Commonwealth of Massachusetts
Executive Office of Health and Human Services
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MASSHEALTH
TRANSMITTAL LETTER DEN-64
March 2003

TO: Dental Providers Participating in MassHealth

FROM: Douglas S. Brown, Acting Commissioner

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

This letter transmits revised dental 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.

This letter also transmits a technical change at 130 CMR 420.410(D). This revision clarifies that the Division pays for prosthodontic services (described in 130 CMR 420.432 through 130 CMR 420.439) for members aged 21 and older only when the provider has obtained prior authorization from the Division and that the member meets the special circumstances criteria set forth in 130 CMR 420.410 (D)(1).

These regulations are effective April 1, 2003.

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

Dental Manual

Pages iv, 4-1, 4-2, 4-7, 4-8, and 4-11 through 4-16

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(The pages listed here are no longer in effect.)

Dental Manual

Pages iv and 4-11 through 4-16 — transmitted by Transmittal Letter DEN-59

Pages 4-1, 4-2, 4-7, and 4-8 — transmitted by Transmittal Letter DEN-62

4. PROGRAM REGULATIONS

420.401: Introduction

(A) 130 CMR 420.000 contains regulations governing dental services under MassHealth. All dental providers participating in MassHealth must comply with the regulations of the Division governing MassHealth, including but not limited to Division regulations at 130 CMR 420.000 and 450.000.

(B) In general, and as further described below, coverage of dental services varies for
(1) members under age 21;
(2) members aged 21 and older with special circumstances that meet the criteria in 130 CMR 420.410(D); and
(3) all other members aged 21 and older.

(C) Coverage for members under age 21 includes services essential for the prevention and control of dental diseases and the maintenance of oral health. Coverage for members aged 21 and older with special circumstances that meet the criteria in 130 CMR 420.410(D) is similar, but not identical, to coverage for members under age 21. Coverage for all other members aged 21 and older includes emergency care, exodontic services, oral surgery, and some X-ray services.

(D) The service descriptions and limitations applicable to each group are set forth in the regulations that follow. Where noted, certain service descriptions are the same for all members, regardless of age or circumstances.

420.402: Definitions

The following terms used in 130 CMR 420.000 have the meanings given in 130 CMR 420.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 420.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 420.000 and in 130 CMR 450.000.

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

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.

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 420.418(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 420.000.

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.

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.

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.

420.403: Eligible Members

(A) (1) MassHealth Members. The Division pays for dental services provided to MassHealth members, subject to the restrictions and limitations described in the Division's regulations. 130 CMR 450.105 specifically states for each MassHealth coverage type, which services are covered and the members eligible to receive those services.
(2) Recipients of Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

(4) The Division reviews prior-authorization requests with consideration, where applicable, for whether the restoration work requested involves teeth that will be retained for many years and are critical to the member's long-term oral health.
(5) The Division does not consider prior-authorization requests for noncovered services for members aged 21 and older (see 130 CMR 420.408 and service limitations described throughout 130 CMR 420.000.).

(B) Other Requirements for Payment.
(1) Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment such as member eligibility or resort to health-insurance payment.
(2) The Division will not pay for a prior-authorized service when the member's MassHealth eligibility is terminated on or before the date of service or a date adjudicated by the Division.
(3) When the member's MassHealth eligibility is terminated prior to delivery of a special-order good, such as a denture, the provider may claim payment in accordance with the provisions of 130 CMR 450.231(B). Refer to 130 CMR 450.231(B) for special procedures in documenting member eligibility for special-order goods.

(C) Services Requiring Prior Authorization.
(1) Services requiring prior authorization include, but are not limited to, the following:
(a) deep scaling and curettage;
(b) gingivectomy or gingivoplasty;
(c) mouth guard;
(d) interceptive orthodontic treatment visits;
(e) orthodontic treatment;
(f) diagnostic casts;
(g) diagnostic photographs;
(h) crowns, posts, cores, and fixed bridgework;
(i) endodontics (root canals and apicoectomies);
(j) prosthodontics (full, partial, and immediate dentures);
(k) rebase of complete upper or lower denture;
(l) reline of complete upper or lower denture;
(m) removal of impacted tooth (soft tissue, partial bony, or complete bony);
(n) surgical exposure of impacted tooth or unerupted tooth to aid eruption (for orthodontic purposes);
(o) vestibuloplasties (ridge extensions);
(p) excision of hyperplastic tissue, per arch;
(q) use of a hospital (inpatient or outpatient) or a freestanding ambulatory surgery center;
(r) certain surgical services performed in a hospital (for example, orthognathic surgery);
(s) additional fee for management of a physically or developmentally disabled member in the office;

(t) maxillofacial prosthetics;
(u) oral screenings of members undergoing radiation treatment, chemotherapy, or organ transplant; and
(v) any other service designated "P.A." in Subchapter 6 or Appendix E of the *Dental Manual*.

(2) The prescription of certain drugs requires prior authorization, as specified in 130 CMR 420.418.

(D) Prior Authorization for Diagnostic, Preventive, Restorative, Prosthodontic, and Endodontic Services for Members Aged 21 and Older. The Division pays for diagnostic, preventive, restorative, prosthodontic, and endodontic services (described in 130 CMR 420.432 through 130 CMR 420.439) for members aged 21 and older only when the provider has obtained prior authorization from the Division that the member meets the special circumstances criteria set forth in 130 CMR 420.410(D)(1).

(1) To demonstrate special circumstances, the member must have
(a) a severe, chronic disability that
(i) is attributable to a mental or physical impairment or combination of mental or physical impairments;
(ii) is likely to continue indefinitely; and
(iii) results in the member's inability to maintain oral hygiene; or
(b) a clinical condition (such as human immunodeficiency virus or cancer) that has advanced to a stage where an infection resulting from oral disease would likely be life-threatening.

(2) The provider's prior-authorization request must contain a clear, written statement signed by the member's physician or primary care clinician (on the clinician's letterhead) describing the member's disability or clinical condition, including but not limited to, the member's specific diagnosis and expected prognosis, and
(a) whether, and specifically why, the member's disability results in the member's inability to maintain oral hygiene; or
(b) whether the member's clinical condition has advanced to a stage where an infection resulting from oral disease would likely be life-threatening, including reference to specific supporting diagnostic evidence.

(3) For purposes of 130 CMR 420.410(D)(1)(a) and (2)(a), "inability to maintain oral hygiene" means that
(a) the member is unable to
(i) independently or with assistance (provided that such assistance actually is available), brush and floss his or her teeth and perform other routine acts of personal oral hygiene; or
(ii) report oral pain; or
(b) the nature of the member's disability is such that routine acts of personal oral hygiene are insufficient to effectively maintain such hygiene.

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 the Division 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, 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 420.416(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 420.416(D)(2).

(2) Exceptions to Days' Supply Limitations. The Division 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. The Division 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.

(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 I of the *Dental 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).

420.418: 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 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. 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 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 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.

(D) Insurance Coverage.

(1) 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.

(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 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 420.418(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.

420.419: 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 420.417(A)(1) 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 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 *Dental Manual*. If the Division approves the request, the Division will notify both 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 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.

(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. The Division will evaluation 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, 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.

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 the Division, 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 the Division are not of good diagnostic quality, the provider may not claim payment for any retake X rays requested by the Division. 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 the Division's reimbursement for a full-mouth series, the provider may only claim reimbursement in an amount not to exceed the Division's reimbursement for a full-mouth series.