Commonwealth of Massachusetts
Executive Office of Health and Human Services
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MASSHEALTH
TRANSMITTAL LETTER PHY-95
March 2003

TO: Physicians Participating in MassHealth

FROM: Douglas S. Brown, Acting Commissioner

RE: *Physician Manual* (Revised Regulations about Pharmacy Services)

This letter transmits revised physician regulations. The pharmacy-related provisions have been revised to:

- remove the definitions of financial terms that apply only to pharmacies;
- modify the definition of interchangeable drug product;
- define the MassHealth Drug List;
- reduce the number of allowable refills from 11 to five;
- clarify specific drug limitations and prior-authorization requirements; and
- clarify the impact of managed-care enrollment and insurance coverage on MassHealth pharmacy claims.

These regulations are effective April 1, 2003.

NEW MATERIAL
(The pages listed here contain new or revised language.)

Physician Manual

Pages iv-a, 4-1 through 4-4, and 4-29 through 4-32

OBSOLETE MATERIAL
(The pages listed here are no longer in effect.)

Physician Manual

Pages iv-a, 4-1 through 4-4, and 4-29 through 4-32 — transmitted by Transmittal Letter PHY-92

4. PROGRAM REGULATIONS (cont.)

PART 1. GENERAL INFORMATION

433.401: Definitions

The following terms used in 130 CMR 433.000 have the meanings given in 130 CMR 433.401 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 433.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 433.000 and in 130 CMR 450.000.

Adult Office Visit – a medical visit by a member 21 years of age or older to a physician's office or to a hospital outpatient department.

Community-Based Physician – any physician, excluding interns, residents, fellows, and house officers, who is not a hospital-based physician.

Consultant – a licensed physician whose practice is limited to a specialty and whose written advice or opinion is requested by another physician or agency in the evaluation or treatment of a member's illness or disability.

Consultation – a visit made at the request of another physician.

Controlled Substance – a drug listed in Schedule II, III, IV, V, or VI of the Massachusetts Controlled Substances Act (M.G.L. c. 94C).

Cosmetic Surgery – a surgical procedure that is performed for the exclusive purpose of altering appearance and is unrelated to physical disease or defect, or traumatic injury.

Couple Therapy – therapeutic services provided to a couple for whom the disruption of their marriage, family, or relationship is the primary reason for seeking treatment.

Diagnostic Radiology Service – a radiology service intended to identify an injury or illness.

Domiciliary – for use in the member's place of residence, including a long-term-care facility.

Drug – a substance containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Emergency Admission Service – a complete history and physical examination by a physician of a member admitted to a hospital to treat an emergency medical condition, when definitive care of the member is assumed subsequently by another physician on the day of admission.

Emergency Medical Condition – a medical condition, whether physical or mental, manifesting itself by symptoms of sufficient severity, including severe pain, that the absence of prompt medical attention could reasonably be expected by a prudent layperson who possesses an average knowledge of health and medicine, to result in placing the health of the member or another person in serious jeopardy, serious impairment to body function, or serious dysfunction of any body organ or part, or, with respect to a pregnant woman, as further defined in §1867(e)(1)(B) of the Social Security Act, 42 U.S.C. §1395dd(e)(1)(B).

Emergency Services – medical services that are furnished by a provider that is qualified to furnish such services, and are needed to evaluate or stabilize an emergency medical condition.

Family Planning – any medically approved means, including diagnosis, treatment, and related counseling, that helps individuals of childbearing age, including sexually active minors, to determine the number and spacing of their children.

Family Therapy – a session for simultaneous treatment of two or more members of a family.

Group Therapy – application of psychotherapeutic or counseling techniques to a group of persons, most of whom are not related by blood, marriage, or legal guardianship.

High-Risk Newborn Care – care of a full-term newborn with a critical medical condition or of a premature newborn requiring intensive care.

Home or Nursing Facility Visit – a visit by a physician to a member at a residence, nursing facility, extended care facility, or convalescent or rest home.

Hospital-Based Entity – any entity that contracts with a hospital to provide medical services to members on the same site as the hospital's inpatient facility or hospital-licensed health center.

Hospital-Based Physician – any physician, excluding interns, residents, fellows, and house officers, who contracts with a hospital to provide services to members on the same site as the hospital's inpatient facility or hospital-licensed health center.

Hospital-Licensed Health Center – a facility that:

(1) operates under a hospital's license but is not physically attached to the hospital;
(2) operates within the fiscal, administrative, and clinical management of the hospital;
(3) provides services to patients solely on an outpatient basis;
(4) meets all regulatory requirements for participation in MassHealth as a hospital-licensed health center; and
(5) is enrolled with the Division as a hospital-licensed health center with a separate hospital-licensed health center MassHealth provider number.

Hospital Visit – a bedside visit by a physician to a hospitalized member, except for routine preoperative and postoperative care.

Hysterectomy – a medical procedure or operation for the purpose of removing the uterus.

Individual Psychotherapy – private therapeutic services provided to a member to lessen or resolve emotional problems, conflicts, and disturbances.

Institutionalized Individual – a member who is either:

(1) involuntarily confined or detained under a civil or criminal statute in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or

(2) confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

Intensive Care Services – the services of a physician other than the attending physician, provided for a continuous period of hours (rather than days), required for the treatment of an unusual aspect or complication of an illness, injury, or pregnancy.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, "A-rated") by the Food and Drug Administration for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

Legend Drug – any drug for which a prescription is required by applicable federal or state law or regulation.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the Division. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 433.443(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 433.000.

Mentally Incompetent Individual – a member who has been declared mentally incompetent for any purpose by a federal, state, or local court of jurisdiction, unless the individual has been declared competent to consent to sterilization.

Multiple-Source Drug – a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Nonlegend Drug – any drug for which no prescription is required by federal or state law.

Not Otherwise Classified – a term used for service codes that should be used when no other service code is appropriate for the service provided.

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

Pediatric Office Visit – a medical visit by a member under 21 years of age to a physician's office or to a hospital outpatient department.

Pharmacy On-Line Processing System (POPS) – the on-line, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Prolonged Detention – constant attendance to a member in critical condition by the attending physician.

Reconstructive Surgery – a surgical procedure performed to correct, repair, or ameliorate the physical effects of physical disease or defect (for example, correction of cleft palate), or traumatic injury.

Referral – the transfer of the total or specific care of a member from one physician to another. For the purposes of 130 CMR 433.000, a referral is not a consultation.

Respiratory Therapy Equipment – a product that:

(1) is fabricated primarily and customarily for use in the domiciliary treatment of pulmonary insufficiencies for its therapeutic and remedial effect;
(2) is of proven quality and dependability; and
(3) conforms to all applicable federal and state product standards.

Routine Study – a set of X rays of an extremity that includes two or more views taken at one sitting.

Separate Procedure – a procedure that is commonly performed as an integral part of a total service and therefore does not warrant a separate fee, but commands a separate fee when performed as a separate entity not immediately related to other services.

Sterilization – any medical procedure, treatment, or operation performed to make an individual permanently incapable of reproducing.

Therapeutic Radiology Service – a radiology service used to treat an injury or illness.

Trimester – one of three three-month terms in a normal pregnancy. If the pregnancy has existed for less than 12 weeks, the pregnancy is in its first trimester. If the pregnancy has existed for 12 or more weeks but less than 24 weeks, the pregnancy is in its second trimester. If the pregnancy has existed for 24 or more weeks, the pregnancy is in its third trimester.

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken.

433.441: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. The Division pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 433.442(C) only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription, regardless of drug schedule, must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number on the prescription.

(B) Emergencies. When the pharmacist determines that an emergency exists, the Division will authorize a pharmacy to dispense at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations.

(C) Refills.

(1) The Division does not pay for prescription refills that exceed the specific number authorized by the prescriber.

(2) The Division pays for a maximum of five monthly refills.

(3) The Division pays for more than five refills within a six-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 433.441(D).

(4) The Division does not pay for any refill dispensed after six months from the date of the original prescription.

(5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(D) Quantities.

(1) Days' Supply Limitations. The Division requires that all drugs be prescribed and dispensed in at least a 30-day supply, but no more than a 90-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 433.441(D)(2).

(2) Exceptions to Days' Supply Limitations. The Division allows exceptions to the limitations described in 130 CMR 433.441(D)(1) for the following products:

(a) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;

(b) drugs that, in the prescriber's professional judgement, are not clinically appropriate for the member in a 30-day supply;

(c) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;

(d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 90-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);

(e) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments); and

(f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs).

(E) Prescription-Splitting. Providers must not split prescriptions by filling them for a period or quantity less than that specified by the provider. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. The Division considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

433.442: Pharmacy Services: Covered Drugs and Medical Supplies

(A) Drugs. The MassHealth Drug List specifies the drugs that are payable under MassHealth.
(1) Legend Drugs. The Division pays only for legend drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8.
(2) Nonlegend Drugs. The Division pays only for the nonlegend drugs listed in Appendix L of the *Physician Manual* (Nonlegend Drug List).

(B) Medical Supplies. The Division pays only for the medical supplies listed below:
(1) blood and urine testing reagent strips used for the management of diabetes;
(2) disposable insulin syringe and needle units;
(3) insulin cartridge delivery devices and needles (for example, pens);
(4) lancets; and
(5) drug delivery systems for use with metered dose inhalers (for example, aerochambers).

433.443: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The Division pays no more for a brand-name interchangeable drug product than its generic equivalent, unless:
(1) the prescriber has requested and received prior authorization from the Division for a nongeneric multiple-source drug (see 130 CMR 433.444); and
(2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(B) Drug Exclusions. The Division does not pay for the following types of drugs or drug therapy.
(1) Cosmetic. The Division does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.
(2) Cough and Cold. The Division does not pay for legend or nonlegend preparations that contain an antitussive or expectorant as a major ingredient, or any drug used solely for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized member.
(3) Fertility. The Division does not pay for any drug used to promote male or female fertility.
(4) Obesity Management. The Division does not pay for any drug used for the treatment of obesity.
(5) Smoking Cessation. The Division does not pay for any drug used for smoking cessation.
(6) Less-Than-Effective Drugs. The Division does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

(7) Experimental and Investigational Drugs. The Division does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

(1) The Division covers drugs that are not explicitly excluded under 130 CMR 433.443(B). The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 433.000. The MassHealth Drug List can be viewed on the Division's Web site, and copies may be obtained upon request. The Division will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List accordingly. (See 130 CMR 450.303.)

(2) The Division does not pay for the following types of drugs or drug therapy without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH);

(b) nongeneric multiple-source drugs;

(c) drugs used for the treatment of male or female sexual dysfunction;

(d) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. The Division, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993; and

(e) retinoids for members aged 26 or older. The Division pays for retinoids for members under age 26, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

(3) The Division does not pay any additional fees for dispensing drugs in a unit-dose distribution system.

(4) The Division does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the Division determines to be consistent with current medical evidence.

433.444: Pharmacy Services: Insurance Coverage

(A) Managed Care Organizations. The Division does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.

(B) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the Division for the primary insurer's copayment for the primary carrier's preferred drug without regard to whether the Division generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 433.443(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from the Division in order for the pharmacy to bill the Division for the primary insurer's copayment.

433.445: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from the Division for drugs identified by the Division in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 433.442(A) and 433.443(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to the Division for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions for requesting prior authorization in Subchapter 5 of the *Physician Manual*. If the Division approves the request, it will notify the pharmacy and the member.

(C) The Division will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) The Division acts on requests for prior authorization for a prescribed drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements of other health insurers.

433.446: Pharmacy Services: Member Copayments

Under certain conditions, the Division requires that members make a copayment to the dispensing pharmacy for each original prescription and for each refill for all drugs (whether legend or nonlegend) covered by MassHealth. The copayment requirements are detailed in the Division's administrative and billing regulations at 130 CMR 450.130.

433.447: Pharmacy Services: Payment

Drugs dispensed in the office are payable at the physician's actual acquisition cost, subject to the service limitations at 130 CMR 433.404 and 433.443. The Division does not pay for any oral drugs dispensed in the office, with the exception of oral vaccines, for which the physician has not requested and received prior authorization from the Division. Claims for dispensing drugs must include the name of the drug or biological, the strength, and the dosage. A copy of the invoice showing the actual acquisition cost must be attached to the claim form, and must include the National Drug Code (NDC). Claims without this information are denied. Payment for drugs may be claimed in addition to an office visit.

(130 CMR 433.448 through 433.450 Reserved)