Dyken ME, Montano N, Somers VK. Selective potentiation of peripheral chemoreflex sensitivity in obstructive sleep apnea. *Circulation.* 1999;99(9):1183-1189.
12. Ponsaing LB, Lindberg U, Rostrup E, Iversen HK, Larsson HBW, Jennum P. Impaired cerebrovascular reactivity in obstructive sleep apnea: a case-control study. *Sleep medicine.* 2018;43:7-13.
13. Salloum A, Rowley JA, Mateika JH, Chowdhuri S, Omran Q, Badr MS. Increased propensity for central apnea in patients with obstructive sleep apnea: effect of nasal continuous positive airway pressure. *Am J Respir Crit Care Med.* 2010;181(2):189-193.
14. Zhou XS, Shahabuddin S, Zahn BR, Babcock MA, Badr MS. Effect of gender on the development of hypocapnic apnea/hypopnea during NREM sleep. *J Appl Physiol (1985).* 2000;89(1):192-199.
15. Chowdhuri S, Pranathiageswaran S, Loomis-King H, Salloum A, Badr MS. Aging is associated with increased propensity for central apnea during NREM sleep. *J Appl Physiol (1985).* 2018;124(1):83-90.
16. Chowdhuri S, Shanidze I, Pierchala L, Belen D, Mateika JH, Badr MS. Effect of episodic hypoxia on the susceptibility to hypocapnic central apnea during NREM sleep. *J Appl Physiol (1985).* 2010;108(2):369-377.

17. Chowdhuri S, Sinha P, Pranathiageswaran S, Badr MS. Sustained hyperoxia stabilizes breathing in healthy individuals during NREM sleep. *J Appl Physiol (1985).* 2010;109(5):1378-1383.
18. Zhou XS, Rowley JA, Demirovic F, Diamond MP, Badr MS. Effect of testosterone on the apneic threshold in women during NREM sleep. *J Appl Physiol (1985).* 2003;94(1):101-107.
19. Mateika JH, Omran Q, Rowley JA, Zhou XS, Diamond MP, Badr MS. Treatment with leuprolide acetate decreases the threshold of the ventilatory response to carbon dioxide in healthy males. *J Physiol.* 2004;561(Pt 2):637-646.
20. Chowdhuri S, Bascom A, Mohan D, Diamond MP, Badr MS. Testosterone conversion blockade increases breathing stability in healthy men during NREM sleep. *Sleep.* 2013;36(12):1793-1798.
21. Ginter G, Sankari A, Eshraghi M, et al. Effect of acetazolamide on susceptibility to central sleep apnea in chronic spinal cord injury. *J Appl Physiol (1985).* 2020.
22. Nigam G, Pathak C, Riaz M. A systematic review on prevalence and risk factors associated with treatment- emergent central sleep apnea. *Ann Thorac Med.* 2016;11(3):202-210.
23. Nigam G, Riaz M, Chang ET, Camacho M. Natural history of treatment-emergent central sleep apnea on positive airway pressure: A systematic review. *Ann Thorac Med.* 2018;13(2):86-91.
24. Pusalavidyasagar SS, Olson EJ, Gay PC, Morgenthaler TI. Treatment of complex sleep apnea syndrome: a retrospective comparative review. *Sleep Med.* 2006;7(6):474-479.
25. Aurora RN, Chowdhuri S, Ramar K, et al. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. *Sleep.* 2012;35(1):17-40.
26. Randerath W, Verbraecken J, Andreas S, et al. Definition, discrimination, diagnosis and treatment of central breathing disturbances during sleep. *Eur Respir J.* 2017;49(1).
27. Neu D, Balkissou AD, Mairesse O, Pefura-Yone EW, Noseda A. Complex sleep apnea at auto-titrating CPAP initiation: prevalence, significance and predictive factors. *Clin Respir J.* 2017;11(2):200-209.
28. Ratz D, Wiitala W, Badr MS, Burns J, Chowdhuri S. Correlates and consequences of central sleep apnea in a national sample of US veterans. *Sleep.* 2018;41(9).
29. Sands SA, Edwards BA, Kee K, et al. Loop gain as a means to predict a positive airway pressure suppression of Cheyne-Stokes respiration in patients with heart failure. *Am J Respir Crit Care Med.* 2011;184(9):1067-1075.
30. Stanchina M, Robinson K, Corrao W, Donat W, Sands S, Malhotra A. Clinical Use of Loop Gain Measures to Determine Continuous Positive Airway Pressure Efficacy in Patients with Complex Sleep Apnea. A Pilot Study. *Ann Am Thorac Soc.* 2015;12(9):1351-1357.
31. Sands SA, Edwards BA, Kee K, et al. Control theory prediction of resolved Cheyne-Stokes respiration in heart failure. *Eur Respir J.* 2016;48(5):1351-1359.
32. Montesi SB, Bakker JP, Macdonald M, et al. Air leak during CPAP titration as a risk factor for central apnea. *J Clin Sleep Med.* 2013;9(11):1187-1191.

33. Dellweg D, Kerl J, Hoehn E, Wenzel M, Koehler D. Randomized controlled trial of noninvasive positive pressure ventilation (NPPV) versus servoventilation in patients with CPAP-induced central sleep apnea (complex sleep apnea). *Sleep.* 2013;36(8):1163-1171.
34. Morgenthaler TI, Gay PC, Gordon N, Brown LK. Adaptive servoventilation versus noninvasive positive pressure ventilation for central, mixed, and complex sleep apnea syndromes. *Sleep.* 2007;30(4):468-475.
35. Morgenthaler TI, Kuzniar TJ, Wolfe LF, Willes L, McLain WC, 3rd, Goldberg R. The complex sleep apnea resolution study: a prospective randomized controlled trial of continuous positive airway pressure versus adaptive servoventilation therapy. *Sleep.* 2014;37(5):927-934.
36. Arzt M, Floras JS, Logan AG, et al. Suppression of central sleep apnea by continuous positive airway pressure and transplant-free survival in heart failure: a post hoc analysis of the Canadian Continuous Positive Airway Pressure for Patients with Central Sleep Apnea and Heart Failure Trial (CANPAP). *Circulation.* 2007;115(25):3173-3180.
37. Javaheri S. Effects of continuous positive airway pressure on sleep apnea and ventricular irritability in patients with heart failure. *Circulation.* 2000;101(4):392-397.
38. Gay PC. Complex sleep apnea: it really is a disease. *J Clin Sleep Med.* 2008;4(5):403-405.
39. Kuzniar TJ, Kasibowska-Kuzniar K, Ray DW, Freedom T. Clinical heterogeneity of patients with complex sleep apnea syndrome. *Sleep Breath.* 2013;17(4):1209-1214.
40. Cowie MR, Woehrle H, Wegscheider K, et al. Adaptive Servo-Ventilation for Central Sleep Apnea in Systolic Heart Failure. *N Engl J Med.* 2015;373(12):1095-1105.
41. Allam JS, Olson EJ, Gay PC, Morgenthaler TI. Efficacy of adaptive servoventilation in treatment of complex and central sleep apnea syndromes. *Chest.* 2007;132(6):1839-1846.
42. Johnson KG, Johnson DC. Bilevel positive airway pressure worsens central apneas during sleep. *Chest.* 2005;128(4):2141-2150.
43. Bordier P, Lataste A, Hofmann P, Robert F, Bourenane G. Nocturnal oxygen therapy in patients with chronic heart failure and sleep apnea: a systematic review. *Sleep Med.* 2016;17:149-157.
44. Bordier P, Orazio S, Hofmann P, Robert F, Bourenane G. Short- and long-term effects of nocturnal oxygen therapy on sleep apnea in chronic heart failure. *Sleep Breath.* 2015;19(1):159-168.
45. Xie A, Skatrud JB, Puleo DS, Dempsey JA. Influence of arterial O2 on the susceptibility to posthyperventilation apnea during sleep. *J Appl Physiol (1985).* 2006;100(1):171-177.
46. Badr MS, Dingell JD, Javaheri S. Central Sleep Apnea: a Brief Review. *Curr Pulmonol Rep.* 2019;8(1):14-21.
47. Sasayama S, Izumi T, Seino Y, Ueshima K, Asanoi H, Group C-HS. Effects of nocturnal oxygen therapy on outcome measures in patients with chronic heart failure and cheyne-stokes respiration. *Circ J.* 2006;70(1):1-7.
48. Chen C, Wen T, Liao W. Nocturnal supports for patients with central sleep apnea and heart failure: a systemic review and network meta-analysis of randomized controlled trials. *Ann Transl Med.* 2019;7(14):337.
49. Chowdhuri S, Ghabsha A, Sinha P, Kadri M, Narula S, Badr MS. Treatment of central sleep apnea in U.S. veterans. *J Clin Sleep Med.* 2012;8(5):555-563.

50. White DP. Central sleep apnea. *Med Clin North Am.* 1985;69(6):1205-1219.
51. DeBacker WA, Verbraecken J, Willemen M, Wittesaele W, DeCock W, Van deHeyning P. Central apnea index decreases after prolonged treatment with acetazolamide. *Am J Respir Crit Care Med.* 1995;151(1):87-91.
52. Benoist LBL, Vonk PE, de Vries N, Janssen H, Verbraecken J. New-generation positional therapy in patients with positional central sleep apnea. *Eur Arch Otorhinolaryngol.* 2019;276(9):2611-2619.
53. Cassel W, Canisius S, Becker HF, et al. A prospective polysomnographic study on the evolution of complex sleep apnoea. *Eur Respir J.* 2011;38(2):329-337.
54. Lehman S, Antic NA, Thompson C, Catcheside PG, Mercer J, McEvoy RD. Central sleep apnea on commencement of continuous positive airway pressure in patients with a primary diagnosis of obstructive sleep apnea-hypopnea. *J Clin Sleep Med.* 2007;3(5):462-466.
55. Morgenthaler TI, Kagramanov V, Hanak V, Decker PA. Complex sleep apnea syndrome: is it a unique clinical syndrome? *Sleep.* 2006;29(9):1203-1209.
56. Bitter T, Westerheide N, Hossain MS, et al. Complex sleep apnoea in congestive heart failure. *Thorax.* 2011;66(5):402-407.
57. Endo Y, Suzuki M, Inoue Y, et al. Prevalence of complex sleep apnea among Japanese patients with sleep apnea syndrome. *Tohoku J Exp Med.* 2008;215(4):349-354.
58. Lei F, Tan L, Li TM, et al. [Association between mixed sleep apnea and treatment-emergent central sleep apnea]. *Zhonghua Yi Xue Za Zhi.* 2019;99(24):1864-1869.
59. Moro M, Gannon K, Lovell K, Merlino M, Mojica J, Bianchi MT. Clinical predictors of central sleep apnea evoked by positive airway pressure titration. *Nat Sci Sleep.* 2016;8:259-266.

Figure 1. Proposed Treatment Algorithm



Medical Advisory Board

In 1962, combined efforts of the Secretary of State and the Maine Medical Association resulted in the appointment of a neurologist, heart specialist, psychiatrist, internal medicine and eye specialist to the Board. Over the years, the Medical Advisory Board (MAB) has evolved, to their current role. The duties of the board include advising the Secretary of State (SOS) on written medical and vision standards related to operator licensing, coordinating efforts to educate health care providers and the public in the medical aspects of motor vehicle operator licensing. They may be asked to review specific cases and provide opinions to the Secretary of State. They are required to meet at least once every two years. Standards recommended by the board may only be adopted as rules. Statutory requirements for the Medical Advisory Board are described in the Maine Revised Statutes, Title 29-A: Motor Vehicles and Traffic, Chapter 11, section 1258, and may be accessed at, http://legislature.maine.gov/statutes/29-A/title29-Asec1258.html

The board consists of 10 regular members, physicians trained in the specialties of cardiology, gerontology, internal medicine, neurology or neurological surgery, ophthalmology, psychiatry, family practice and rehabilitative medicine. Additional members may also be appointed from other relevant medical fields. The board Chair is a physician appointed by the Secretary of State.

Reports received or made by the board, a member or the Secretary of State for the purpose of assisting the SOS in determining whether a person is qualified to be licensed is confidential and only for the use of the board, the SOS, medical personnel treating the person, and the person subject to review.

The rules governing Physical, Emotional and Mental Competence to Operate a Motor Vehicle may be accessed via the following link:
http://www.maine.gov/sos/bmv/licenses/medical.html

Medical Advisory Board Clerk: Thea Fickett
Telephone: 207-624-9000, ext. 52124
Mailing address: 29 State House Station, Augusta, Maine 04333-0029

Medical Advisory Board Meeting Minutes
NOTE: Personally identifying information in the minutes has been blacked out.

ASLEEP AT THE WHEEL

A NATIONAL COMPENDIUM OF EFFORTS TO ELIMINATE DROWSY DRIVING

U.S. Department of Transportation
National Highway Traffic Safety Administration

NHTSA

CONTENTS

BACKGROUND TO THE ISSUE

Fatigue has costly effects on the safety, health, and quality of life of the American public. Whether fatigue is caused by sleep restriction due to a new baby waking every couple of hours, a late or long shift at work, hanging out late with friends, or a long and monotonous drive for the holidays – the negative outcomes can be the same. These include impaired cognition and performance, motor vehicle crashes, workplace accidents, and health consequences. Addressing these issues can be difficult when our values frequently do not align with avoiding drowsy driving. In a 24/7 society, with an emphasis on work, longer commutes, and exponential advancement of technology, many people do not get the sleep they need.[1] Effectively dealing with the drowsy-driving problem requires fundamental changes to societal norms and especially attitudes about drowsy driving.

Drowsy-driving crashes can happen any time, but most frequently occur at night in the early pre-dawn hours or in the mid-afternoon. Age also plays a significant factor. Research conducted in 2012 by the AAA Foundation for Traffic Safety shows that crash-involved drivers 16 to 24 years old were nearly twice as likely to be drowsy at the time of the crash compared to drivers 40 to 59 years old. Drivers 24 and younger were most likely to report having fallen asleep at the wheel in the past year. These results are consistent with multiple independent studies on this topic.

Unfortunately, determining a precise number of crashes, injuries, and fatalities caused by drowsy driving is not yet possible. Crash investigators can look for clues that drowsiness contributed to a crash, but these clues are not always identifiable or conclusive. NHTSA's census of fatal crashes and estimate of traffic-related crashes and injuries rely on police and hospital reports to determine the incidence of drowsy-driving crashes. NHTSA estimates that in 2015, over 72,000 police-reported crashes involved drowsy drivers. These crashes led to 41,000 injuries and more than 800 deaths. However, there is broad consensus across the traffic safety, sleep science, and public health communities that this is an underestimate of the impact of drowsy driving.

The broader community's best estimate of drowsy-driving crashes is that 7 percent of all crashes and 16.5 percent of fatal crashes involve a drowsy driver. This estimate suggests that approximately 6,000 people died in drowsy-driving-related motor vehicle crashes across the United States last year. This study performed by the AAA Foundation for Traffic Safety (Tefft, 2012) used a statistical multiple imputation process to estimate drowsy driving incidence in the NHTSA NASS Crashworthiness Data System (CDS). Some researchers feel this may still be an underestimate and that there may be more than 8,000 deaths attributable to drowsy driving each year.

While estimates differ on the exact incidence of drowsy driving, we can all agree it is a critical traffic safety issue that leads to thousands of deaths each year and causes an estimated $109 billion of societal harm.[2] A 2002 NHTSA-sponsored Gallup survey showed that 95 percent of the driving population considered drowsy driving to be a major threat to their safety. AAA's 2014 Traffic Safety Culture Index also showed drivers consider it unacceptable for people to drive when they are so sleepy that they have a hard time keeping their eyes open. Despite these findings, more than 1 in 4 drivers (29.4%) reported having driven when they were so tired that they had a hard time keeping their eyes open in the past 30 days. One in five (19.8%) reported having done this more than once, and 2.4 percent reported having done this fairly often or regularly.

1 Watson, N.F., et al. (2015). Recommended Amount of Sleep for a Healthy Adult: A Joint Consensus Statement of the American Academy of Sleep Medicine and Sleep Research Society. *Sleep, 38*, 1161-1183.
2 Higgins, J.S., et al. (In Press). Asleep at the Wheel – The Road to Addressing Drowsy Driving, *Sleep*.

HOW WE GOT HERE

Over the last two decades, public and private organizations have made a number of attempts to address drowsy driving. These efforts have included stakeholder meetings, public information campaigns, development of detection and alerting technology, fatigue management programs in a limited number of workplaces, and passage of State laws. These programs, technologies, and laws aim to contribute in varying degrees to reducing drowsy driving. However, strategies that effectively address attitudes about fatigue among the general driving public are lacking.

The traffic safety community has been successful in developing effective methods to change behavior related to drinking and driving, seat belt use, and a number of other safety risks, but has been unable to mitigate drowsy driving in an effective, widespread and organized manner. Meanwhile, the sleep science community has long recognized the dangers of drowsy driving but has lacked access to the required resources for achieving nationwide change. In order to change the national conversation on drowsy driving, stakeholders from both the traffic safety and sleep science communities are working together on a broad array of actions and activities.

NHTSA convened the forum "Asleep at the Wheel: A Nation of Drowsy Drivers" on November 4 and 5, 2015, during the National Sleep Foundation's National Drowsy Driving Prevention Week. This meeting included more than 100 participants from many diverse organizations, setting the stage for a national coordinated effort by bringing together motor vehicle and highway safety experts with sleep/circadian science experts and the sleep medicine community. NHTSA sought to establish a partnership in which years of unique knowledge and experience could be combined to effectively address the challenge of eliminating drowsy driving.

The forum resulted in a matrix of long- and short-term actions and ideas by the various stakeholders. In this compendium, the matrix has been collapsed into a set of successful efforts and novel ideas organized across topics including research and development, public and private partnerships, public education and awareness, and vehicle technology.

Within each topic area, the challenges to more effectively combat drowsy driving are identified. The compendium also features the various efforts that contributors are taking to address each of these challenges.

RESEARCH AND DEVELOPMENT

- Expand and share crash risk research using converging methodologies (e.g., naturalistic, case-control studies, crash investigations, mobile technologies)
- Improve crash reporting
- Document the economic impact of drowsy driving
- Research and develop new methods for detecting fatigue and sleep restriction (e.g., biomarkers)

PARTNERING WITH PUBLIC AND PRIVATE STAKEHOLDERS

- Evaluate effectiveness of new and existing laws
- Evaluate effectiveness of corporate fatigue-management policies
- Develop fatigue-risk-management programs for high-risk professions such as EMS and public safety
- Explore potential of graduated driver licensing (GDL) laws for reducing drowsy driving
- Facilitate regular engagement of the sleep science community with corporations and the insurance industry
- Provide technical assistance for State policy and program actions based on identified problems

PUBLIC EDUCATION AND AWARENESS NEEDS

- Develop new education and awareness campaign material
- Promote integration into driver licensing manuals and exam questions
- Examine the effectiveness of education efforts in New Jersey and Arkansas regarding existing laws to affect social norms
- Conduct broad public health campaign on sleep and health
- Promote corporate wellness programs

VEHICLE TECHNOLOGY NEEDS

- Promote research and development of drowsiness detection, alerting, and vehicle response systems
- Educate consumers on use of new vehicle technology that will help prevent drowsy-driving crashes
- Encourage adoption of collision avoidance technologies

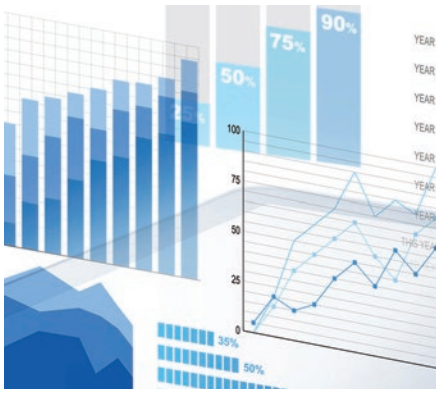
ORGANIZATIONS

A wide variety of public, private, for-profit, and not-for-profit organizations have come together to contribute to this national effort to address drowsy driving:

- American Academy of Sleep Medicine (AASM)
- Centers for Disease Control and Prevention (CDC)
- Faurecia S.A.
- Federal Aviation Administration (FAA)
- Governors Highway Safety Association (GHSA)
- U.S. Food and Drug Administration (FDA)
- General Motors
- Honda
- Insurance Institute for Highway Safety (IIHS)
- State of Iowa
- University of Michigan Transportation Research Institute (UMTRI)
- National Association of State Emergency Medical Services Officials (NASEMSO)
- National Highway Traffic Safety Administration (NHTSA)
- National Safety Council (NSC)
- National Sleep Foundation (NSF)
- Network of Employers for Traffic Safety (NETS)
- Sleep Research Society (SRS)
- Start School Later, Inc.
- Westat, Inc.

RESEARCH AND DEVELOPMENT

Addressing drowsy driving requires a better understanding of the overall prevalence of the problem and who is at risk. With this information, the community is better able to prioritize research, programs, and messaging to most efficiently address the issue. Prevention efforts can also be tracked with appropriate data. However, the biggest challenge is the inability to collect reliable and valid drowsy-driving crash data that provides a true count, or a sound estimate, of the extent of the problem. The community will need to continue its current research as well as develop new technologies and methods to more effectively address gaps in the current state of knowledge.



QUANTIFYING DROWSY DRIVING

The largest and most comprehensive naturalistic driving study to-date, the second Strategic Highway Research Program (SHRP2), was conducted by the Transportation Research Board from 2005 to 2016 and collected data at sites across the United States with varying geographic locations, both urban and rural roads, climate variation, and regional differences in transportation practices. The data set contains approximately 3,900 driver years from participants who ranged from 16 to 80 years old, with an estimated total of 2.5 million trip files. SHRP2 data offers an unparalleled view into the relationship between drowsy driving and crash risk. NHTSA is currently funding research with Westat, Inc., the University of Iowa, and the University of Wisconsin to explore drowsy driving in the SHRP2 data set. NHTSA hopes to better characterize the relationship between drowsy driving and crash risk and driver-critical reasons for crashes and near misses; understand variables that may help identify drowsy drivers in other data sets (e.g., FARS); and identify individual differences that predict the likelihood of drowsy driving.

NATIONAL SURVEY OF DROWSY DRIVING KNOWLEDGE, ATTITUDES, AND BEHAVIORS

To better understand public knowledge, attitudes, and drowsy-driving behaviors, NHTSA is funding a survey to provide national estimates of drowsy-driving knowledge, attitudes, and behaviors. NHTSA is also exploring these topics in New Jersey and Arkansas, the two States with drowsy-driving laws. Understanding the public's attitudes and awareness is an important step in designing and deploying education and other countermeasures that will affect the incidence of drowsy driving across the United States.

Beyond a national survey, collecting statewide drowsy-driving data provides a powerful spotlight on the prevalence of drowsy driving within a State. Iowa posed drowsy-driving questions to people waiting in line at five different driver licensing stations as part of a statewide public awareness and attitude survey. Other States may explore how they too can better understand the attitudes and behaviors of their drivers.

DROWSY-DRIVING DATA COLLECTION AND REPORTING BY LAW ENFORCEMENT

There is little information on whether and how law enforcement officers identify drowsy drivers, or how often they encounter drowsy drivers while on patrol. This information would be useful, both in estimating the magnitude of the problem and possibly in developing reporting protocols and training for law enforcement. To supplement ongoing data-collection initiatives, NHTSA is working with law enforcement officials to gauge drowsy driving encountered during routine contacts (stops, assists, crashes, etc.) with drivers. A reporting protocol for drowsy driving and training may be developed as well.

Including "drowsy or fatigued" under contributing factors or driver's condition in crash reports would help States better understand the scope of the problem. Iowa crash reporting forms did not include this factor until their last crash report update. Since it was added, the State has seen an increase in drowsiness being identified as a factor in crashes.

DRIVER PHYSICAL FACTORS LEADING TO UNINTENTIONAL LANE-DEPARTURE CRASHES

Researchers from the Insurance Institute for Highway Safety (IIHS) examined data from the National Motor Vehicle Crash Causation Study to determine the role that physical factors play in lane departures. The analysis shows that as many as 34 percent of lane-drift crashes – 42 percent of those with serious or fatal injury – involve drivers whom investigators coded as incapacitated, with about half of that number attributed to sleeping. The other half were incapacitated due to illness or blacked out from drug or alcohol use.

BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM

The Centers for Disease Control and Prevention's (CDC) drowsy-driving activities are conducted by the Sleep and Sleep Disorders Team of the National Center for Chronic Disease Prevention and Health Promotion.
The Team works to increase awareness of sleep health and sleep disorders and their impact on the public's health. The Team maintains a drowsy-driving webpage.

The Sleep and Sleep Disorders Team developed and implemented new sleep questions for CDC's public health surveillance systems including the Behavioral Risk Factor Surveillance System (BRFSS), the world's largest, ongoing telephone health survey system that tracks health conditions and risk behaviors in the United States.

The BRFSS's drowsy-driving findings have been published in the CDC's Morbidity and Mortality Weekly Report. BRFSS maintains a website with information on the sleep-related questions that have been included on the CDC's surveys.

SLEEP IN AMERICA POLL

The National Sleep Foundation (NSF) has conducted its annual Sleep in America poll since 1991 to survey Americans' attitudes, opinions and knowledge in regard to sleep health. NSF also surveys Americans on a quarterly basis on their Sleep Health Index (SHI) regarding trends in sleep. The SHI includes a fixed set of questions on drowsy driving.

CRASH AVOIDANCE SYSTEMS DATA ANALYSIS

Ongoing research by IIHS and the Highway Loss Data Institute (HLDI) is investigating the real-world effectiveness of collision avoidance systems. Front crash prevention has been shown to be effective in reducing front-to-rear crashes. Vehicles with front crash prevention systems have fewer claims under property damage liability coverage, which pays for damage to vehicles that an at-fault driver hits. Systems with forward collision warning and automatic braking cut police-reported rear-end crashes in half, while forward collision warning alone reduces them by 27 percent. HLDI has examined blind-spot-monitoring systems from seven manufacturers. Six systems have reduced rates of claims for damage to other vehicles. Although these systems do not directly target drowsy drivers, they have the potential to help drowsy and distracted drivers avoid a crash.

Research has shown few insurance-claim benefits so far for lane departure warning, although there is some evidence that police-reported head-on and run-off-road crashes with injuries have been reduced. Unfortunately, the same analyses show some tradeoff in an increased number of side-swipe crashes with injuries. These conclusions apply only to lane departure warning systems and not systems that act to prevent lane departures or to ensure lane following. The first results of this project were published in 2011, and updates continue.

Other efforts are being proposed by a consortium of General Motors and the University of Michigan Transportation Research Institute. This research effort seeks to perform a large-scale study of driver drowsiness, associated driving behavior, and safety implications. This study will include vehicles with driver assistance systems (e.g., Lane Keep Assist, Lane Departure Warning, Forward Collision Alert) that can be assessed with respect to driver sleep history in order to shed light on prevalence and patterns of drowsy driving and the extent to which these driver assistance systems may be mitigating the substantial number of crashes, injuries, and fatalities associated with drowsy driving.

NHTSA recently performed a basic analysis of the societal impact of drowsy driving. The current estimate of the associated societal costs of drowsy driving is $109 billion per year, based on a 2010 NHTSA report on the societal costs of motor vehicle crashes. This estimate only takes into account crashes in which at least one person was hospitalized or killed. This does not account for the many property-damage-only crashes related to drowsy driving.

BIOMARKER DEVELOPMENT

With major scientific and technological advances in neuroscience, the biomolecular mechanisms underlying drowsiness are increasingly well understood, and the establishment of a panel of biomarkers for drowsiness is within reach. The Sleep Research Society (SRS), as part of an international collaboration with other sleep and circadian science organizations, is at the forefront in supporting biomarker development for sleep deficiency, circadian misalignment, and drowsiness. Specifically, the SRS is supporting: (1) international meetings and workshops to bring stakeholders together; (2) development of research definitions and experimental standards for drowsiness biomarker studies; (3) workshops on high-throughput sleep/circadian phenotyping to enable biomarker studies; and (4) training of sleep and circadian scientists to conduct biomarker studies.

The Federal Aviation Administration (FAA) is also working toward a test to detect fatigue through gene expression biomarkers. While crash prevention is the higher aim, FAA hopes to apply biomarker detection of fatigue in crash investigations. This project was started in 2011 and is envisioned to continue until available resources and capable workforce are sufficient, nationally and internationally, to make the development of a biomarker panel of drowsiness a reality.

APPROACHES TO ADDRESS DROWSY DRIVING

To motivate behavior change, policies and laws have proven to be effective tools in highway safety programs when combined with appropriate education efforts. Not only can laws and policies provide a system where an inappropriate and dangerous behavior is discouraged, but they can also communicate appropriate societal norms.

DROWSY DRIVING AT WORK

One of the most recognizable causes of fatigue is career-related. Motor vehicle crashes, on and off the job, cost employers nearly $50 billion in 2013. Many of these were likely due to fatigue. These numbers do not account for the substantially larger cost of all injuries on the job or other costly workplace mistakes leading to lost time and productivity or lawsuits. Fatigue may play a significant role in these workplace incidents and cost businesses billions of dollars annually. Addressing the root causes of sleep restriction or dangerous levels of fatigue can lead to more efficient and safer work practices, as well as less drowsy driving both at work and on the way to/from work. Providing employers with methods to address drowsy driving and workplace fatigue will not only improve their bottom lines, but positively affect road safety.

HELPING EMPLOYERS ADDRESS DROWSY DRIVING AT WORK

Through policies, awareness and information, employers are able to reach a large portion of the driving population in the United States, and even more when the outreach includes family members and community members. Each year, the Network of Employers for Traffic Safety (NETS) sponsors Drive Safely Work Week and produces a toolkit on a specific theme for the week. In 2016, NETS developed a Drive Safely Work Week toolkit focusing on the dangers of drowsy driving. NETS produced two additional documents that help employers address drowsy driving: NETS's Comprehensive Guide to Road Safety™ and NETS's Recommended Road Safety Practices.™ Register for free access to these and other NETS resources at http://trafficsafety.org/registration.

In addition to recently developed material, NETS, the Volpe National Transportation Systems Center, and the National Institute for Occupational Safety and Health (NIOSH) have assembled a team to develop material about fatigue and drowsy driving. The objective is to publish a series of free, brief and actionable documents for use by employers.

The National Safety Council (NSC) is also heavily involved in employer programs and education to address drowsy driving (and workplace fatigue in general). NSC is working to develop a fatigue cost calculator. This calculator will bring awareness to the cost of fatigued employees in terms of decreased productivity and safety incidents. The calculator will allow employers to look at costs by industry, including but not limited to the transportation industry. In 2017, the National Safety Council (NSC) is planning to release a fatigue toolkit of educational resources and model policies for employers. The kit will include sample policies to address risks such as drowsy driving. The collection of policies will allow employers to quickly adopt policies with ready-to-launch material.

Our Driving Concern (ODC): Employer Traffic Safety Program, a program of the National Safety Council in cooperation with the Texas Department of Transportation, provides necessary traffic safety information to keep employees safe on Texas roads. ODC provides free traffic safety information, resources, and training to equip employers in addressing traffic safety in the workplace. Drowsy driving, distracted driving, impaired driving, passenger restraint, aggressive driving, and other important traffic safety topics are addressed in the ODC program. Free and ongoing support to and for employers include Huddle Sheets, a mobilized website, webinars and mini-webinars, train the trainer, talking points, and safety coach and educational material. This program expanded to the State of Oklahoma in 2016.

FATIGUE TRAINING AND INTERVENTION RESEARCH

A number of organizations involved in developing this compendium are involved in fatigue management training program research and development. One excellent example is recent research performed at the John A. Volpe National Transportation Systems Center. Volpe explored the effectiveness of training programs designed to reduce the effects of drowsiness. The research showed that drowsiness decreases critical hazard anticipation, hazard mitigation, and attention maintenance skills in nurses involved in shift work. The most exciting finding was that a Volpe-developed training program was able to successfully reduce the effects of drowsiness. Volpe is continuing this research and plans to extend it to other populations.

FATIGUE RISK MANAGEMENT GUIDELINES FOR EMERGENCY MEDICAL SERVICES

NHTSA, the National Association of State EMS Officials (NASEMSO), and the University of Pittsburgh Medical Center are working to improve awareness and eliminate hazards related to drowsy driving in high-risk professions through the development of Evidence-Based Fatigue Risk Management Guidelines for Emergency Medical Services. This partnership is working to systematically review, synthesize, and grade the quality of evidence related to the measurement and effect of fatigue among EMS personnel; the relationship of shift work and fatigue; effective fatigue countermeasures; sleep and rest strategies to mitigate fatigue; enhanced fatigue education and training; the use of statistical models to mitigate fatigue; and the relationship of workload to fatigue. Additional background material is available.

COMMERCIAL MOTOR VEHICLE OPERATORS AND RAIL WORKERS

In March 2016, the U.S. Department of Transportation's (DOT) Federal Motor Carrier Safety Administration (FMCSA) and Federal Railroad Administration (FRA) requested public input on the impacts of screening, evaluating and treating rail workers and commercial motor vehicle operators (CMVO) for obstructive sleep apnea (OSA). The joint Advance Notice of Proposed Rulemaking was the first step as both agencies consider whether to propose specific requirements. The American Academy of Sleep Medicine submitted a response to the FMCSA and FRA proposal and attended the FMCSA Medical Review Board (MRB) hearing on August 22-23, 2016.

LEGISLATION AND ENFORCEMENT

Currently there are only two States with laws that expressly codify the punishment of drivers involved in drowsy-driving crashes: Arkansas and New Jersey.

CURRENT STATE LAWS

Two States have enacted laws specifically addressing drowsy and fatigued driving, while others have used broader statutes (e.g., reckless or careless driving) as a means for controlling this behavior. NHTSA is working to determine how the laws are enforced, as well as exploring the potential of conducting awareness and prevention programs in these States. Researchers at the University of Maryland are working to understand and document the legislative successes and challenges around the Nation. In addition, NHTSA is investigating drowsy-driving legislative activity in other States and documenting successes or obstacles encountered.

FUTURE STATE LAWS

The National Sleep Foundation is working with its members and partners, such as Start School Later, Inc., to support public advocacy of drowsy driving prevention at the State level by creating a Drowsy Driving State Advocacy Toolkit as well as model State legislation. These efforts are designed to motivate and empower citizens and State legislators to increase State legislative action on drowsy driving prevention.

Teen drivers are among the most at risk when it comes to drowsy driving, and stakeholders are taking varied approaches to address that risk. For example, both graduated driver licensing (GDL) and school start times represent important factors impacting teen health and safety. Through GDL programs, every State, except Vermont, restricts the nighttime hours that young, inexperienced drivers may drive without adult supervision (11 p.m. to 5 a.m., for example). It is also important to give teens enough time to get sufficient sleep before school. Organizations such as Start School Later, Inc. are working toward ensuring that students get the sleep they need to be happy, healthy, and safer drivers.

LAW ENFORCEMENT

There is little information on how law enforcement officers identify drowsy drivers, or how often they encounter a drowsy driver while on patrol. This information would be useful both in estimating the magnitude of the problem and in developing reporting protocols and training for law enforcement. NHTSA recently started a project to further explore this issue.

To address the large number of crashes involving commercial motor vehicles, the Iowa State Patrol partnered with FMCSA to provide additional training to troopers. The Iowa State Patrol plans to expand this training opportunity to county and local officers in the future.

HIGHWAY SAFETY IN THE STATES

The Governors Highway Safety Association (GHSA) recently released a report on drowsy driving, *Wake Up Call! Understanding Drowsy Driving and What States Can Do*. The report highlights just a few of the innovative and creative State efforts to address drowsy driving.

NHTSA's Highway Safety Program provides direction to State Highway Safety Offices for the formulation of their highway safety plans, which identify highway safety problems and countermeasures to address those problems. Problem identification and countermeasures are quite mature for several highway safety issues, such as impaired driving, occupant protection, pedestrian and bicycle safety, speed management, and emergency medical services, among others. However, effective approaches to address issues such as drowsy and distracted driving are still in development. While much progress has been made, more work is needed.

U.S. DOT is working to disseminate information and increase awareness among roadway and traffic safety decision-makers of the potential role of rumble strips in

addressing drowsy-driving risks. For example, roadway rumble strips have proven to be particularly cost-effective in reducing crash types that are associated with drowsy and distracted driving. Installation of rumble strips is inexpensive compared to other infrastructure improvements (about $1,000-$5,000 per mile). Evaluations indicate that rumble strips can reduce lane departure crashes by 50 percent or more depending on location. NHTSA and FHWA are working together to promote widespread adoption of rumble strip technology.

PUBLIC EDUCATION AND AWARENESS

An important step in changing drowsy-driving behavior is ensuring that people understand the related risks, behavioral signs, and appropriate countermeasures. With this knowledge, people have the basic tools to make better decisions about their own behavior. This is only part of the formula, though. People need to be convinced to use this knowledge and change their behavior. NHTSA's experience with other safety behaviors, including seat belt use, drinking and driving, and driver distraction, indicates that awareness and knowledge alone will not yield sufficient change. However, public education is a necessary program component, along with policy development and enforcement. A diverse range of public awareness and education efforts across a broad range of related topics are highlighted below. Also highlighted are an increasing number of meetings and forums being held on the topic that foreshadow many future efforts across partners.

PUBLIC MEETINGS

THE IOWA DROWSY DRIVING SUMMIT

The Iowa Department of Public Safety's (DPS) Iowa Governor's Traffic Safety Bureau (GTSB) co-hosted the first-in-the-Nation statewide Drowsy Driving Summit in Iowa City on June 29, 2016. The summit was designed to increase public awareness of the drowsy-driving issue. Current research on education, enforcement, and engineering prevention strategies was highlighted. Additionally, a PSA designed to increase public awareness of drowsy driving (developed by GTSB and The Integer Group) was released.

SLEEP HEALTH AND SAFETY: TAKING CONTROL OF OUR ROADWAYS

IIn 2015, as part of its conference, Sleep Health and Safety: Taking Control of Our Roadways, the NSF declared its commitment to collaborate with all stakeholders in roadway safety to help prevent drowsy driving; NSF is eager to work with industry on education, technical standards in regard to driver vigilance, and alertness and safety, as well as to organize cooperative ventures among other stakeholders toward public awareness and an end to drowsy-driving-related deaths.

FATIGUE BLUE RIBBON PANEL

On December 13, 2016, NSC held the Fatigue Blue Ribbon Panel in Chicago, Illinois, to bring together fatigue researchers and industry safety professionals to discuss the scope of the problem, share knowledge, explore collaborations, and help identify potential solutions. This panel focused on addressing fatigue both in the workplace and on the roads.

NATIONAL CONFERENCE ON TEEN SLEEP AND SCHOOL START TIMES

In collaboration with the RAND Corporation, researchers from Harvard Medical School/Boston Children's Hospital and others, Start School Later is planning a national conference to be held April 27-28, 2017, in Washington, DC. Early school start

times are widely recognized as a major contributor to both teen sleep deprivation and to drowsy driving among teenagers. This national conference aims to provide educational policymakers and advocates with practical guidance that includes clear implementation guidelines for school districts that often struggle in relative isolation to implement this policy change, as well as a forum for sharing ideas and networking.

MANAGING FATIGUE

In March 2017, 10th Annual International Managing Fatigue Conference is being held in in San Diego, California, in 2017. The "Managing Fatigue" conference series is a distinguished forum for the presentation of research and formative discussions within the fatigue management community. Each conference has focused primarily on fatigue in the transportation industry with support from government, industry, and academia. Recent iterations of the conference have begun focusing beyond transportation to include mining, healthcare, and the military.

EDUCATION AND AWARENESS PROGRAMS

IOWA

The Iowa Department of Transportation utilizes electronic variable message signs along State interstate systems to post traffic safety messages weekly, commonly referred to as "Message Mondays." Messages specific to drowsy driving have been displayed throughout the year, such as "Give It a Rest, Don't Drive Drowsy" and "Drowsy? Crash on a Couch Not a Road." The Iowa Department of Transportation plans to continue using drowsy-driving messages in this initiative. Other efforts to educate the public on the dangers of drowsy driving include presentations by the Iowa State Patrol at schools, businesses and service/community organizations.

The Governor's Traffic Safety Bureau partnered with Hy-Vee Supermarket in a public awareness campaign to help spread the word about drowsy driving through the development and distribution of bag stuffers. Hy-Vee is a large supermarket chain in the Midwest with 230 locations throughout eight States (IA, IL, KS, MN, MO, NE, SD, and WI). During this public awareness/educational campaign, a total of 241,000 bag stuffers were developed, paid for and distributed by Hy-Vee. A goal of the State is to continue the partnership and possibly expand awareness efforts about effects of prescription medicines through the supermarkets' pharmacies.

DROWSY DRIVING PREVENTION WEEK

Every year at the end of Daylight Saving Time, NSF begins Drowsy Driving Prevention Week to raise awareness and educate the public regarding drowsy driving–its dangers and how to avoid it.

NHTSA

NHTSA is currently working to develop and test effective messages. Material incorporating these messages will be ready for use by State and local constituents in 2017.

FDA

The Food and Drug Administration's Safe Use Initiative Team has provided funding to the Traffic Injury Research Foundation to conduct a two-year study to develop innovative methods to better understand and reduce the occurrence of adverse events in the post-market use of drugs. In particular, it addresses the development of an evidence-based educational resource using innovative messaging strategies and mobile technologies to inform a cross-section of healthcare professionals about effective ways to communicate to patients the risks associated with operating a motor vehicle in conjunction with prescribed drugs. The expected benefits of the project include improved communication between healthcare professionals and patients, and ultimately an increased level of road safety.

SLEEP AND PUBLIC HEALTH

The Sleep Research Society has teamed up with the American Academy of Sleep Medicine and the Centers for Disease Control and Prevention to form the National Healthy Sleep Awareness Project (NHSAP). The long-term goal of the NHSAP is to promote improved sleep health in the United States. The project will increase public awareness of the importance of healthy sleep. NHSAP has developed an "Awake at the Wheel" campaign to increase awareness of the dangers of drowsy driving to the general public.

COLLEGE STUDENT EDUCATION

Sleep 101 is a novel and far-reaching approach to addressing healthy sleep in college students. Developed jointly by Healthy Hours, the educational arm of Start School Later, and the Sleep Health Institute at Brigham and Women's Hospital, this brief, self-guided online program incorporates videos, animations, and games relevant to college life so that students see how sleep affects physical and mental health, safety, and performance in and out of the classroom. Several activities target drowsy driving specifically, including a test of reaction times, a game about ways to avoid drowsy driving, and a drowsy driving video. Designed to be part of pre-freshmen orientation activities, this one-hour course fits well into any existing suite of health and wellness programming, such as alcohol education and sexual assault programs for incoming students. Sleep 101 was piloted at a handful of schools in the summer and fall of 2016, with a target date of fall 2017 for full implementation.

SLEEP PHYSICIANS

The American Academy of Sleep Medicine is creating an electronic Frequently Asked Questions document for their member board certified sleep physicians, primary care physicians, and occupational medicine physicians to help them manage Commercial Motor Vehicles Operators (CMVO) with Obstructive Sleep Apnea (OSA) and the regulatory issues they face. This FAQ will address a number of key questions and issues that sleep specialists must address when caring for a CMVO with OSA.

DRIVER EDUCATION AND TEENS

This year, DriveitHOME™, an NSC resource for parents of new teen drivers, added "Drowsy Driving" as a teen driver risk. The new drowsy-driving page on DriveitHOME.org includes information on the risks of teens' drowsy driving as well as how parents can address the issue with their teen.

Currently, 47 States and Washington, DC, have information about drowsy driving in their driver's manuals, and 17 States include drowsy-driving education in their driver's education curricula. However, the quality of the information varies widely.

The AASM Sleep and Transportation Safety Awareness Task Force has developed driver's manual language, a model curriculum, and exam questions to improve States' accuracy and consistency of their drowsy-driving content. As of this report, Alaska, California, Illinois, Indiana, Nebraska, South Carolina, and Virginia have indicated they will include the language in their manuals. AASM will continue to contact States about including the template language in their manuals.

AASM is also working to support victims' advocates. The emotionally impactful experiences that victims of drowsy driving are able to share make a strong and lasting impact on audiences.

VEHICLE TECHNOLOGY

A number of vehicle and equipment manufacturers have developed technology that detects variations in driver behavior or physiology and provides a drowsiness or attention warning. Recent NHTSA research also indicates that vehicle-based algorithms can detect drowsiness and predict lane departures. However, improved understanding of human factors issues regarding such devices is needed, especially driver response to various types of warning signals and analysis of the effectiveness of such devices in leading to appropriate driver actions and prevention (e.g., getting needed rest before continuing a trip).

Direct detection of drowsiness or other indicators of inattention are not the only way to help prevent drowsy-driving crashes. Some of the consequences of drowsy driving may be addressed through Advanced Driver Assistance Systems (ADAS), such as forward collision warning, lane departure warning, automatic emergency braking, and other systems.

FOUNDATIONS OF DROWSY DRIVER FEEDBACK

To understand the current state of drowsiness detection and alerting systems, as well as the future of these systems, NHTSA recently began work with Westat, Inc. and the University of Iowa on a project that is exploring currently available drowsiness detection and alerting systems. NHTSA is working with original equipment manufacturers (OEMs), suppliers, and aftermarket producers to discuss the function, testing, and future of drowsy driving detection systems. Additionally, NHTSA is working to develop a methodology to help determine what vehicle warnings and messages can be effective in preventing drowsy driving. Currently, OEM drowsy driving detection systems alert drivers that they are drowsy with simple warnings (e.g., a red coffee cup icon). It is unclear whether these cues are sufficient to affect an immediate remedy (e.g., stopping to rest) or longer-term behavior change (e.g., adoption of an adequate sleep pattern). To determine what type of alerting strategy is most effective, a methodology that will allow in-vehicle alerts and messages to be tested in motivationally and emotionally valid environments is being developed (e.g., the driver returning home after a long drive).

VEHICLE TECHNOLOGY ADOPTION AND EDUCATION

NSC advocates for installation of advanced safety technologies in cars, in addition to voluntary industry agreements among manufacturers to install them. Additionally, MyCarDoesWhat has partnered with the National Automobile Dealership Association (NADA) to provide educational material to U.S. dealerships and with the American Association of Motor Vehicle Administrators (AAMVA) to ensure the education material will be made available in DMVs around the country.

MyCarDoesWhat has a variety of material that teaches drivers about drowsiness alerts – for example, a feature that tracks driver movements and alerts them after recording lane weaving, as well as associated lane departure warning and lane keeping assist features. The associated educational assets in the campaign include video animations, videos filmed with real-life actors, long-form infographics, short-form graphics, Q&A's, webpages, and quiz questions. The campaign's material and public-facing presence are dynamic, allowing interaction and questions from drivers about drowsy-driving mitigating technologies.

AUTOMATED TECHNOLOGIES AND VEHICLES

U.S. DOT and NHTSA recently issued the *Federal Automated Vehicles Policy* for the safe and rapid development of advanced automated vehicle safety technologies. With the potential to transform personal mobility and to open doors to people and communities – people with disabilities, aging populations, and car sharing in communities where car ownership is prohibitively expensive — advanced vehicle technology has the potential to address virtually all human factors risks, including drowsy driving.

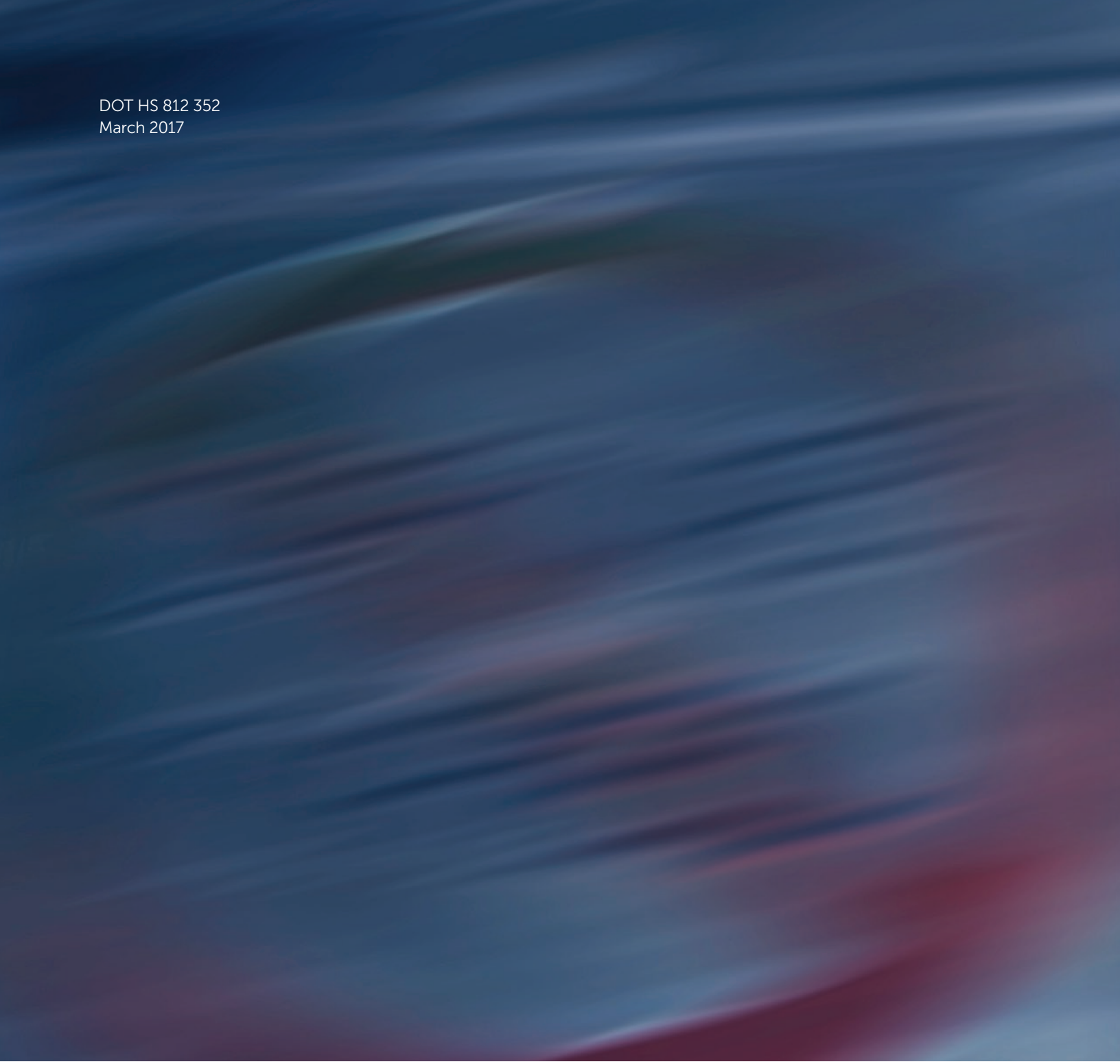
PARTNERSHIPS AND FUTURE COORDINATION

Drowsy driving is not a new highway safety issue, but it is a problem that has not received the attention it demands. The societal harm of drowsy-driving crashes, estimated at an annual cost of $109 billion, justifies a significant effort toward its prevention. Putting this into perspective, the cost of drowsy-driving crashes represents about 13 percent of the total $836 billion in societal costs of traffic crashes. Other significant sources of cost are alcohol (28%), speeding (24%), and distraction (15%). The future of drowsy-driving prevention relies on substantial partnership to continue beyond the work of the many involved partners. Together, these organizations have made significant initial progress on many of the goals outlined above, but there is still much work to do. While the U.S. Department of Transportation has the capacity to perform some of the work called for in this plan, the broad scope of the work required to address the issue requires significant participation and support from a wide range of sources, private and public.

NHTSA is dedicated to establishing more collaboration between government agencies involved in safety, health, labor, and defense to address this issue. The partners listed in this compendium will continue to meet with one another and encourage new groups to join our efforts to eliminate drowsy driving. Collectively we will focus on addressing the needs outlined in this document as well as identifying new needs that, if addressed, will impact the prevalence of drowsy driving across the United States. This compendium is only an initial draft of the work that is to come.

To get involved in these efforts, please contact any of the contributing organizations. Together we can eliminate drowsy driving.

DOT HS 812 352
March 2017



U.S. Department of Transportation
National Highway Traffic Safety Administration

NHTSA

12723-031917-v4b

Sleep apnea: A slow killer lurks among OTR truck drivers

Fatigue management and safety programs are taking root in the freight business, as trucking firms address the issue without federal regulators.

AUTHOR Jim Stinson@JimStinson
PUBLISHED Feb. 25, 2021

Bob Stanton was an OTR driver for 20 years, and in that time, it was never the weather nor the bad drivers that almost killed him.

Stanton said poor breathing at night almost did him in. By that, he means obstructive sleep apnea, an often-undiagnosed condition that robs sleepers of rest and deep dreaming.

"If I hadn't gotten treated back in 2002, I'd be dead by now," said Stanton, who recently became a referral coordinator for Dedicated Sleep, a specialty medical group that treats apnea.

Sleep apnea is an involuntary stoppage of breathing when one sleeps, according to the American Sleep Apnea Association. The body recognizes the problem and causes the sleeper to awaken, but not fully. Then the process starts all over again. The association said some people are disturbed in this manner hundreds of times in one night.

The condition prevents true sleep, when the body can dream and fully rest. It can also rob the body of proper oxygen levels, which has a cascading effect on health. The condition can attack the circulatory and cardiovascular systems. Thus, apnea can be a slow killer, Stanton said, and it increases the risk of truck crashes.

The condition is taken seriously by the FMSCA, although apnea is not targeted specifically by the federal agency. The Obama administration favored mandatory screenings for all commercial drivers, but former President Donald Trump, eager to roll back regulations, halted that effort, according to Stanton.

The industry now has what Stanton calls "no-rules rules" on apnea. FMCSA groups apnea with other conditions that interfere with safe driving.

"A person with a medical history or clinical diagnosis of any condition likely to interfere with their ability to drive safely cannot be medically qualified to operate a commercial motor vehicle (CMV) in interstate commerce," FMCSA's website states. But once treated, a driver may regain "medically-qualified-to-drive" status.

Stanton and other experts say truck drivers are loath to be tested for the condition. "Most drivers don't want to be told they have sleep apnea," said Stanton. "They are afraid they may lose their medical card."

But screening and treating drivers for sleep apnea could result in cost savings for fleets. A Virginia Tech Transportation Institute study found a trucking firm saved $441 per driver per month with an employer-mandated program to screen, diagnose and treat drivers for apnea.

Plus, many times, the driver is looking at $1,400 or so in medical deductibles, Stanton said. That's why he said carriers should reform their insurance rules and make apnea treatment 100% covered. That would help dispel the rumors among drivers that apnea is a fake condition, or a "money grab," Stanton said.

The American Sleep Apnea Association said the disorder can cause weight gain, sexual dysfunction, high blood pressure and cardiovascular diseases. For drivers, the risks multiply, because the disorder can cause daily memory problems, headaches, daytime fatigue and difficulty focusing on the road.

Common symptoms of sleep apnea

- Loud snoring.
- Morning headaches and nausea.
- Gasping or choking while sleeping.
- Loss of sex drive/impotence.
- Excessive daytime sleepiness.
- Irritability and/or feelings of depression.
- Disturbed sleep.
- Concentration and memory problems.
- Frequent nighttime urination.

A recent study by VTTI found as many as 47% of commercial vehicle drivers are at potential risk for sleep apnea because of weight or neck size. The institute looked at about 20,000 drivers, according to Jeffrey Hickman, a research scientist at VTTI.

Hickman believes the actual diagnosis of apnea in the general population is between 6% to 17%. In truck drivers, it's about 33%.

"It's higher than the national average, it's much higher," said Hickman. "If you treat [apnea], not only will it make them healthier, it will make them better drivers."

Trucking firms are thus wary of undiagnosed drivers, and some carriers have stepped up efforts to eradicate apnea in their OTR fleets. In 2006, Schneider became the first large firm to "screen, diagnose and monitor obstructive sleep apnea, and in 2019, Schneider received the National Safety Council's Green Cross for Safety Innovation Award and the Robert C. Johns Research Partnership Award for [its] efforts," according to the Schneider website.

Sleep apnea estimated to be more prevalent in truck drivers

Estimated percentage of population with sleep apnea, according to Jeffrey Hickman, a research scientist at VTTI

Most carriers appear to deal with the issue behind the scenes. But Schneider has a webpage on the issue and highlights its treatment options. Schneider requires all new drivers to be screened for apnea. If they have apnea, the TL firm gets them the treatment they need.

Tom DiSalvi, Schneider vice president of safety and loss prevention, said part of the initial problem was getting truckers screened, diagnosed and treated in a timely manner, without costing them time on the road. The process could take up to eight weeks in 2006, DiSalvi said.

"We recognized there was a lot of delay in the process," said DiSalvi.

Schneider began to shorten any delays and to refine the process, starting with a screening in the form of a questionnaire. Schneider also sought out a vendor for CPAPs — small machines that provide continuous positive airway pressure while the persons sleep. Schneider had to consult with its OEM on power issues for the devices because, initially, the CPAPs made it necessary for the trucks to have inverters and to use diesel as the trucks idled while parked. Inverters and idling are now no longer necessary, DiSalvi said.

Schneider requires all new drivers to be screened for apnea. If they have apnea, the TL firm gets them the treatment they need.

Schneider also made the process cost-free to insured drivers. Today, the result is health-cost savings of $440 per month, per driver. When a third-party study first reported that number to the carrier, DiSalvi said it must be a mistake. Surely the report meant "annually."

Schneider also said retention improved. Drivers with apnea were retained at a 30% improvement rate, he said.

Fatigue management, as it called by some industry officials, is taking root in freight businesses. A number of fleets have apnea and fatigue management programs, including Marten, Maverick, Old Dominion, Saia and Southeastern Freight, according to Mary Convey, vice president of corporate health and safety programs for SleepSafe Drivers, a fatigue management business focused on transport companies.

Without breath

Richard Bren, a board member of the American Sleep Apnea Association, has worked more than 25 years in the trucking-industry risk and insurance sector. The issue is

important to him because he too suffers from apnea, and he has used a CPAP for 18 years.

"My father had [apnea]. It's in our DNA," said Bren, who has used a CPAP machine for 18 years as he sleeps. Apnea, he said, is caused by the airway constricting at night. Contributing factors can be weight and neck size.

For Bren, now 58, the disorder meant as he slept, his airway constricted every 40 seconds or so. His body, in a state of sleep, would gasp for air, gently waking him to a degree. He would then fall back into a deep sleep for a minute or two.

"You don't get into a deep sleep," said Bren.

Now, Bren puts a CPAP mask on, and he said he looks a bit like a jet pilot as he sleeps. The intrusion of the machine in bedtime patterns is why so many people eventually stop using their CPAPs, he said. But the technology works, he adds — very well.

"The first time I was treated, my wife thought I was dead," said Bren. But in fact, he was deep asleep and not gasping, he said. The CPAP forced air past his airway and allowed him to sleep peacefully. The next day, Bren was rested and ready, and he had energy.

"I felt like I'd been drinking Red Bull," said Bren.

Common risk factors for sleep apnea

- A family history of sleep apnea.
- Having a small upper airway.
- Being overweight.
- Having a recessed chin, small jaw, or a large overbite.
- A large neck size (17 inches or greater for men, 16 inches or greater for women).
- Smoking and alcohol use.
- Being age 40 or older.
- Ethnicity.

Dr. Jordan Stern, a New York-based physician, treats sleep apnea and has treated transport workers. The workers are reluctant to be tested for the disorder, Stern said, but he has been working on options for patients.

"CPAP is only one of the treatments for apnea," said Stern. "Seventy percent of our patients don't want a CPAP."

Stern said he offers CPAP machines and medical mouthguards for patients, and conducts his tests through telemedicine. His sleep tests can be done at home. Stern called in-clinic sleep tests "the dinosaur experience," and said better tech has been around for 15 years. Stern's office mails the patient a disposable diagnostic machine that can be used as the patient sleeps.

More and more transportation companies are requiring workers get tested, Stern said. In New York City, the Metropolitan Transportation Authority requires apnea testing if the worker is over a certain BMI (body mass index) — more than 30 — or a certain neck size — 17 inches for men and 16 inches for women.

Some MTA workers come in and express reluctance, Stern said. He can usually spot that reluctance when adults say they don't get sleepy during the day. Anyone who is referred and says their sleep is totally fine raises a red flag, he said. And to the reluctance, Stern has a simple reply.

"I say, 'Look, I am going to get you fixed,'" Stern said.

A catch-all at the FMCSA

Stanton said the FMCSA needs to improve its rules on apnea, and one start would be to specifically mention it in its rules. Right now, obstructive sleep apnea is part of a catch-all classification of conditions that reduce safety if untreated. The FMCSA is part of the North America Fatigue Management Program, which seeks "to develop guidelines and materials that enable motor carriers to implement a comprehensive Fatigue Management Program (FMP) and means of delivering an FMP to motor carriers throughout North America."

With specific apnea mention and rules, the FMCSA could establish testing formats and treatment guidance, Stanton said.

Bren compared the condition to high blood pressure. If untreated, the condition gets worse and affects other organs and other conditions.

"These things start to compound," said Bren.

Many OTR drivers are documented to have other conditions such a Type 2 diabetes, high blood pressure, overweight and heart issues. Obstructive sleep apnea only worsens those conditions, Stanton said.

Undiagnosed sleep apnea cost the US $150B in 2015

Chart: Shefali Kapadia / Transport Dive Source: American Academy of Sleep Medicine Get the data Created with Datawrapper

Estimated economic costs of undiagnosed sleep apnea in billions of dollars

Bren said he would like to see more carriers discuss sleep apnea. The condition needs to be publicized and taken care of internally before it becomes a large problem that the FMCSA has to heavily regulate, he said.

Convey said she does not think federal regulation will happen but believes addressing the apnea problem can be done without laws and Congress.

"It has to be all parties, your medical provider," said Bren. "Trucking would be better off addressing this themselves than letting the federal regulators get too deep into it."

TO: **Thea Fickett**
Medical Review Coordinator
Bureau of Motor Vehicles - SHS 29
Augusta, Maine 04333-0029
March 8, 2021

Based on review of my records, testing showed that even with CPAP, BiPAP and ASV, my AHI does not fall below 15.
In Therapeutic #1 with BiPAP, my AHI fell to 18.6. In Therapeutic #2 with ASV, my AHI rose to 36.2. Both tests did note a substantial difference depending on sleep position T#1 = 26.8, T#2 = 13.2 Test #2 did show that non-supine AHI was a mere 1.2. As you will see from reading the PSG reports, there is an extreme inconsistency in the conclusions reached in Therapeutic Study #2.

Needless to say, the findings negate the Severe Status of 3C on the sleepiness chart based on the 15% since there is no actual evidence of benefit to me from PAP therap. It is also obvious, from the reports, that alternatives were never considered by the ENT who wrote the reports. It I medical impossible to conclude that an AHI of 36.2 equates to "Adequate control achieved with ASV therapy."

Thus I default to my Personal Safe Driving Plan which I have followed for years.

1) I never drive when I know I am tired.
2) If I start to lose concentration, I pull over and take a short refreshing roadside nap.
3) I never drive more than one hour in any direction. That is about the limit of my concentration.
4) I drink **2 liters of PEPSI** plus two cups of coffee every day. Always have Pepsi in the car.
5) I usually have the radio or CD player going in the car.
6) Always wear sunglasses to prevent retinal fatigue.
7) I am intentionally aware of my problem and pay good attention.
8) I have a good driving record which is an indication that I have not had prior problems with driving.
9) I have driven just over 4000 miles a year in the last two ears. I don't travel far nor often.
10) I do not drink.
11) I do not smoke.
12) I manage my meds so they won't affect me when I will be driving.
13) I use Melatonin to sleep better at night and be more alert during the day.
14) I rarely/never drive after sunset.
15) I rarely if ever have passengers nor let them distract me.
16) I have an anti-drowsiness device I wear for non-local ventures.
17) I am ADHD with an emphasis on Hyper-attentive if you know what that means.

And I emphasize important factors from my PSGs that should be considered

1) high sleep latency (hard time falling asleep
2) extended periods of wakefulness after arousals
3) low levels of SaO2 desaturation
4) mild score on Epworth Sleepiness Scale
5) My sleep efficiency scores indicate hard time falling asleep also (Normal sleep efficiency is considered to be 80% or greater.)

The fact that my test data was misrepresented as "responsive" but "non-compliant"); the fact that I have a safe driving record; the fact that I have developed a self-management plan for preventing driving mishaps; and the fact that my plan depends on a deliberate conscious awareness of my state of mind, I assert that my so called sleepiness is indeed better managed without assistive devices. As such, I ask that my privilege to drive and to obtain a license be reinstated. If that comes with stipulations, I would certainly consider them.

Sincerely,
Kenneth A. Capron
1375 Forest Avenue D-11
Portland, ME 04103
Maine DL 4320004C

ANALYSES

What is the objective of restricting driving for individuals who have sleep apnea? "**Driver sleepiness is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with obstructive sleep apnea (OSA) are at increased risk for car accidents.** [alleged but unproven]

1. Excessive Daytime Sleepiness (Drowsiness/sleepiness)
2. Fatigue
3. Loss of Concentration and attention
4. 52% of treated PAP recipients still experience EDS

How relevant is the number of AHI incidents in determining?

1. Polysomnogram (PSG) alleges an AHI (apnea/ hypopnea index) of less than 15 per hour is healthy. So what?
   Capron's early PSG (2002-2004) showed **51 AHI**. Now showing **36 AHI** on T#2. No noticeable difference in sleepiness.
2. What about sustained **O2 saturation**? Isn't it the oxygen deprivation associated with apnea that generates the fatigue and tiredness? No matter how many events, if SaO2 remains strong then AHI events become irrelevant.
3. Epworth Sleepiness Scale (ESS) = expectation of "dozing" in a variety of situations. Score of less than 8 is healthy? (range from 7 to 12 depending on source). Difference between **Intentional** dozing vs **Involuntary** dozing.
4. Does an AHI of less than 15 **guarantee** against EDS? **NO**

Are there other factors which affect **Excessive Daytime Sleepiness**?

1. Diet/weight
2. Mental Health
3. Hyperactivity (ADHD)
4. Distractibility
5. Napping
6. Medications, stimulants - no doze
7. Medications, sleep inducers
8. Electronic anti-drowsiness devices (https://amazon.com/gp/product/B00NAQOVF6)
9. Time of day and Circadian Rhythm
10. Insomnia
11. RLS (Restless Leg Syndrome)
12. Depression
13. Age
14. Caffeine consumption
15. Exercise
16. Excitability
17. Anxiety
18. Noise

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MMP Otolaryngology/Maine Sleep Institute
Memorial Sleep Center
P: (207) 661-4740

Article: **Sleep Apnea - A Slow Killer Lurks.pdf**

Dr. Jordan Stern, a New York-based physician, treats sleep apnea and has treated transport workers. The workers are reluctant to be tested for the disorder, Stern said, but he has been working on options for patients.
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North America Fatigue Management Program, which seeks "to develop guidelines and materials that enable motor carriers to implement a comprehensive Fatigue Management Program (FMP). Convey said she does not think federal regulation will happen but believes addressing the apnea problem can be done without laws and Congress.

Website: for professionals; extensive sourcing in footnotes.

https://edsandosa.com/ **Excessive Daytime Sleepiness**
https://edsandosa.com/prevalence-of-eds-in-osa
https://edsandosa.com/real-impact-of-eds-in-osa/eds-osa-patients
https://edsandosa.com/treating-eds-in-osa

NOTES:

- The diagnosis must be made after airway treatment is implemented and all other causative disorders have been considered. These include other untreated sleep disorders, **mental disorders**, or the effects of **medications**.
- While continuous positive airway pressure (CPAP) is considered the gold standard of treatment for obstructive sleep apnea (OSA), EDS may persist despite optimal CPAP use
- Pharmacotherapy may be an option for patients with unresolved EDS [No Doze, Melatonin, …]
- 52% Reported Feeling Sleepy During The Day Despite Any Amount Of CPAP Use.
- 1 In 3 Who Used Their CPAP => 5 Hours A Night Still Reported Feeling Sleepy During The Day.
- While CPAP is needed to address the airway issue in patients with OSA, it may not address all aspects of compromised neuronal activity, and EDS may persist.
- Sleep apnea treatments like CPAP have been proven to decrease symptoms such as apneas, hypopneas, and snoring, and improve sleep structure in patients with OSA. However, CPAP and CPAP alternatives may not address the brain alterations and subsequent neurologic dysfunction that OSA can leave behind.

The American Academy of Sleep Medicine (AASM) defines EDS as:

- The inability to maintain wakefulness and alertness during the major waking episodes of the day. PAP tests do not measure this.
- Resulting in periods of irrepressible need for sleep or unintended lapses into drowsiness or sleep.

"While involuntary episodes of sleep are more likely to occur during relaxing or inactive situations, for some, they can also occur during those situations that require active participation."

In an online survey, patients shared the real impact of EDS in OSA:

- 21% reported falling asleep while working or during a meeting
- 31% felt that EDS negatively affected their romantic partnerships
- 64% said EDS impacted their ability to enjoy activities or hobbies

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Website: https://www.merckmanuals.com/professional/neurologic-disorders/sleep-and-wakefulness-disorders/insomnia-and-excessive-daytime-sleepiness-eds
Essentially says the same things as the Jazz Pharmaceuticals website above.

SOS/BMV

Dept. OSA Guidelines https://www.maine.gov/sos/bmv/licenses/OBSTRUCTIVE%20SLEEP%20APNEA.pdf

Premise: "Driver sleepiness is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with obstructive sleep apnea (OSA) are at increased risk for car accidents." SOURCES NOT ATTACHED?

1. For further discussion regarding OBSTRUCTIVE SLEEP APNEA, please refer to NARRATIVE found at beginning of this section.

2. For further explanation of degree of impairment, please refer to SECTION 3. This diagnosis should be made only after a sleep study. Neurology or sleep med specialists are often the clinicians to provide follow-up.

3. For those with dental device, repeat PSG must be done with device in place.
4. AHI: apnea/hypopnea index: number of obstructive events per hour of sleep.
5. Epworth Sleepiness Scale: validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A scale of 0 to 7 is normal, 8-12 is mild, 13-16 is moderate, and 17 or greater is severe. (Hirshkowitz M, Gokcebayu N, Iqbal S, et al: Epworth Sleepiness Scale and sleep disordered breathing: Replication and extension. Sleep Res 1995; 24:249).
6. Treatment with positive airway pressure therapy. PAP devices include but are not limited to, CPAP (continuous positive airway pressure), BiPAP (bi-level positive airway pressure), and ASV (adaptive servo-ventilation).
7. Adherence to or compliance with CPAP treatment derived from Medicare guidelines: use of PAP an average of four or more hours per night at least 70% of the time. === (4 hours x 7 nights x 70% = **19.6 hours per week**)**(2.8 hrs. nightly)**

FUNCTIONAL ABILITY PROFILE

Profile Levels	Degree of Impairment/ Potential for At Risk Driving	Condition Definition / Example GREEN identifies steps I have achieved	Interval for Review and Other Actions
1.	No diagnosed condition	No known disorder	N/A
2.	Condition fully recovered	Recovered after Treatment(s) **other than CPAP**, such as • surgical intervention, • weight loss or • dental device3. • Polysomnogram (PSG) demonstrates an AHI (apnea/ hypopnea index) of less than 15. • ESS (Epworth Sleepiness Scale) score of less than 8. • No report of accident or near miss.	N/A
3.	Active impairment	This diagnosis should be made only after a sleep study. Neurology or sleep med specialists are often the clinicians to provide follow-up.	
	a. Mild	• AHI < 15 on diagnostic PSG and • not sleepy, • ESS less than 8. • Not on treatment.	Three years
	b. Moderate	• PAP download demonstrates adherence to treatment. • AHI less than 15 on download from CPAP. • ESS less than 8. • No crashes or near misses.	Yearly
	c. Severe	History of falling asleep while driving or near miss, or strong suspicion of OSA with concern for unsafe driving; and/or Non-responsive or non-adherent to therapy.	No driving

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SOS/BMV

NOTES about OBSTRUCTIVE SLEEP APNEA.pdf:

- Only concerned with daytime sleepiness
- increased risk of motor vehicle crashes (2% to 7%) in those with OSA - how severe? Fender Benders?
- recent estimates suggesting that 25% of adult men in the US are affected - affected by what? Apnea, EDS, accidents?
- frequency of occurrence increases with: occurrence of what - apnea or accidents?
    - age,

- BMI (body mass index) and
- comorbid conditions such as diabetes

Symptoms of concern:

- delayed reaction times and
- inattentiveness in addition to
- Frank sleepiness.
- unaware of their sleepiness and cognitive impairment

Observations from BMV materials:

- excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea
- increased risk of motor vehicle crashes is present in those with mild OSA as well as those with severe disease
- Treatment of OSA generally improves daytime sleepiness - studies suggesting that daytime symptoms improve within two weeks. It is the **only treatment modality demonstrated to reduce crash risk** (except ones that already work better and prevent crashes).
- Other treatment options
  - bariatric surgery for morbid obesity
  - oral mandibular advancement devices
  - upper airway surgery
  - craniofacial surgery
  - Hypoglossal nerve stimulators
- It is difficult for clinicians to assess sleepiness (and possible impairment while driving) in a patient with OSA. Sleepiness cannot be measured easily by objective testing.
- Maintenance of Wakefulness Tests (MWT) and Multiple Sleep Latency Tests (MSLT) are the best objective measures of daytime sleepiness in those with OSA, but are performed only in Sleep Centers, are expensive and time consuming. They are not routinely used to assess daytime sleepiness in drivers.
- subjective reports = Epworth Sleepiness Scale; PCP observations;
- Objective data from CPAP downloads to ➔ only assess adherence to treatment.
- AHI determines the severity of OSA - an AHI of 15 or fewer obstructive events per hour is considered mild
- Driving safety is ultimately the individual's responsibility.

- Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy.

SOS/BMV

Sent: Tuesday, February 16, 2021 11:33 AM
To: Patty Morneault at SOS/BMV/Hearings
Subject: Appeal Hearing re: Suspension of License due to sleep apnea

Ms. Morneault,
I couldn't find anything on your website indicating that an appeal couldn't be submitted by email. So I have attached my Appeal and request a Hearing re: Suspension of License due to sleep apnea.
The letter from BMV/Medical was postmarked February 10, 2021 and thus this filing is timely.

I have reviewed the rules and my medical records and completely disagree with the severity as provided by NP Kivela. In order for OSA to be severe, one must consider past driving experience. Kivela never asked for historical driving information. I explained to Kivela several other mitigating factors I use to assure safe driving as well as other interventions I use. I have demonstrated successful management of my driving safety. And I have to refuse the use of CPAP/BiPAP/ASV because it was ineffective in modifying my sleep patterns. And that's why I have developed other strategies which have proven successful. Although I drive less than 6000 miles a year, I need my license for the limited driving I undertake.
I believe Kivela's application of the OSA rules is misguided and simply inaccurate.

Epworth Sleepiness Scale

0 Would never doze
1 Slight chance of dozing
2 Moderate chance of dozing
3 High chance of dozing

- **Unintentional**
- **Irrepressible**
- **Involuntary**

Sitting and reading	0	1	2	3	I don't read anything that would make me sleepy. I do not sit and read
Watching television	0	1	2	3	catnap by choice
Sitting inactive in a public place (e.g., a theater or a meeting)	0	1	2	3	only by choice
As a passenger in a car for an hour without a break	0	1	2	3	depends on conversations, visual and audio stimulants
Lying down to rest in the afternoon when circumstances permit	0	1	2	3	Intentional napping
Sitting and talking to someone	0	1	2	3	Stimulating conversation is energizing
Sitting quietly after a lunch without alcohol	0	1	2	3	only by choice
In a car, while stopped for a few minutes in traffic	0	1	2	3	Never

A score of 7 or less out of 24 is considered normal (not sleepy). The acceptable range cutoff value is subject to debate, with some researchers suggesting that 7 or less is normal (not sleepy): others suggesting 12 or less).

MY CHART - MaineHealth

03/02/2021 04:30 PM Vu Uy Ho "From the documents available on the BMV website for obstructive sleep apnea (https://www.maine.gov/sos/bmv/licenses/OBSTRUCTIVE%20SLEEP%20APNEA.pdf), in regards to profile level 3C, a footnote for non-adherent (7) states: Adherence to or compliance with CPAP treatment derived Medicare guidelines: use of PAP an average of **four** or more **hours per night at least 70% of the time**. Footnote (6): treatment with positive airway therapy. PAP devices include but are not limited to, CPAP (continuous positive airway pressure), BiPAP (bi-level positive airway pressure), and ASV (adaptive servo-ventilation). From these guidelines and footnotes provided from the BMV for sleep apnea, the listed profile 3C would be valid for non-adherence to ASV. [and non-responsive]

The BMV does allow for alternative therapies that treat the underlying sleep apnea syndrome, which may include weight loss, positional therapy, oral dental appliance, and surgery (if proper candidate) that I had mentioned in my last correspondence. Alert devices and self-monitoring are helpful adjunct mechanism for safe driving, but do not address the underlying disease process of sleep apnea syndrome that may result in the sleepiness / drowsiness that can reduce alertness while driving. I read the article you provided (https://www.transportdive.com/news/OTR-truck-drivers-sleep-apnea-schneider-safety/594568), which placed an emphasis on the importance of sleep apnea screening, evaluation and treatment as part of Fatigue Management Program. The program in of itself does not exclude the treatment of sleep apnea.

I spoke with Thea at the BMV to review guidelines. The BMV guidelines require therapeutic options be interventions / therapies that treat the underlying sleep apnea. Available options may include weight loss, oral dental appliance, and/or positional therapy, though effectiveness is variable. With alternative therapies, there needs to be a reduction in the AHI below 15 events per hour on a follow-up sleep study and an Epworth Sleepiness Scale of less than 8 for your category profile to be adjusted to level 2. Profile level 3B would require resuming ASV/PAP therapy with adequate adherence, AHI less than 15, and an Epworth Sleepiness Scale of less than 8. Fatigue Management Program (without treatment of sleep apnea) or alert monitoring device is not sufficient for intervention as this does not address the underlying disease process of sleep apnea. If you would like to discuss these alternative treatment options, follow-up appointment may be arranged in our sleep clinic. If you prefer, referral to another sleep provider/clinic can be arranged for a second opinion."

3/2/2021 2:13 PM EST Kenneth A Capron "Dr. Ho,
I have read the BMV guidelines. I think you are misinterpreting them to imply that non-compliance with use of ASV is the deciding factor. In my discussions with Thea at the BMV, the proper interpretation would be non-compliance with any therapy, including a Fatigue Management Plan such as is being used by truck drivers with apnea
(see https://www.transportdive.com/news/OTR-truck-drivers-sleep-apnea-schneider-safety/594568/).
This plan consists of a variety of options that reduce driver sleepiness or increase driver safety and alertness. I described my use of alternate means to Kivela which have worked obviously quite well since I have no significant lifetime events on my driver's record. I explained that to Kivela also.

I do manage my own driving concerns quite effectively - even having gone so far as to obtain a drowsiness alert device. I do not believe I have reached the severity of 3C. The problem is that Kivela failed to consider alternatives functionally equivalent."

03/02/2021 01:50 PM Vu Uy Ho "I can understand your frustration with the classification profile for the Bureau of Motor Vehicle (BMV) and the suspension of motor vehicle license. Carri Kivela, N.P., had categorized your functional ability profile at 3C based upon the BMV guideline put forth by the State of Maine. In patients with obstructive sleep apnea, a classification profile of 3C are for individuals having a baseline apnea hypopnea index (AHI) of greater than 15 events per hour during a sleep study **and** any of the following: 1. History of falling asleep while driving or near miss or; 2. Strong suspicion of OSA with concern for unsafe driving; 3. And/or non-responsive or non-adherent to therapy. In your particular case, non-responsive or non-adherent to therapy (adaptive servo-ventilation – ASV) would result in classification at profile 3C. Therefore, I agree with Carri Kivela's placement of 3C profile on the BMV form.

In the past, you considered the option to re-trial ASV after your sleep cycle had improved, but this appears to no longer be the case. Though ASV, a form positive airway pressure therapy, is the most common and preferred therapy for mixed apnea syndrome, potential alternative options for therapy that may treat and/or reduce the degree of your sleep apnea syndrome include **weight loss, positional therapy, and/or mandibular advancement** device (oral dental appliance). However, the effectiveness are variable and not necessarily **guaranteed** with each of the processes given the presence of mixed apneas (obstructive, mixed, and central respiratory events) on your previous sleep study. With alternative therapies, a reduction below an apnea-hypopnea index below 15 would considered effective therapy per BMV guideline. Follow-up in our clinic could be arranged to discuss these options in more detail. If you prefer, referral to another sleep clinic/provider can be arranged for a second opinion. "

2/26/2021 1:14 PM EST Kenneth A Capron "Dr. Ho, I need to ask if you agree with your associate N.P. Kivela as to the CR24 indicating that my sleep apnea is as bad as Level 3C. I would like to avoid legal involvement but I cannot accept suspension of my license as the ONLY solution to address sleep apnea. I have been pretty forthcoming about the mitigating factors but to no avail. We all know that the risks posed by sleep apnea depend a lot on the individual. In my case, I have lived with apnea for 2 decades. During that time, my driving record shows only one accident, in 2014. Other than that, there have been no incidents. I have explained that I monitor/manage my apnea by limiting how far, how long, I drive to 60 minutes. I pull over to the side of the road to take a short nap if my concentration falls. At home, I use naps to increase my functioning. I have recently been using melatonin to get better night time sleep. I also have an over-the-ear drowsiness alarm used for longer distances. I drive about 4000 miles per year."

02/17/2021 05:07 PM Carri Kivela "The sleep study I referenced on **5/14/19** was your diagnostic study where the **severity of sleep apnea** was determined.

There is information on the MMC website re: requesting medical records at Medical Records Release Forms | Maine Medical Center | Portland, ME (mainehealth.org) and the form you will need to complete is also on the website at https://www.mainehealth.org/-/media/Maine-Medical-Center/Files/Patients-Visitors/Authorization-to-Release-and-Disclose-Patient-Information.pdf

The office visits with Dr. Ho are dated **2/24/20** and **4/6/20**.
The phone calls with me are dated **5/23/19**, **7/30/19** and **12/26/19**.
It helps to be specific with your request."

2/16/2021 10:45 AM EST Kenneth A. Capron "I was able to find **several Sleep Studies**. I am unsure why you referenced the 5/14/19 sleep study. I only found the **Jan-2021 progress notes**. I did not find the following tests: **Maintenance of Wakefulness Test**; **Multiple Sleep Latency Test**; nor the **Epworth Sleepiness Scale**. I did not find a patient intake questionnaire if there was one.

In reviewing your report which asserts a level 3c Severe Impairment, I did not find the evidence of "History of falling asleep while driving or near miss, or strong suspicion of OSA with concern for unsafe driving" which is a requirement for the Severe rating. I found no notes relating your severity rating to the DMV rules regarding OSA. After reading the rules, I find no evidence of a problematic or severe limitation. In fact, I have historically had a great driving record and have never had an incidence of nodding off while driving.

You were told about the mitigating strategies I use to minimize any potential risk and yet you failed to mention same.

02/16/2021 07:53 AM Carri Kivela "The diagnostic sleep study dated 5/14/2019 should be visible in MyChart. You should also be able to read the progress notes by Dr. Ho and myself. Please let me know if these are not visible to you."

2/15/2021 4:32 PM EST Kenneth A Capron "Carri, I am scheduling an appeal with the State and will require you as a witness, willing or otherwise, as the diagnosing provider for "Severe" Obstructive Sleep Apnea. At this time, I need to obtain the exact documents you used

to base your evaluation upon. I don't believe I have seen those tests or documents. So please provide them immediately since the clock is running on my suspension.

As I mentioned in a previous communication, I have acquired a device intended to detect if a person is nodding off while driving. Although there is absolutely no evidence that I have ever done so. In fact there is no evidence that sleep issues have ever resulted in poor driving, driving citations, accidents, nor any activity that would raise concerns about falling asleep while driving. Please provide all relevant materials that prove our diagnosis. You know that my apnea is primarily central. You also know that sleep/wake schedule is different from other people. Your response is requested ASAP"

01/20/2021 05:09 PM Carri Kivela "I feel badly about this. I am bound by state requirements. You fall in the category 3C on the form - severe sleep apnea non-adherent to PAP therapy. Do you not agree? I can refer you to another sleep medicine physician or you can see Dr. Ho again if you'd like a second opinion. How would you like to proceed?"

1/20/2021 10:12 AM EST Kenneth A. Capron "Carri, you do what you have to do. I suspect you could reach a positive conclusion if you take into account the fact that I have driven safely despite apnea for over two decades. Having driven barely 4000 miles in two years is also an indicator of the low risk I may be and my high level of self-management. I don't have the form in front of me, but I don't think it asks if I am safe to drive.

I believe I have taken that The Epworth Sleepiness Scale - which is a widely used measure of subjective daytime sleepiness. I believe it supports my assertions. You have no evidence from PAP downloads. My apnea is primarily central, not obstructive.

Based on your limited assessment, you would have me in a convalescent home. I'm not that bad. I am not a risk.
You need to be prepared to take a stand in the courts. I am not going to sit idly by while you understate my ability. Maybe if I drove for a living, I might agree. But I don't. I have decades of driving ahead. I am not going to use a CPAP."

01/20/2021 07:55 AM Carri Kivela "I understand what you're saying but as you noted below the state requires subjective AND objective information from PAP downloads. This is why I can't approve driving. I can't rely solely on patient self-management to fill out the form stating you're safe. "

1/19/2021 4:25 PM EST Kenneth A Capron "I met with Carri this afternoon and reached the same conclusion as before. I have also reread the instructions from the BMV - attached.

- "The clinician must use subjective reports as well as objective data from CPAP downloads to assess adherence to treatment and level of daytime sleepiness."
- "The clinician must educate patients that driving safety is ultimately the individual's responsibility. Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy."

- ❖ I have consistently stated that I have had no incidents related to driving.
- ❖ I self-manage.
- ❖ I only drive during the day;
- ❖ I only drive when I am not tired;
- ❖ I never drive more than an hour in any direction;
- ❖ If I were to feel sleepy, I would pull over and rest;
- ❖ I drove only 4025 miles in the past two years

The patient has been advised of his responsibility and has demonstrated a record of safe driving.
Clinician relies on patient's self-management."

11/30/2020 05:16 PM Zhyldyz Kabaeva "Ken, It would make more sense to stay with the same office as they have done the testing and know the results and your history. You may request to see a different doctor at the same office."

11/27/2020 9:57 PM EST Kenneth A Capron "Did you have some communication with DME? According to the regs., they are only concerned with obstructive sleep apnea and not central. I prefer not to go to ENT because I have had a bad experience with Dr. Murray. It is also such an unnecessary expense. And I am trapped and not a happy camper! "

11/27/2020 05:33 PM Zhyldyz Kabaeva "To add to my previous message. I also wanted to let you know that DME require patients with sleep apnea to be treated to have continued driving privileges. The regulations might have changed over the several years but in the past we also did not have access to your sleep study. With now sleep study showing severe sleep apnea I would not be able to renew the DME form. ENT will have to do it. I am sorry, but there are certain policies which we have to follow. Thank you for understanding. "

11/27/2020 05:29 PM Zhyldyz Kabaeva "Just wanted to touch base with you to see if you were able to schedule an appointment with ENT to follow-up on sleep apnea. Next time we might have difficulty renewing your driving license because of the regulations we have in place. "

10/20/2020 12:12 PM Zhyldyz Kabaeva "I still strongly recommend to see the ENT and review your symptoms and driving approach you use as they are obligated to inform BME about the treatment plan."

10/20/2020 11:42 AM EDT Kenneth A Capron "We have known of the sleep apnea risk for many years. I tried the CPAP or whatever, it helped in one way and disrupted in other ways. So I have opted not to use it. There has been no change from prior years. I can still perform all the driving functions. The fact is that I self-limit my driving time to one hour. That is my "treatment". I manage my driving based on my ability to concentrate.

I only revisited my sleep apnea over the past couple of years to
1) See if things were worse and
2) To get on oxygen and
3) To see if there were any new treatments that would work.
Nothing has changed. The PAP devices are just as disrupting. So I default to what has worked for over a decade. I take naps and limit my driving. And I am smart enough to know when not to drive. So if you are looking for something to put on the State form, try something like "self-managed with napping and driving limits".

There is no "treatment" that works for me. I apply self-control."

10/20/2020 10:56 AM EDT Zhyldyz Kabaeva "The ENT team reached out to me that based on the sleep study results, the untreated sleep apnea poses a safety risk for driving. I do recommend to schedule an appointment with them to discuss potential treatment options to avoid having restrictions on your driving license."

MY CHART - sleep studies

2019-05-06 MSI DIAG Polysomnography 8986427 (1-9)

BMI= 39.1 --- Awakenings= 26 --- Sleep Efficiency= 53.5% --- Average SaO2 Desaturation 5% **AHI 28.4**

Physician Interpretation - This diagnostic study reveals the following:

1) Moderate to severe sleep related breathing disorder.
2) Mild oxygen desaturations during sleep.
3) Increased limb movement activity.
4) Moderately disrupted sleep architecture.
5) Snoring is moderate.

Other comments: The patient has a prolonged sleep latency and **extended periods of wakefulness after arousals that resulted in reduce sleep efficiency**.

Recommendations include determining the **necessity for supplemental oxygen**

2019-07-20 MSI THER#1 Polysomnography 10683304 (1-10)

BMI= 39.3 --- Awakenings= 17 --- Sleep Efficiency= 57.8% --- Average SaO2 Desaturation 4% **AHI 18.6**

Physician Interpretation

1) Therapeutic intervention utilizing CPAP resulted in development of **treatment emergent central sleep apnea**. Therapeutic control of sleep disordered was not achieved with CPAP therapy due to treatment emergent central sleep apnea.
2) Sleep efficiency is reduced.
3) Sleep architecture is abnormal despite therapy
4) Respiratory events occurred more frequently in the supine position (supine AHI 26.1, non-supine 1.2).

2019-12-09 MSI THER#2 Polysomnography 3189372 (1-10)

BMI= 39.0 --- Awakenings= 18 --- Sleep Efficiency= 63.2% --- Average SaO2 Desaturation= 5% **AHI 32.6**

Physician Interpretation

- REM sleep was not achieved
- AHI supine was mildly elevated at 13.2 events per hour

1) Therapeutic control of SRBD is demonstrated with ASV at an EPAP min of 5 cmH_20 and Min PS of 5 cmH_20 and Max PS of 5 cmH_20. **Test results contradict this**
2) Desaturations are controlled with therapy. **Test results contradict this**
3) No significant limb movement is demonstrated. **Test results contradict this**
4) Sleep efficiency is near normal with therapy. **Test results contradict this**
5) Sleep architecture is normal. **Test results contradict this**

Adequate control achieved with ASV therapy. **Test results contradict this**

CAPRON/KIVELA

How do I obtain a copy of my health information and/or medical records?

"A patient or their legal representative may inspect and/or obtain a copy of their health information, or have copies of their records sent to another facility elsewhere. You may request a copy of your records on paper, USB flash drive, or on a compact disc (CD)."

A completed and signed Authorization to Release Protected Health Information form along with valid signature is required for copies of records to be released. Please bring photo ID when picking medical records up at any of our locations. To request the form be faxed or mailed to you, please call 207-662-2211. Click here for assistance in completing the form. You may also pick up a copy of the form at any of our Health Information Management Department locations.

Please forward the completed signed form, indicating date and time signed, to Health Information Management Department 301C US Route One, Scarborough, ME 04074. Email: MHmedicalrecords@mainehealth.org. Fax: 207-761-3092.

Name: Ken A Capron | PCP: Zhyldyz Kabaeva, MD

As of August 1, 2019, you now can use MyChart to view your office visit notes at all MaineHealth locations, not just Maine Medical Center and Maine Medical Partners. Certain exclusions apply.

All MaineHealth patients are able to request their medical records through our Health Information Management Department here. Office visit notes will be offered through MyChart only on a prospective basis beginning August 1, 2019. Requests for notes prior to this date must be submitted to the Health Information Management Department.

Progress Notes

Carri Kivela at 01/19/21 1507

MMP OTOLARYNGOLOGY & SLEEP MEDICINE TELEPHONE VISIT
Date: 1/19/21
Time in: 3:07pm
Time out: 3:24pm
Due to the current pandemic of COVID-19, a face-to-face visit could not be conducted. Patient (or legal guardian) provided verbal consent to conduct this telephone encounter and service was provided via telephone.
Patient Status: New or Established Pt: This is an established patient.

Kenneth A Capron is a 69 y.o. who presents with a chief complaint of had concerns including Apnea..

No Link Provided

Patient contacted by MMP sleep disorders clinic in regards to PAP compliance. He was unable to sign onto Zoom platform for telemedicine so visit completed by phone. Patient with history of obesity, paroxysmal atrial fibrillation, hypertension, chronic kidney disease, and complex sleep apnea. He reports this visit is to talk about his driver's license.

Interval history per Dr. Ho's note from last visit 4/6/2020 :
As previously noted, the patient had a previous diagnosis of complex sleep apnea, but deferred treatment due to confusion of CPAP resulting in worsened sleep-disordered breathing. Eventually, the patient reconsidered and he was agreeable to re-evaluation. The patient underwent an in-lab polysomnography on 5/6/2019, which revealed moderate to severe sleep related breathing disorder with an overall AHI of 28.4 events per hour (worse in supine position). Therapeutic polysomnography on 7/6/2019 revealed inadequate control of sleep related breathing disorder with CPAP/BPAP due to complex sleep apnea syndrome. Therapeutic study on 12/9/2019 showed ASV resulted in adequate treatment of sleep disordered breathing.

Patient reports he tried ASV PAP therapy and didn't tolerlate. He reports sleep quality and daytime fatigue levels were no better on PAP therapy. Sleep patterns continue to be erratic with periods of difficulty initiating and maintaining sleep followed by periods of more consolidated sleep. He reports he will never resume PAP therapy. He finds he can control his fatigue levels with naps and avoid driving when fatigued. Asking if there are other therapies for complex sleep apnea. Expressed frustration with state requirements for license. Reports he will forgo his license before agreeing to PAP therapy again.

Current Outpatient Medications

Medication
• sildenafil 20 MG Tab
• cyclobenzaprine 5 MG Tab
• furosemide 20 MG Tab

- Omeprazole Magnesium 20 MG Tablet Delayed Response
- PARoxetine 30 MG Tab
- zoster vaccine recombinant (SHINGRIX) 50 MCG/0.5ML Recon Susp
- MELATONIN PO
- aluminum chloride 20 % SOLN
- Cyanocobalamin 1000 MCG TABS
- aspirin 325 MG TABS
- Naproxen Sodium (ALEVE) 220 MG TABS
- menthol-zinc oxide (CALMOSEPTINE) 0.44-20.625 % OINT
- MULTIVITAMINS PO CAPS

No current facility-administered medications for this visit.

Past Medical History:

Diagnosis	Date
Anxiety	
Atrial premature depolarization	
BPH (benign prostatic hyperplasia)	
Chickenpox	
Chronic kidney disease	
Depression	
Dyspnea	
Dysrhythmia *pvcs*	
GERD (gastroesophageal reflux disease)	
Hiatal hernia	
Internal hemorrhoids with other complication	9/30/2013
Irritable bowel syndrome	
Neurological disorder *mild cognitive impairment*	
Obesity	
Palpitations	11/29/2005
Pruritus genitalia	7/2/2013
Reactive airway disease	
Restless leg syndrome	
Seborrheic dermatitis	9/20/2012
Sleep apnea *central sleep apnea*	
Supraventricular tachycardia (CMS-HCC)	
Tinnitus *Onset Date: 20080616 20080616 - Comment only - CHRISTOPHER WELLINS Probably due to high frequency hearing loss. No significant balance issues to suggest Ménière's. Plan: Refer to Northeast hear**	6/16/2008
Ulnar nerve entrapment at elbow, left	5/19/2015
Ventricular premature depolarization	

Review of Symptoms:
Denies change in health status this year.

Results/Data:
Sleep study:
Diagnostic polysomnography 5/6/19 - Moderate to severe sleep related breathing disorder, AHI 28.4 with severe positional response, AHI non-supine 6.5, supine 54.7.
Obstructive index 2.0, central index 5.7, mixed index 15.3.
Mild oxygen desaturations during sleep. Increased limb movement activity. Moderately disrupted sleep architecture. Snoring is moderate.

Other comments: The patient had a prolonged sleep latency and extended periods of wakefulness after arousals that resulted in reduce sleep efficiency.

Prior therapeutic study with CPAP resulted in treatment emergent central sleep apnea, which prompted follow-up therapeutic polysomnography.
Study 12/9/19 - BPAP remained ineffective in treatment of sleep-disordered breathing due to continued treatment emergent central sleep apnea. Adequate control achieved with ASV therapy.

Oximetry: NA

Labs:
Echocardiogram 12/28/2018 concluded:
1. Normal left ventricular size, with normal wall thickness. Normal global systolic function with ejection fraction calculated at
60% by biplane Simpson method. Indeterminate diastolic function.
2. Normal right ventricular size, with normal systolic function. Systolic pressure unable to be estimated.
3. Aortic sclerosis without significant stenosis.
4. Borderline dilated proximal ascending aorta at 4.3 cm, indexed to 1.8 cm/m². Aortic root dilated at 3.9 cm.showed

Assessment:

1. **Complex sleep apnea syndrome**
2. Paroxysmal atrial fibrillation (CMS-HCC)
3. Stage 3 chronic kidney disease, unspecified whether stage 3a or 3b CKD
4. Overweight (BMI 25.0-29.9)

Severe complex sleep apnea remains untreated at patient's request.

Plan:
Advised I'm not aware of any treatment for severe complex sleep apnea other than PAP therapy that will meet the state's requirements to continue driving.
Discussed state license requirements in regards to sleep apnea in detail. Advised where he can find these requirements on state web site. Patient reports he will take the state to court if needed.
Patient is aware I will not be completing BMV form to renew license. Advised even though he may not feel tired he is still at higher risk for accidents based on his diagnosis.
Discussed potential medical complications of untreated severe complex sleep apnea including cardiac disease, stroke, cognitive changes, mood disorder, kidney disease. Patient states he understands the risk.
Advised I'll let his primary doctor know of his decision.
Advised to follow up as needed.

Patient expressed verbal understanding with the plan, all questions answered.
I spent a total of 17 minutes with patient in telephone conversation, providing counseling, recommendations and discussion about sleep apnea.

Carri Nix Kivela, MS, NP-C
Family Nurse Practitioner
MMP Otolaryngology/Maine Sleep Institute
Memorial Sleep Center
P: (207) 661-4740

KenCapron1

From: "KenCapron1" <kcapron1@maine.rr.com>
Date: Wednesday, March 17, 2021 1:54 AM
To: "Fickett, Thea" <Thea.Fickett@maine.gov>
Subject: Re: Request to reconsider suspension due to sleep disorder

Dear Thea, thank you your efforts. Nothing here is as simple as it seems. There are several questions – general and specific – that need answers.

1. Someone needs to explain what objective is to be achieved in this effort. The information from the doctors seems to be pointing to a concern for their patient's health – not their driving risks. There are no serious in-depth studies that affirm that driving risk is reduced by any form of PAP therapy. In fact most literature makes it clear – there are no guarantees. We can discuss what therapy to use, CPAP or ASV, forever, but that is about healing the patient and not about preventing accidents. As the reviewer indicated, all I need to do is sleep on my side and I pass – with or without The Mask.
2. If your objective is to reduce risk of driving, are you limiting this to zero tolerance? The best therapy anyone can offer is an educated guess. And that still has only a 50-50 chance of being right. The best indicator of sleepiness is the Epworth Scale. But that is still crude. The Epworth is flawed in that it does not suggest whether the answers relate to accidentally falling asleep or intentionally. Its one thing to doze off as a passenger on a long trip, except that whether it happens in the middle of a good conversation or as the result of a decision to get a few winks on the way to the conference. In one of those situations, I will close my eyes and intentionally allow myself to sleep, while in the other, I will not fall sleep in the middle of a stimulating converstion. The Epworth doesn't distinguish. And that's a flaw. If the Epworth asked "Do you ever fall asleep unintentionally while riding as a passenger on a long ride?" vs "Do you take intentional naps as a passenger on a long ride?"
3. I think every source I have read, including the reviewer's comment, repeat your own literature "It is important to recognize that excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea." So someone is grasping for straws here. The only value of PAP therapy is in some case it gives someone a sense of having slept better. So are you trying to treat me medically or do your want something that provides greater reassurance of not dozing off while driving. There-in lies a class of products worn over the ear or elsewhere which buzz loudly if the drivers chin drops. Isn't an active device better than a guestimate?
4. The reviewer's article abstract states "Other treatment options include supplemental oxygen, and pharmacologic therapy". I have said from day one, I primarily submitted m self for PSG testing because I have been asking to try oxygen for years. And yet none of the PSGs included evaluation of O2 assistance. I will gladly try that option. The pharm approach includes melatonin for sleep and no-doze when wakefulness is needed for driving. Of course, since I drink a lot of Pepsi, no-doze would be redundant. (And for the record, I don't drink 2L Pepsi because of my apnea. I drink it to resolve my dry mouth brought on by my medications. Nothing else works. The reviewer made assumptions when he should not have.
5. Other medical conditions: I cannot use a nerve stimulator because I have a serious and complex set of irregularities in my heart rhythm at times. An oral apparatus is irrelevant since obstructive is not the primary issue.
6. Look at the cases:
    1. Result – AHI decreased to 23/hr so it fails your standards
    2. Result – AHI of 17.4/hr at best and still intolerant = fails your parameters
7. The greatest impact of apnea is a reduction in oxygenation. The O2 deprivation affects the entire body and may leave the person tired. None of these medical professionals even mention the O2 correlation. But that is what is most beneficial IMHO. A health SaO2 is 95%. Values under 90% are considered low. TECSA Article:
    - "Oxygen therapy had been proven to reduce CAI"
    - "The study demonstrated that home oxygen therapy significantly reduced AHI"
    - "New generation sleep position devices may be efficacious as salvage therapy for patients with CSA who are intolerant to PAP therapy"

And so on ...

I am willing to pursue home oxygen therapy, and possibly retest with PSG using O2 therapy and positional adjustment if ENT will go along with that. Otherwise, I will have to challenge the standards you set since no number of events assures any correlation between driver safety and PAP therapy. But I do need to point out that events are totally irrelevant - excessive daytime

sleepiness and crash risk may not correlate with the severity of the sleep apnea. So no therapy options really matter. The ONLY option would be a device triggered by chin drop while driving.

All the rest is targeted to treatment and not driver wakefulness. There is nothing that reliably assures against EDS.
Let's talk after you read this and if you agree I will arrange oxygen and prop myself up on one side or the other – anything to avoid supine.

Ken Capron

From: Fickett, Thea
Sent: Monday, March 15, 2021 11:24 AM
To: KenCapron1
Subject: RE: Request to reconsider suspension due to sleep disorder

Dear Mr. Capron,
Below is the response from our Medical Advisory Board member who reviewed your case. Attached is the article he referenced.
I hope this is helpful. Thea

> I have reviewed the polysomnography data and information provided by the BMV regarding this patient.
>
> In summary, the patient had evidence of primarily obstructive sleep apnea on his initial sleep study with an AHI of 28 events per hour. There were central sleep apnea present at 5 events per hour. However even if you remove the central events he has moderate sleep apnea with an AHI of 23 events per hour. Of note his sleep apnea is very positional with the majority of his events occurring while supine. I do not have any clinical information to determine if his central events are related to other medical conditions such as congestive heart failure, prior stroke/neurologic condition, or the use of respiratory depressants such as narcotics. In addition, we don't have any recent clinical data such as an Epworth score to assess his sleepiness.
>
> Patient had two therapeutic polysomnography studies, initially with CPAP and then the second with ASV. He was noted to have treatment emergent central sleep apnea in both studies. When reviewing the studies, it appeared that his AHI was lower with less central events on CPAP. ASV did not resolve his treatment emergent sleep apnea and his obstructive events appeared higher during that titration study.
>
> Treatment emergent central sleep apneas is well described upon initiation of Pap therapy. It is often managed expectantly with the majority of events improving within 3 to 4 months of Pap therapy. I do not see evidence of the patient using PAP therapy after his therapeutic sleep studies with SmartCard download that demonstrated persistent central events. I also do not see evidence of use of non-Pap therapy treatments for sleep apnea such as an oral appliance or surgical options, both of which may be appropriate given the positional nature of his sleep apnea.
>
> I have attached a timely article from Chest this month detailing an approach to treatment emergent central sleep apnea.
>
> Finally, I acknowledge the diligence and effort he has put into the behavioral changes to make himself safe to drive. I also appreciate that he does not have any record of accidents or incidents related to hypersomnia while driving. Though, I am concerned that he requires 2 L of Pepsi plus coffee to deal with his symptoms. Unfortunately, given the severity of his obstructive sleep apnea on his diagnostic polysomnography, based on current BMV FAP guidelines he needs to undergo treatment unless he can demonstrate an AHI < 15 on repeat PSG testing.
>
> Impression:
> Patient has moderate obstructive sleep apnea with treatment emergent central sleep apnea. This is under the assumption that the patient has no other potential causes of central sleep apnea. Based on her FAP requirements this degree of sleep apnea requires treatment beyond behavioral/lifestyle changes.
>
> Recommendations:

1. Would work with his sleep provider to initiate Pap therapy
- There is a good chance (> 50%) that his central sleep apnea will gradually improve with consistent CPAP use
- However, if he continues to have an elevated AHI related primarily to central events that is > 15 events, then I would be comfortable renewing his license **if** he demonstrates compliance with PAP > 70% and Epworth score 8 or less. The reason for this recommendation is that central sleep apnea is not clearly addressed in the current FAP version and CSA contribution to fatigue and hypersomnia is less clear than obstructive sleep apnea

2. If the patient does not want to pursue PAP therapy then could consider referral for an oral appliance or ENT evaluation.
- Would need repeat PSG after treatment demonstrating an AHI < 15

3. He can also consider a repeat PSG in which he attempts to sleep primarily on his side/prone.
- His AHI in the non-supine position was 6 events/hour well below the threshold needed to avoid OSA treatment if he does not have excessive hypersomnia.

4. It would be reasonable to renew his license for 4 to 6 months as he pursues these treatment/diagnostic options if he is willing to work with his sleep provider.

Please let me know if there are any questions.

Thea Fickett, Medical Review Coordinator
Bureau of Motor Vehicles
Tel: 207-624-9000, ext. 52124
Fax: 207-624-9319

From: KenCapron1 <kcapron1@maine.rr.com>
Sent: Monday, March 08, 2021 3:40 PM
To: Fickett, Thea <Thea.Fickett@maine.gov>
Subject: Request to reconsider suspension due to sleep disorder
Importance: High

Thea Fickett
Medical Review Coordinator
Bureau of Motor Vehicles - SHS 29
Augusta, Maine 04333-0029

Attached are my letter to you, Thea, and 3 PSGs and 1 contemporary article about Fatigue Management Programs in the trucking industry.

Thank you for your courteousness,

Kenneth A. Capron, ret. CPA, MCSE
1375 Forest Avenue D-11
Portland, Maine 04103
Phone: 207-797-7891
Email: kcapron1@maine.rr.com

APPENDIX

BIBLIOGRAPHY
(References are included for information only, and are not a part of rules.)

OBSTRUCTIVE SLEEP APNEA

[A]*Vorona RD, Ware JC: Sleep disordered breathing and driving risk. Curr Opin Pulm Med 2002; 8: 506-510*

[B]*Tregear,S Reston J, Phillips B: Continuous positive airway pressure reduces risk of motor vehicle crash among drivers with obstructive sleep apnea: systematic review and meta-analysis. Sleep, 2010; 33(10): 1373-1380.*

[C]*Weaver TE, Mancini C, Maislin G, Cater J, Staley B, Landis JR, Ferguson KA, George CF, Schulman DA, Greenberg H, Rapoport DM, Walsleben JA, Continuous positive airway pressure treatment of sleepy patients with milder obstructive sleep apnea: results of the CPAP Apnea Trial North American Program (CATNAP) randomized clinical trial. AM J Resp Critical Care Med, 2012 Oct 1;186(7):677-83.*

[D]*George CF: Reduction in motor vehicle collisions following treatment of sleep apnea with nasal CPAP. Thorax 2001; 56:508-512*

[E]*Sassani A, Findley LJ, Kryger M, et al: Reducing motor vehicle collisions, costs, and fatalities by treating obstructive sleep apnea. Sleep, 2004; 27(3): 453-458.*

[F]*Kribbs NB, NB, Pack AI, Kline LR, et al: Effects of one night without nasal CPAP treatment on sleep and sleepiness in patients with obstructive sleep apnea. AM Rev Respir Dis, 1993; 147-:1162-1168*

[G]*Malhotra, Atul. Hypoglossal-nerve stimulation for obstructive sleep apnea. N Engl J Med, 2014 Jan 9; 370(2):170-1.*

[H]*Johns MW: Sleepiness in different situations measured by the Epworth Sleepiness Scale. Sleep 1994; 17(8):703-710.*

[I]*Centers for Medicare and Medicaid Services, Medicare Learning Network, MLN Matters, SE1238, p.6*
http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1238.pdf

STATUTORY AUTHORITY: 29-A M.R.S.A. §§ 153, 1258

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December 31, 2016 – filing 2016-080