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Master Manual

The information provided in this manual is meant to provide a thorough overview of the processes and procedures utilized in the sleep services we provide to our patients. It is our goal to deliver outstanding, consistent practices at each of the SleepSafe Driver (SSD) partner site locations.

Communication

As a reminder, SSD has multiple contracts with fleets. We ask that you respect those contracts and not contact our fleets directly. All communication is to go through SleepSafe Drivers. SSD is contracted with the fleet and you (the partner site) are contracted with SSD. We will facilitate all communication with our contracted fleets. When in doubt, please call SSD at 855.723.3378 x1.

Primary Contact Information

SleepSafe Drivers Inc. office is located at 11300 Strang Line Rd Lenexa, KS 66215

Main phone number: 855.723.3378

Main fax number: 855.723.3377

Hours: 8:00am - 5:00pm (Central Standard Time) Monday – Friday

All drivers/patients are to be given the following number to contact SleepSafe Drivers. 855.723.3378 (CST)

Shawn Knight – Compliance Coordinator

Shelley Hecht – Compliance Coordinator

Chris Cox – Compliance Coordinator

855.723.3378 x2

Referral Coordinator

855.723.3378 x1

Director Clinical Services & Compliance

855.723.3378

Tony Cruise – Director Customer Service

855.723.3378 x6

SSD PROCESSES DEFINED

Types of Referred Patients

Based on the individual SSD contracts, there are various types of drivers/patients that will be seen. Some contracts are insurance based which involves collecting from the driver's privately or their individual insurance. Other contracts are benefit based in which the driver's employer is billed for the services provided to the driver.

NOTE: Drivers are never to be billed by the partner site. The partner site is only to bill SleepSafe Drivers via the FEE Ticket for services rendered to the driver/patient.

The DOT examiner may also refer a driver to be tested. This type of referral is MANDATORY for the driver to be tested.

Referrals

The referral is faxed to the sleep center when 2 or more objective sleep apnea screening criteria, as defined by the Fleet's sleep policy are met. SleepSafe Drivers Referral Coordinator contacts the driver, reviews the program and selects the best location for the driver to be tested.

SleepSafe Drivers Referral Coordinator faxes the referral form to the Sleep Center partner site where the Sleep Specialist is licensed in the state where services have been requested and the location designated as the driver's choice for sleep services.

Partner site contacts the driver within 24-48 hours of receiving the referral. Partner site schedules patient for pre consult or HST according to physician protocols.

NOTE: If 3 attempts are made to contact the driver within 72 hours with no response; please email the SSD Intake Coordinator to let them know. They will then assist you with making contact with the driver.

Physician Consults

Physician consults are allowed and paid for both pre and post sleep testing. Physician consults may be obtained face to face or by telephone. Physician notes from the consult must be included when billing for the consult.

The sleep specialist physician that works with the SSD partner site becomes BOTH the ordering and interpreting physician. That is, the sleep specialist orders the actual sleep study; interprets the results of the sleep study; makes recommendations and orders appropriate therapy based on the results of the sleep study.

Pre Consult

The Sleep Specialist reviews the referral, and completes a thorough History and Physical and makes a determination for sleep testing based on specific driver criteria as to medical necessity and acceptance criteria for Home Sleep Testing (HST) or Attended Complex Polysomnogram (PSG) and/or initial sleep consultation services as required.

**** Note: Documentation (physician notes) from pre and post consults must be included with the Fee Ticket in order to receive payment. ****

HST or Inlab Sleep Studies

All referrals for sleep studies sent to the partner site location are to be considered referrals for HST- Home Sleep Testing. The physician will determine if HST is appropriate for Sleep testing or if an Inlab sleep study is necessary. HST testing must be conducted face to face—no HST devices are to be mailed by the sleep lab or physician. All inlab testing requires preauthorization through SSD.

Medical Necessity Parameters:

Home Sleep Testing shall be performed with Type III testing devices.

Type III Testing Device defined:

A minimum of 4 parameters, including ventilation or airflow (at least 2 channels of respiratory movement or respiratory movement and airflow), heart rate, ECG and oxygen saturation. Any brand name Type III device is acceptable for use EXCEPT FOR WatchPat and Ares-Watermark.

Pre-Authorization for Inlab Studies is REQUIRED

If the physician has determined that an Inlab sleep test is necessary, the following must occur. An email to the SSD Clinical Director is required requesting the Inlab sleep test and the RATIONALE for ordering the Inlab sleep test. Are there comorbid factors? Etc. Once received, the Clinical Director will email a response and approval for the Inlab sleep study. This will provide documentation showing that prior approval was obtained.

A phone call to the Clinical Director is also acceptable but email is preferred to provide documentation for the sleep study approval. Email Chris Cox at chrisc@sleepsafedivers.com.

NOTE: Prior approval for the Inlab study must be obtained in order to be paid for this service. NO Exceptions.

Positive Home Sleep Study Results

If an HST sleep study result is positive for Obstructed Sleep Apnea (OSA), the driver is then set up with an APAP device the same day. The physician will write the order for the therapy, device and parameter. SSD prefers that the initial order, if the physician agrees, to be set at 5cmH₂O to 20cmH₂O. The low parameter to be determined by the physician based on the driver's expected tidal volumes based on height and weight. If necessary, a set pressure can also be programmed to the device.

For HST positive sleep results, the SSD expectation is that the sleep study must be scored and if positive, the driver should be setup and instructed with an APAP device within 4-6 hours. (Before driver leaves to go home).

Most partner site locations will have their physician write a standing order for this population. The order will typically include an order for AutoCPAP set 5cmH₂O to 20cmH₂O. It is the responsibility of the partner site to renew or update this standing physician order per internal protocols.

Negative Home Sleep Study Results

If an HST sleep study result is negative, the following must be determined:

If the sleep study is negative but there was a high pre-test probability for OSA, an Inlab sleep study must then be completed. Pre Authorization for the Inlab study is required. Based on the results of the Inlab sleep study the interpreting physician's recommendations are then followed.

If the sleep study is negative and there is NOT a high pre-test probability for OSA, then the driver is considered negative and no sleep restrictions are necessary provided that concurs with the physician's recommendations.

NOTE: A tech should NEVER discuss a negative or positive result with the driver. The physician must determine if the sleep test is negative. The tech will let the driver know that the physician must first review the study before the result will be known. NO OTHER INFORMATION IS TO BE GIVEN TO THE DRIVER.

NOTE: All sleep reports must be reviewed and signed by the interpreting physician before they are faxed to SSD.

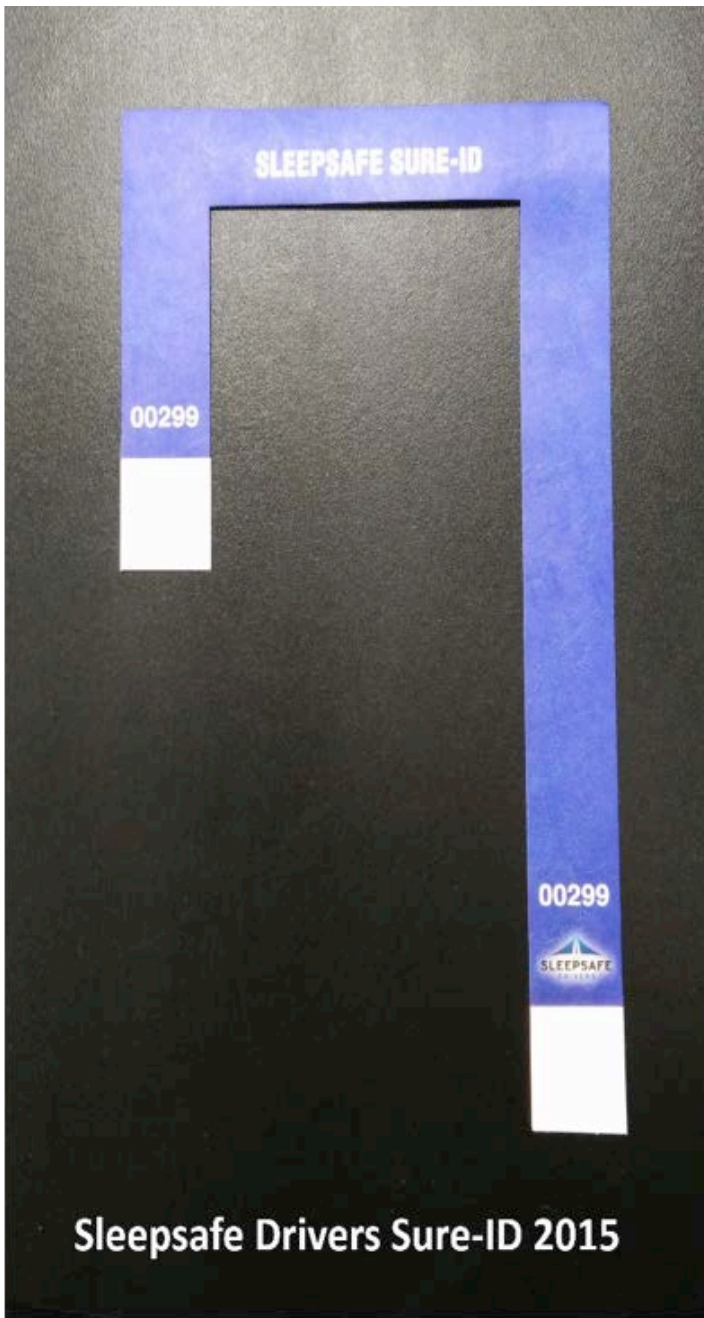
Chain of Custody

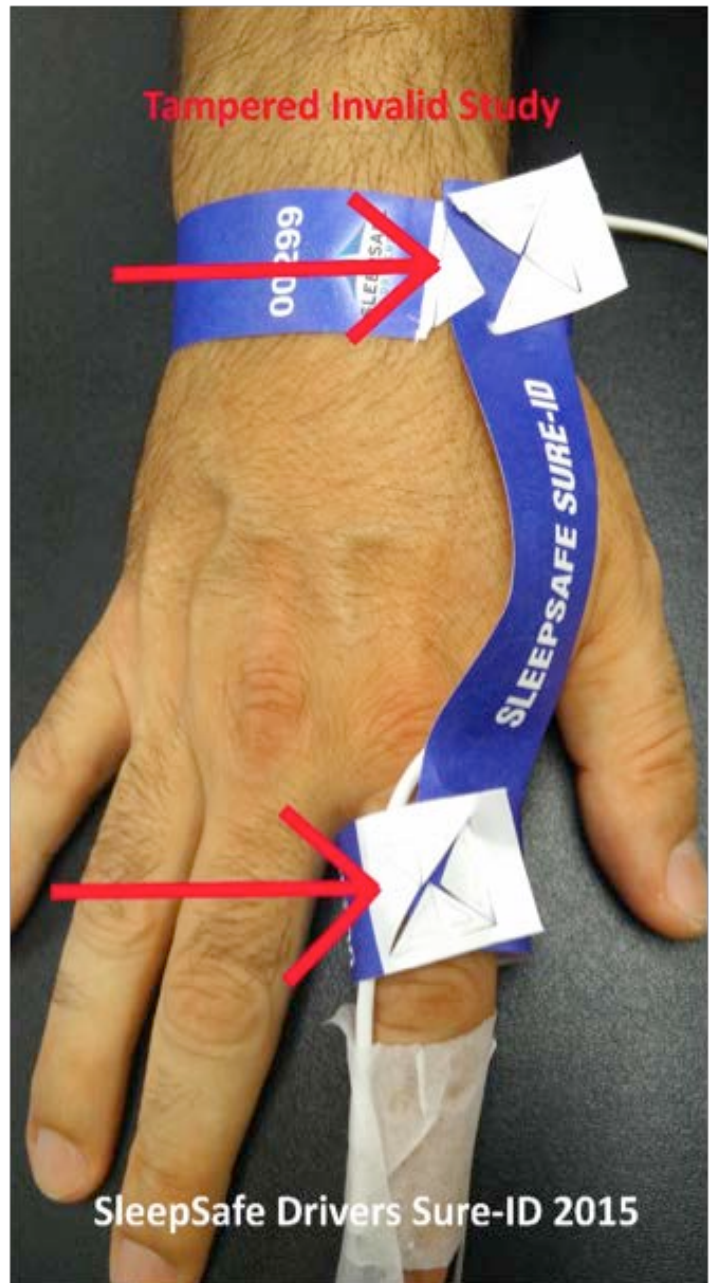
SleepSafe Drivers has a proprietary and patented "Sure-ID" testing process that helps to lessen the possibility of test fraud and specifically manages chain of custody issues. This process involves visual verification of identification of the driver/patient both for setup and return of the home testing device as well as application of a patented identity band which is attached by the therapist. This identity band will show obvious signs of tampering if it is removed or altered.

****If the Sure ID band is tampered with in any way or removed the sleep study is deemed invalid. ****

- **Check the patient's CDL or regular driver's license to positively confirm identity, documenting that on the same page as photocopy of driver's license, along with the two SleepSafe Sure-ID™ bands serial numbers (located on the finger and wrist) and the date, which the patient reviews and initials as being accurate.**
- Attach the oximetry cable to the user's fingertip; configure the SleepSafe Sure-ID™ band in which the smaller identification band will fit around a patient's finger, a larger one to fit around a patient's wrist.
- The "Bridge Band" connects the finger band to the wrist band and insures that the finger band cannot be removed or slipped off over the knuckle.
- Place the oximetry cable up the finger and wrist. Then secure the cable by removing the adhesive strip on the SleepSafe Sure-ID™ band and placing the sticky surface over the cable. Do the same procedure for the wrist. (See photos on the following pages)
- If SleepSafe Sure-ID™ comes back tampered/invalid (See photo #4 below), please contact Sleepsafe Drivers for approval of inlab study. DO NOT REPEAT HST.

If you need more Sure ID bands email Tony Cruise. tonyc@sleepsafedivers.com





Criteria for Home Sleep Test Procedure

The following criteria must be met in order for the Driver to be accepted for Home Sleep Testing:

- Meets medical necessity requirements for Home Sleep Testing.
- Driver elects to have a Home Sleep Test.

A Valid Home Sleep Test order has been received and signed by a sleep specialist.

The ordering sleep specialist will be notified of the scheduled study date to ensure that interpretation of the study occurs within 4-6 hours of completion of the sleep study OR the standing physician order will be followed.

Medical Necessity Requirements for Home Sleep Testing:

To confirm a diagnosis of obstructive sleep apnea in individuals with a high pre-test probability of moderate to severe obstructive sleep apnea based on the presence of two or more of the following criteria:

- Habitual snoring
- Epworth Sleepiness Scale-score greater than 10
- Obesity (BMI > 30)
- Neck size:
 - 17 inches for males
 - 15.5 inches for females
- Witnessed apnea
- Past medical history
- Hypertension
- Obesity
- Type II diabetes
- Hypothyroidism
- Congestive Heart Failure (CHF)
- Chronic Obstructive Pulmonary Disease (COPD)
- Neuromuscular Disease
- Suspicion of other sleep disorder e.g. narcolepsy, central sleep apnea, cardiovascular disease, cerebral vascular disease (stroke), and periodic limb movement disorder.

Note: A physician standing order for Home Sleep Testing and subsequent treatment may also be kept on file within the sleep center. This order must be signed by a board certified sleep specialist and updated and signed on an annual basis.

Diagnosis:

If obstructive sleep apnea is diagnosed, according to the clinical guidelines, the treating sleep specialist will prescribe auto-PAP (APAP) including remote compliance tracking with heated humidification.

Set up:

The driver will be set up with APAP therapy including remote compliance tracking by a Respiratory Therapist or Registered Polysomnographic Technologist based on individual state licensure requirements. The APAP setup will occur as defined by state medical practice regulations based on the receipt of a valid order for therapy, signed by the attending sleep specialist.

Prescription:

Based on medical necessity, the Driver will receive a prescription for PAP therapy and PAP device from the sleep specialist. A signed physician prescription for APAP therapy must be faxed to SSD.

Changes in Therapy:

Any adjustments to therapy will be provided by SleepSafe Drivers providers as directed by the sleep specialist. The sleep lab or physician's office will fax a signed order to SSD for any changes. **ALL changes are to be done by SSD and NOT by the physician or sleep lab staff.** Compliance will be monitored initially according to the Employer contract to show compliance and allow for acclimation before being allowed back on the road and then monitored daily going forward.

The driver will take compliance data to the Department of Transportation (DOT) examiner to determine fitness for duty and sign off. SSD will supply compliance data to the driver and/or directly to the DOT examiner as predetermined by the driver and the DOT examiner once all Release of Medical Records and consents have been signed and received by SSD. Compliance data is also given to the driver's employer per the contracted agreement with SSD. **Absolutely no data downloads on any SSD patient are to be done by the physician or sleep lab staff. All data downloads are to be done ONLY by SSD staff members. NO EXCEPTIONS!!**

Treatment of Obstructive Sleep Apnea

The treatment of OSA is considered medically necessary for individuals who meet either of the following criteria for diagnostic testing:

- **Apnea Hypopnea Index (AHI)** greater than or equal to 15 events per hour.
- AHI greater than or equal to 5, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
 - Excessive daytime sleepiness, as documented by either a score of greater than 10 on the Epworth Sleepiness Scale or inappropriate daytime napping (ex: while driving, during conversation or while eating) or sleepiness that interferes with daily activities.
 - Impaired cognition or mood disorders
 - Hypertension
 - Ischemic heart disease or history of stroke
 - Cardiac arrhythmias
 - Pulmonary hypertension
 - Hypothyroidism
 - Diabetes

Note: AHI is equal to the average number of episodes of apneas and hypopneas per hour and must be based on a minimum of two hours of recorded sleep time. The AHI may not be extrapolated or projected.

CPAP for the treatment of OSA is considered medically necessary when the following criteria are met:

- There is a documented diagnosis of OSA
- Polysomnography demonstrates an apnea index or apnea- hypopnea index equal to or greater than 1.

Auto-CPAP (APAP) is considered medically necessary:

- when used as an alternative to technician titrated CPAP
- documented moderate to severe OSA, AHI greater than or equal to 15 without significant comorbidities such as CHF, COPD, central sleep apnea and hypoventilation syndrome or AHI greater than or equal to 5-15 with significant comorbidities present.

Auto-CPAP (APAP) is considered medically necessary as a second or third line alternative therapy for OSA when documentation of the following is available:

- The level of fixed CPAP required is at least 10 cm H₂O as evidenced by an in-laboratory, technician attended CPAP titration during polysomnography; AND
- The individual is intolerant of fixed high CPAP pressures greater than 10 cmH₂O despite appropriate education and interventions to improve comfort and compliance.

The use of Auto-CPAP is considered NOT medically necessary:

- When the above criteria are not met.
- The use of Auto-CPAP (APAP) as an alternative to technician –titrated CPAP to determine a fixed level of CPAP is considered NOT medically necessary if the individual does not snore (naturally or resulting from palate surgery) or when the conditions indicated above for the use of APAP to determine a fixed level of CPAP are not met.
- For the treatment of individuals with the following conditions
 - Central apnea
 - Congestive heart failure
 - Lung disease (COPD)
 - Nocturnal oxygen desaturation due conditions other than OSA
 - OSA in the absence of snoring (natural or resulting from palate surgery).
>> In these cases, APAP devices rely on vibration or sound and the device's algorithm should not be used.

Failed CPAP is defined as any of the following criteria documented in the medical record:

- Claustrophobia
- Inability to breathe through the nose
- Pain or discomfort
- User intolerance
 - Individuals at higher pressures of CPAP (greater than 10 cm H₂O) complaining of pressure discomfort.

Attended Complex Polysomnogram Procedures — Inlab Testing Procedures

A driver that is not a candidate for Home Sleep Testing will be scheduled for a comprehensive evaluation with the sleep specialist prior to the initiation of any testing OR will be scheduled for an In-Lab PSG as ordered by the sleep specialist.

Drivers who meet the criteria for an In-Lab PSG will be followed and managed by the ordering sleep specialist. All clinical and professional services will be followed according to the direction of the ordering sleep specialist in accordance with the standard practice parameters by the American Academy of Sleep Medicine (AASM) for Accredited Sleep Centers and based on accepted medical necessity guidelines.

Medical Necessity Requirements for Supervised Type I Polysomnography (PSG)

- PSG for ADULTS is considered medically necessary in the diagnosis of the following conditions:
- Sleep-related breathing disorders such as obstructive sleep apnea, upper airway resistance syndrome.
- Narcolepsy or idiopathic hypersomnia (performed in conjunction with a multiple sleep latency test).
- Sleep-related violent or injurious behavior such as: REM Behavior Disorder or suspected nocturnal seizures.

- Periodic Limb Movement Disorder
- Witnessed apnea during sleep greater than 10 seconds in duration OR any of two or more of the following symptoms of sleep apnea:
 - Excessive Daytime Sleepiness (EDS) as evidenced by inappropriate daytime napping (ex: while driving, during conversation or when eating);sleepiness that interferes with daily activities not explained by other conditions (ex: poor sleep hygiene, medications, drug or alcohol use psychiatric or psychological disorders or Epworth Sleepiness Scale with a score greater than 10.
 - Persistent or frequent disruptive snoring, choking, or gasping episode associated with awakening.
 - Obesity (BMI > 30 kg/m²)
 - Unexplained hypertension
 - Craniofacial or upper airway soft tissue abnormalities
 - Symptoms suggestive of narcolepsy (EX: sleep paralysis, hypnagogic hallucinations, and cataplexy.
 - Violent or injurious behavior during sleep
 - Nocturnal oxygen desaturation with unexplained right heart failure, polycythemia, cardiac arrhythmias during sleep or pulmonary hypertension.
 - Unusual or Atypical parasomnias based on age, frequency or duration of behavior.
 - Individuals with a history of congestive heart failure, stroke/TIA, coronary artery disease, or significant tachycardic or bradycardic arrhythmias who have nocturnal symptoms suggestive of a sleep related breathing disorder or otherwise suspected of having sleep apnea.

Repeat PSG testing may be required under the following circumstances:

- To re-evaluate an individual with failure of resolution of symptoms or recurrence of symptoms during treatment;
- To evaluate the impact of uvulopalatopharyngoplasty (UPPP) or other surgeries for obstructive sleep apnea (OSA) after appropriate recovery from surgery;
- To re-evaluate the diagnosis of OSA and need for continued CPAP in a person previously diagnosed by PSG and currently using CPAP, if a significant weight loss has occurred since the initial study;
- Individuals with clinical symptoms suspicious for obstructive sleep apnea (OSA), where initiation of treatment is felt to be urgent.
- Follow-up after the diagnosis has already been established by standard polysomnography and therapy has been initiated. For example: to evaluate the need for continuing positive airway pressure (CPAP) therapy in the individual who it is thought may no longer require therapy as a result of other lifestyle modifications, including significant weight reduction.
- To evaluate the impact of weight loss after bariatric surgery

Multiple Sleep Latency Testing (MSLT)

Pre Authorization is REQUIRED.

Multiple Sleep Latency Testing (MSLT) is considered medically necessary for the evaluation of the following two conditions:

- Narcolepsy
- suspected idiopathic hypersomnia

MSLT is considered NOT medically necessary in the following conditions:

- When performed for routine diagnosis of obstructive sleep apnea
- For routine follow-up after treatment of sleep related disorders
- For evaluation of sleepiness in medical or neurological disorders (other than narcolepsy or idiopathic hypersomnia) including, but not limited to, insomnia, circadian rhythm disorders, and shift work sleep disorder (SWSD)
- Portable MSLT performed in the home setting

Maintenance of Wakefulness (MWT)

Pre Authorization is REQUIRED.

MWT tests the patient's ability to stay awake in circumstances which are normally difficult to stay awake. MWT's are sometimes ordered in conjunction with or in the place of MSLT. No standard method for this study has been documented and its reliability has not been established. Often used to test the severity of Narcolepsy because it tests the ability to stay awake versus falling asleep.

SSD PAPERWORK

- Documents that MUST be SIGNED by the Driver
- Authorization for Release of Medical Records
- Consent to Treatment
- Driver Responsibility Form- Privacy Notice-if setup completed.
- Fee Ticket

NOTE: If the driver refuses to sign any of these documents the sleep test or setup should NOT occur. Contact Chris Cox (855.723.3378 x110), Clinical Director immediately for direction.

ALL PAPERWORK should be faxed to SSD at 855.723.3377 immediately post setup.

The following are required SSD documents:

Authorization for Release of Medical Information

This document allows information to be released and shared with the necessary parties involved in the patient's care. The driver must sign this document.

Consent to Treatment and Privacy Practices

This document is consent from the patient for diagnostics testing, necessary treatment and follow up care. The driver must sign this document.

Driver SSD Compliance Contact Letter

This document is to be given to the driver upon set up of PAP device. It gives the driver SSD contact information so they are able to reach us for compliance, therapy needs, supplies or any issues that may arise.

Driver Responsibility Notice

This document is an acknowledgement by the driver of the diagnosis of OSA, of training and education on PAP device and masks. It is also an acknowledgement that they are aware and understand the usage requirements. The driver and tech must sign this document.

SSD Fee Ticket

This document is for the partner site to fill out and fax to SSD to receive payment for services from SSD. The driver and tech must sign this document.

Physician Consult Note

Both PRE and POST consults must have a physician note faxed to SSD in order to be paid. Physician consults billed that do not have a physician note will not be paid.

InLab Study Pre Authorization

Inlab Preauthorization is simply an email sent to chris@sleepsafedivers.com to request authorization. The email should include the patient's name and the REASON for the inlab. Physician notes are fine but not necessary for authorization. Once approved the partner site will receive an email back stating the inlab study is approved.

SSD Billing

Each month Tony Cruise will send the sleep lab a list of current payables. You will be able to review and correct at that time.

SSD Inventory

This document is completed quarterly by the partner site. This document is used to tally any existing SSD inventory at the end of each quarter. Tony Cruise will send each location a printout of their inventory each quarter. Partner sites just need to verify the counts that are shown and send back to tonyc@sleepsafedivers.com within 24 hours. This process must be completed in order for partner sites to be paid for their services.

SSD DME Replenishment

This document is used by the partner site to order any inventory or supplies that are needed for treating SSD patients. All supply orders should be emailed to tonyc@sleepsafedivers.com. It is the partner site's responsibility to maintain your SSD inventory levels. Supply orders will not be overnighted.

SSD Compliance Center

The SSD Compliance Center is the main contact for all drivers. The Compliance Center is staffed by credentialed respiratory therapists with expertise in Respiratory Care and Sleep Technology. The Compliance Center monitors the driver's compliance and therapy needs. They also provide all equipment and supply needs.

Once the driver is set up; the partner site will give the driver the Driver Compliance Contact Sheet and instruct the driver to contact SSD. This letter instructs the driver to call the Compliance Center so our clinicians can verify serial numbers and explain the compliance process to the driver.

Communication is imperative to the success of our compliance program. It is of the utmost importance that the drivers be given the Driver Compliance Contact Sheet so they know how to contact us. The number for the Compliance Center is 855.723.3378 x2.

Our clinicians are working with drivers and safety managers all over the country every day. If you or a driver happen to get voicemail when calling in, please leave your name and location, the driver's name and best number to call back.

Compliance is monitored daily and therapy needs are also assessed. If problems arise with therapy needs, the clinicians work with the driver to correct those issues. If troubleshooting therapy issues does not work, the clinicians will refer the driver back to the sleep specialist for further evaluation.

Once the driver is set up for compliance monitoring, the driver is monitored daily for minimum requirements but also encouraged by our clinicians to exceed the minimum requirement for optimum therapeutic outcomes.

The Compliance Center manages all data reporting to the contracted fleets.

Federal Motor Carrier Safety Administration (FMCSA)

Proposed Recommendations on Obstructive Sleep Apnea

Full recommendations can be found in the Federal Register/Vol.77, No. 77/Friday, April 20, 2012/Notices.

Background

49 CFR 391.41 (b)(5) provides that a person is qualified physically to drive a CMV if that person has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with the ability to control and drive a CMV safely.

Basis for Proposed Guidance on OSA

The existing advisory criteria or the Respiratory Dysfunction requirement (391.41 (b) (5) states that "There are many conditions that interfere with oxygen exchange and may result in incapacitation, including (among others) sleep apnea. If the medical examiner detects a respiratory dysfunction, that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver must be referred to a specialist for further evaluation and therapy." Currently, FMCSA relies on medical examiners to apply professional judgment in applying FMCSA's advisory criteria On OSA to determine whether a driver has a respiratory dysfunction such as OSA that may affect his or her ability to operate a CMV safely.

Proposed Recommendation

Minimally acceptable compliance with Positive Airway Pressure (PAP) treatment consists of at least 4 hours per day of use for 70 percent of days. Drivers should be made aware that more hours of PAP use is preferable and that optimal treatment efficacy occurs with 7 or more hours of daily use during sleep.

HIPAA BUSINESS ASSOCIATE AGREEMENT

This Agreement is made effective this _____, by and between _SleepSafe Drivers, Inc. with its principal place of business at 11300 Strang Line Rd Lenexa, Kansas 66215 ("Covered Entity"), ("Business Associate"), (individually, a "Party" and collectively, the "Parties").

WITNESSETH:

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, known as "the Administrative Simplification provisions," direct the Department of Health and Human Services to develop standards to protect the security, confidentiality and integrity of health information; and

WHEREAS, pursuant to the Administrative Simplification provisions, the Secretary of Health and Human Services has issued regulations modifying 45 CFR Parts 160 and 164 (the "HIPAA Security and Privacy Rule"); and

WHEREAS, covered health care providers must comply with Subpart D of 42 CFR Part 164 of the HIPAA Security and Privacy Rule related to the security standards for the protection of Electronic Protected Health Information (collectively, the "Security Regulations") no later than April 20, 2005 (the "Security Regulations Effective Date");

WHEREAS, the Parties wish to enter into or have entered into an arrangement whereby Business Associate will provide services ("Services") to Covered Entity, and, pursuant to such arrangement, Business Associate may be considered a "business associate" of Covered Entity as defined in the HIPAA Security and Privacy Rule; and

WHEREAS, Business Associate may have access to Protected Health Information (as defined below) in fulfilling its responsibilities under such arrangement;

THEREFORE, in consideration of the Parties' continuing obligations involved in the purchase and sales of Services, compliance with the HIPAA Security and Privacy Rule, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the provisions of this Agreement in order to address the requirements of the HIPAA Security and Privacy Rule and to protect the interests of both Parties.

I. DEFINITIONS

Except as otherwise defined herein, any and all capitalized terms in this Section shall have the definitions set forth in the HIPAA Security and Privacy Rule. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the HIPAA Security and Privacy Rule, as amended, the HIPAA Security and Privacy Rule shall control. Where provisions of this Agreement are different than those mandated in the HIPAA Security and Privacy Rule, but are nonetheless permitted by the HIPAA Security and Privacy Rule, the provisions of this Agreement shall control; provided, however, obligations hereunder deriving from the Security Regulations shall be applicable to the Parties as of the Security Regulations Effective Date.

The term "Protected Health Information" means individually identifiable health information including, without limitation, all information, data, documentation, and materials, including without limitation, demographic, medical and financial information, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. "Protected Health Information" includes without limitation "Electronic Protected Health Information" as defined below.

The term "Electronic Protected Health Information" means Protected Health Information which is transmitted by Electronic Media (as defined in the HIPAA Security and Privacy Rule) or maintained in Electronic Media.

Business Associate acknowledges and agrees that all Protected Health Information that is created or received by Covered Entity and disclosed or made available in any form, including paper record, oral communication, audio recording, and electronic display by Covered Entity or its operating units to Business Associate or is created or received by Business Associate on Covered Entity's behalf shall be subject to this Agreement.

II. CONFIDENTIALITY AND SECURITY REQUIREMENTS

(a) Business Associate agrees:

(i) to use or disclose any Protected Health Information solely: (1) for meeting its obligations as set forth in any agreements between the Parties evidencing their business relationship, or (2) as required by applicable law, rule or regulation, or by accrediting or credentialing organization to whom Covered Entity is required to disclose such information or as otherwise permitted under this Agreement or the HIPAA Security and Privacy Rule, and (3) as would be permitted by the HIPAA Security and Privacy Rule if such use or disclosure were made by Covered Entity;

(ii) at termination of this Agreement, or any other business relationship between the Parties, or upon request of Covered Entity, whichever occurs first, if feasible, Business Associate will return or destroy all Protected Health Information received from or created or received by Business Associate on behalf of Covered Entity that Business Associate still maintains in any form and retain no copies of such information, or if such return or destruction is not feasible, Business Associate will extend the protections of this Agreement to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information not feasible; and

(iii) to ensure that its agents, including a subcontractor, to whom it provides Protected Health Information received from or created by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply to Business Associate with respect to such information, and agrees to implement reasonable and appropriate safeguards to protect any of such information which is Electronic Protected Health Information. In addition, Business Associate agrees to take reasonable steps to ensure that its employees' actions or omissions do not cause Business Associate to breach the terms of this Agreement.

(b) Notwithstanding the prohibitions set forth in this Agreement, Business Associate may use and disclose Protected Health Information as follows:

(i) if necessary, for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that as to any such disclosure, the following requirements are met:

(A) the disclosure is required by law; or

(B) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached;

(ii) for data aggregation services, if to be provided by Business Associate for the health care operations of Covered Entity pursuant to any agreements between the Parties evidencing their business relationship. For purposes of this Agreement, data aggregation services means the combining of Protected Health Information by Business Associate with the protected health information received by Business Associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

(c) Business Associate will implement appropriate safeguards to prevent use or disclosure of Protected Health Information other than as permitted in this Agreement. Business Associate will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity as required by the HIPAA Security and Privacy Rule.

(d) The Secretary of Health and Human Services shall have the right to audit Business Associate's records and practices related to use and disclosure of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Security and Privacy Rule.

(e) Business Associate shall report to Covered Entity any use or disclosure of Protected Health Information which is not in compliance with the terms of this Agreement of which it becomes aware. Business Associate shall report to Covered Entity any Security Incident of which it becomes aware. For purposes of this Agreement, "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. In addition, Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.

(f) Covered Entity agrees:

i. That it is the sole responsibility of Covered Entity to ensure that appropriate mechanisms, as provided by Business Associate, are used to secure Protected Health Information while in transit from

Covered Entity to Business associate or from Business Associate to Covered Entity, including, without limitation, to utilize secure transport methods and not to utilize their account in such a way as to send or receive Protected Health Information via unencrypted email transport.

ii. That Business Associate will have no responsibility for any unauthorized use or disclosure of Protected Health Information that occurs while the information is in transit from Business Associate to Covered Entity or from Covered Entity to Business Associate.

iii. The obligations of Covered Entity under this Section '(f)' shall survive the expiration, termination, or cancellation of this Agreement, and/or the business relationship of the Parties, and shall continue to bind Covered Entity, its agents, employees, contractors, successors, and assigns as set forth herein.

III. AVAILABILITY OF PHI

Business Associate agrees to make available Protected Health Information to the extent and in the manner required by Section 164.524 of the HIPAA Security and Privacy Rule. Business Associate agrees to make Protected Health Information available for amendment and incorporate any amendments to Protected Health Information in accordance with the requirements of Section 164.526 of the HIPAA Security and Privacy Rule. In addition, Business Associate agrees to make Protected Health Information available for purposes of accounting of disclosures, as required by Section 164.528 of the HIPAA Security and Privacy Rule.

IV. TERMINATION

Notwithstanding anything in this Agreement to the contrary, either Party shall have the right to terminate this Agreement immediately if that Party determines that the other Party has violated any material term of this Agreement. If Party reasonably believes that the other Party will violate a material term of this Agreement and, where practicable, Party gives written notice to the other Party of such belief within a reasonable time after forming such belief, and the other Party fails to provide adequate written assurances to Party that it will not breach the cited term of this Agreement within a reasonable period of time given the specific circumstances, but in any event, before the threatened breach is to occur, then Party shall have the right to terminate this Agreement and any other agreement between the Parties immediately.

V. MISCELLANEOUS

Except as expressly stated herein or the HIPAA Security and Privacy Rule, the Parties to this Agreement do not intend to create any rights in any third parties. The obligations of Parties under this Section shall survive the expiration, termination, or cancellation of this Agreement, and/or the business relationship of the Parties, and shall continue to bind Parties, their agents, employees, contractors, successors, and assigns as set forth herein.

This Agreement may be amended or modified only in a writing signed by the Parties. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship.

This Agreement shall be governed by and construed in accordance with the laws of the State of Alabama, without regard to its conflict of law provisions, and the Parties hereby consent and attorn to the exclusive jurisdiction of such State and agree that all disputes shall be tried in the State of Alabama in the County of Madison.

No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

The Parties agree that, in the event that any documentation of the arrangement pursuant to which Business Associate provides services to Covered Entity contains provisions relating to the use or disclosure of Protected Health Information which are more restrictive than the provisions of this Agreement, the provisions of the more restrictive documentation will control. The provisions of this Agreement are intended to establish the minimum requirements regarding Business Associate's use and disclosure of Protected Health Information.

In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect. In addition, in the event a Party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of the HIPAA Security and Privacy Rule, such Party shall notify the other party in writing. For a period of up to thirty days, the Parties shall address in good faith such concern and amend the terms of this Agreement, if necessary to bring it into compliance. If, after such thirty-day period, the Agreement fails to comply with the HIPAA Security and Privacy Rule, then either Party has the right to terminate upon written notice to the other Party.

VI. LIMITATION OF LIABILITY

Neither party shall be liable to the other party for any incidental, consequential, special, or punitive damages of any kind or nature, whether such liability is asserted on the basis of contract, tort (including negligence or strict liability), or otherwise, even if the other party has been advised of the possibility of such loss or damages.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year first written above.

COVERED ENTITY:
SleepSafe Drivers, Inc.
11300 Strang Line Rd
Lenexa, KS 66215

BUSINESS ASSOCIATE:

By: _____

By: _____

Print Name: Adrian Knight
Title: Vice President of Operations

Print Name:
Title:

Frequently Asked Questions and Answers

What is the difference between Voluntary studies vs Mandatory studies?

Voluntary studies are when a driver volunteers to have a sleep study in accordance with their employers program.

Mandatory studies may be required of the employer or the DOT may refer a driver for testing. All DOT referrals are Mandatory for testing.

All drivers must bring a compliance report with them to their DOT exam. All downloads of data must be done through the Compliance Center. Sleep Labs and physician offices should not complete data downloads on any SSD drivers.

Who has initial contact with the driver/patient?

Ashley Kidd, SSD Referral Coordinator, makes the initial contact with the driver to verify demographic information and determine location for testing.

Partner sites are NEVER to bill the driver or their health plan directly. All billing is to SleepSafe Drivers for payment. DO NOT collect billing information for the drivers/patients.

Sometimes the referral comes without patient history filled in, can SSD obtain that information?

If it is readily available-yes. Most of the time this information is obtained through a pre consult with the physician where a comprehensive history and physical is obtained.

How do I get a pre authorization for inlab studies?

Email Chris Cox. chrisc@sleepsafedrivers.com. In the email include your name and location, the patient's name, and the reason for the inlab study. A return email with authorization will be sent to you.

What if an HST study is negative?

Let the driver know the physician will need to review the study and make recommendations. Please DO NOT tell the driver they are negative or positive as they may be required to return for an inlab study. Be sure physician concurs with negative diagnosis before any information is shared with the driver.

What if I can't get in touch with the driver? How long do we have to contact the driver?

Please attempt first contact with the driver within 24-48 hours and attempt to call the driver 3 times in 72 hours. If you do not receive a response, please contact Tony Cruise at tonyc@sleepsafedrivers.com. She will contact the safety manager to ask for their assistance in connecting with the driver.

Who follows the drivers/patients after setup?

The SSD Compliance Center follows all drivers/patients after setup. Drivers are followed for compliance and therapy on a daily basis. Any driver concerns, questions etc. are to be referred to the Compliance Center at 855.723.3378 x2. If trouble shooting an issue is not satisfactory then the driver will be referred back to the sleep physician.

What if the driver doesn't like a mask?

SSD provides 2 masks only. One full face mask and either a nasal mask or nasal pillows interface. If the masks we have provided for inventory are not good options, you may supply a mask from your inventory and email tonyc@sleepsafedrivers.com to let him know what mask type and size you provided from your own inventory and we will replace it. We will not pay for masks you supply from your own inventory, but we will replace the same mask back into your own inventory.

How do we get paid for services from SleepSafe Drivers?

A fee ticket is filled out for services provided to the driver/patient. Please fax the Fee Ticket to 855.723.3377.

We only want the Fee Ticket and any required documentation. We do not want an invoice from your location for billing.

Who do I contact if the driver is behaving inappropriately?

If a driver is acting inappropriately, feel free to ask that driver to leave the premises. Contact Chris Cox immediately. 855.723.3378 x110 (Central Standard Time) chrisc@sleepsafedrivers.com. We never want our partners to be in a threatening or dangerous situation – if absolutely necessary, call 911.

What are standing physician orders?

Most partner site locations will obtain a standing order from their physician for this population. Most physicians will write a standing order for AutoPAP 5cmH₂O-20cmH₂O. This helps to expedite setup upon a positive HST result.

What about turn-around time?

A quick turn-around time is essential. Many drivers are pulled from the road and not working while awaiting a sleep study result and treatment. We ask that HST's are scored and driver setup if positive within 4-6 hours after the driver returns the HST device. For Inlab studies, we understand that scoring and interpretations take a little longer. We ask to have completed interpretations within 48 hours.

Who do I order SSD inventory/supplies from?

Please fill out a DME Replenishment Form and email to tonyc@sleepsafedrivers.com.

Who do I ask about Compliance or Therapy Reports?

All compliance and Therapy reports come from the SSD Compliance Center. If your physician needs a copy, please call 855.723.3378 x2 or email: shawnk@sleepsafedrivers.com; shelleyh@sleepsafedrivers.com or chrisc@sleepsafedrivers.com.

UNDER NO CIRCUMSTANCES IS THE PARTNER SITE OR DISTRIBUTION CENTER TO PROVIDE COMPLIANCE DOWNLOADS TO OUR DRIVERS. Refer all drivers to the Compliance Center.

Who do I contact with clinical questions?

Chris Cox 855.723.3378 x110 (Central Standard Time) chrisc@sleepsafedrivers.com.

Who do we contact with billing or payment questions?

Tony Cruise tonyc@sleepsafedrivers.com

When is the driver eligible for more supplies?

It depends on the contracted employer. Please have driver contact the **SSD Compliance Center 855.723.3378 x5** regarding all supplies.