



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

- Preproposal Statement of Inquiry was filed as WSR 15-07-081 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR _____
- Continuance of WSR _____

Title of rule and other identifying information:

WAC 182-531-0950 Office and other outpatient physician-related services
 WAC 182-531-1500 Sleep studies
 WAC 182-551-0400 Respiratory care – Continuous positive airway pressure (CPAP) device and supplies

Hearing location(s):

Health Care Authority
 Cherry Street Plaza Building; Sue Crystal Conf Rm 106A
 626 - 8th Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:
http://www.hca.wa.gov/documents/directions_to_csp.pdf
 or directions can be obtained by calling: 360-725-1000

Date: September 22, 2015 Time: 10:00 a.m.

Date of intended adoption: Not sooner than September 23, 2015 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: HCA Rules Coordinator
 Address: PO Box 45504, Olympia WA, 98504-5504
 Delivery: 626 – 8th Avenue, Olympia WA 98504
 e-mail: arc@hca.wa.gov
 fax (360) 586-9727

by **5:00 PM on September 22, 2015**

Assistance for persons with disabilities: Contact Contact Amber Lougheed by September 18, 2015.
 e-mail: amber.lougheed@hca.wa.gov or (360) 725-1349

TTY (800) 848-5429 or 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

Revisions to these sections are necessary to:

- 1) Strike the last sentence in WAC 182-531-0950(7) regarding immunizations given in a health department. This change aligns with national correct coding initiative (NCCI) edits.
- 2) Add coverage for unattended sleep studies in WAC 182-531-1500.

Reasons supporting proposal: See purpose.

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE
August 19, 2015

NAME (type or print)
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

**OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED**

DATE: August 19, 2015
TIME: 10:15 AM
WSR 15-17-124

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: Health Care Authority

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting.....Wendy Barcus	PO Box 42716, Olympia WA 98504-2716	(360) 725-1306
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Enforcement..... Tonja Nichols/Lisa Humphrey/ Erin Mayo	PO Box 45502, Olympia WA 98504-5502	(360) 725-1658

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone () _____

fax () _____

e-mail _____

No. Explain why no statement was prepared.

The agency has determined that the proposed filing does not impose a disproportionate cost impact on small businesses or nonprofits.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone () _____

fax () _____

e-mail _____

No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

WAC 182-531-0950 Office and other outpatient physician-related services. (1) The medicaid agency pays eligible providers for the following:

(a) Two calls per month for routine medical conditions for a client residing in a nursing facility; and

(b) One call per noninstitutionalized client, per day, for an individual physician, except for valid call-backs to the emergency room per WAC 182-531-0500.

(2) The provider must provide justification based on medical necessity at the time of billing for visits in excess of subsection (1) of this section and follow the requirements in WAC 182-501-0169.

(3) See the agency's physician-related services billing instructions for procedures that are included in the office call and that cannot be billed separately.

(4) Using selected diagnosis codes, the agency reimburses the provider at the appropriate level of physician office call for history and physical procedures in conjunction with dental surgery services performed in an outpatient setting.

(5) The agency may reimburse providers for injection procedures and/or injectable drug products only when:

(a) The injectable drug is administered during an office visit; and

(b) The injectable drug used is from office stock and which was purchased by the provider from a pharmacy, drug manufacturer, or drug wholesaler.

(6) The agency does not reimburse a prescribing provider for a drug when a pharmacist dispenses the drug.

(7) The agency does not reimburse the prescribing provider for an immunization when the immunization material is received from the department of health; the agency does reimburse an administrative fee. (~~(If the immunization is given in a health department and is the only service provided, the agency reimburses a minimum E&M service.)~~)

(8) The agency reimburses immunizations at **estimated acquisition costs (EAC)** when the immunizations are not part of the vaccine for children program. The agency reimburses a separate administration fee for these immunizations. Covered immunizations are listed in the fee schedule. Refer to WAC 182-531-0150 (1)(r) for vaccines recommended or required for the sole purpose of international travel.

(9) The agency reimburses therapeutic and diagnostic injections subject to certain limitations as follows:

(a) The agency does not pay separately for the administration of intra-arterial and intravenous therapeutic or diagnostic injections provided in conjunction with intravenous infusion therapy services. The agency does pay separately for the administration of these injections when they are provided on the same day as an E&M service. The agency does not pay separately an administrative fee for injectables when both E&M and infusion therapy services are provided on the same day. The agency reimburses separately for the drug(s).

(b) The agency does not pay separately for subcutaneous or intramuscular administration of antibiotic injections provided on the same day as an E&M service. If the injection is the only service provided, the agency pays an administrative fee. The agency reimburses separately for the drug.

(c) The agency reimburses injectable drugs at **acquisition cost**. The provider must document the name, strength, and dosage of the drug and retain that information in the client's file. The provider must provide an invoice when requested by the agency. This subsection does not apply to drugs used for chemotherapy; see subsection (11) in this section for chemotherapy drugs.

(d) The provider must submit a manufacturer's invoice to document the name, strength, and dosage on the claim form when billing the agency for the following drugs:

(i) Classified drugs where the billed charge to the agency is over one thousand, one hundred dollars; and

(ii) Unclassified drugs where the billed charge to the agency is over one hundred dollars. This does not apply to unclassified antineoplastic drugs.

(10) The agency reimburses allergen immunotherapy only as follows:

(a) Antigen/antigen preparation codes are reimbursed per dose.

(b) When a single client is expected to use all the doses in a multiple dose vial, the provider may bill the total number of doses in the vial at the time the first dose from the vial is used. When remaining doses of a multiple dose vial are injected at subsequent times, the agency reimburses the injection service (administration fee) only.

(c) When a multiple dose vial is used for more than one client, the provider must bill the total number of doses provided to each client out of the multiple dose vial.

(d) The agency covers the antigen, the antigen preparation, and an administration fee.

(e) The agency reimburses a provider separately for an E&M service if there is a diagnosis for conditions unrelated to allergen immunotherapy.

(f) The agency reimburses for **RAST** testing when the physician has written documentation in the client's record indicating that previous skin testing failed and was negative.

(11) The agency reimburses for chemotherapy drugs:

(a) Administered in the physician's office only when:

(i) The physician personally supervises the E&M services furnished by office medical staff; and

(ii) The medical record reflects the physician's active participation in or management of course of treatment.

(b) At established maximum allowable fees that are based on the medicare pricing method for calculating the estimated acquisition cost (EAC), or maximum allowable cost (MAC) when generics are available;

(c) For unclassified antineoplastic drugs, the provider must submit the following information on the claim form:

(i) The name of the drug used;

(ii) The dosage and strength used; and

(iii) The national drug code (NDC).

(12) Notwithstanding the provisions of this section, the agency reserves the option of determining drug pricing for any particular drug based on the best evidence available to the agency, or other good and sufficient reasons (e.g., fairness/equity, budget), regarding the actual cost, after discounts and promotions, paid by typical providers nationally or in Washington state.

(13) The agency may request an invoice as necessary.

WAC 182-531-1500 Sleep studies. (1) Purpose. For the purposes of this section, sleep studies include polysomnography (PSG), unattended home sleep test (HST), and multiple sleep latency testing (MSLT). The medicaid agency covers attended, full-channel, PSG (~~and~~), MSLT, and HSTs when:

- (a) Ordered by the client's physician;
- (b) Performed (~~in~~) by an agency-designated center of excellence (COE) that is an independent diagnostic testing facility, sleep laboratory, or outpatient hospital; and
- (c) Results are used to:
 - (i) Establish a diagnosis of narcolepsy or sleep apnea; or
 - (ii) Evaluate a client's response to therapy, such as continuous positive airway pressure (CPAP).

(2) Definitions. The following definitions, those found in chapter 182-500 WAC, and definitions found in other sections of this chapter, apply to this section:

(a) "American Academy of Sleep Medicine" or "AASM" - The only professional society dedicated exclusively to the medical subspecialty of sleep medicine. AASM sets standards and promotes excellence in health care, education, and research. Members specialize in studying, diagnosing, and treating disorders of sleep and daytime alertness such as insomnia, narcolepsy, and obstructive sleep apnea.

(b) "Continuous positive airway pressure" or "CPAP" - See WAC 182-552-0005.

(c) "Core provider agreement" or "CPA" - The basic contract the agency holds with providers serving medical assistance clients.

(d) "Multiple sleep latency test" or "MSLT" - A sleep disorder diagnostic tool used to measure the time elapsed from the start of a daytime nap period to the first signs of sleep, called sleep latency. The MSLT is used extensively to test for narcolepsy, to distinguish between physical tiredness and true excessive daytime sleepiness, or to assess whether treatments for breathing disorders are working.

(e) "Obstructive sleep apnea" or "OSA" - See WAC 182-552-0005.

(f) "Polysomnogram" - The test results from a polysomnography.

(g) "Polysomnography" - A multiparametric test that electronically transmits and records specific physical activities while a person sleeps. The recordings become data that are analyzed by a qualified sleep specialist to determine whether or not a person has a sleep disorder.

(h) "PSG" - The abbreviation for both "polysomnography" and "polysomnogram."

(i) "Registered polysomnographic technologist" or "RPSGT" - A sleep technologist credentialed by the board of registered polysomnographic technologists to assist sleep specialists in the clinical assessment, physiological monitoring and testing, diagnosis, management, and prevention of sleep-related disorders with the use of various diagnostic and therapeutic tools. These tools include, but are not limited to, polysomnograph, positive airway pressure devices, oximeter, capnograph, actigraph, nocturnal oxygen, screening devices, and questionnaires. To become certified as a registered polysomnographic technologist, a sleep technologist must have the necessary clinical experience, hold CPR certification or its equivalent, adhere to the board of registered polysomnographic technologists standards of conduct, and

pass the registered polysomnographic technologist examination for polysomnographic technologists.

(3) Client eligibility. Clients in the following agency programs are eligible to receive sleep studies as described in this section:

(a) Categorically needy (CN);

(b) Apple health for kids and other children's medical assistance programs as defined in WAC 182-505-0210;

(c) Medical care services as described in WAC 182-508-0005 (within Washington state or border areas only);

(d) Alcoholism and Drug Addiction Treatment and Support Act (ADATSA) (within Washington state or border areas only); and

(e) Medically needy (MN) only when the client is either:

(i) Twenty years of age or younger and referred by a screening provider under the early and periodic screening, diagnosis, and treatment program as described in chapter 182-534 WAC; or

(ii) Receiving home health care services as described in chapter 182-551 WAC, subchapter II.

(4) Provider requirements. To be paid for providing sleep studies as described in this section to eligible clients, the facility must:

(a) Be a sleep study COE. Refer to subsection (5) of this section for information on becoming an agency-approved sleep study COE;

(b) Be currently accredited by AASM and continuously meet the accreditation standards of AASM;

(c) Have at least one physician on staff who is board certified in sleep medicine; and

(d) Have at least one registered polysomnographic technologist (RPSGT) in the sleep lab when studies are being performed.

(5) Documentation.

(a) To become an agency-approved COE, a sleep center must send the following documentation to the Health Care Authority, c/o Provider Enrollment, P.O. Box 45510, Olympia, WA 98504-5510:

(i) A completed CPA; and

(ii) Copies of the following:

(A) The sleep center's current accreditation certificate by AASM;

(B) Either of the following certifications for at least one physician on staff:

(I) Current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or

(II) Current subspecialty certification in sleep medicine by a member of the American Board of Medical Specialties (ABMS); and

(C) The certification of an RPSGT who is employed by the sleep center.

(b) Sleep centers must request reaccreditation from AASM in time to avoid expiration of COE status with the agency.

(c) At least one physician on staff at the sleep center must be board certified in sleep medicine. If the only physician on staff who is board certified in sleep medicine resigns, the sleep center must ensure another physician on staff at the sleep center obtains board certification or another board-certified physician is hired. The sleep center must then send provider enrollment a copy of the physician's board certification.

(d) If a certified medical director leaves a COE, the COE status does not transfer with the medical director to another sleep center.

(e) The COE must maintain a record of the physician's order for the sleep study.

(6) Coverage.

(a) The agency covers only medically necessary sleep studies. The need for the sleep study must be confirmed by medical evidence (e.g., physician examination and laboratory tests).

(b) For clients age twenty-one (~~((years of age))~~) and older, the agency covers:

(i) An unattended home sleep test (HST) as follows:

(A) Using one of the following HST devices:

(I) Type II home sleep monitoring device;

(II) Type III home sleep monitoring device; or

(III) Type IV home sleep monitoring device that measures at least three channels.

(B) To confirm obstructive sleep apnea (OSA) in an individual with signs or symptoms consistent with OSA (e.g., loud snoring, awakening with gasping or choking, excessive daytime sleepiness, observed cessation of breathing during sleep, etc.).

(ii) Full-night, in-laboratory PSG for either of the following:

(A) Confirmation of obstructive sleep apnea (OSA) in an individual with signs or symptoms consistent with OSA (e.g., loud snoring, awakening with gasping or choking, excessive daytime sleepiness, observed cessation of breathing during sleep, etc.); or

(B) Titration of positive airway pressure therapy when initial PSG confirms the diagnosis of OSA, and positive airway pressure is ordered; or

~~((i))~~ (iii) Split-night, in-laboratory PSG in which the initial diagnostic portion of the PSG is followed by positive airway pressure titration when the PSG meets either of the following criteria:

(A) The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to fifteen events per hour (~~((with a minimum of thirty events))~~); or

(B) The AHI or RDI is greater than or equal to five and less than or equal to fourteen events per hour (~~((with a minimum of ten events))~~) with documentation of either of the following:

(I) Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or

(II) Hypertension, ischemic heart disease, or history of stroke.

(c) For clients (~~((younger than twenty one years of))~~) age twenty and younger, the agency considers any of the following indications as medically necessary criteria for a sleep study:

(i) OSA suspected based on clinical assessment;

(ii) Obesity, Trisomy 21, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidosis (MPS), prior to adenotonsillectomy in a child;

(iii) Residual symptoms of OSA following mild preoperative OSA;

(iv) Residual symptoms of OSA in a child with preoperative evidence of moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, or neurologic disorder following adenotonsillectomy;

(v) Titration of positive airway pressure in a child with OSA;

(vi) Suspected congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorder or chest wall deformities;

(vii) Primary apnea of infancy;

(viii) Evidence of a sleep-related breathing disorder in an infant who has experienced an apparent life threatening event;

(ix) Child being considered for adenotonsillectomy to treat OSA;

or

(x) Clinical suspicion of an accompanying sleep-related breathing disorder in a child with chronic asthma, cystic fibrosis, pulmonary hypertension, bronchopulmonary dysplasia, or chest wall abnormality.

(7) Noncoverage. The agency does not cover sleep studies:

(a) (~~When the sleep study is an unattended home study;~~

~~(b)~~) When documentation for a repeat study does not indicate medical necessity (e.g., no new clinical documentation indicating the need for a repeat study); or

(~~(e)~~) (b) For the following indications, except when an underlying physiology exists (e.g., loud snoring, awakening with gasping or choking, excessive daytime sleepiness, observed cessation of breathing during sleep, etc.):

(i) Chronic insomnia; and

(ii) Snoring.

WAC 182-552-0400 Respiratory care—Continuous positive airway pressure (CPAP) device and supplies. (1) The medicaid agency covers, without prior authorization, one continuous positive airway pressure (CPAP) device including related supplies, per client, every five years. The CPAP device must have a data card and the client must meet the following clinical criteria:

(a) The client is diagnosed with obstructive sleep apnea (OSA) using a clinical evaluation and a positive attended polysomnogram (PSG) performed in a sleep laboratory (~~(. Unattended home sleep studies do not meet the medicaid agency's clinical criteria for reimbursement) or an unattended home sleep test;~~ and

(b) For clients (~~(thirteen years of)~~) age twenty-one and older:

(i) The client's polysomnogram or home sleep test demonstrates an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to fifteen events per hour (~~(with a minimum of thirty events)~~); or

(ii) The client's polysomnogram or home sleep test demonstrates the AHI or RDI is greater than or equal to five and less than or equal to fourteen events per hour (~~(with a minimum of ten events)~~) with clinical documentation of:

(A) Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or

(B) Hypertension, ischemic heart disease, or history of stroke.

(c) For clients (~~(twelve years of)~~) age twenty and younger, the clinical criteria is considered met when there is a documented diagnosis of OSA and polysomnography demonstrates an apnea index (AI) or AHI equal to or greater than one and:

(i) Adenotonsillectomy has been unsuccessful in relieving OSA; or

(ii) Adenotonsillar tissue is minimal; or

(iii) Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., craniofacial anomaly, obesity) or adenotonsillectomy is contraindicated; or

(iv) Family does not wish to pursue surgical intervention.

(2) If a client meets the criteria in subsection (1) of this section but a CPAP device has been tried and proven ineffective, the medicaid agency will cover a bi-level respiratory assist device (RAD) without the back-up rate. Ineffective, in this case, is defined as documented failure to meet therapeutic goals using a CPAP during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure setting).

(3) The AHI is calculated on the average number of events per hour. If the AHI is calculated based on less than two hours of sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a two-hour period (i.e., must reach greater than or equal to thirty events without symptoms or greater than or equal to ten events with symptoms). The medicaid agency pays for an initial three-month rental period for CPAP devices.

(4) The medicaid agency purchases a CPAP device after the three-month rental period when the following documentation of clinical benefit is recorded in the client's file:

(a) A face-to-face clinical reevaluation of the client by the authorized prescriber which documents that symptoms of obstructive sleep apnea are improved; and

(b) A review of objective evidence by the authorized prescriber of the client's adherence to use of the CPAP device. Adherence is defined as use of the CPAP device greater than or equal to four hours per night on seventy percent of nights during a consecutive thirty-day period anytime during the first three months of initial usage.

(5) The medicaid agency does not pay for a CPAP device when the client is diagnosed with upper airway resistance syndrome (UARS).

(6) The medicaid agency pays for the purchase of a heated humidifier for a CPAP device, once every five years from the date the item was deemed purchased, per client.

(7) Replacement of CPAP device.

(a) The medicaid agency requires prior authorization for the replacement of a CPAP device if the client has had the device for less than five years.

(b) After five years, the client must have a face-to-face evaluation with the treating authorized prescriber that documents that the client continues to use and benefit from the device. The medicaid agency does not require a new PSG (sleep test), trial period, or prior authorization.

(c) Replacement supplies - The medicaid agency pays for replacement supplies for a CPAP device as follows:

(i) Full face mask, limit one every six months;

(ii) Face mask interface for full face mask, limit one every three months;

(iii) Nasal interface (mask or cannula type), with or without head strap, limit one every six months;

(iv) Cushion for use on nasal mask interface, limit one every three months;

(v) Pillow for use on nasal cannula type interface, limit one pair every three months;

(vi) Headgear, chin strap, and tubing with or without integrated heating element, limit one every six months;

(vii) Filters - Disposable, limit two every thirty days;

(viii) Filters - Nondisposable, limit one every six months; and

(ix) Water chamber for humidifier, limit one every six months.

(d) Prior authorization is required if the client does not meet the clinical criteria in this section or if the medicaid agency has purchased a bi-level respiratory assist device for the client within the last five years.