

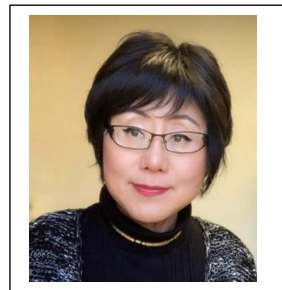
The Mobile Sleep Medicine-The Innovative Mobile Sleep Medicine Patient-Centered Care Model (Mobile Sleep Care Model) for OSA management from Hospital to Home.

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1. Executive Summary: Introducing Mobile Sleep Medicine: An Innovative Mobile Sleep Medicine Patient-Centered Care Model (Mobile Sleep Care Model) for OSA Management from Hospital to Home

The **Mobile Sleep Medicine Care Model (MSCM)** is an innovative, progressive, patient-centered, integrative, complete cycle, clinical outcome-based program that uses the **Mobile Sleep Unit (MSU)** as a methodological tool—a “sleep lab on wheels”—designed to improve access to OSA Sleep Care for 80% of Americans at all levels of care, from hospital to home. No OSA patient will be left behind.

The Problem: Protected sleep is an essential human right that is denied most Americans by the current healthcare model, which ignores the most significant health care threat: Obstructive Sleep Apnea (OSA).

OSA—the leading sleep-disruptive force—breaks down sleep protection and causes significant neurocognitive, cardio-vascular, and cerebro-vascular (CCV) impairments in humans. The timely treatment of OSA with PAP therapy protects human sleep, reduces cardio-cerebrovascular risks, and improves the quality of human life.

Currently, the majority (80%) of the general US population, especially hospitalized patients, do not have access to sleep medicine care despite the alarming statistics affirming the prevalence of OSA in the given vulnerable populations.

How can we protect patients’ sleep and deliver timely, much-needed OSA management to our patients in both inpatient and outpatient settings? The Mobile Sleep Medicine Care Model and Mobile Sleep Unit Methodology can solve this problem.

The Solution: The **Mobile Sleep Medicine Care Model (MSCM)** is an innovative, progressive, patient-centered, integrative, complete cycle, clinical outcome-based program that uses the **Mobile Sleep Unit (MSU)** as a methodological tool called a “sleep lab on wheels,” designed to improve the access to OSA Sleep Care for 80% of Americans at all Levels of Care, from Hospital to Home. No OSA patient will be left behind.

Components of Mobile Sleep Unit (MSU):

- **Module 1.** “**GOLD Standard**”: **Mobile Polysomnography (mPSG)**
- **Module 2.** “**SILVER Standard**”: **Portable Out-of-Center Sleep Testing (OCST)**
(NOX-T3, Embletta, Stardust, etc.)

- **Synonyms:**

- **(CP) Cardiopulmonary Studies**
- **HSAT (Home Sleep Ambulatory Testing)**
- **(OCST) = (CP) = HSAT**

- **Module 3.** **PAP titration unit: CPAP/BiPAP/AVAPS/ASV**

At minimal operational costs, any existing sleep technology company can manufacture a Mobile Sleep Medicine Unit, and all related sleep medicine equipment, devices, and supplies. There will be no need to build specially assigned sleep lab rooms inside the hospital. The Mobile Sleep Lab on Wheels (nicknamed “S.L.O.W. Mobile”) can be placed in any patient’s room without extra costs and logistical issues.

Why now?: Digital technology has given the world access to mobile, portable, digital robotic devices, and wireless communication systems that have advanced medical care to more personalized, precise models. Unfortunately, the Sleep Medicine field has not taken full

advantage of new mobile technologies to deliver patient-oriented Sleep Medicine care to patients with OSA. Instead of practicing 21st-century sleep medicine, we are practicing 20th-century sleep medicine restricted by 19th-century methodology. We must disrupt outdated practices and act now to build a strong foundation for the 22nd century of the Sleep Medicine field.

Let us unite and fight for protected sleep for all—an essential human right.

2. Situational/SWOT Analysis

In the US, 70% of adults report obtaining insufficient/“unprotected” sleep at least one night a month, and 11% report obtaining insufficient sleep every night. It is estimated that sleep-related problems affect **50-70 million Americans** of all ages and socioeconomic classes.

Protected, sufficient sleep is an essential human right denied most Americans by the current healthcare model, which ignores Obstructive Sleep Apnea (OSA), the most significant health care threat.

25 Million US adults suffer from OSA—the leading sleep-disruptive force that breaks down sleep protection and causes insufficient sleep, significant neurocognitive, cardio-vascular and cerebro-vascular (CCV) impairments in humans. The timely treatment of OSA with PAP therapy protects human sleep, reduces cardio-cerebro-vascular risks, and improves the quality of human life.

Currently, the majority (80%) of the general US population and about **36 million hospitalized patients** do not have access to sleep medicine care despite alarming statistics affirming the significant prevalence of OSA in the given vulnerable populations.

While the prevalence of OSA in an unselected adult population is generally estimated at about 5% (1-3), the prevalence of OSA in some medical and neurological populations is significantly elevated, ranging from 10.2% to 82% in epilepsy patients (4-6), from 50% to 94% in stroke and transient ischemic attack (TIA) (3, 7-12), from 11% to 82% in arterial hypertension (HTN) (13, 14), from 30% to 40% in acute coronary syndrome (ACS) and myocardial infarction (MI)(3,15), from 3% to 49% in Atrial fibrillation (16-19), from 10% to 43% in congestive heart

failure (CHF) (3, 20-22), 23% in traumatic brain injury (TBI) (23), from 21% to 38% in Multiple Sclerosis (MS) (24, 25), from 20% to 56% in Parkinson's Disease (PD) (26-31), 40% in Alzheimer's Dementia (32), from 11% to 36% in Neuromuscular conditions (33), and from 17% to 76% in ALS (34, 35).

Timely-delivered positive airway pressure therapy (PAP) appears to produce beneficial effects on patients with OSA in the general population (36, 37), ischemic stroke and TIA (38-40), Epilepsy (41-43), HTN (44-46), ACS/MI (47), Atrial fibrillation (48-50), CHF (51-53), TBI (23), Multiple Sclerosis (24), PD (54), Alzheimer's Dementia (32, 55-57), and Neuromuscular conditions (58, 59), ALS (59-62).

How can we protect patients' sleep and deliver timely, much-needed OSA management to our patients in both inpatient and outpatient settings? The **Mobile Sleep Care Model** and **Mobile Sleep Unit Methodology** can solve this problem.

The **Mobile Sleep Medicine Care Model (MSCM)** is an innovative, progressive, patient-centered, integrative, complete cycle, clinical-outcome-based program, which uses a Mobile Sleep Medicine Unit as a methodological tool—a “sleep lab on wheels”—designed to improve access to OSA Sleep Care for 80% of Americans at all levels of care, from hospital to home. No OSA patient will be left behind.

The SWOT analysis supports the need for the Mobile Sleep Medicine Care Model:

Strengths of MSCM:

- Patient-centered, innovative design supported by modern, well-established sleep medicine methodology
- Delivers mobile sleep care to vulnerable, high-risk CCV populations at any level of care
- Portable, mobile, gold standard, delivered in attended/unattended format in bedside hospital or outpatient settings
- Can be used in any pandemic (e.g., COVID-19, etc.) in combination with negative pressure rooms and viral diagnostic testing to minimize the risk of contamination
- Reduces operational costs and increases efficacy and efficiency with a flexible (tech: patient) ratio from 1:3 to 1:10 for attended and unattended studies with strong reimbursement
- Maintains the continuity of sleep medicine care and integration with the home health system, and other systems/levels of medical care from acute, hospital to outpatient settings.

Weaknesses of MSCM:

- Needs an established, in-patient sleep medicine consulting service to manage appointments
- Needs an implemented OSA/SDB screening program in acute and/or outpatient care settings

Opportunities for MSCM:

- Establishes a new marketplace for the sleep medicine industry, technology, and manufacturers
- Delivers and expands Sleep Medicine Care to both vulnerable acute inpatient and outpatient populations
- Expands the sleep medicine field to acute hospital medical care settings to cover all levels of medical care
- Can be used in any setting (in-patient, out-patient, COVID-19, or other viral pandemic crises)
- Reduces hospital readmission rates, improves clinical recovery and outcomes in high-risk cardio-vascular and cerebro-vascular (CCV) patients (Stroke, MI, CHF, A-fib, HTN, preeclampsia, etc.)
- Shortens the length of ICU and hospital stay (i.e., OSA patients with post-operative respiratory failure, COPD, CHF, OHS, etc.)
- Upgrades the case mix index and diagnosis-related group (DRG) reimbursement level for hospital operations with boosted reimbursement
- Increases the referral base to outpatient sleep center and home health by approximately 1300 patients per year

Threats for MSCM:

- Stigmatization of Sleep Medicine as an “Outpatient-Only” field
- Cultural/societal misperception and misunderstanding of the need for protected sleep as an essential human right and key element of good health
- Reluctance and limited exposure to the benefits of using mobile technology in the sleep field
- Inadequate support in non-academic programs due to policies written prior to the emergence of the acute sleep medicine field and digital technology.
- Lack of strategic understanding of the sleep medicine field, its potential, and its role in acute care

Why does it make sense to start from the acute hospital level of care? Why does the **Mobile Sleep Medicine Model** address the hospital level first and make it a **top** priority? Because US statistics are striking and alarming.

The facts tell us that the hospital is a controlled, structured environment where the patient can receive qualified, competent medical care. So, the level of acute hospital care is the place of opportunity for care to be administered safely to patients.

The Center for Disease Control and Prevention has labeled insufficient, “unprotected” sleep as a “public health epidemic.” Approximately 70 million Americans suffer from a sleep problem, and 60% of that number have a chronic sleep illness, such as obstructive sleep apnea (OSA).

80% of the US general population has never been evaluated for the presence of sleep disorders neither in outpatient nor inpatient settings. 80% of OSA patients remain undiagnosed and untreated (63).

For example, in 2019, according to the American Hospital Association, 36,241,815 Americans were admitted to hospitals in the US. Based on the above data, this means 28,993,452 hospitalized patients were not evaluated for the presence of sleep disorders.

Why did this happen? What is the main barrier that prevented health care professionals from conducting timely evaluations of hospitalized patients for OSA, the leading sleep-disruptive force that breaks down sleep protection and causes significant neurocognitive, cardio-vascular and cerebro-vascular (CCV) impairments in humans?

The answer is very simple. It is the lack of access to an innovative health care model and an effective methodological tool to deliver well-deserved Sleep Care and expertise to patients at the hospital bedside and across all levels of healthcare elsewhere.

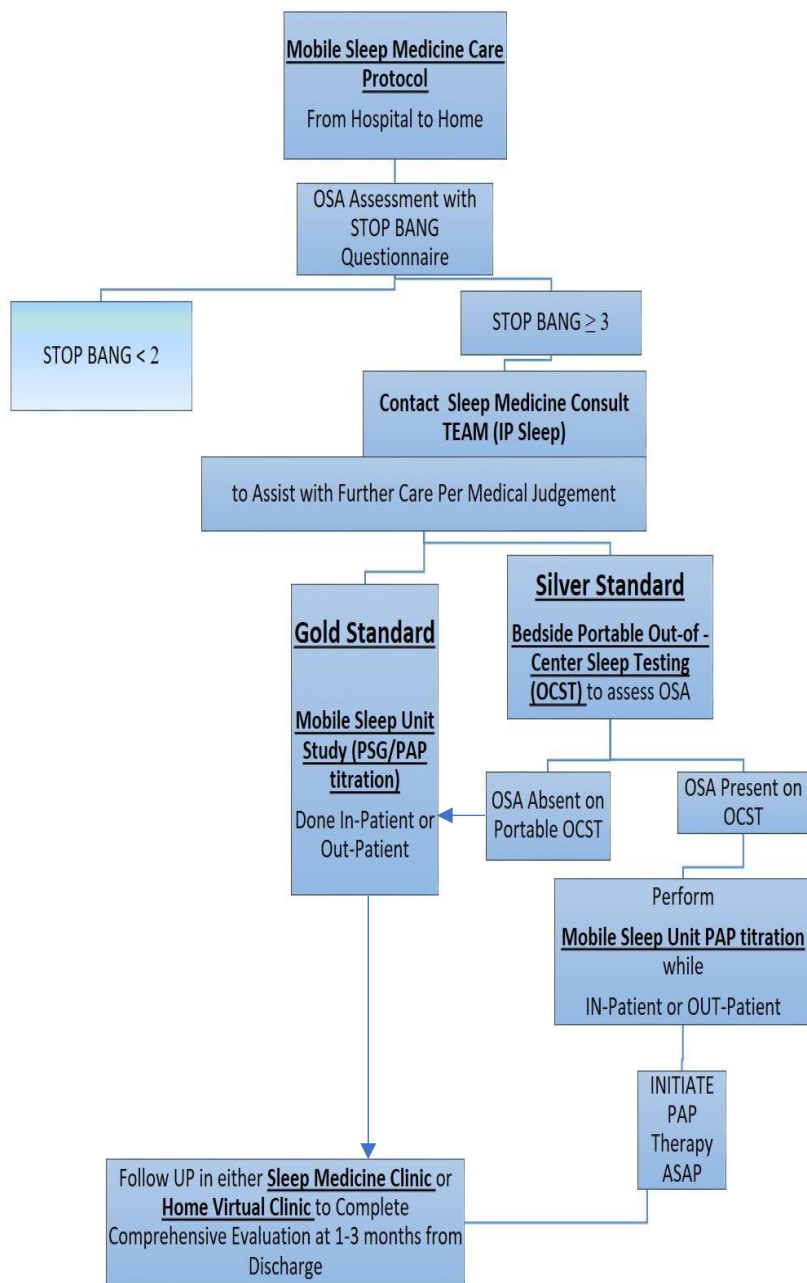
3. Solution Framework: How the Solution Will Be Operationalized

A. Delivery Model: Operational Infrastructure Requirements:

The **Mobile Sleep Medicine Care Model (MSCM)** is an innovative, progressive, patient-centered, integrative, complete cycle, clinical outcome-based program that uses the **Mobile Sleep Medicine Unit** as a methodological tool—a “sleep lab on wheels”—designed to deliver access to OSA Sleep Care for 80% of Americans at all levels of care, from the hospital to home. No OSA patient will be left behind.

The protocol for the MSCM delivery Model includes 3 levels of operations (see Fig.1) on the next page (13):

- 1) Screening
- 2) Testing/Treatment
- 3) Follow-up



1. Screening

2. Testing/Treatment

3. Follow-up

Figure 1: Example of Mobile Sleep Medicine Care Protocol

- 1) **Screening**: Designed to provide effective and efficient OSA screening for patients admitted to hospital (or any other health care facility, e.g., rehab, specialty/subspecialty clinic, etc.), including the patients with high risk of CCV (Stroke, MI, CHF, A-fib, HTN, preeclampsia, etc.). After completing OSA screening either in-person or via EMR or via Tele-Virtual/My Chart system, the Primary Team communicates with the Mobile Sleep Medicine Team/ In-patient Sleep Medicine Consulting Team (IP Sleep) to request Sleep consultation for further management.
- 2) **Testing/Treatment**: Designed to deliver timely sleep medicine expertise to patients screened positively for OSA. IP SLEEP/Mobile Sleep Medicine Team evaluates patients and develops the diagnostic and treatment plan with use of Mobile Sleep Unit technology.
- 3) **Follow-up**: IP SLEEP/Mobile Sleep Medicine Team coordinates further sleep medicine care in sleep clinic, sleep lab, home health, virtual telemedicine health.

Mobile Sleep Unit—“**Sleep Lab on Wheels**”—is a technological, methodological tool designed to deliver sleep medicine evaluation directly to the patient’s bedside.

MSU assembles with 3 functional technological modules representing modern sleep technology, which is used as the standard of care in the Sleep Medicine field.

Mobile Sleep Unit:

Module 1: “Gold Standard”: Mobile PSG- Attended Type 1 Sleep Testing Device.

- **Mobility and Portability**: Full sleep lab service delivered directly to the patient’s bedside either inside hospital or at the patient’s place of residence

- Capacity:
 - 1 tech performs 1 full overnight attended diagnostic sleep study (CTP 95810) or if necessary, per MD order, can be combined with PAP Titration unit (Module 3) to perform mobile PSG/Split or/ PAP titration studies (CTP 95811)
 - To increase capacity and minimize cost, the mobile PSG (“Gold Standard”) can be combined with Module 2 (“Silver Standard”), then 1 tech performs 2-10 overnight unattended sleep studies (CTP 95806) per MD order
 - Cost: reduced or no cost. No need to pay for the following: (1) keeping extra space necessary for stationary sleep lab rooms or (2) maintaining stationary sleep equipment inside hospital

Module 2: “Silver Standard”: Unattended Type 3 Sleep Testing Device named in sleep literature (OCST) = (CP) = HSAT and produced by several manufacturers (e.g., NOX-T3, Embletta, Stardust, PDX, etc.).

- Mobility and Portability: type 3 (4 channels) sleep lab service delivered directly to the patient’s bedside either inside hospital or at the patient’s place of residence with average set up time 5-10 minutes
- Capacity:
 - 1 tech performs 1-10 overnight unattended sleep studies per MD order (diagnostic only)
 - To increase capacity and minimize the cost, “Silver Standard” can be combined with mobile PSG/Module 1 (“Gold Standard”) or/and PAP Titration unit/ Module 3 to

perform Comprehensive Sleep Testing and Treatment (CTP 95806, CTP 95810, CTP 95811)

- Cost: Inexpensive with reduced, or no cost. No need to pay for the following: (1) keeping extra space necessary for stationary sleep lab rooms, and (2) maintaining stationary sleep equipment inside hospital.

Module 3: PAP titration unit: CPAP/BiPAP/AVAPS/ASV: Provides titration sleep study “on the spot.”

- Used for PAP titration in combination with Module 1/mobile PSG (“Gold Standard”) to perform mobile attended PSG/Split or/ PAP titration studies (CTP 95811)
- Not expensive
- Average set-up time: 5 minutes

B. Cost: Vertical Referral Integration of Trans-Level-of-Care Operational

Reimbursement (VRIO) Model: Designed to obtain collections from sleep-related operations performed on each level of care from hospital to sleep lab/home:

- 1) Technical charges and professional charges will be collected based on appropriate CTP codes per the type of study performed:
- 2) Sleep Studies (unattended and attended)
- 3) Clinical In-patient Sleep Consults and Outpatient Sleep Clinical Visits
 - a. Collections from each level will be combined to 100% and directed to support Mobile Sleep Unit Operations from hospital to home.
 - b. The sources of reimbursement obtained from each level of care:

a) Acute hospital level of care:

- i. Screening/evaluation for OSA/SDB will bring up DRG reimbursement based on the following:
- ii. Elevated complexity of comorbidities rule and increased case mix index
- iii. Improvement of hospital performance statistics due to significant reduction in readmission rates in sensitive CCV populations (CHF, chronic respiratory failure, obesity hypoventilation, Stroke, Afib, MI, HTN, seizure disorders, myasthenia gravis, ALS, etc.)
- iv. 33% of collections from each level will be directed to support Mobile Sleep Unit Operations from hospital to home

b) Sleep lab/sleep center: Sleep Medicine Referrals from Inpatient Sleep Medicine consulting service (IP sleep):

- Will boost the sleep referral base to Internal Sleep Lab/Center by about 1300 patients per year (5 consults per day X 5 days per week X 52 weeks)
- Will prevent “referral leaks” to external systems and maintain the integrity of collections
- 33% of collections from each level will be directed to support Mobile Sleep Unit Operations from hospital to home.

c) Home health integration: Patient-centered, unattended or/and attended sleep studies will be conducted at the patient’s residence (house, rehab, nursing home, etc.) and achieve the following:

- Integrate mobile sleep medicine care into home health care model
- Reduce the operational costs by 50% with flexible technician: patient ratio (from 1:3 to 1:10) for unattended studies with strong reimbursement for each study performed

- 33% of collections from each level will be directed to support Mobile Sleep Unit Operations from hospital to home.

C. Description of infrastructure and operational plan: The following infrastructure is necessary to provide daily Mobile Sleep Medicine Care operations:

1. Business Physical location, Facilities, and Equipment:

The Control Center of Operations (CCO) of the Mobile Sleep Medicine Team (MSMT) is located in the Sleep Medicine Center. The goal of CCO is to provide the hub coordination and logistical support to Mobile Sleep Care Model operations in assigned spoke locations (assigned hospitals/rehabs, sleep lab, nursing home, and/or patient's home).

CCO will utilize the local electronic medical records (EMR) or other confidential systems (in-person, telemedicine, virtual, "My Chart" etc.) to communicate with other members of the Sleep Medicine Team and all parties involved in the management of Mobile Sleep Care Model operations. Most of the modern EMRs are capable of integrating sleep medicine technology to medical charting and placing orders and referrals without extra cost to the facility. CCO coordinators via EMR are capable of monitoring the progress of the patient case from initial evaluation to the completion of sleep study reporting, follow up, and scheduling at the sleep center (or sleep lab or/and sleep clinic). All members of the MSMT will have access to the EMR to perform specifically assigned duties and essential functions such as scheduling appointments, placing sleep orders, and reading and interpreting sleep studies and lab results, etc.

The Sleep Medicine Center should have both physical and EMR (Virtual/"My Chart") access to the Acute Care Facility (hospital or rehab) to be able to provide necessary services.

The In-patient Sleep Medicine Consulting Team (IP Sleep) will receive requests for Mobile Sleep Medicine Evaluations from Primary Admitting Teams (Internal Medicine, Neurology, Family Medicine, Pediatrics, Cardiology, Pulmonology, etc.) after initial OSA screening is completed either via the digital EMR incorporated system or In-person screening tools (e.g., STOP BANG Questionnaires) (see Figure 1).

The RN performs OSA risk screening using STOP BANG questionnaire in one of available confidential ways (in-person, EMR, telemedicine, virtual, “My Chart” etc.). Once identified at high risk the following will happen:

- A wrist band and an “OSA RISK” sign will be placed on the patient’s wrist and outside the patient’s door respectively

- Banner on EMR will show “OSA RISK”

- The floor team will be informed and will decide whether to:

- i. Call in-patient sleep consult
- ii. Arrange outpatient sleep consult, or
- iii. Discharge paper recommends outpatient sleep consult

After the sleep consult is received via pager or other confidential communication systems, a member of the mobile sleep team (e.g., NP, PA, RN, MD) will triage the consult request and inform on-call attending or NP. The on-call attending or NP will see patients and determine which sleep study (unattended or attended) is needed. Patients with OSA and hypercapnic respiratory failure have first priority for attended sleep study because a PAP treatment study may guide in-patient and outpatient treatment. If there is no urgent need to perform a sleep study during hospital admission, the CCO will be contacted and an outpatient sleep study or follow up sleep clinic (virtual or in-person) visit will be arranged.

During the COVID-19 pandemic, Medicare COVID-19 policy allows directly ordering a PAP unit for the patient with established OSA diagnosis to reduce the risk of COVID-19 contamination during formal in-lab PAP titration. Of note, the Mobile Sleep Unit can be used to perform the safe, low contamination risk, formal in-lab PAP titration during COVID-19 or any other viral pandemic by using sleep equipment in negative pressure rooms in hospital or in outpatient facility. CCO will arrange further sleep medicine care after the patient is discharged from the hospital.

2. HR/Employees:

The **Mobile Sleep Medicine Team (MSMT)** resembles the traditional sleep center operational style, with the addition of accelerated Out-of-Center operations, which can vary in size and include 9-20 team members depending on patient flow and operational volume processing from 5-60 cases per day (both in-patient and out-patient combined):

- Director/Physician of Sleep Medicine Center: Oversees all operations in CCO, Sleep Lab, and Sleep Clinic
- Manager of Sleep Medicine CCO: Supervises all Mobile Sleep Care Model operations and reports to the Director
- Manager of Sleep Lab operations: Reports to Director and CCO manager, supervises all sleep lab operations, schedules sleep studies, communicates technical issues with sleep techs, PAs/NPs, physicians, and other members of MSMT
- Manager of Clinical Sleep Center Operations: Reports to Director and CCO manager, supervises all clinical sleep operations, schedules clinical sleep-related, in-person, and virtual appointments (initial, follow up, CPAP compliance clinics, etc.), communicates clinical issues with sleep techs, RTs, PAs/NPs, physicians, and other members of MSMT

- Sleep Medicine techs (1-8): Will be assigned to set up and perform type 1 (“Gold standard” with or without PAP titration) and type 3 (“Silver standard”) sleep testing in all locations. They will participate in technical components of sleep studies which include: setting up, monitoring, taking down sleep equipment for download, instruct and advise the patients about sleep testing process and procedures
- Sleep Medicine Physicians (1-6): Will provide clinical and neurophysiological expertise, perform direct patient care, evaluation, management (e.g., screening, ordering studies/tests and sleep study staging, scoring, interpretation, etc.) and supervise NPs, PAs, RTs, Nurses
- Middle level providers (1-8)- NPs, PAs, RTs, Nurses: Will report to and assist Sleep Medicine Physicians in providing clinical and neurophysiological expertise, performing direct patient care, evaluation and management (e.g., screening, ordering studies/tests and sleep study staging, scoring, interpretation, etc.)

3. Inventory requirements, suppliers:

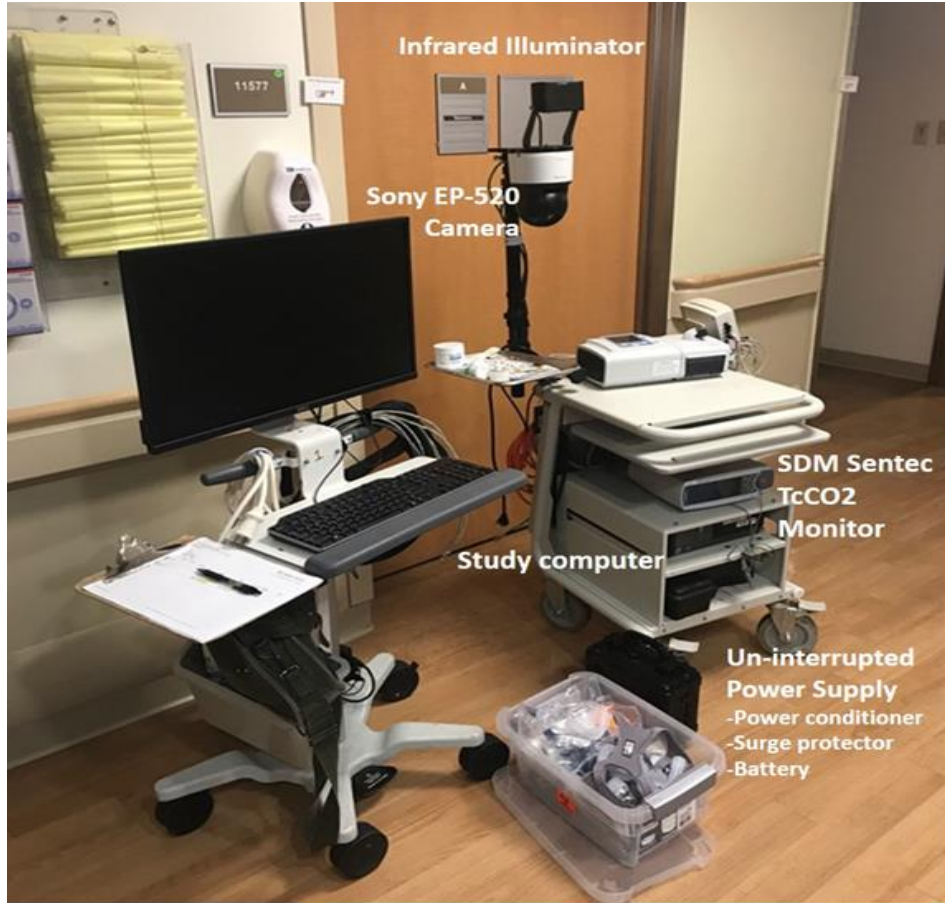
Any existing sleep technology company is capable of manufacturing the Mobile Sleep Unit and the necessary Sleep Medicine equipment, devices, supplies to them with reasonable minimal operational costs. It will be no need to build especially assigned Sleep Lab Rooms inside the hospital. Mobile Sleep Lab on wheels can be placed in any patient room without extra costs and logistical issues.

Mobile Sleep Unit with 1 mobile PSG (Type 1, “Gold standard”) and 4 Type 3 (“Silver standard”) units will be used to perform sleep testing either hospitalized or/and sleep lab locations or at the patient’s home per MD order after IP Sleep consultation team completes evaluation and shares the treatment plan with the patient and CCO.

Components of Mobile Sleep Unit (MSU):

- **Module 1.** “GOLD Standard”: Mobile Polysomnography (mPSG)
- **Module 2.** “SILVER Standard”: Portable Out-of-Center Sleep Testing (OCST) (NOX-T3, Embletta, Stardust etc)
 - Synonyms:
 - (CP) Cardiopulmonary Studies
 - HSAT (Home Sleep Ambulatory Testing)
 - (OCST) = (CP) = HSAT
- **Module 3.** PAP titration unit: CPAP/BiPAP/AVAPS/ASV

Figure 1: Example of Mobile Sleep Unit



One sleep technician will go to the hospital. First, the technician will setup unattended studies (“Silver standard”) (from 1 to 4), and then stay at the patient’s bedside to perform the overnight attended study using mobile PSG unit (Type 1, “Gold standard” with or without PAP titration) per MD order.

In the morning, after the end of the attended study, the technician will collect all the unattended sleep studies and upload the results to the main sleep lab via EMR. This one technician can perform from 4 to 10 unattended (“Silver standard”) studies, and one attended (“Gold standard”) study per night. This flexible, patient-centered approach will greatly reduce

the cancellations or no-shows common with traditional sleep lab appointments, decrease the cost of sleep studies, and make them logistically easier to manage.

Technical Specifications for In-patient Sleep Studies in Hospital using Mobile Sleep

Medicine care model and MSU:

The Sleep Center should start operations with 1-2 mobile polysomnogram systems (Type 1, “Gold standard”) for use anywhere on the hospital campus (the number of MSUs can be flexibly adjusted per patient’s volume of operations). See Figure 2 (p. 22) for a prototype of the MSU, which will include the following equipment:

- JE-921 Differential Amplifier
- Sony EP-520 camera
- Bosch Infrared Illuminator
- Dell Optiplex X PC
- Sleep system software includes
 - Polysmith 11 (build 8957)
 - Omnilab Direct version 2.4
 - Sony SNC toolbox
- Respironics Omni Advanced Plus Titration system
- UPS battery back-up with power conditioner/surge protection
- USB point-to-point extender
- Metal surgical tray with IV pole clip

The mobile sleep study unit will be placed at the patient’s bedside and remain there throughout the study. The technologist will interface with the cart in one of three ways:

- 1) Direct connection of a 2nd cart, via USB extender system and 2 cat 6 plenum cables, that will house a monitor, mouse, and keyboard. The tech will control the study from the mobile interface located outside of the patient's room during the study.
- 2) The connection will use an external laptop running remote desktop software to the PC on the mobile cart. This connection will be direct, using a cat 6 plenum cable through a direct network connection to an Ethernet port, or indirect, using a wi-fi connection to the Ethernet. In order to connect through the Ethernet, the mobile cart will be connected to an Ethernet portal available in the patient's room.
- 3) The connection will use any PC located on the hospital campus. The computer will use a remote desktop connection to the Dell PC on the cart. The mobile cart will be connected to the hospital Ethernet via the port in the patient's room.

4. Anticipated Impact

The **Mobile Sleep Medicine Care Model** works. It prioritizes effective, efficient, and patient-centered sleep medicine care; therefore, all parties and segments of care that receive and provide clinical sleep medicine services will benefit in a variety of measurable ways.

A. Benefits for Patients:

- 1) Patient-centered sleep care delivered directly and conveniently to a patient at any setting/level of care: hospital, home, virtual telemedicine clinic, or in-person clinic
- 2) The **Mobile Sleep Medicine Care Model** improves the overall patient experience by bringing sleep medicine expertise and testing directly to the patient's bedside without the unnecessary delays in care currently observed in the traditional sleep medicine model (e.g., self-scheduling for sleep clinic and sleep lab with long waiting time, and/or multiple missed/cancelled appointments, etc.).
- 3) Improved sleep quality, sleep-related quality of life, participation in recovery and rehab activities due to controlled OSA related issues: daytime sleepiness, fatigue, concentration and/or memory, altered mental status, delirium, and dyspnea

B. Benefits for Hospital/ Healthcare System:

- 1) Screening/evaluation for OSA/SDB will upgrade case-mix index and bring up diagnosis related group (DRG) reimbursement based on:
 - a) Elevated complexity of comorbidities rule and increased case mix index

- b) Improvement of hospital performance statistics due to:
 - i. Significant reduction in-hospital mortality and readmission rates in CCV sensitive populations (CHF, chronic respiratory failure, obesity hypoventilation, Stroke, Afib, MI, HTN, seizure disorders, neuromuscular disease, myasthenia gravis, ALS, etc.)
 - ii. Shortened the length of:
 - a. ICU stay
 - b. Hospital stay (i.e. patients with OSA, OHS, post-operative respiratory failure, COPD, CHF, etc.)
 - iii. Prevention of escalation in level of care, intubation, transfer to the intensive care unit (ICU), rapid response team (RRT)
 - iv. Prevention of hypoxemia and/or hypoventilation
 - v. Control of referral base and prevention of referral leaks (increase referral base to sleep center by 1300 patients per year)

C. Benefits for Business and Industry:

- 1) New market with increased sales and production/supply chain
- 2) Expansion of use of mobile sleep medicine methodology, equipment and Pap technology to all relevant medical settings: hospital, home, clinic

D. Benefits for Payors:

- 1) Low cost for improved access to Sleep medicine care for pediatric and adult patients
- 2) Reduced costs and more effective CCV risk factors management due to Primary and Secondary CCV Prevention

E. Benefits for Academic Sleep Medicine Field:

- 1) Expansion of Sleep Medicine into all medical settings and levels of care with opportunities to monitor relevant OSA related clinical outcomes and measure responses to targeted clinical interventions at real time while patient is moving via levels of care;
- 2) Establishing the methodological basis for development of digital evidence-based precision sleep medicine:
 - a) To effectively control and reduce OSA related CCV risk factors
 - b) Improve recovery and rehabilitation
- 3) Removal of “stigma” of being “OUTPATIENT ONLY” specialty with minimal impact on patients’ clinical outcomes.

F. National Health Benefits:

- 1) Overall reduction of OSA related morbidity and mortality
- 2) Data from Mobile Sleep Care Model would contribute to development of evidence-based Precision Sleep Medicine.

We anticipate that the **Mobile Sleep Medicine Care Model** and **Mobile Sleep Unit** will have positive, measurable impact on all parties involved, including the patient, the hospital/healthcare system, the field of sleep medicine, and the entire even the nation. With a broad, effective implementation of the MSM model and MSU methodological tool, the field of Sleep Medicine can take us a giant step forward in its effort to treat OSA and protect sleep for all—a basic human right—by promoting safe, flexible, efficient sleep care anytime, anywhere.

5. Supporting Documents: data and evidence of exiting pilot

Data from Current Pilot Operations:

1) At Washington University:

Please review the data from the Pilot Mobile Sleep Medicine Care Model at Washington University:

	Sleep Consult	Attended Study	Unattended Study
2015 MD 50% FTE	464	264	56
2016 MD 50% FTE NP 100% FTE	894 (572+322)	324	228
2017 MD 25% FTE NP 100% FTE	752 (343+409)	310	339

The Washington University In-patient Sleep Medicine Consulting Team started operations in 2015 with 464 sleep consults, 264 attended sleep studies, and 56 unattended sleep studies. Over 2 years the IP SLEEP service grew by 30%-50% with 752 sleep consults, 310 attended sleep studies, and 339 unattended sleep studies. These operations brought in collectively about \$3 million to the facility, providing resources for Medical Clinical Staff salaries and equipment. Reimbursements came from improved hospital health care operational service lines statistics in the following areas:

- Readmission to the hospital
- Length of hospitalization

- Occurrence of cardiovascular conditions (e.g., hypertension, atrial fibrillation, myocardial infarction, heart failure)
- Occurrence of neurologic conditions (e.g., stroke, neuromuscular disease, seizures)
- Occurrence of pulmonary conditions (e.g., chronic obstructive pulmonary disease, asthma, interstitial lung disease)
- Occurrence of intensive care unit conditions (e.g., hypoventilation syndromes, respiratory failure)
- Reduction in need for sleep aids such as sedative hypnotics

Washington University's pilot of the **Mobile Sleep Medicine Care Model** confirms that providing Sleep services to hospitalized patients and expanding the Sleep Medicine field to an acute care setting can benefit all parties involved in health care.

2) **At LSU Health Sciences Center in Shreveport, LA:**

At LSU Health, we implemented the **Mobile Sleep Medicine Care Model** and MSU during the COVID-19 crisis from March 2020 to January 2021. We placed one (1) MSU in a negative pressure room to provide access to all Sleep Lab operations, especially formal PAP In lab titrations and Split studies, which were significantly limited in other centers without access to negative pressure rooms, per the CDC order (especially in March 2020-July 2020). The MSU's flexibility allowed quick adaptation to the new environment and the safe performance of 4 titration/Split studies per week in both adult and pediatric populations. Of note, from March 2020 to August 2020, CDC COVID-19 protocols permitted pediatric sleep studies in regular Sleep labs only if such labs had access to negative pressure rooms. Most the community sleep labs had

limited access to negative pressure rooms and were therefore forced to cancel their operations. As LSU Health met the required protocols and had implemented the Mobile Sleep Medicine Care Model, we were able to perform about 128 studies from March 2020-October 2020. We tested and monitored all our patients during that time and none of our patients got sick with COVID-19 within 21 days prior or after sleep testing. We contained all necessary sleep medicine clinical operations via Virtual Telemedicine. All Sleep Team members kept their jobs during the pandemic, while other stand-alone sleep labs had to lay off staff, especially techs. The **Mobile Sleep Medicine Care Model** saved our local healthcare system approximately \$200,000 over the last fiscal year.

The evidence gathered from both pilots affirms that The **Mobile Sleep Medicine Model** and **Mobile Sleep Unit** together constitute a timely, cost-effective solution to a national problem. With a broad, effective implementation of the MSM model and MSU methodological tool, the field of Sleep Medicine can take a giant step closer to treating OSA more effectively and protecting sleep for all—a basic human right—by promoting safe, flexible, efficient sleep care anytime, anywhere.

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