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MASSHEALTH
TRANSMITTAL LETTER DEN-68
December 2004

TO: Dental Providers Participating in MassHealth

FROM: Beth Waldman, Medicaid Director BW

RE: *Dental Manual* (Revised Pharmacy Services Regulations)

This letter transmits revisions to the dental regulations about prescription drugs. These revisions allow refills of prescriptions for up to one year, prohibit pharmacies from automatically refilling prescriptions without a request from the member or caregiver, and make other clarifying changes.

MassHealth is removing Appendix I from the *Dental Manual*. Appendix I listed the nonlegend drugs that are covered by MassHealth. An up-to-date list of nonlegend drugs can be found at www.mass.gov/druglist.

These regulations are effective January 1, 2005.

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

Dental Manual

Pages vi and 4-11 through 4-16

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(The pages listed here are no longer in effect.)

Dental Manual

Page vi — transmitted by Transmittal Letter DEN-62

Pages 4-11 through 4-16 — transmitted by Transmittal Letter DEN-64

Pages I-1 and I-2 — transmitted by Transmittal Letter DEN-67

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420.415: Report Requirements

(A) General Report. A general written report that includes a diagnosis and a description of the service performed must accompany the dentist's claim for payment when the service description in Subchapter 6 or Appendix E of the *Dental Manual* stipulates "with report only," when the service is designated "I.C.," or when a service code for an unlisted procedure is used. This report must be sufficiently detailed to enable MassHealth to assess the extent and nature of services performed. The report can be on the claim form or on a separate piece of paper with the dentist's or hospital's letterhead. Supporting documentation, including pathology, admission, and operative reports, must be attached.

(B) Operative Report. For surgical procedures designated "I.C." and for any service that is an unlisted or unspecified procedure, an operative report must accompany the provider's claim. An operative report must contain the name of the surgical procedure, the name and date of birth of the member, the date of the service, the preoperative diagnosis, the postoperative diagnosis, the names of the surgeon and of any assistant, and the technical procedures performed.

420.416: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. Legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 420.417(C) are covered 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 practitioner has no DEA registration number, the practitioner must provide the state registration number on the prescription.

(B) Emergencies. When the pharmacy determines that an emergency exists, MassHealth will pay a pharmacy for at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations. Emergency dispensing to a MassHealth member who is enrolled in the Controlled Substance Management Program (CSMP) must comply with 130 CMR 406.442(C)(2).

(C) Refills.

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

(2) MassHealth pays for a maximum of 11 monthly refills, except in circumstances described in 130 CMR 420.416(C)(3).

(3) MassHealth pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 420.416(D).

(4) MassHealth does not pay for any refill dispensed after one year from the date of the original prescription.

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

(6) MassHealth does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by the provider of a prescription with remaining refills does not in itself constitute a request to refill the prescription.

(D) Quantities.

(1) Days' Supply Limitations. MassHealth 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 420.416(D)(2).

(2) Exceptions to Days' Supply Limitations. MassHealth allows exceptions to the limitations described in 130 CMR 420.416(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 judgment, 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. MassHealth considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

420.417: Pharmacy Services: Covered Drugs and Medical Supplies

(A) Drugs. The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, MassHealth 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.

(B) Medical Supplies. MassHealth pays only for the medical supplies listed in 130 CMR 420.417(B)(1) through (6):

(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 or other devices for injection of medication (for example, Epipens);

(4) lancets;

(5) drug delivery systems for use with metered dose inhalers (for example, aerochambers); and

(6) alcohol swabs.

420.418: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. MassHealth 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 MassHealth for a nongeneric multiple-source drug (see 130 CMR 420.419); 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. MassHealth does not pay for the following types of drugs or drug therapy.

(1) Cosmetic. MassHealth does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.

(2) Cough and Cold. MassHealth does not pay for legend or nonlegend drugs used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient unless dispensed to an institutionalized member.

(3) Fertility. MassHealth does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. MassHealth does not pay for any drug used for the treatment of obesity.

(5) Smoking Cessation. MassHealth does not pay for any drug used for smoking cessation.

(6) Less-Than-Effective Drugs. MassHealth 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. MassHealth does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 420.418(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 420.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. MassHealth 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) MassHealth 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. MassHealth, 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) topical acne products for members aged 21 or older. MassHealth pays for topical acne products for members under age 21, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

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

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

(5) MassHealth does not pay for drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307.

(D) Insurance Coverage.

(1) Managed Care Organizations. MassHealth 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.

(2) 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 MassHealth for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether MassHealth generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 420.418(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from MassHealth in order for the pharmacy to bill MassHealth for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq.

420.419: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 420.417(A) and 420.418(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 MassHealth 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 *Dental Manual*. If MassHealth approves the request, it will notify both the pharmacy and the member.

(C) MassHealth will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See U.S.C. 1396r-8(d)(5).) MassHealth 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.

(E) 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 420.416 through 420.419. MassHealth will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

420.420: Pharmacy Services: Member Copayments

Under certain conditions, MassHealth 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 130 CMR 450.130.

420.421: Service Descriptions and Limitations: Introduction — Members Under Age 21

Service descriptions and limitations that are specific to members under age 21 are set forth in 130 CMR 420.422 through 420.429. Services that apply to all members, including members under age 21, are set forth in 130 CMR 420.452 through 420.457. In addition, services provided to members under age 21 must comply with all applicable requirements for Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services set forth in 130 CMR 450.140 through 450.149.

420.422: Service Descriptions and Limitations: Diagnostic Services — Members Under Age 21

The following service descriptions and limitations apply to preventive services provided to members under age 21.

(A) Comprehensive Oral Evaluation. A comprehensive oral evaluation by a dentist of a new member is reimbursable. A comprehensive oral evaluation is more thorough than a periodic oral evaluation, and is reimbursable only once per member for a dentist, dental group, or dental clinic. A comprehensive oral evaluation includes a written review of the member's medical and dental history, the examination and charting of the member's dentition and associated structures, periodontal charting if applicable, the diagnosis, and the preparation of treatment plans and reporting forms.

(B) Periodic Oral Evaluation. A periodic oral evaluation is reimbursable, only once per 12-month period, and no sooner than 12 months from the date of the most recent prior oral evaluation (whether periodic or comprehensive). For example, if the last evaluation was performed on February 20th, the next evaluation is reimbursable no sooner than February 20th of the following year. A periodic oral evaluation includes an update of the member's medical and dental history, the examination and charting of the member's dentition and associated structures, periodontal charting if applicable, the diagnosis, and the preparation of treatment plans and reporting forms. This service is not reimbursable on the same date of service as an emergency treatment visit and is not reimbursable if the visit results in a referral to a specialist.

(C) Emergency Dental Care. An emergency care visit is one that is intended to eliminate or alleviate acute pain or infection or both. Services that may be provided as part of an emergency care visit are those minimally required to address the immediate emergency and include, but are not limited to, diagnosis, draining of an abscess, or prescribing pain medication or antibiotics. The dentist must maintain in the member's dental records a diagnostic report of the treatment provided and must document the emergent nature of the care provided. No other services except X rays subject to limitations set forth in 130 CMR 420.423 and dental management of a physically or developmentally disabled member in the office (see 130 CMR 420.457) are reimbursable with a visit for emergency dental care. That is, if nonemergency treatment is provided during the same visit, the provider must bill for the nonemergency services, not for emergency dental care.

420.423: Service Descriptions and Limitations: X Rays — Members Under Age 21

The following service descriptions and limitations apply to X-ray services provided to members under age 21.

(A) Introduction. X rays must be taken as an integral part of diagnosis and treatment planning. The intent of limitations placed on X rays is to confine radiation exposure of members to the minimum necessary to achieve satisfactory diagnosis. The provider must document efforts to obtain any previous X rays before prescribing more. X rays must be of good diagnostic quality and, when submitted to MassHealth, must be properly and securely mounted, dated, labeled for right and left views, and fully identified with the names of the dental provider and the member. When X rays submitted to MassHealth are not of good diagnostic quality, the provider may not claim payment for any retake X rays requested by MassHealth. Prior-authorization requests that are submitted with X rays that are not of good diagnostic quality will be deferred, pending submission of X rays that are of good diagnostic quality, or denied. X rays are considered to be of good diagnostic quality when they meet the following criteria:

(1) standard illumination permits differentiation between the various structures of the tooth, the periodontal ligament spacings, the supporting bone, and the normal anatomic landmarks;
(2) all crowns and roots, including apices, are fully depicted together with interproximal alveolar crests, contact areas, and surrounding bone regions; and
(3) images of all teeth and other structures are shown in proper relative size and contour with contiguous images, where anatomically possible.

(B) Intraoral X Rays.

(1) (a) Full-Mouth X Rays. Full-mouth X rays are reimbursable only for members 13 through 20 years of age and only once every three calendar years without prior authorization. Prior authorization is required for more frequent X rays. Full-mouth X rays must consist of either a minimum of 12 periapical X rays and two posterior bitewing X rays or a panoramic X ray plus two-to-four bitewing X rays. Full-mouth X rays must include all existing dentition and must be of good diagnostic quality as defined in 130 CMR 420.423(A). However, panoramic X rays cannot be substituted for X rays required for prior authorization. When the provider's total fee for individual periapical X rays (with or without bitewings) exceeds MassHealth's reimbursement for a full-mouth series, the provider may only claim reimbursement in an amount not to exceed MassHealth's reimbursement for a full-mouth series.