

907 KAR 1:479. Durable medical equipment covered benefits and reimbursement.

RELATES TO: KRS 205.520, 205.560, 42 C.F.R. Part 414, 424.57, 440.230, 45 C.F.R. Part 160, 162.1002, Part 164, 42 U.S.C. 1320d, 1395m, 1395w-4, 1396d(i)

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the provisions relating to coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics.

Section 1. Definitions.

- (1) "Certificate of Medical Necessity" or "CMN" means a form required by the department to document medical necessity for durable medical equipment, medical supplies, prosthetics, or orthotics.
- (2) "CMS" means the Centers for Medicare and Medicaid Services.
- (3) "Covered benefit" or "covered service" means an item of durable medical equipment, a prosthetic, an orthotic, or a medical supply for which coverage is provided by the department.
- (4) "Customized" means that an item has been constructed, fitted, or altered to meet the unique medical needs of an individual Medicaid recipient and does not include the assemblage of modular components or the addition of various accessories that do not require unique construction, fitting, or alteration to individual specifications.
- (5) "Date of service" means:
 - (a) The date the durable medical equipment, prosthetic, orthotic, or supply (DMEPOS) is provided to the recipient;
 - (b) For mail order DMEPOS, the later of the shipping date or the date the recipient was discharged home from an inpatient hospital stay or nursing facility;
 - (c) For DMEPOS delivered to a recipient's home immediately subsequent to a hospital inpatient stay, the date of final discharge; or
 - (d) Up to two (2) calendar days prior to discharge from a hospital or nursing facility if:
 1. The item was provided for purposes of fitting or training of the patient;
 2. The item is ready for use in the recipient's home; and
 3. Billing is not done prior to the date of the recipient's discharge from the facility.
- (6) "Department" means the Department for Medicaid Services or its designee.
- (7) "DMEPOS" means durable medical equipment, prosthetics, orthotics, or supplies.
- (8) "Durable medical equipment" or "DME" means medical equipment that:
 - (a) Withstands repeated use;
 - (b) Is primarily and customarily used to serve a medical purpose;
 - (c) Is generally not useful to a person in the absence of an illness or injury; and
 - (d) Is appropriate for use in the home.
- (9) "Healthcare common procedure coding system" or "HCPCS" means a collection of codes acknowledged by the Centers for Medicare and Medicaid Services (CMS) that represents procedures or items.
- (10) "Home" means a place where the recipient resides excluding:
 - (a) A nursing facility;
 - (b) A hospital;
 - (c) An intermediate care facility for individuals with an intellectual disability; or
 - (d) An institution for mental diseases as defined by 42 U.S.C. 1396d(i).
- (11) "Incidental" means that a medical procedure or service:

- (a) Is performed at the same time as a more complex primary procedure or service; and
- (b)
 - 1. Requires little additional resources; or
 - 2. Is clinically integral to the performance of the primary procedure or service.
- (12) "Invoice price" means an itemized account of a manufacturer's actual charges that are billed to a supplier for goods or services provided by the manufacturer or distributor.
- (13) "Medicaid Program DME Fee Schedule" means a list, located at <http://chfs.ky.gov/dms>, that:
 - (a) Contains the current Medicaid maximum allowable amount established by the department for a covered item of durable medical equipment, a prosthetic, an orthotic, or a medical supply; and
 - (b) Is updated at least quarterly to coincide with the quarterly updates made by the Centers for Medicare and Medicaid Services as required by 42 U.S.C. 1395m and 1395w-4 and 42 C.F.R. Part 414.
- (14) "Medical supply" means an item that is:
 - (a) Consumable;
 - (b) Nonreusable;
 - (c) Disposable; and
 - (d) Primarily and customarily used to serve a medical purpose.
- (15) "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.
- (16) "Medicare accreditation" means having met the quality standards established in 42 U.S.C. 1395m(a)(20).
- (17) "Mutually exclusive" means that two (2) DMEPOS items:
 - (a) Are not reasonably provided in conjunction with each other during the same patient encounter on the same date of service;
 - (b) Represent duplicate or very similar items; or
 - (c) Represent medically inappropriate use of HCPCS codes.
- (18) "Nutritional supplement" means a liquid or powder administered enterally or orally that is specially formulated to supply complete diagnosis-appropriate nutrition, including kilocalories, protein, vitamins, and minerals.
- (19) "Orthotic" means a mechanical device or brace that is designed to support or correct a defect or deformity or to improve the function of a movable part of the body.
- (20) "Prescriber" means a physician, podiatrist, optometrist, dentist, advanced practice registered nurse, physician assistant, or chiropractor who:
 - (a) Is acting within the legal scope of clinical practice under the licensing laws of the state in which the health care provider's medical practice is located;
 - (b) If the individual is an enrolled Kentucky Medicaid provider, is in compliance with all requirements of:
 - 1. 907 KAR 1:671; and
 - 2. 907 KAR 1:672;
 - (c) Is in good standing with the appropriate licensure board and CMS; and
 - (d) Has the legal authority to write an order for a medically necessary item of durable medical equipment, a medical supply, a prosthetic, or an orthotic for a recipient.
- (21) "Prior authorization" means approval that a supplier shall obtain from the department before being reimbursed.
- (22) "Prosthetic" means an item that replaces all or part of the function of a body part or organ.
- (23) "Reasonableness" means:
 - (a) The expense of the item does not exceed the therapeutic benefits that could ordinarily be derived from use of the item;

(b) The item is not substantially more costly than a medically-appropriate alternative;
and

(c) The item does not serve the same purpose as an item already available to the recipient.

(24) "Supplier" means a Medicare-certified provider of durable medical equipment, medical supplies, prosthetics, or orthotics who is enrolled in the Kentucky Medicaid Program.

(25) "Usual and customary charge" means the uniform amount that a supplier bills to the general public for a specific covered benefit.

Section 2. General Coverage.

(1) Except as provided in subsection (2) of this section, coverage for an item of durable medical equipment, a medical supply, a prosthetic, or an orthotic shall:

- (a) Be based on medical necessity and reasonableness;
- (b) Be clinically appropriate pursuant to the criteria established in 907 KAR 3:130;
- (c) Require prior authorization in accordance with Section 7 of this administrative regulation;
- (d) Be provided in compliance with 42 C.F.R. 440.230(c); and
- (e) Be restricted to an item used primarily in the home.

(2)

(a) Except as provided in paragraph (b) of this subsection, the criteria referenced in subsection (1) of this section that was in effect on the date the durable medical equipment, prosthetic, orthotic, or medical supply is provided shall be used as the basis for the determination of coverage, subject to medical necessity override by the department to ensure compliance with 42 C.F.R. 440.230(c).

(b) If criteria referenced in subsection (1) of this section does not exist or is unavailable for a given item or service, the Medicare criteria in effect on the date the durable medical equipment, prosthetic, orthotic, or medical supply is provided shall be used as the basis for the determination of coverage, subject to medical necessity override by the department to ensure compliance with 42 C.F.R. 440.230(c).

(3) Unless specifically exempted by the department, a DME item, medical supply, prosthetic, or orthotic shall require a CMN that shall be kept on file by the supplier for the period of time mandated by 45 C.F.R. 164.316.

(4) An item for which a CMN is not required shall require a prescriber's written order.

(5) If Medicare is the primary payor for a recipient who is dually eligible for both Medicare and Medicaid, the supplier shall comply with Medicare's CMN requirement and a separate Medicaid CMN shall not be required.

(6) A required CMN shall be:

- (a) The appropriate Medicare CMN in use at the time the item or service is prescribed;
- (b) A MAP-1000, Certificate of Medical Necessity, Durable Medical Equipment; or
- (c) A MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Foods.

(7) A CMN shall contain:

- (a) The recipient's name and address;
- (b) A complete description of the item or service ordered;
- (c) The recipient's diagnosis;
- (d) The expected start date of the order;
- (e) The length of the recipient's need for the item;
- (f) The medical necessity for the item;
- (g) The prescriber's name, address, telephone number, and National Provider Identifier (NPI), if applicable; and
- (h) The prescriber's signature and date of signature.

- (8) Except as specified in subsections (9) and (10) of this section, a prescriber shall examine a recipient within sixty (60) calendar days prior to the initial order of a DME item, medical supply, prosthetic, or orthotic.
- (9) Except as specified in subsection (11) of this section, a prescriber shall not be required to examine a recipient prior to subsequent orders for the same DME item, medical supply, prosthetic, or orthotic unless there is a change in the order.
- (10) A prescriber shall not be required to examine a recipient prior to the repair of a DME item, prosthetic, or orthotic.
- (11) A change in supplier shall require a new CMN signed and dated by a prescriber who shall have seen the recipient within sixty (60) calendar days prior to the order.
- (12) A CMN shall be updated with each request for prior authorization.
- (13) The department shall only purchase a new DME item.
- (14) A new DME item that is placed with a recipient initially as a rental item shall be considered a new item by the department at the time of purchase.
- (15) A used DME item that is placed with a recipient initially as a rental item shall be replaced by the supplier with a new item prior to purchase by the department.
- (16) A supplier shall not bill Medicaid for a DME item, medical supply, prosthetic, or orthotic before the item is provided to the recipient.
- (17) A supplier shall not ship supplies to a recipient unless the supplier has:
- (a) First had direct contact with the recipient or the recipient's caregiver; and
 - (b) Verified:
 - 1. That the recipient wishes to receive the shipment of supplies;
 - 2. The quantity of supplies in the shipment; and
 - 3. Whether or not there has been a change in the use of the supply.
- (18) A verification referenced in subsection (17) of this section for each recipient shall be documented in a file regarding the recipient.
- (19) If a supplier ships more than a one (1) month supply of an item, the supplier shall assume the financial risk of nonpayment if the recipient's Medicaid eligibility lapses or a HCPCS code is discontinued.
- (20) A supplier shall have an order from a prescriber before dispensing any DMEPOS item to a recipient.
- (21) A supplier shall have a written order on file prior to submitting a claim for reimbursement.

Section 3. Purchase or Rental of Durable Medical Equipment.

- (1) Except as established on the Medicaid Program DME Fee Schedule, durable medical equipment shall be covered through purchase or rental based upon anticipated duration of medical necessity.
- (2)
- (a) A MAP 1001 form shall be completed if a recipient requests an item or service not covered by the department.
 - (b) A recipient shall be financially responsible for an item or service requested by the recipient via a MAP 1001 that is not covered by the department.
 - (c) A MAP 1001 shall be completed as follows:
 - 1. The DME supplier shall ensure that the recipient or authorized representative reads and understands the MAP 1001;
 - 2. The recipient or authorized representative shall indicate on the MAP 1001 if the recipient chooses to receive a noncovered service;
 - 3. The DME supplier shall complete the supplier information on the MAP 1001;
 - 4. The DME supplier shall provide a copy of the completed MAP 1001 to the recipient; and

5. The DME supplier shall maintain the completed MAP 1001 on file for at least the period of time mandated by 45 C.F.R. 164.316.

(d) If an item or service was denied due to the supplier not meeting the timeframes to obtain a prior authorization or the item or service does not meet medical necessity for a prior authorization, the MAP 1001 shall not be used to obligate the recipient for payment.

Section 4. Special Coverage.

(1) An augmentative communication device or other electronic speech aid shall be covered for a recipient who is permanently unable to communicate through oral speech if:

(a) Medical necessity is established based on a review by the department of an evaluation and recommendation submitted by a speech-language pathologist; and

(b) The item is prior authorized by the department.

(2) A customized DME item shall be covered only if a noncustomized medically appropriate equivalent is not commercially available.

(3) A physical therapy or occupational therapy evaluation shall be required for:

(a) A power wheelchair; or

(b) A wheelchair for a recipient who, due to a medical condition, is unable to be reasonably accommodated by a standard wheelchair.

(4) Orthopedic shoes and attachments shall be covered if medically necessary for:

(a) A congenital defect or deformity;

(b) A deformity due to injury; or

(c) Use as a brace attachment.

(5) A therapeutic shoe or boot shall be covered if medically necessary to treat a nonhealing wound, ulcer, or lesion of the foot.

(6) An enteral or oral nutritional supplement shall be covered if:

(a) The item is prescribed by a licensed prescriber;

(b) Except for an amino acid modified preparation or a low-protein modified food product specified in subsection (7) of this section, it is the total source of a recipient's daily intake of nutrients;

(c) The item is prior authorized; and

(d) Nutritional intake is documented on the CMN.

(7) An amino acid modified preparation or a low-protein modified food product shall be covered:

(a) If prescribed for the treatment of an inherited metabolic condition specified in KRS 205.560(1)(c);

(b) If not covered through the Medicaid outpatient pharmacy program;

(c) Regardless of whether it is the sole source of nutrition; and

(d) If the item is prior authorized.

(8) A DME item intended to be used for postdischarge rehabilitation in the home may be delivered to a hospitalized recipient within two (2) calendar days prior to discharge home for the purpose of rehabilitative training.

(9) An electric breast pump shall be covered for the following:

(a) Medical separation of mother and infant;

(b) Inability of an infant to nurse normally due to a significant feeding problem; or

(c) An illness or injury that interferes with effective breast feeding.

(10) Rental of an airway clearance vest system for a three (3) month trial period shall be required before purchase of the equipment.

Section 5. Coverage of Repairs and Replacement of Equipment.

(1) The department shall not be responsible for repair or replacement of a DME item, prosthetic, or orthotic if the repair or replacement is covered by a warranty.

- (2) Reasonable repair to a purchased DME item, prosthetic, or orthotic shall be covered:
 - (a) During a period of medical need;
 - (b) If necessary to make the item serviceable;
 - (c) If a warranty is not in effect on the requested repair; and
 - (d) In accordance with Section 6(3) of this administrative regulation.
- (3) Extensive maintenance to purchased equipment, as recommended by the manufacturer and performed by an authorized technician, shall be considered to be a repair.
- (4) The replacement of a medically necessary DME item, medical supply, prosthetic, or orthotic shall be covered for the following:
 - (a) Loss of the item;
 - (b) Irreparable damage or wear; or
 - (c) A change in a recipient's condition that requires a change in equipment.
- (5) Suspected malicious damage, culpable neglect, or wrongful disposition of a DME item, medical supply, prosthetic, or orthotic shall be reported by the supplier to the department if the supplier is requesting prior authorization for replacement of the item.

Section 6. Limitations on Coverage.

- (1) The following items shall be excluded from Medicaid coverage through the DME Program:
 - (a) An item covered for Medicaid payment through another Medicaid program;
 - (b) Equipment that is not primarily and customarily used for a medical purpose;
 - (c) Physical fitness equipment;
 - (d) Equipment used primarily for the convenience of the recipient or caregiver;
 - (e) A home modification;
 - (f) Routine maintenance of DME that includes:
 1. Testing;
 2. Cleaning;
 3. Regulating; and
 4. Assessing the recipient's equipment;
 - (g) Except as specified in Section 7(1)(j) of this administrative regulation, backup equipment; or
 - (h) An item determined not medically necessary, clinically appropriate, or reasonable by the department.
- (2) Except if Medicare is the primary payer, the following diabetic supplies (HCPCS codes) shall be covered as a pharmacy benefit at the point of sale:
 - (a) A4206, a syringe with needle (sterile, 1cc or less);
 - (b) A4250, urine test or reagent strips or tablets;
 - (c) A4252, blood ketone test or reagent strip;
 - (d) A4253, blood glucose test or reagent strips;
 - (e) A4256, calibrating solutions;
 - (f) A4258, lancet device;
 - (g) A4259, lancets; or
 - (h) E0607, home blood glucose monitor.
- (3) An estimated repair shall not be covered if the repair cost equals or exceeds:
 - (a) The purchase price of a replacement item; or
 - (b) The total reimbursement amount for renting a replacement item of equipment for the estimated remaining period of medical need.
- (4) Durable medical equipment, prosthetics, orthotics, and medical supplies shall be included in the facility reimbursement for a recipient residing in a hospital, nursing facility, or intermediate care facility or institution for individuals with an intellectual or developmental disability.

Section 7. Prior Authorization Requirements and Process.

- (1) Prior authorization shall be required for the following:
 - (a) An item or repair billed to the department at \$500 or more;
 - (b) Rental of equipment as indicated on the Medicaid Program DME Fee Schedule excluding oxygen services after twelve (12) continuous months of service;
 - (c) Orthopedic shoes;
 - (d) An adjustment to a prosthetic or orthotic;
 - (e) An augmentative communication device;
 - (f) A customized DME item;
 - (g) A replacement DME item, prosthetic, or orthotic if replacement is prior to the:
 1. Usual and customary lifetime of the item; or
 2. Limitation set by the department as indicated in the Medicaid Program DME Fee Schedule;
 - (h) A nutritional supplement;
 - (i) An amino acid modified preparation or a low-protein modified food product;
 - (j) A loaner item for a member-owned piece of equipment that is being repaired;
 - (k) A DMEPOS item denoted by a general or nonspecific HCPCS code;
 - (l) An item designated on the Medicaid Program DME Fee Schedule as requiring prior authorization;
 - (m) An item that exceeds the quantity limitation established in the Medicaid Program DME Fee Schedule; or
 - (n) An item designated by an HCPCS code not indicated on the Medicaid Program DME Fee Schedule that is determined by the department to be a covered benefit.
- (2)
 - (a) If an item requires prior authorization, a supplier shall:
 1.
 - a. Submit all required documentation prior to the date of service; or
 - b. Within one (1) year from the date of service with department approval;
 2. Submit a written request to the department for prior authorization, which shall include the prescriber's order; and
 3. Submit a completed CMN to the department within ninety (90) business days of the date of the request for prior authorization.
 - (b) If the required prior authorization submittals required by paragraph (a) of this subsection are not submitted within the established time frames, the prior authorization request shall be denied.
- (3) If an item requires an evaluation or recommendation by a specialist, the evaluation or recommendation shall be in writing and submitted with the CMN.
- (4) The supplier shall not bill a recipient for a DME item, medical supply, prosthetic, or orthotic if the supplier has not completed the prior authorization process within the timeframe specified in subsection (2) of this section.
- (5) If a supplier provides an item that requires prior authorization before the prior authorization is received, the supplier shall assume the financial risk that the prior authorization might not be subsequently approved.
- (6) A supplier may initially obtain a faxed CMN from a prescriber to expedite the prior authorization process, but a signed, original CMN subsequently shall be required.
- (7) A supplier shall request prior authorization by mailing, faxing, or electronically submitting the following information to the department:
 - (a) A completed prior authorization form MAP-9;
 - (b) A completed CMN; and
 - (c) If requested by the department, additional information required to establish medical necessity, clinical appropriateness, or reasonableness.

- (8) The following additional information shall be required for prior authorization of a customized item:
- (a) An estimate of the fitting time;
 - (b) An estimate of the fabrication time;
 - (c) A description of the materials used in customizing the item; and
 - (d) An itemized estimate of the cost of the item, including the cost of labor.
- (9) The following additional information shall be required for prior authorization of a repair to purchased equipment:
- (a) A description of the nature of the repair;
 - (b) An itemization of the parts required for the repair;
 - (c) An itemization of the labor time involved in the repair; and
 - (d) A copy of the manufacturer's warranty indicating the purchase date or a written notice from the DME supplier stating that the requested repair is not covered by the warranty.
- (10) An item shall be prior authorized based on:
- (a) Medical necessity and the corresponding prior-authorized period of medical necessity; and
 - (b)
 - 1. Clinical appropriateness pursuant to the criteria established in 907 KAR 3:130; or
 - 2. Medicare criteria if the criteria referenced in subparagraph 1. of this paragraph does not exist or is unavailable.
- (11) A prior authorization period shall be extended upon the provision of a new CMN indicating current medical necessity and:
- (a) Clinical appropriateness pursuant to the criteria established in 907 KAR 3:130; or
 - (b) Medicare criteria if the criteria referenced in paragraph (a) of this subsection does not exist or is unavailable.
- (12)
- (a) Prior authorization by the department shall not:
 - 1. Be a guarantee of recipient eligibility; or
 - 2. Guarantee reimbursement.
 - (b) Eligibility verification shall be the responsibility of the supplier.
- (13) Upon review and determination by the department that removing prior authorization shall be in the best interest of Medicaid recipients, the prior authorization requirement for a specific covered benefit shall be discontinued, at which time the covered benefit shall be available to all recipients without prior authorization.
- (14) If it is determined by the department to be in the best interest of Medicaid recipients, the department may designate that an item of durable medical equipment suitable for use in the home may be provided, if prior authorized, to a recipient temporarily residing in a hospital that does not bill patients, Medicaid, or other third-party payers for any health care services.
- (15)
- (a) For purposes of obtaining prior authorization, a signed invoice price quote from the manufacturer shall be acceptable documentation.
 - (b) If the invoice price differs from the manufacturer's invoice price quote, the supplier shall amend the prior authorization and shall maintain documentation of the quote and the invoice.

Section 8. Reimbursement for Covered Services.

- (1) Except for an item specified in subsections (2) and (5) of this section, a new item that is purchased shall be reimbursed at the lesser of:
- (a) The supplier's usual and customary charge for the item;
 - (b) The purchase price specified in the Medicaid Program DME Fee Schedule; or

- (c) If indicated in the Medicaid Program DME Fee Schedule as manually priced, invoice price plus twenty (20) percent for an item not utilizing a billing code.
- (2) Pursuant to 45 C.F.R. 162.1002, the department shall recognize U.S. Department for Health and Human Services quarterly HCPCS code updates.
- (a) An item denoted by an HCPCS code not currently on the Medicaid Program DME Fee Schedule that has been determined by the department to be a covered service shall be manually priced using the actual invoice price plus twenty (20) percent.
- (b)
1. The department shall post HCPCS code change information on its Web site accessible at <http://chfs.ky.gov/dms>.
 2. The information may also be obtained by writing the Department for Medicaid Services at 275 East Main Street, Frankfort, Kentucky 40621.
- (3) If a copayment is required, copayment provisions, including any provider deduction, shall be as established in 907 KAR 1:604.
- (4) For a service covered under Medicare Part B, reimbursement shall be in accordance with 907 KAR 1:006.
- (5) Reimbursement for the purchase of an item that has been rented for less than ten (10) months shall be the purchase price specified in subsection (1) of this section minus the cumulative rental payment made to the supplier.
- (6) A rental item shall be reimbursed as follows, but reimbursement shall not exceed the supplier's usual and customary charge for the item:
- (a) The rental price specified in the Medicaid Program DME Fee Schedule; or
- (b) If indicated in the Medicaid Program DME Fee Schedule as manually priced:
1. Ten (10) percent of the purchase price per month for the monthly rental of an item; or
 2. Two and one-half (2.5) percent of the purchase price per week for the weekly rental of an item that is needed for less than one (1) month.
- (7) If reimbursement for a rental item has been made for a period of ten (10) consecutive months, the item shall be considered to be purchased and shall become the property of the recipient.
- (8) Labor costs for a repair shall be billed in quarter hour increments using the HCPCS codes for labor specified in the Medicaid Program DME Fee Schedule and shall be reimbursed the lessor of:
- (a) The supplier's usual and customary charge; or
- (b) The reimbursement rate specified in the Medicaid Program DME Fee Schedule.
- (9) Reimbursement shall include instruction and training provided to the recipient by the supplier.
- (10) The rental price of an item shall include rental of the item and the cost of:
- (a) Shipping and handling;
- (b) Delivery and pickup;
- (c) Setup;
- (d) Routine maintenance; and
- (e) Essential medical supplies required for proper use of the equipment.
- (11) The purchase price of a prosthetic or orthotic shall include:
- (a) Acquisition cost and applicable design and construction;
- (b) Required visits with a prosthetist or orthotist prior to receipt of the item;
- (c) Proper fitting and adjustment of the item for a period of one (1) year;
- (d) Required modification, if not a result of physical growth or excessive change in stump size, for a period of one (1) year; and
- (e) A warranty covering defects in material and workmanship.

Section 9. Conditions for Provider Participation. A participating DME provider shall:

- (1) Have an active Medicare DME provider number;
- (2) Adhere to all CMS supplier standards in accordance with 42 C.F.R. 424.57;
- (3)
 - (a) Provide proof of Medicare accreditation, by an approved Medicare accreditation entity, to the department every three (3) years unless exempt from Medicare accreditation by CMS; or
 - (b) If exempt from Medicare accreditation by CMS, provide a letter to the department on company letterhead that indicates the CMS exemption status;
- (4) Be enrolled in the Kentucky Medicaid Program in accordance with:
 - (a) 907 KAR 1:671; and
 - (b) 907 KAR 1:672;
- (5) Comply with the requirements regarding the confidentiality of personal medical records pursuant to 42 U.S.C. 1320d and 45 C.F.R. Parts 160 and 164; and
- (6) Comply with the following:
 - (a) A supplier shall bill Medicaid rather than a recipient for a covered service;
 - (b) A supplier shall not bill a recipient for a service that is denied by the department on the basis that the service is incidental to, or mutually exclusive with, a covered service; and
 - (c) A supplier may bill a recipient for a service not covered by Medicaid if the provider informed the recipient of noncoverage prior to providing the service.

Section 10. Managed Care Organizations and Reimbursement. A managed care organization shall not be required to reimburse the same amount as the department reimburses for a service or item covered pursuant to this administrative regulation.

Section 11. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement for services pursuant to this administrative regulation shall be contingent upon:

- (1) Receipt of federal financial participation for the coverage and reimbursement; and
- (2) Centers for Medicare and Medicaid Services' approval for the coverage and reimbursement.

Section 12. Appeal Rights.

- (1) If an individual is denied prior authorization for DMEPOS based upon an application of this administrative regulation, the DME supplier involved in the prior authorization request may appeal the denial. To appeal the denial, the DME supplier shall submit to the department, within thirty (30) calendar days of the prior authorization denial, a written request, by mail or fax, for a reconsideration review.
- (2) Upon receipt of a reconsideration request and any supporting documentation, the department shall:
 - (a) Conduct a reconsideration review within thirty (30) calendar days from the receipt of the request;
 - (b) Base the reconsideration review decision solely upon information that is:
 1. Contained in the individual's medical records; and
 2. Submitted with the written request pursuant to subsection (1) of this section; and
 - (c) Issue a notification of approval or denial within five (5) working days of a reconsideration review.
- (3) If an outcome of a services reconsideration review results in a denial, the department shall grant an appeal.
- (4) An appeal of a department decision regarding a Medicaid recipient who is:
 - (a) Enrolled with a managed care organization shall be in accordance with 907 KAR 17:010; or

(b) Not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(5) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

Section 13. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) Form MAP-9, "Prior Authorization for Health Services", July 2010;

(b) Form MAP-1000, "Certificate of Medical Necessity, Durable Medical Equipment", July 2010;

(c) Form MAP-1000B, "Certificate of Medical Necessity, Metabolic Formulas and Foods", July 2010 edition; and

(d) Form MAP 1001, "Advance Member Notice", September 2006.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law:

(a) At the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.; or

(b) Online at the department's Web site at <http://www.chfs.ky.gov/dms/incorporated.htm>.

(27 Ky.R. 2618; Am. 3263; eff. 6-8-2001; 29 Ky.R. 2558; 30 Ky.R. 42; eff. 7-16-2003; 31 Ky.R. 641; 1188; eff. 1-21-2005; 33 Ky.R. 602; 1380; 1564; eff. 1-5-2007; 35 Ky.R. 309; 571; eff. 10-3-2008; 37 Ky.R. 564; 1455; eff. 12-1-2010; TAm 7-16-2013; 44 Ky.R. 398, 1042; eff. 1-5-2018.)