RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

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STATE OF WASHINGTON
FILED

DATE: June 28, 2023
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WSR 23-14-064

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

☐ 31 days after filing.

☒ Other (specify) August 1, 2023 **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: The agency is removing outdated clinical criteria for coverage of oxygen and replacing them with Medicaid's current clinical criteria under the Centers for Medicare and Medicaid.

Citation of rules affected by this order:

New:
Repealed:
Amended: 182-552-0005, 182-552-0200, 182-555-0800
Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 23-11-134 on May 23, 2023 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	____	Amended	____	Repealed	____

The number of sections adopted at the request of a nongovernmental entity:

	New	____	Amended	____	Repealed	____

The number of sections adopted on the agency's own initiative:

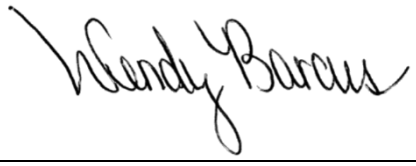
	New	____	Amended	____	Repealed	____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	____	Amended	3	Repealed	____

The number of sections adopted using:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	____	Amended	3	Repealed	____

Date Adopted: June 28, 2023	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

AMENDATORY SECTION (Amending WSR 12-14-022, filed 6/25/12, effective 8/1/12)

WAC 182-552-0005 Respiratory care—Definitions. The following definitions and those in chapter 182-500 WAC apply to this chapter.

"Adult family home" - A residential home licensed to care for up to six residents that provides rooms, meals, laundry, supervision, assistance with activities of daily living, and personal care. In addition to these services, some homes provide nursing or other special care and services.

"Apnea" - The cessation of airflow for at least ((~~ten~~)) 10 seconds.

"Apnea-hypopnea index (AHI)" - The average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this chapter, respiratory effort related arousals (RERAs) are not included in the calculation.

"Arterial PaO_2" - Measurement of partial pressure of arterial oxygen.

"Authorized prescriber" - A health care practitioner authorized by law or rule in the state of Washington to prescribe oxygen and respiratory care equipment, supplies, and services.

"Base year" - As used in this chapter, means the year in which the respiratory care ((~~medicaid provider guide's~~)) current fee schedule is adopted.

"Bi-level respiratory assist device with backup rate" - A device that allows independent setting of inspiratory and expiratory pressures to deliver positive airway pressure (within a single respiratory cycle) by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, these devices have a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

"Bi-level respiratory assist device without backup rate" - A device that allows independent setting of inspiratory and expiratory pressures to deliver positive airway pressure (within a single respiratory cycle) by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

"Blood gas study" - For the purposes of this chapter, is either an oximetry test or an arterial blood gas test.

"Boarding home" - Adult residential care (ARC) facility, enhanced adult residential care (EARC) facility, or assisted living (AL) facility.

"Central sleep apnea (CSA)" - Is defined as:

(1) An apnea-hypopnea index (AHI) greater than or equal to five; and

(2) Central apneas/hypopneas greater than ((~~fifty~~)) 50 percent of the total apneas/hypopneas; and

(3) Central apneas or hypopneas greater than or equal to five times per hour; and

(4) Symptoms of either excessive sleepiness or disrupted sleep.

"Chronic obstructive pulmonary disease (COPD)" - Any disorder that persistently obstructs bronchial airflow. COPD mainly involves two related diseases: Chronic bronchitis and emphysema. Both cause chronic obstruction of air flowing through the airways and in and out

of the lungs. The obstruction is generally permanent and worsens over time.

"Complex sleep apnea (CompSA)" - A form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas, upon exposure to CPAP or a bi-level respiratory assist device without a back-up rate feature, when obstructive events have disappeared. These clients have predominantly obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to five times per hour. With use of a CPAP or bi-level respiratory assist device without a back-up rate feature, the client shows a pattern of apneas and hypopneas that meets the definition of central sleep apnea (CSA).

"Continuous positive airway pressure (CPAP)" - A single-level device which delivers a constant level of positive air pressure (within a single respiratory cycle) by way of tubing and an interface to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

"Dependent edema" - Fluid in the tissues, usually ankles, wrists, and the arms.

"Emergency oxygen" - The immediate, short-term administration of oxygen to a client who normally does not receive oxygen((~~,~~)) but is experiencing an acute episode which requires oxygen.

"Erythrocythemia" - More hematocrit (red blood cells) than normal.

"FIO_2" - The fractional concentration of oxygen delivered to the client for inspiration. For the purpose of this policy, the client's prescribed FIO_2 refers to the oxygen concentration the client normally breathes when not undergoing testing to qualify for coverage of a respiratory assist device (RAD). That is, if the client does not normally use supplemental oxygen, their prescribed FIO_2 is that found in room air.

"FEV1" - The forced expired volume in one second.

"FVC" - The forced vital capacity.

"Group I" - Clinical criteria, set by medicare, to identify ((~~chronic oxygen~~)) clients ((~~with obvious respiratory challenges as evidenced by low oxygen saturation. The clinical criteria for Group I include any of the following:~~

~~• An arterial PaO_2 at or below fifty-five mm Hg or an arterial oxygen saturation (SaO_2) at or below eighty-eight percent taken at rest (awake); or~~

~~• An arterial PaO_2 at or below fifty-five mm Hg, or an arterial oxygen saturation at or below eighty-eight percent for at least five minutes taken during sleep for a client who demonstrates an arterial PaO_2 at or above fifty-six mm Hg or an arterial oxygen saturation at or above eighty-nine percent while awake; or~~

~~• A decrease in arterial PaO_2 more than ten mm Hg, or a decrease in arterial oxygen saturation more than five percent from baseline saturation for at least five minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia; or~~

~~• An arterial PaO_2 at or below fifty-five mm Hg or an arterial oxygen saturation at or below eighty-eight percent, taken during exercise for a client who demonstrates an arterial PaO_2 at or above fifty-~~

~~six mm Hg or an arterial oxygen saturation at or above eighty-nine percent during the day while at rest. In this case, oxygen is provided during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the client was breathing room air~~)) requiring oxygen. The agency follows the Group I clinical criteria listed in the Centers for Medicare and Medicaid Services National Coverage Determination for Home Use of Oxygen, which is found in the Medicare Coverage Database.

"Group II" - Clinical criteria, set by medicare, to identify ((~~borderline oxygen clients. Their blood saturation levels seem to be within the normal range, but there are additional extenuating issues that suggest a need for oxygen. The clinical criteria for Group II include any of the following:~~

~~• The presence of an arterial PaO_2 of fifty-six to fifty-nine mm Hg or an arterial blood oxygen saturation of eighty-nine percent at rest (awake), during sleep for at least five minutes, or during exercise (as described under Group I criteria); and~~

~~• Any of the following:~~

~~- Dependent edema suggesting congestive heart failure; or~~

~~- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than three mm in standard leads II, III, or AVF); or~~

~~- Erythrocythemia with a hematocrit greater than fifty-six percent.~~)) clients who require oxygen. Their blood oxygen levels may be within normal range, however, they have complicating conditions that require supplemental oxygen use. The agency follows the Group II clinical criteria listed in the Centers for Medicare and Medicaid Services National Coverage Determination for Home Use of Oxygen, which is found in the Medicare Coverage Database.

"Group III" - Clients for whom intermittent home oxygen therapy is considered medically necessary to treat cluster headaches. These clients also have a documented clinical history that includes all of the following:

• At least five attacks of severe, strictly unilateral pain that is orbital, supraorbital, temporal, or in any combination of these sites, lasting 15 to 180 minutes, and occurring at least once every other day up to eight times a day;

• At least one of the following symptoms or signs, ipsilateral to the headache:

- Conjunctival injection and/or lacrimation;
- Nasal congestion and/or rhinorrhea;
- Eyelid edema;
- Forehead and facial sweating; or
- Miosis and/or ptosis;

• Occurring with a frequency at least once every other day up to eight times per day;

• Not better accounted for by another ICHD-3 diagnosis;

• Prevents ability to function in all activities; and

• Other treatment has failed.

"Home and community residential settings" - In-home, adult family home, or boarding home.

"Hypopnea" - A temporary reduction of airflow lasting at least ten seconds and accompanied with a ((~~thirty~~)) 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a four percent decrease in oxygen saturation. The AHI is the

average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

"Hypoxemia" - Less than normal level of oxygen in the blood.

"Maximum allowable" - The maximum dollar amount the medicaid agency reimburses a provider for a specific service, supply, or piece of equipment.

"Month" - For the purposes of this chapter, means ((~~thirty~~)) 30 days.

"Nebulizer" - A medical device which administers drugs for inhalation therapy for clients with respiratory conditions such as asthma or emphysema.

"Obstructive sleep apnea (OSA)" - This syndrome refers to the interruption of breathing during sleep, due to obstructive tissue in the upper airway that collapses into the air passage with respiration.

"Oxygen" - Medical grade liquid or gaseous oxygen.

"Oxygen concentrator" - A medical device that removes nitrogen from room air and retains almost pure oxygen (((~~eighty-seven~~)) 87 percent to ((~~ninety-five~~)) 95 percent) for delivery to a client.

"Oxygen system" - All equipment necessary to provide oxygen to a client.

"Portable oxygen system" - A system which allows the client to be independent of the stationary system for several hours, thereby providing mobility for the client.

"Pulmonary hypertension" - High blood pressure in the vessels that feed through the lungs, causing the right side of the heart to work harder to oxygenate blood.

"Respiratory care" - The care of a client with respiratory needs and all related equipment, oxygen, services, and supplies.

((~~**"Respiratory care medicaid provider guide"** - A manual containing procedures for billing, which is available online at http://maa.dshs.wa.gov/download.~~))

"Respiratory care practitioner" - A person licensed by the department of health according to chapter 18.89 RCW and chapter 246-928 WAC as a respiratory therapist (RT) or respiratory care practitioner (RCP).

"Respiratory effort related arousals (RERA)" - These occur when there is a sequence of breaths that lasts at least ((~~ten~~)) 10 seconds, characterized by increasing respiratory effort or flattening of the nasal pressure waveform, which lead to an arousal from sleep. However, they do not meet the criteria of an apnea or hypopnea.

"Restrictive thoracic disorders" - This refers to a variety of neuromuscular and anatomical anomalies of the chest/rib cage area that may result in hypoventilation, particularly while the client sleeps at night.

"Reasonable useful lifetime (RUL)" - For ((~~thirty-six~~)) 36 month capped oxygen equipment, the RUL is five years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of the rental and runs for five years from that date.

"Stationary oxygen system" - Equipment designed to be used in one location, generally for the purpose of continuous use or frequent intermittent use.

AMENDATORY SECTION (Amending WSR 12-14-022, filed 6/25/12, effective 8/1/12)

WAC 182-552-0200 Respiratory care—Provider requirements. (1) To receive payment for respiratory care equipment and supplies under this chapter, a provider must:

(a) Meet the general provider requirements in chapter 182-502 WAC;

(b) Obtain prior authorization from the medicaid agency, if required, before delivery to the client and before billing the agency;

(c) Keep initial and subsequent prescriptions according to the requirements within this chapter;

(d) Provide instructions to the client and/or caregiver on the safe and proper use of equipment provided;

(e) Have a licensed health care professional whose scope of practice allows for the provision of respiratory care. The licensed health care professional must also:

(i) Check equipment and ensure equipment settings continue to meet the client's needs; and

(ii) Communicate with the client's authorized prescriber if there are any concerns or recommendations.

(f) Verify that the client has a valid prescription.

(i) To be valid, a prescription must:

(A) Be written, and signed and dated by a physician, advanced registered nurse practitioner (ARNP), or physician's assistant certified (PAC); and

(B) State the specific items or services requested, including the quantity, frequency, and duration/length of need. Prescriptions that only state "as needed" or "PRN" are not sufficient; and

(C) For an initial prescription, not be older than three months from the date the prescriber signed the prescription; or

(D) For subsequent prescriptions, not be older than one year from the date the ((~~prescriber signs the~~)) initial prescription ((~~(see WAC 182-552-0800 for exception to this time frame for oxygen).~~

~~(ii) If oxygen is prescribed:~~

~~(A) The following additional information is required:~~

~~(I) Flow rate of oxygen;~~

~~(II) Estimated length of need;~~

~~(III) Frequency and duration of oxygen use; and~~

~~(IV) The client's oxygen saturation level.~~

~~(B) For clients who meet:~~

~~(I) Group I clinical criteria, recertification is required one year after initial certification.~~

~~(II) Group II clinical criteria, recertification is required three months after the initial certification and annually thereafter.~~

~~(C) Providers may use the client's oxygen saturation or laboratory values to meet recertification requirements.~~)) was signed. (See WAC 182-552-0800 for exceptions.)

(2) The medicaid agency does not pay for respiratory care equipment and/or supplies furnished to the agency's clients when:

(a) The authorized prescriber who provides medical justification to the agency for the item provided to the client is an employee of, has a contract with, or has any financial relationship with the provider of the item; or

(b) The authorized prescriber who performs a client evaluation is an employee of, has a contract with, or has any financial relationship with a provider of respiratory care equipment, supplies, and related items.

AMENDATORY SECTION (Amending WSR 12-14-022, filed 6/25/12, effective 8/1/12)

WAC 182-552-0800 Respiratory care—Covered—Oxygen and oxygen equipment. ((~~The medicaid agency follows medicare clinical guidelines for respiratory care, unless otherwise described in this chapter.~~))

(1) The medicaid agency covers((~~, without prior authorization,~~)) oxygen and oxygen equipment as provided in this chapter.

(2) The agency pays for the rental of a stationary oxygen system and/or a portable oxygen system, as follows:

(a) For clients, ((~~twenty years of~~)) age 20 and younger, when prescribed by the client's treating practitioner; or

(b) For clients, ((~~twenty-one years of~~)) age 21 and older, when prescribed by a practitioner and the client meets ((~~medicare~~)):

(i) Medicare's Group I or Group II clinical criteria ((~~as defined in WAC 182-552-005.~~)); or

(ii) The Group III clinical criteria described in WAC 182-552-0005.

(c) If a client age 21 and older does not meet the clinical criteria in this subsection, prior authorization is required ((~~for clients, twenty-one years of age and older, who do not meet medicare clinical criteria.~~

~~(2)~~)). The agency reviews requests for prior authorization under WAC 182-501-0165.

(3) Oxygen and oxygen equipment - Capped rental:

(a) Capped rental applies to in-home oxygen use ((~~by medical assistance clients~~)) only;

(b) The medicaid agency's payment for stationary oxygen system equipment and/or portable oxygen system equipment is limited to ((~~thirty-six~~)) 36-monthly rental payments. During the rental period, the medicaid agency's payment includes any supplies, accessories, oxygen contents, delivery and associated costs, instructions, maintenance, servicing, and repairs;

(c) Oxygen systems are deemed capped rental (provider continues to own the equipment) after ((~~thirty-six~~)) 36 months.

(i) The supplier who provides the oxygen equipment for the first month must continue to provide any necessary oxygen equipment and related items and services through the ((~~thirty-six~~)) 36-month rental period unless one of the exceptions in (e) of this subsection is met.

(ii) The same provider is required to continue to provide the client with properly functioning oxygen equipment (including maintenance and repair), and associated supplies for the remaining ((~~twenty-four~~)) 24 months of the equipment's reasonable useful lifetime (RUL).

(iii) The same provider may bill the medicaid agency for oxygen contents, disposable supplies, and maintenance fees only. Maintenance fee payment is limited to one every six months.

(d) At any time after the end of the five-year RUL for the oxygen equipment, the provider may replace the equipment, thus beginning a new ((~~thirty-six~~)) 36-month rental period.

(e) A ((~~thirty-six~~)) 36-month rental period may restart before the end of the five-year RUL in the following situations only. Providers must follow the medicaid agency's expedited prior authorization process, see WAC 182-552-1300, Respiratory care—Authorization.

(i) The initial provider is no longer providing oxygen equipment or services;

(ii) The initial provider's core provider agreement with the medicaid agency is terminated or expires;

(iii) The client moves to an area which is not part of the provider's service area (this applies to medicaid only clients);

(iv) The client moves into a permanent residential setting; or

(v) The pediatric client is transferred to an adult provider.

(f) The medicaid agency may ((~~authorize a~~)) restart ((~~of~~)) the ((~~thirty-six~~)) 36-month rental period when ((~~extenuating circumstances exist that result in a loss or destruction of oxygen equipment that occurred while the client was exercising reasonable care under the circumstances (e.g., fire, flood, etc.) (see~~)) equipment is replaced under WAC 182-501-0050(7)((~~.~~)). Providers must obtain prior authorization from the medicaid agency.

((~~(3)~~)) (4) Stationary oxygen systems/contents.

(a) The medicaid agency pays a maximum of one rental payment for stationary oxygen systems including contents, per client, every ((~~thirty~~)) 30 days. The medicaid agency considers a stationary oxygen system as one of the following:

(i) Compressed gaseous oxygen;

(ii) Stationary liquid oxygen; or

(iii) A concentrator.

(b) Contents only: The medicaid agency pays a maximum of one payment for stationary oxygen contents, per client, every ((~~thirty~~)) 30 days, when the client owns the stationary oxygen system or the capped monthly rental period is met.

(c) Maintenance: The medicaid agency pays for one maintenance fee of 50 percent of the monthly rental rate for a stationary oxygen concentrator and oxygen transfilling equipment every six months only when the capped rental period is met or the client owns the stationary oxygen concentrator((~~. The maintenance fee is fifty percent of the monthly rental rate~~)).

((~~(4)~~)) (5) Portable oxygen systems/oxygen contents:

(a) The medicaid agency pays a maximum of one rental payment for portable oxygen systems including oxygen contents, per client, every ((~~thirty~~)) 30 days. The medicaid agency considers a portable oxygen system to be either gas or liquid.

(b) Contents only: The medicaid agency pays a maximum of one payment for portable oxygen contents, per client, every ((~~thirty~~)) 30 days, when the client owns the portable oxygen system or when the capped monthly rental period is met.

(c) Maintenance: The medicaid agency pays for one maintenance fee of 50 percent of the monthly rental rate for a portable oxygen concentrator and oxygen transfilling equipment every six months only when the capped rental period is met or the client owns the portable oxygen concentrator((~~. The maintenance fee is fifty percent of the monthly rental rate~~)).

((~~(5)~~)) (6) The medicaid agency does not pay for oxygen therapy and related services, equipment or supplies for clients ((~~twenty-one~~)) 21 years of age and older, with, but not limited to, the following conditions:

(a) Angina pectoris in the absence of hypoxemia;

(b) Dyspnea without cor pulmonale or evidence of hypoxemia; and

(c) Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia.

((~~(6)~~)) (7) The medicaid agency does not pay separately for humidifiers with rented oxygen equipment. All accessories, such as humidifiers necessary for the effective use of oxygen equipment are included in the monthly rental payment.

((~~(7)~~)) (8) The medicaid agency does not pay separately for spare tanks of oxygen and related supplies as backup or for travel.

((~~(8)~~)) (9) The medicaid agency requires a valid prescription for oxygen in accordance with WAC 182-552-200. ((~~In addition,~~))

(a) For both initial and ongoing prescriptions for the use of oxygen, the medicaid agency requires ((~~the following:~~

~~(a) For clients who meet medicare's group I criteria (chronic oxygen clients):~~

~~(i) A prescription for the initial twelve months or the authorized prescriber's specified length of need, whichever is shorter, and a renewed prescription at least every twelve months thereafter; and~~

~~(ii)~~)) documented verification((~~, at least every twelve months,~~)) that oxygen saturations or lab values substantiate the need for continued oxygen use for each client((~~. For ongoing coverage, the provider may perform the oxygen saturation measurements~~)).

(b) The medicaid agency does not accept lifetime certificates of medical need (CMNs).

((~~(b) For clients who meet medicare's group II criteria (borderline oxygen clients):~~

~~(i) A prescription for the initial three months or the authorized prescriber's specified length of need, whichever is shorter and a renewed prescription is required three months after the initial certification and annually thereafter.~~

~~(ii) Verification that oxygen saturations or lab values substantiate the need for continued oxygen use must be documented in the client's file. For ongoing coverage, the provider may perform the oxygen saturation measurements. The medicaid agency does not accept lifetime CMNs.~~

~~(9)~~)) (10) The medicaid agency requires that documentation of oxygen saturation and lab values taken to substantiate the medical necessity of continued oxygen be kept in the client's record.

((~~(10)~~)) (11) Oxygen supplies - Replacement. The medicaid agency pays for replacement oxygen supplies after the ((~~thirty-six~~)) 36 month capped rental period or if the client owns the equipment as follows:

(a) Nasal cannula, limited to two per client every ((~~thirty~~)) 30 days;

(b) Tubing (oxygen), limited to one replacement per client every ((~~thirty~~)) 30 days; and

(c) Variable concentration mask, limited to two per client every ((~~thirty~~)) 30 days.

((~~(11)~~)) (12) See WAC 182-552-1200, Respiratory care—Noncovered services.