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427.401: Introduction

130 CMR 427.000 establishes the requirements and procedures for the purchase, rental, and repair of oxygen and respiratory therapy equipment and supplies under the Medical Assistance Program.

427.402: Definitions

The following terms used in 130 CMR 427.000 have the meanings given in 130 CMR 427.402 unless the context clearly requires a different meaning.

Accessory Equipment — a product fabricated primarily and customarily to modify or enhance the usefulness or functional capability of other equipment and that is generally useful only in the presence of other equipment.

Apnea Monitor — a device that has the ability to recognize central or mixed apneas and bradycardia as they occur and to record these events for subsequent review. It must:

- (1) have alarms that accurately reflect the predisposing condition and that consistently alert and are understandable to the caregiver;
- (2) be capable of monitoring its own internal essential functions to assure proper operation;
- (3) be noninvasive; and
- (4) be easy to use and understand.

Adjusted Acquisition Cost — the price paid to a supplier by a provider for oxygen and respiratory therapy equipment, excluding all associated costs such as, but not limited to, shipping, handling, and insurance costs.

Customized Equipment — durable medical equipment that is made or adapted to meet the specific needs of a particular patient and that is sufficiently specialized or modified to preclude the use of such equipment by subsequent patients. Customized equipment may be either custom fabricated or custom fitted.

- (1) custom fabricated — equipment made for a patient from measurement or patterns, or both.

The following list describes various types of custom-fabricated equipment:

- (a) casting — encasing a body part in a cast;
 - (b) molded to patient model — equipment that is fabricated from a positive mold developed from a plaster cast taken of the involved portion of the patient's body;
 - (c) non-molded — no casting or molding techniques are used in the fabrication of the equipment, which may be either a stock item or made from measurement or patterns, or both.
- (2) custom fitted — no casting or molding techniques used in the fabrication of the equipment, which is a stock item that is fitted and adjusted to the patient.

Durable Medical Equipment — products that are:

- (1) fabricated primarily and customarily to fulfill a medical purpose;
- (2) generally useful only in the presence of illness or injury;
- (3) able to withstand repeated use over an extended period of time; and
- (4) appropriate for home use.

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EOHHS – the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Licensed Physician — a physician who is licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

Licensed Respiratory Care Practitioner — a respiratory therapist or technician recognized by the Commonwealth of Massachusetts, Division of Registration, as qualified to provide respiratory care services in Massachusetts.

MassHealth – the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c. 118E, and other applicable laws and waivers to provider and pay for medical services to eligible members.

Medical and Surgical Supplies — medical products that are:

- (1) fabricated primarily and customarily to fulfill a medical or surgical purpose;
- (2) generally useful only in the presence of illness or injury;
- (3) used in the treatment of a specific medical condition; and
- (4) nonreusable and disposable.

Member (formerly “recipient”) — a person determined by the MassHealth agency to be eligible for MassHealth.

Oximetry — provides estimates of arterial oxyhemoglobin saturation (SaO₂) by utilizing selective wavelengths of light to determine noninvasively the percentage of hemoglobin saturated with oxygen.

Oxygen — gaseous or liquid medical-grade oxygen that conforms to United States Pharmacopoeia Standards.

Oxygen and Respiratory Therapy Equipment — equipment and supplies used in the administration of oxygen therapy or the administration of respiratory therapy.

Oxygen and Respiratory Therapy Equipment Provider — an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency that meets all applicable requirements of 130 CMR 427.404 and 130 CMR 450.000: *Administrative and Billing Regulations*. Oxygen and respiratory therapy equipment providers may include MassHealth providers also enrolled as MassHealth participating durable medical equipment and supplies (DME) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and pharmacy providers eligible to enroll with an oxygen specialty under 130 CMR 427.404(B), who also meet all applicable requirements of 130 CMR 427.000.

Oxygen-Generating Equipment — any device suitable for domiciliary use that produces oxygen by any chemical or physical means, such as, but not limited to, oxygen concentrators and oxygen enrichers, and that conforms to such standards as may be required by federal or state law.

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Oxygen Delivery Systems — a comprehensive oxygen service that includes, but is not limited to, gaseous and liquid oxygen, oxygen-generating equipment and related delivery-systems container or cylinder, manifold system whenever high-volume oxygen is used, stand, cart, walker or stroller, supply reservoir, contents indicator, regulator with flow gauge, humidification devices, cannula, mask, and special administration device tubing and refill adapter.

Oxygen Therapy — the administration of oxygen at concentrations greater than that in the ambient air with the intent of treating the signs and symptoms of tissue hypoxia resulting from abnormal blood oxygen levels.

Respiratory Therapy — treatment that maintains or improves the ventilatory function of the respiratory tract.

Respiratory Therapy Equipment and Supplies — modalities and necessary ancillary equipment generally used in the care and treatment of pulmonary insufficiency that are prescribed by a licensed physician or independent nurse practitioner for therapeutic and remedial effect and that meet standards required by federal or state law. Respiratory therapy devices include, but are not limited to, the complete device and its related delivery-system accessories, including regulator, humidification and heating units, filters, cannulas, masks, and special administration device tubing adapters.

Servicing Facility — a business or branch of a business where oxygen and respiratory therapy equipment, supplies, and services, especially repairs and replacements, can be obtained.

Usual and Customary Charge — the lowest fee charged by an oxygen and respiratory therapy equipment provider to the general public.

427.403: Eligible Members

(A) MassHealth Members. MassHealth covers oxygen and respiratory therapy equipment provided to eligible MassHealth members, subject to the restrictions and limitations described in regulations at 130 CMR 427.000 and 450.000: *Administrative and Billing Regulations*. 130 CMR 450.105: *Coverage Types* specifically states, for each coverage type, which services are covered and which members are eligible to receive those services.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106: *Emergency Aid to the Elderly, Disabled and Children Program*.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

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427.404: Provider Eligibility

(A) Participating Provider Requirement. Payment for the services described in 130 CMR 427.000 is made to oxygen and respiratory therapy equipment providers and repair service providers who are participating in MassHealth; to providers also enrolled as MassHealth participating durable medical equipment and supplies (DME) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and to MassHealth-enrolled pharmacy providers who have been assigned an oxygen and respiratory therapy equipment specialty in accordance with 130 CMR 427.404(B). Participating oxygen and respiratory therapy equipment providers must be accredited by an accrediting body that is acceptable to the Centers for Medicare & Medicaid Services. Applicants must meet the requirements in 130 CMR 450.000: *Administrative and Billing Regulations*, as well as the requirements in 130 CMR 427.000. Participating oxygen and respiratory therapy equipment providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency.

(B) Pharmacy Providers Assigned Oxygen and Respiratory Therapy Equipment Specialty. Applicants or providers enrolled as a MassHealth pharmacy provider under 130 CMR 406.000: *Pharmacy Services* may qualify to provide oxygen and respiratory therapy equipment services if the following conditions are met:

- (1) the applicant or provider meets all other conditions under CMR 427.000 to provide oxygen and respiratory therapy equipment and supplies; and
- (2) the MassHealth agency has assigned a specialty of oxygen and respiratory therapy equipment to the applicant's or provider's existing provider number for pharmacy services.

(C) In State.

- (1) A provider located in Massachusetts must engage in the business of supplying oxygen and respiratory therapy equipment to the public and must meet all state and local requirements for engaging in such business.
- (2) A provider located in Massachusetts must employ a minimum of one respiratory care practitioner licensed by the Commonwealth of Massachusetts.
- (3) A provider who furnishes services to recipients in Massachusetts and whose main office is located out of state must have a servicing facility in Massachusetts.

(D) Out of State. A provider located outside of Massachusetts is eligible to participate in MassHealth only if it participates in the Medicaid program (or equivalent) of the state in which it primarily conducts business and meets the requirements in 130 CMR 427.404(A).

427.405: Services Provided by Out-of-State Providers

The Division pays for services provided in another state to the same extent that it pays for services within its boundaries if the services are provided to a recipient who is a resident of Massachusetts and any of the following conditions are met:

- (A) services are needed because of a medical emergency;
- (B) services are needed and the recipient's health would be endangered if the recipient were required to travel to the Commonwealth;

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(C) the Division determines, on the basis of medical advice, that the needed services, or necessary supplementary resources, are more readily available in another state; or

(D) the recipient lives in an area of Massachusetts that borders another state, and it is a general practice of recipients in that area to use medical resources in the adjacent state.

427.406: Reimbursable Services

The Division pays for the purchase, rental, and repair of oxygen and respiratory therapy equipment and supplies subject to the restrictions and limitations in 130 CMR 427.000.

427.407: Nonreimbursable Services

The Division does not pay for the following equipment and services:

- (A) any equipment or services that are investigative or experimental in nature;
- (B) any equipment or services for which, under comparable circumstances, the provider does not customarily bill private patients who do not have health insurance;
- (C) nonmedical equipment or supplies. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use. For example, equipment whose primary function is environmental control, comfort, or convenience is not reimbursable;
- (D) any equipment or services that are not both necessary and reasonable for the treatment of a recipient's pulmonary condition. This includes but is not limited to:
 - (1) equipment or services that cannot, based on medical standards as determined by the Division, reasonably be expected to make a meaningful contribution to the treatment of a recipient's pulmonary condition;
 - (2) equipment or services that are substantially more costly than a medically appropriate and feasible alternative; and
 - (3) equipment or services that serve essentially the same purpose as equipment already available to the recipient;
- (E) accessory equipment (except when the item it accessorizes is reimbursable);
- (F) the repair of equipment that is not reimbursable under these regulations;
- (G) routine periodic testing, cleaning, regulating, and checking of equipment. This limitation does not apply to extensive maintenance that, based on the manufacturer's recommendations, must be performed by authorized technicians. Such extensive maintenance is a repair service reimbursable under 130 CMR 427.426;
- (H) equipment and supplies that are not of proven quality and dependability;

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- (I) equipment that does not conform to all applicable federal and state product standards; and
- (J) diagnostic tests used to determine the medical need for oxygen or respiratory therapy equipment, or associated medical supplies.

427.408: Prescription Requirements

(A) The purchase or rental of any equipment or services described in 130 CMR 427.000 is reimbursable only after the provider has obtained a written prescription signed by a licensed physician or independent nurse practitioner. The prescription must be dated within 90 days of the initial date of service and include the following information:

- (1) the recipient's name, address, and recipient identification number (RID);
- (2) the oxygen and respiratory equipment requested;
- (3) the diagnosis associated with the prescribed therapy
- (4) specific therapeutic objectives;
- (5) for oxygen therapy equipment, the liter flow and hours per day;
- (6) for respiratory therapy equipment, the frequency of use per day;
- (7) the estimated length of time that the equipment will be used by the recipient;
- (8) the prescriber's address and telephone number; and
- (9) the date the prescription was signed by the prescriber.

(B) The Division shall accept a prescription in the following forms:

- (1) on a sheet from the prescriber's desk pad;
- (2) on the prescriber's letterhead stationery; or
- (3) on a Certificate of Medical Necessity from the Durable Medical Equipment Regional Carrier (DMERC) for the federal Health Care Financing Administration's Region A. If this certificate is used, it must be completed in accordance with the instructions established by the Region A DMERC and satisfy all requirements in 130 CMR 427.000.

427.409: Prior Authorization

(A) The Division requires that the provider obtain prior authorization as a prerequisite to payment for the oxygen and respiratory therapy equipment and services listed in 130 CMR 427.410 and 427.411, except as specified in 130 CMR 427.427(B). Prior authorization determines only the medical necessity of the authorized item or service and does not waive any other prerequisites to payment such as recipient eligibility or resort to health insurance payment.

(B) Providers must submit requests for prior authorization in accordance with the instructions in Subchapter 5 of the *Oxygen and Respiratory Therapy Equipment Manual*. Before determining the medical necessity of an item or service for which prior authorization is requested, the Division may, at its discretion, require the prescriber to submit an assessment of the recipient's pulmonary disability and to describe the specific therapeutic goals of the requested service.

(C) For each item requested, the prior-authorization request must include an invoice that reflects the provider's adjusted acquisition cost as described in 130 CMR 427.420. The invoice must be placed in the recipient's record and made available to the Division pursuant to 130 CMR 427.430.

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(D) The provider must submit the prior-authorization request within 90 days of the requested date of service (date of delivery). Failure to submit the request within this 90-day period will result in denial of the request.

(E) The Division will send written notification of the prior authorization decision to the recipient and the provider. The notification will indicate approval, deferral because additional information is necessary, modification, or denial. Notification of denial will include the reason for denial. The recipient, the provider, and the prescriber have the right to resubmit a request and furnish additional information. The recipient may appeal the denial of a prior-authorization request within 30 days after the date of the notice of denial. Procedures for such an appeal are set forth in 130 CMR 610.000.

427.410: Purchases Requiring Prior Authorization

The purchase of any of the following requires prior authorization:

- (A) oxygen or respiratory therapy equipment costing more than \$35.00;
- (B) gaseous or liquid oxygen; and
- (C) repair services costing more than \$35.00.

427.411: Rentals Requiring Prior Authorization

The rental of any of the following requires prior authorization:

- (A) oxygen or respiratory therapy delivery systems;
- (B) suction apparatus;
- (C) nebulizers;
- (D) intermittent positive pressure breathing (IPPB) machines; and
- (E) equipment that is not listed as a rental item in Subchapter 6 of the *Oxygen and Respiratory Therapy Equipment Manual*.

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427.420: Adjusted Acquisition Cost

- (A) The adjusted acquisition cost must not exceed the manufacturer’s current catalog (list) price and must be evidenced by the purchase price of the equipment listed on a copy of a received invoice from the seller.
- (B) Any additional discounts must be properly disclosed and appropriately reflected in the cost claimed or charges made by the provider pursuant to M.G.L. c. 118E, § 41, and U.S.C. § 1320a-7b(b)(3)(A).
- (C) If the equipment has not been purchased by the provider at the time of the prior-authorization request, a quote reflecting the absolute lowest price of the item and the catalog (list) price may be substituted for the received invoice. The quotation shall be on the manufacturer’s letterhead or form and be addressed to the provider.
- (D) The actual received invoice must be placed in the recipient’s records. This record shall be maintained and available to the Division pursuant to 130 CMR 427.430.

427.421: Rates of Payment

The Massachusetts Division of Health Care Finance and Policy determines the maximum allowable fees for oxygen and respiratory therapy equipment. Payment is always subject to the conditions, exclusions, and limitations set forth in 130 CMR 427.000.

427.422: Individual Consideration

- (A) Some services listed in Subchapter 6 of the *Oxygen and Respiratory Therapy Equipment Manual* are designated “I.C.”, an abbreviation for individual consideration. Individual consideration means that a fee could not be established by the Division of Health Care Finance and Policy. The payment for an individual-consideration service will be determined by the Division’s professional advisors. Before making a determination, the Division’s professional advisors will analyze the provider’s report of services submitted, the cost of constructing or adapting the device, and the adjusted acquisition cost of the materials.
- (B) Providers must maintain adequate records to determine the appropriateness of individual-consideration claims and must provide these documents to the Division upon demand. Payment to a provider for an individual-consideration claim shall be in accordance with 130 CMR 427.000.

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427.423: Purchase of Oxygen and Respiratory Therapy Equipment

- (A) Payment to a provider for the purchase of oxygen and respiratory therapy equipment shall be the lowest of:
- (1) the provider's usual and customary charge to the general public;
 - (2) the adjusted acquisition cost of the item plus a markup not to exceed:
 - (a) 50% for any item whose adjusted acquisition cost is less than \$25;
 - (b) 45% for any item whose adjusted acquisition cost is \$25 or greater and less than \$100;
 - (c) 40% for any item whose adjusted acquisition cost is \$100 or greater and less than \$200;
 - (d) 35% for any item whose adjusted acquisition cost is \$200 or greater and less than \$300;
or
 - (e) 30% for any item whose adjusted acquisition cost is \$300 or greater; and
 - (3) the fee set forth in the applicable fee schedule of the Division of Health Care Finance and Policy.
- (B) When oxygen is provided in partially full tanks, the rate of payment shall be prorated by multiplying the maximum allowable fee by the percentage of the complete tank consumed.
- (C) Payment for the following is included in the fee for the purchase of gaseous and liquid oxygen calculated in accordance with 130 CMR 427.423(A):
- (1) delivery of gaseous or liquid oxygen, including the cost of 24-hour service;
 - (2) instruction of the recipient and caregiver, if any, in the safe and proper use of oxygen; and
 - (3) accessories required for the initial setup.
- (D) Payment for the following is included in the fee for the purchase of oxygen and respiratory therapy equipment calculated in accordance with 130 CMR 427.423(A):
- (1) delivery to and installation at the site where the equipment will be used;
 - (2) instruction of the recipient and caregiver, if any, in the proper operation of the equipment; and
 - (3) accessories required for the initial setup.
- (E) Purchased oxygen and respiratory therapy equipment must be:
- (1) clean and sterilized when appropriate;
 - (2) in proper working condition; and
 - (3) new at the time of purchase, except for equipment purchased pursuant to 130 CMR 427.425.

427.424: Rental of Oxygen and Respiratory Therapy Equipment

- (A) The monthly rental payment to a provider for respiratory therapy equipment shall be the lowest of:
- (1) 1/6 of the adjusted acquisition cost of the equipment for the first six months and 1/12 of the adjusted acquisition cost of the equipment for each month after the first six months;
 - (2) the provider's usual and customary rental charge to the general public for one month; or
 - (3) the fee set forth in the applicable fee schedule of the Division of Health Care Finance and Policy.

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(B) The monthly rental payment to a provider for oxygen-generating and delivery devices shall be the lowest of:

- (1) the provider's usual and customary charge to the general public; or
- (2) the fee set forth in the applicable fee schedule of the Division of Health Care Finance and Policy.

(C) Payment for accessory equipment necessary for the proper functioning of the rented equipment shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B). Accessory equipment includes but is not limited to:

- (1) flowmeter;
- (2) regulator;
- (3) reservoir;
- (4) manifold;
- (4) walker, stand, or cart; and
- (6) backup gaseous oxygen and delivery systems (when use of an oxygen-generating device is prescribed).

(D) Payment for disposable items necessary for the proper functioning of the rented equipment shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B).

Accessory equipment includes but is not limited to:

- (1) tubing;
- (2) humidification devices;
- (3) cannulas;
- (4) masks;
- (5) filters; and
- (6) nebulizers.

(E) Payment for the maintenance, cleaning, and inspection of the rented equipment shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B). This includes the replacement of disposable parts periodically or as needed.

(F) Payment for repairs necessary to ensure the proper functioning of rented equipment shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B). This includes the replacement of defective parts and the loan of replacement equipment while rented equipment is being repaired.

(G) Payment for delivery to and installation at the site where the equipment will be used shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B).

(H) Payment for instruction of the recipient in the proper use of the equipment shall be included in the fee calculated in accordance with 130 CMR 427.424(A) and (B).

(I) Rented oxygen and respiratory therapy equipment must be in proper working order. Equipment must be clean and, when appropriate, sterilized at the time of rented.

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427.425: Purchase of Oxygen and Respiratory Therapy Equipment Rented by the Division

The Division at its discretion may purchase, at the following rates of payment, oxygen and respiratory therapy equipment that is being provided on a monthly rental basis.

(A) If the Division exercises the option to purchase the equipment within three months from the date of delivery of the equipment, 70% of the total rental payments shall be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 427.423(A) and (B).

(B) If the Division exercises the option to purchase the equipment any time after three months from the date of delivery of the equipment, 70% of the first three monthly rental payments and 50% of all subsequent monthly rental payments shall be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 427.423(A) and (B).

427.426: Repair of Oxygen and Respiratory Therapy Equipment Purchased by the Division

(A) Prior authorization is required for all repair services costing more than \$35. Prior authorization requests for repair services must be submitted in accordance with the instructions in Subchapter 5 of the *Oxygen and Respiratory Therapy Equipment Manual*.

(B) All claims for repair services costing \$35 or less must be accompanied by a service report written on the provider's business stationary. The report must include the following information:

- (1) the name of the person who requested the service and the date of the request;
- (2) a specific description of the equipment malfunction that was repaired;
- (3) a list of procedures and parts furnished to complete the repair; and
- (4) the cost of each procedure and part furnished and the time required to complete the repair.

(C) If equipment cannot be repaired immediately at the recipient's place of residence, the provider must supply on a rental basis comparable equipment for the recipient's use during the time that the purchased equipment is being repaired. The daily rental fee shall be 1/30 of the monthly rental fee calculated in accordance with 130 CMR 427.424(A) and (B). No payment for the rental of substitute equipment shall be made for any day following the fifth business day after the date of removal of the equipment from the residence unless the provider obtains prior authorization from the Division.

(D) The provider of repair services is responsible for the quality of the workmanship and parts and for ensuring that repaired equipment is in proper working condition.

(E) The Division does not pay for repairs or damage resulting from abuse or misuse of equipment.

(F) The Division does not pay for the repair of oxygen or respiratory therapy equipment if a repair or replacement of the item was performed within the preceding 12 months.

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427.427: Medicare Coverage

(A) When Medicare-covered oxygen and respiratory therapy equipment or services are furnished to a recipient who receives Medicare Part B benefits, the rate of payment is always based on the Medicare amount approved. The Division’s payment for such services is limited to the coinsurance and deductible amounts. The provider must submit claims for services furnished to recipients receiving Medicare benefits in accordance with the instructions in Subchapter 5 of the *Oxygen and Respiratory Therapy Equipment Manual*.

(B) Prior authorization from the Division is not required for Medicare-covered services that are furnished to recipients who receive Medicare Part B benefits.

(C) When Medicare Part B, or any other primary insurer, denies services or considers services not covered, the provider must obtain prior authorization in accordance with 130 CMR 427.409 through 427.411.

427.428: Oxygen and Respiratory Therapy Equipment for Institutionalized Recipients

(A) Nursing Facilities. The Division pays for the purchase, rental, and repair of oxygen and respiratory therapy equipment provided to a recipient residing in a nursing facility, subject to the limitations set forth in 130 CMR 427.000, with the following exception: the Division does not pay for oxygen or respiratory therapy equipment prescribed for standby emergency or *pro re nata* (PRN) use, which is covered under the nursing facility’s *per diem* rate.

(B) Acute Inpatient Hospitals, Chronic Disease Hospitals, and Rehabilitation Hospitals. The Division does not pay for the purchase, rental, or repair of oxygen or respiratory therapy equipment furnished to a hospitalized recipient, except for oxygen and respiratory therapy equipment prescribed primarily for the home use of the recipient after discharge.

(C) Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) with 16 Beds or More (State Schools). The Division does not pay for the purchase, rental, or repair of oxygen or respiratory therapy equipment furnished to a recipient residing in a state school.

427.429: Provider Responsibility

(A) The provider must make reasonably certain that the oxygen and respiratory therapy equipment and supplies furnished are the most cost effective available, given the medical need for which they are prescribed and the recipient’s physical limitations.

(B) Before purchasing oxygen or respiratory therapy equipment and supplies, the provider must make a reasonable effort to purchase from the least costly reliable source by comparing prices charged by different suppliers for comparable items.

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427.430: Recordkeeping Requirements

Payment for any service listed in 130 CMR 427.000 is conditioned upon its full and complete documentation in the recipient's medical record. In addition to fulfilling all the recordkeeping requirements of 130 CMR 450.205, the provider must keep a record of all oxygen and respiratory therapy equipment and repair services furnished to a recipient for at least four years following the date of service. This record must include the following:

- (A) a prescription for all rentals and purchases that fulfills the requirements of 130 CMR 427.408;
- (B) a copy of the approved prior-authorization request for all equipment, supplies, or services requiring prior authorization;
- (C) an acknowledgment of receipt, including:
 - (1) the date the equipment was delivered or the service was furnished;
 - (2) a description of the equipment or service, including the manufacturer's brand name, model number, and serial number; and
 - (3) the signature of the recipient or the recipient's legal representative, acknowledging receipt of the equipment, supplies, or services on that date; and
- (D) a manufacturer's invoice or cost report demonstrating the cost to the provider of the materials.

(130 CMR 427.431 through 427.439 Reserved)

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427.440: Clinical Requirements: Introduction

Any deviation from the following clinical requirements must be justified through the submission of clear and objective data supporting therapeutic intervention. This data must originate from recognized medical journals and demonstrate statistically significant and generally accepted results. Documentation of medical necessity must be submitted with the prior-authorization request (*see* 130 CMR 427.409). For services that do not require prior authorization, this documentation must be kept in the recipient record for review pursuant to 130 CMR 450.205. In addition, all services must meet Division regulations regarding cost and alternative available treatment at 130 CMR 427.407 through 427.411 and 427.420 through 427.422.

427.441: Clinical Requirements: Oxygen Therapy Equipment

(A) Requirements for Coverage. Oxygen therapy equipment is reimbursable for the treatment of severe lung diseases (for example, chronic bronchitis, emphysema, and interstitial lung disease) that cause hypoxemia and where oxygen therapy can reasonably be expected to correct the patient's hypoxemia.

(B) Laboratory Evidence.

(1) The initial prior-authorization request for oxygen therapy equipment in the home must include laboratory evidence of chronic hypoxemia. This evidence must be in the form of an arterial blood gas analysis ($\text{PaO}_2 \leq 55$ torr while breathing room air) or an oximetry reading ($\text{SaO}_2 \leq 88\%$ while breathing room air).

(2) The arterial blood gas analysis or oximetry reading must reflect the recipient's baseline and stable blood-oxygen status. The reading must be performed as close as possible to the time of discharge from the hospital or close to the set up time of the equipment in the home.

(3) The test for evidence of hypoxemia must be performed while the recipient is in a resting state and breathing room air. Prior authorization will be deferred for services based on tests performed while the recipient is breathing supplemental oxygen unless the physician can certify that removing the oxygen from the patient could be life threatening.

(C) Evidence of Hypoxemia. One or both of the following test results are sufficient evidence of hypoxemia if they are performed while the patient is breathing room air and are in association with cor pulmonale, congestive heart failure, or erythrocythemia with a hematocrit of more than 56:

(1) $\text{PaO}_2 = 56 - 59$ torr, or

(2) $\text{SaO}_2 \leq 89\%$.

(D) Qualification for Supplemental Oxygen Therapy Equipment. Some recipients may not qualify for oxygen at rest, but may qualify for supplemental oxygen during ambulation, sleep, or exercise. Oxygen therapy equipment may be reimbursable during these specific activities when SaO_2 is demonstrated to fall to 88% or less.

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(E) Prescriptions for Supplemental Oxygen Therapy Equipment. Prescriptions for noncontinuous supplemental oxygen therapy must include the following information:

- (1) the number of hours per day supplemental oxygen will be required;
- (2) the activity during which the prescribed supplemental oxygen will be utilized; and
- (3) the total hours of use per day.

Example:

Nasal cannula (2 liters/minute): 8 hours sleeping
 +2 hours walking
 10 hours total

(F) Requirements for Portable Oxygen. A patient meeting all of these requirements may qualify for a portable oxygen system. The prescriber must document that the recipient’s activities take him or her beyond the functional limits of the stationary system.

(G) Reasons for Noncoverage. Oxygen therapy shall not be approved for the following conditions:

- (1) angina pectoris in the absence of hypoxemia;
- (2) breathlessness without cor pulmonale or evidence of hypoxemia;
- (3) peripheral vascular disease resulting in desaturation in one or more extremities without evidence of central hypoxemia; and
- (4) terminal illness that does not involve the lungs.

(H) Required Documentation. The provider must submit the following documentation for reimbursement for oxygen therapy:

- (1) a written prescription pursuant to 130 CMR 427.408;
- (2) prior authorization pursuant to 130 CMR 427.409; and
- (3) documentation of the medical necessity for oxygen therapy in the treatment of hypoxemia (*see* 130 CMR 427.407(D) and 450.208).

427.442: Clinical Requirements: Respiratory Therapy Equipment — Apnea Monitor

(A) Requirements for Coverage. The Division pays for apnea monitoring for certain infants at high risk for sudden death. A pneumogram or multichannel sleep study is not required, but may serve to document one or more of the following requirements:

- (1) infants with one or more documented severe apparent life-threatening events (ALTEs) requiring mouth-to-mouth resuscitation or vigorous stimulation;
- (2) symptomatic pre-term infants (exhibiting pathologic apnea or bradycardia associated with cyanosis, marked pallor, or hypotonia at the time of discharge);
- (3) a sibling of two or more victims of sudden infant death syndrome (SIDS);
- (4) a sibling of one SIDS victim, if both the primary care provider and the parents agree that monitoring is indicated and agree that if the infant has one or two continuous months without significant numbers of alarms or episodes of apnea (that is, without requiring vigorous stimulation or resuscitation) monitoring will be discontinued;
- (5) central hypoventilation documented by oximetry; and
- (6) other conditions in which the infant is at an extraordinarily high risk for sudden death that monitoring can help prevent.

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- (B) Reasons for Noncoverage. An apnea monitor shall not be approved for the following:
- (1) normal asymptomatic newborns;
 - (2) routine monitoring of asymptomatic pre-term infants; and
 - (3) when an infant with ALTEs has had one or two continuous months without significant numbers of alarms or episodes of apnea, bradycardia, or cyanosis that require vigorous stimulation or resuscitation. Discontinuance or renewal of services must be documented through personal observations of professional caregivers at home or through data captured by a smart monitor and documented by a pediatrician.
- (C) Required Documentation. The provider must submit the following documentation for reimbursement for apnea monitoring:
- (1) a written prescription pursuant to 130 CMR 427.408;
 - (2) prior authorization pursuant to 130 CMR 427.409; and
 - (3) documentation of the medical necessity for an apnea monitor, consisting of notation in the patient record of apneic episodes (*see* 130 CMR 427.407(D) and 450.206). A pneumogram or multichannel sleep study is not required, but may serve to document one or more of the requirements in 130 CMR 427.442(B).

427.443: Clinical Requirements: Respiratory Therapy Equipment — Oximetry

- (A) Requirements for Use.
- (1) Spot Checks. Spot checks are reimbursable when used to document the presence of hypoxemia and to quantitate the response of arterial oxyhemoglobin saturation to therapeutic intervention when hypoxemia is transient and unpredictable even in the presence of supplemental oxygen.
 - (2) Continuous. Continuous oximetry is reimbursable when hypoxemia (SaO₂ is less than 90% or decreases 5% from baseline) is transient, variable, and unpredictable, even in the presence of supplemental oxygen, and occurs frequently on a regular basis, so that it requires frequent changes in the supplemental oxygen in response to and to correct hypoxemic episodes.
- (B) Reasons for Noncoverage. If oximetry demonstrates hypoxemia that is correctable and stabilized with supplemental oxygen (that is, during sleep, exercise, or seizures) or some other therapeutic intervention, continued monitoring is not reimbursable.
- (C) Required Documentation. The provider must submit the following documentation for reimbursement for oximetry:
- (1) a written prescription pursuant to 130 CMR 427.408;
 - (2) prior authorization pursuant to 130 CMR 427.409; and
 - (3) documentation of the medical necessity for oximetry and that the test was performed and results documented under the conditions that the oximeter is requested through notation in the medical record and in the prior-authorization request of the results, therapeutic intervention, and clinical decisions based on SaO₂ measurements (*see* 130 CMR 427.407(D) and 450.206).

REGULATORY AUTHORITY

130 CMR 427.000: M.G.L. c. 118E, §§ 7 and 12.