CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Division of Provider Operations

(Amendment)

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

RELATES TO: KRS 205.520, 42 C.F.R. 424.57, 440.230, 441 Subpart B, 45 C.F.R. 162.1002, 42 U.S.C. 1396d(r), 42 USC 1395mm(20)

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 42 U.S.C. 1396a, b, d, Part I. G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health 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 for the provision of medical assistance to Kentucky's indigent citizenry. 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) 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. No billing is 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, and supplies.

(8) "Durable medical equipment" or "DME" means medical equipment which:

(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) "Family choices" means a benefit plan for an individual who:

(a) Is covered pursuant to:

1. 42 U.S.C. 1396a(a)(10)(A)(i)(I) and 1396u-1;

2. 42 U.S.C. 1396a(a)(52) and 1396r-6 (excluding children eligible under Part A or E of title IV, codified as 42 U.S.C. 601 to 619 and 670 to 679b);

3. 42 U.S.C. 1396a(a)(10)(A)(i)(IV) as described in 42 U.S.C. 1396a(l)(1)(B);

4. 42 U.S.C. 1396a(a)(10)(A)(i)(VI) as described in 42 U.S.C. 1396a(l)(1)(C);

5. 42 U.S.C. 1396a(a)(10)(A)(i)(VII) as described in 42 U.S.C. 1396a(l)(1)(D); or

6. 42 C.F.R. 457.310; and

(b) Has a designated package code of 2, 3, 4, or 5.

(10) "Healthcare common procedure coding system" or "HCPCS" means a collection of codes acknowledged by the Centers for Medicare and Medicaid Services that represent procedures.

(11) "Home" means a place where the recipient resides excluding:

(a) A nursing facility;

(b) A hospital;

(c) An intermediate care facility for individuals with mental retardation or a developmental disability; or

(d) An institution for individuals with a mental disease as defined in 42 U.S.C.

1396d(i).

(12) "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.

(13) "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.

(14) "Medicaid DME Program Fee Schedule" means a list, located at http://chfs.ky.gov/dms, containing 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.

(15) "Medical supply" means an item that is:

(a) Consumable;

(b) Nonreusable;

(c) Disposable; and

(d) Primarily and customarily used to serve a medical purpose.

(16) "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.

(17) <u>“Medicare accreditation” means having met the quality standards established in 42 USC 1395mm(20).</u>

<u>(18)</u> "Mutually exclusive" means that two (2) DMEPOS items:

(a) Are not reasonably provided in conjunction with one another 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.

(19)[~~(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.

(20)[~~(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.

(21)[~~(20)~~] "Prescriber" means a physician, podiatrist, optometrist, dentist, advanced registered nurse practitioner, physician's assistant, or chiropractor[~~or physician's assistant~~] 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 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.

(22)[~~(21)~~] "Prior authorization" means approval which a supplier shall obtain from the department before being reimbursed.

(23)[~~(22)~~] "Prosthetic" means an item that replaces all or part of the function of a body part or organ.

(24)[~~(23)~~] "Reasonableness" means:

(a) The expense of the item does not exceed the therapeutic benefits which 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.

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

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

1. Be based on medical necessity and reasonableness;

2. Be clinically appropriate pursuant to the criteria established in 907 KAR 3:130;

3. Require prior authorization in accordance with Section 7 of this administrative regulation;

4. Be provided in compliance with 42 C.F.R. 440.230(c); and

5. Be restricted to an item used primarily in the home.

(b) Coverage of prosthetic devices shall not exceed $1,500 per twelve (12) month period per member of the family choices benefit plan.

(2) Unless otherwise established in this administrative regulation;

(a) Except as provided in paragraph (b) of this subsection, the criteria referenced in subsection (1)(a) 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)(a) 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; 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)[~~Unique Provider Identification Number (UPIN)~~], 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) 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) 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 non-payment if the recipient's Medicaid eligibility lapses or a HCPCS code is discontinued.

Section 3. Purchase or Rental of Durable Medical Equipment. (1) The following items shall be covered for purchase only:

(a) A cane;

(b) Crutches;

(c) A standard walker;

(d) A prone or supine stander;

(e) A noninvasive electric osteogenesis stimulator; or

(f) Other items designated as purchase only in the Medicaid DME Program Fee Schedule.

(2) The following items shall be covered for rental only:

(a) An apnea monitor;

(b) A respiratory assist device having bivalve pressure capability with backup rate feature;

(c) A ventilator;

(d) A negative pressure wound therapy electric pump;

(e) An electric breast pump;

(f) The following oxygen systems:

1. Oxygen concentrator;

2. Stationary compressed gas oxygen;

3. Portable gaseous oxygen;

4. Portable liquid oxygen; or

5. Stationary liquid oxygen; or

(g) Other items designated as rental only in the Medicaid DME Program Fee Schedule.

(3) With the exception of items specified in subsections (1) or (2) of this section, durable medical equipment shall be covered through purchase or rental based upon anticipated duration of medical necessity.

(4)(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 by a physician for the treatment of an inherited metabolic condition specified in KRS 205.560;

(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 post discharge rehabilitation in the home may be delivered to a hospitalized recipient within two (2) 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 as follows:

(a) During a period of medical need;

(b) If necessary to make the item serviceable;

(c) If no warranty is in effect on the requested repair; and

(d) In accordance with Section 6(2) of this administrative regulation.

(3) Extensive maintenance to purchased equipment, as recommended by the manufacturer and performed by authorized technicians, 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)(k) of this administrative regulation, backup equipment; or

(h) An item determined not medically necessary, clinically appropriate or reasonable by the department.

(i) Diabetic supplies, as indicated on the Medicaid DME Program Fee Schedule, shall:

a. Be covered via the Medicaid outpatient pharmacy program; and

b. Not be covered via the Medicaid durable medical equipment program.

(2) 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.

(3) Durable medical equipment, prosthetics, orthotics and medical supplies shall be included in the facility reimbursement for a recipient residing in a hospital, nursing facility, intermediate care facility for individuals with mental retardation or a developmental disability, or an institution for individuals with a mental disease and shall not be covered through the durable medical equipment program.

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[~~$300~~] or more;

(b) Rental of equipment as indicated on the Medicaid DME Program Fee Schedule excluding oxygen services after twelve (12) continuous months of service;

(c) [~~A therapeutic shoe or boot;~~

~~(d)~~] Orthopedic shoes;

(d)[~~(e)~~] An adjustment to a prosthetic or orthotic;

(e)[~~(f)~~] An augmentative communication device;

(f)[~~(g)~~]A customized DME item;

(g)[~~(h)~~]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 the Medicaid DME Program Fee Schedule;

(h)[~~;~~

~~(i)~~]A nutritional supplement;

(i)[~~(j)~~]An amino acid modified preparation or a low-protein modified food product;

(j)[~~(k)~~]A loaner item for a member-owned piece of equipment that is being repaired;

(k)[~~(l)~~]A DMEPOS item denoted by a general or nonspecific HCPCS code;

(l)[~~(m)~~]An item designated on the Medicaid DME Program Fee Schedule as requiring prior authorization;

(m)[~~(n)~~]An item which exceeds the quantity limitation set in the Medicaid DME Program Fee Schedule; or

(n)[~~(o)~~]An item designated by a HCPCS code not indicated on the Medicaid DME Program Fee Schedule that is determined by the department to be a covered benefit.

(2) If an item requires prior authorization, a supplier shall comply with the following:

(a) Submit all required documentation prior to or within one (1) year from the date of service;

(b) Submit a written request to the department for prior authorization which shall include the prescriber's order; and

(c) Submit a completed CMN to the department within ninety (90) business days of

the date of the request for prior authorization.

(d) If the required prior authorization submittals referenced in 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 may 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[~~or faxing~~] 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 may 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 shall have the authority to 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 DME Program Fee Schedule; or

(c) If indicated in the Medicaid DME Program Fee Schedule as manually priced:

1. Invoice price plus twenty (20) percent for an item not utilizing a billing code specified in subparagraph 2 or 3 of this paragraph;

2. The manufacturer's suggested retail price minus fifteen (15) percent for HCPCS codes E1037 through E1039, E1161, E1220, E1229, E1231 through E1238, or K0009; or

3. The manufacturer's suggested retail price minus twenty-two (22) percent for a customized component billed using HCPCS codes E0955 through E0957, E0960, E1002 through E1010, E1015, E1028 through E1030, E2201 through E2204, E2300, E2301, E2310, E2311, E2321 through E2330, E2340 through E2343, E2373 through E2376, E2381 through E2392, E2394 through E2397[~~E2396, E2399~~], E2601 through E2621, K0108, K0669, K0734 through K0737, or L8499.

(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 a HCPCS code not currently on the Medicaid DME Program 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) The department shall post HCPCS code change information on its web site accessible at http://chfs.ky.gov/dms. 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 is currently being rented shall be[~~:~~

~~(a)~~] For an item that has been rented for less than ten (10)[~~three (3)~~] months, the purchase price specified in subsection (1) of this section minus the cumulative rental payment made to the supplier; or

[~~(b) For an item that has been rented for three (3) months or more, 120 percent of 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 DME Program Fee Schedule; or

(b) If indicated in the Medicaid DME Program 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) Except for an item specified in Section 3(2) of this administrative regulation, if reimbursement for a rental item has been made for a period of ten (10)[~~twelve (12)~~] 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 DME Program 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 DME Program 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

<u>(2) Adhere to all CMS supplier standards in accordance with 42 CFR 424.57;</u>

<u>(3)(a) Provide proof of accreditation, by an approved Medicare accreditation entity, to</u>

the department every three (3) years unless exempt from accreditation by CMS;

(b) If exempt from accreditation by CMS, provide a letter to the department on company letterhead that indicates the CMS exemption status;

(4)[~~,and adhere to all CMS supplier standards in accordance with 42 C.F.R. 424.57;~~

~~(2)~~] Be enrolled in the Kentucky Medicaid Program in accordance with:

(a) 907 KAR 1:671; and

(b) 907 KAR 1:672;

(5)[~~(3)~~] 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)[~~(4)~~] 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 so informed the recipient of noncoverage prior to providing the service.

Section 10. Appeal Rights. (1) If an individual is not prior authorized for DMEPOS based upon an application of this administrative regulation, the department shall:

(a) Conduct a reconsideration review within thirty (30) 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.

(2) If an outcome of a services reconsideration review results in a denial, the department shall grant an appeal in accordance with 907 KAR 1:563.

(3)[~~(1)~~] An appeal of a department decision regarding a Medicaid recipient based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:563.

(4)[~~(2)~~] An appeal of a department decision regarding Medicaid eligibility of an individual shall be in accordance with 907 KAR 1:560.

(5)[~~(3)~~] 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 11. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Form MAP-9, Prior Authorization Form", July 2010[~~February 2005~~] edition, Department for Medicaid Services;

(b) "Form MAP-1000, Certificate of Medical Necessity", July 2010[~~February 2005~~] edition, Department for Medicaid Services;

(c) "Form MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Foods", July 2010[~~February 2005~~] edition, Department for Medicaid Services;

(d) "Medicaid DME Program Fee Schedule", July 2010[~~January 2008~~] edition; and

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

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

copyright law, at the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. through 4:30 p.m. (27 Ky.R. 2618; Am. 3263; eff. 6-8-2001; 29 Ky.R. 2558; 30 Ky.R. 42; eff. 7-16-03; 31 Ky.R. 641; 1188; eff. 1-21-05; 33 Ky.R. 602; 1380; 1564; eff. 1-5-07; 35 Ky.R. 309; 571; eff. 10-3-08.)

907 KAR 1:479

REVIEWED:

Date	Elizabeth A. Johnson, Commissioner Department for Medicaid Services

APPROVED:

Date	Janie Miller, Secretary Cabinet for Health and Family Services

907 KAR 1:479

A public hearing on this administrative regulation shall, if requested, be held on August 23, 2010 at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by August 16, 2010 five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2010. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:479
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Patricia Biggs (502) 564-2687 or Stuart Owen (502) 564-4321

(1) Provide a brief summary of:
(a) What this administrative regulation does: This administrative regulation establishes provisions related to the coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics.
(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish provisions related to coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing provisions related to coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing provisions related to coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: Among the amendments are: establishing that diabetic supplies will be reimbursed via the Medicaid pharmacy program rather than the durable medical equipment program; raising the prior authorization threshold for items from $300 to $500; reducing the time frame for when an item converts from a rental to a purchase (twelve months to ten months); defining Medicare accreditation and requiring suppliers to document Medicare accreditation to DMS; establishing a reconsideration review option of a prior authorization denial and authorizing chiropractors to prescribe as the Centers for Medicare and Medicaid Services (CMS) permits this.
(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to comply with the “budget bill” (specifically Part I. G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly) mandate to implement Medicaid pharmacy efficiencies. Moving diabetic supplies to the pharmacy program will enable the Department for Medicaid Services (DMS) to procure rebates on the supplies.
(c) How the amendment conforms to the content of the authorizing statutes: This

amendment conforms to the content of the authorizing statutes by moving diabetic supply reimbursement from the durable medical equipment program to the Medicaid pharmacy program as a pharmacy efficiency implemented in accordance with Part I. G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly. Additionally, it amends Medicaid durable medical equipment policy as authorized by KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560(1) and 42 USC 1396a, b, and d.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: amendment conforms to the content of the authorizing statutes by moving diabetic supply reimbursement from the durable medical equipment program to the Medicaid pharmacy program as a pharmacy efficiency implemented in accordance with Part I. G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly. Additionally, it amends Medicaid durable medical equipment policy as authorized by KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560(1) and 42 USC 1396a, b, and d.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: DMS estimates that 2,896 DME providers are enrolled in the Medicaid program. Currently, there are approximately 807,000 enrolled Medicaid recipients.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. DME providers will have to provide Medicare accreditation documentation to DMS every three (3) years.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Regulated entities should benefit from policy clarifications and a reduced administrative burden.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS anticipates no additional cost and estimates that increasing the prior authorization threshold from $300 to $500 will reduce expenditures by $150,000 annually (state and federal combined) due to reduced contractor costs (as prior authorization for this is performed by a contractor.) Additionally, DMS anticipates receiving $2.0 million (state and federal combined) annually in rebates as a result of reimbursing for diabetic supplies via the pharmacy program rather than the durable medical equipment program.

(b) On a continuing basis: DMS DMS anticipates no additional cost and estimates that increasing the prior authorization threshold from $300 to $500 will

reduce expenditures by $150,000 annually (state and federal combined) due to reduced contractor costs (as prior authorization for this is performed by a contractor.) Additionally, DMS anticipates receiving $2.0 million (state and federal combined) annually in rebates as a result of reimbursing for diabetic supplies via the pharmacy program rather than the durable medical equipment program.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Sources of funding to be used for the implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX and Title XXI of the Social Security Act and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary to implement this amendment.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not impose or increase any fee to a provider.

(9) Tiering: Is tiering applied? (Explain why tiering was or was not used)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation #: 907 KAR 1:479
Agency Contact Person: Patricia Biggs (502) 564-2687 or Stuart Owen (502) 564-4321

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

   Yes _X__ No ____
   If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) is the only government entity affected by this administrative regulation.

3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. Part I. G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly, 42 CFR 424.57, 45 CFR 162.1002 and 45 CFR 164.316.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate any additional revenue for state or local governments during the first year of implementation.
   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate any additional revenue for state or local governments during subsequent years of implementation.
   (c) How much will it cost to administer this program for the first year? DMS anticipates no additional cost. DMS anticipates no additional cost and estimates that increasing the prior authorization threshold from $300 to $500 will reduce expenditures by $150,000 annually (state and federal combined) due to reduced contractor costs (as prior authorization for this is performed by a contractor.) Additionally, DMS anticipates receiving $2.0 million (state and federal combined) annually in rebates as a result of reimbursing for diabetic supplies via the pharmacy program rather than the durable medical equipment program.
   (d) How much will it cost to administer this program for subsequent years? DMS anticipates no additional cost. DMS anticipates no additional cost and estimates that increasing the prior authorization threshold from $300 to $500 will reduce

expenditures by $150,000 annually (state and federal combined) due to reduced contractor costs (as prior authorization for this is performed by a contractor.) Additionally, DMS anticipates receiving $2.0 million (state and federal combined) annually in rebates as a result of reimbursing for diabetic supplies via the pharmacy program rather than the durable medical equipment program.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): ____

Expenditures (+/-): ____

Other Explanation: No additional expenditures are necessary to implement this amendment.

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:479, Durable Medical Equipment Covered Benefits and Reimbursement

Summary of Material Incorporated by Reference

1. "Form MAP-9, Prior Authorization Form", July 2010 edition replaces the February 2005 edition as the term “prescriber” replaces provider in box 5.b.; and the prescriber and provider numbers are now ten (10) digit numbers rather than eight (8) digit numbers. This form is used by DME providers to request prior authorization for designated items and equipment. This form consists of one (1) page.

2. “Form MAP-1000, Certificate of Medical Necessity”, July 2010 edition replaces the February 2005 edition as the National Provider Identifier (NPI) is now used rather than a National Supplier Clearinghouse (NSC) number. This form is used to document medical necessity for durable medical equipment, medical supplies, prosthetics, or orthotics. This form contains two (2) pages.

3. “Form MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Foods”, July 2010 edition replaces the February 2005 edition. This form is used to document medical necessity for metabolic formulas and foods. This form contains one (1) page.

4. “Medicaid DME Program Fee Schedule”, July 2010 edition replaces the January 2008 edition. This schedule is a list of Medicaid's current maximum allowable payment rates for coverable durable medical equipment, prosthetics, orthotics, or medical supplies. This schedule contains one-hundred and twelve (112) pages.

5. "Form MAP 1001, Advance Member Notice", September 2006 edition. This form is used as notice to a recipient that a service or item is not covered by the department and the recipient will be financially responsible for the item or service. The form consists of one (1) page and is not being revised.

A total of one-hundred and seventeen (117) pages are incorporated by reference into this administrative regulation.