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MASSHEALTH
TRANSMITTAL LETTER AOH-12
May 2007

TO: Acute Outpatient Hospitals Participating in MassHealth

FROM: Tom Dehner, Acting Medicaid Director

RE: *Acute Outpatient Hospital Manual* (Revisions to Regulations about Medicare Part D)

This letter transmits revisions to the acute outpatient hospital regulations about Medicare Part D, as provided in the Massachusetts state budget for fiscal year 2007. The provision extends and expands the state pharmacy assistance available to MassHealth members who have Medicare.

The fiscal year 2007 budget extended the availability of one-time 30-day supplies of prescribed medications for members with Medicare for dates of pharmacy service from July 1, 2006, until December 31, 2006. After this supply, MassHealth paid for a one-time 72-hour supply of the prescribed medication, without a copayment. Effective July 1, 2006, payment for these one-time supplies will be available when a pharmacist is unable to bill a Medicare Part D plan or the point-of-sale facilitator (currently WellPoint/Anthem). Effective January 1, 2007, the one-time 30-day supplies will no longer be available, but MassHealth will still pay for a one-time 72-hour supply of prescribed medications.

Effective July 1, 2006, for cost-sharing assistance for MassHealth members who are enrolled in a Medicare Part D prescription drug plan, if the Medicare Part D copayment or deductible is in excess of the member's applicable MassHealth copayment, the MassHealth member will pay the applicable MassHealth copayment and MassHealth will pay the difference between the applicable MassHealth copayment and the amount charged by the Medicare Part D prescription drug plan.

These regulations are being issued as emergency regulations and are effective July 1, 2006.

If you have any questions about the information in this transmittal letter please contact MassHealth Customer Service at 1-800-841-2900, e-mail your inquiry to providersupport@mahealth.net, or fax your inquiry to 617-988-8974.

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

Acute Outpatient Hospital Manual

Pages iv-a and 4-39 through 4-44

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(The pages listed here are no longer in effect.)

Acute Outpatient Hospital Manual

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(B) Drug Exclusions. The MassHealth agency does not pay for the following types of drugs or drug therapy:

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

(2) Cough and Cold. The MassHealth agency does not pay for legend or nonlegend drugs used solely for the symptomatic relief of cough or 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. The MassHealth agency does not pay for any drug used to promote male or female fertility.

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

(5) Less-Than-Effective Drugs. The MassHealth agency 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.

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

(7) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for drugs when used for the treatment of male or female sexual dysfunction.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 410.463(B). The limitations and exclusions in 130 CMR 410.463(B)(1) through (5) do not apply to medically necessary drug therapy for MassHealth Standard enrollees under age 21. 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 410.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. The MassHealth agency 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 MassHealth agency 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; and

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

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

(4) The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence.
(5) The MassHealth agency 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. The MassHealth agency 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 MassHealth agency for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether the MassHealth agency generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 410.463(C)(2)(a) and (c). In such cases, the prescriber must obtain prior authorization from the MassHealth agency in order for the pharmacy to bill the MassHealth agency for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq. and the hospital's Request for Applications and Contract, if applicable.
(3) Medicare Part D.
(a) Overview. Except as otherwise required in 130 CMR 406.414(C)(2) and (3), for MassHealth members who have Medicare, the MassHealth agency does not pay for any Medicare Part D drugs, or for any cost-sharing obligations (including premiums, copayments, and deductibles) for Medicare Part D drugs, whether or not the member has actually enrolled in a Medicare Part D drug plan. Medications excluded from the Medicare Part D drug program continue to be covered for MassHealth members eligible for Medicare, if they are MassHealth-covered medications.
(b) Medicare Part D One-Time Supplies. The MassHealth agency pays for one-time supplies of prescribed medications, as described in 130 CMR 406.414(C)(2)(a) and (b), if the medication is a MassHealth-covered medication and the MassHealth member would otherwise be entitled to MassHealth pharmacy benefits but for being eligible for Medicare prescription drug coverage. MassHealth prior authorization does not apply to such one-time supplies. Between January 1 and June 30, 2006, the MassHealth agency pays for the one-time supplies only if the MassHealth member's Medicare Part D prescription drug plan will not cover the prescribed medication at the time the prescription is presented. Effective July 1, 2006, the MassHealth agency pays for the one-time supplies in all instances in which the pharmacist cannot bill a Medicare Part D prescription drug plan at the time the prescription is presented.

(i) Between January 1 and December 31, 2006, the MassHealth agency pays for a one-time 30-day supply of prescribed medications. Any copayment that would have been charged to the member under MassHealth will apply to a one-time 30-day supply. After this supply of the prescribed medication, the MassHealth agency pays for a one-time 72-hour supply of the same prescribed medication.
(ii) Effective January 1, 2007, the MassHealth agency pays for a one-time 72-hour supply of prescribed medications.

(c) Cost-Sharing Assistance for MassHealth Members Enrolled in a Medicare Part D Prescription Drug Plan. For the purpose of 130 CMR 410.463(D)(3)(c)(i) and (ii), the "applicable MassHealth copayment" is the copayment the MassHealth member would pay for prescription drugs if the drugs were covered by MassHealth and not covered by Medicare Part D.

(i) Between January 1 and June 30, 2006, for MassHealth members who are enrolled in a Medicare Part D prescription drug plan and are charged a copayment in excess of the member's applicable MassHealth copayment for a drug that MassHealth would otherwise cover, the member pays the applicable MassHealth copayment and the MassHealth agency pays the difference to the pharmacy, up to the amount that the Medicare Part D prescription drug plan is permitted to charge an eligible enrollee who has both MassHealth and Medicare.
(ii) Effective July 1, 2006, for MassHealth members who are enrolled in a Medicare Part D prescription drug plan and are charged a copayment or deductible in excess of the member's applicable MassHealth copayment for a drug that MassHealth would otherwise cover, the member pays the applicable MassHealth copayment and the MassHealth agency pays the difference between the applicable MassHealth copayment and the amount charged by the Medicare Part D prescription drug plan.

410.464: Pharmacy Services: Drugs and Medical Supplies Provided by Hospital-Based Pharmacies

Drugs and medical supplies provided by hospital-based pharmacies must be provided and billed in accordance with MassHealth regulations governing pharmacy services in 130 CMR 406.000.

410.465: Pharmacy Services: Drugs and Medical Supplies for Members in Institutions

(A) The MassHealth agency does not pay for nonlegend drugs or medical supplies provided to an institutionalized member, except in circumstances described in 130 CMR 410.465(C).

(B) The MassHealth agency pays for legend drugs provided to an institutionalized member.

(C) The MassHealth agency pays for insulin prescribed for members who are residents of a nursing facility or rest home.

410.466: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by the MassHealth agency in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 410.462(A) and 410.463(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 MassHealth agency for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Acute Outpatient Hospital Manual* or the *Chronic Disease and Rehabilitation Outpatient Hospital Manual*, as applicable. If the MassHealth agency approves the request, it will notify both the pharmacy and the member.

(C) The MassHealth agency 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 MassHealth agency 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 from 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 410.461 through 410.466. The MassHealth agency will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

410.467: Pharmacy Services: Member Copayments

Under certain conditions, the MassHealth agency 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.

410.468: Participation in the 340B Drug-Pricing Program for Outpatient Pharmacies

(A) Notification of Participation. A hospital outpatient department or a hospital-licensed health center that is a 340B-covered entity may provide drugs to MassHealth members through the 340B drug-pricing program provided that it notifies the MassHealth agency by submitting to the MassHealth agency a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and, if applicable, a copy of the OPA form used to certify the contracted pharmacy services. The hospital may provide and bill for 340B drugs to MassHealth members, provided directly or through a subcontract, after the MassHealth agency confirms, in writing, its receipt of the hospital's notification and a copy of the OPA registration form, in accordance with 130 CMR 410.468(A).

(B) Subcontracting for 340B Outpatient Pharmacy Services.

(1) A hospital outpatient department or hospital-licensed health center that is a 340B-covered entity may contract with a MassHealth pharmacy provider to dispense 340B drugs for the 340B-covered entity's MassHealth patients. All such subcontracts between the 340B-covered entity and a pharmacy provider must be in writing, ensure continuity of care, specify that the hospital pays the pharmacy, specify that such payment constitutes payment in full for 340B drugs provided to MassHealth members, be consistent with all applicable provisions of 130 CMR 406.000, and are subject to MassHealth approval. The 340B-covered entity must comply with the requirements of 130 CMR 410.468(A) by submitting to the MassHealth agency a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and a copy of the OPA form used to certify the contracted pharmacy services for the 340B drug-pricing program.

(2) The hospital is legally responsible to MassHealth for the performance of any subcontractor. The hospital must ensure that every pharmacy subcontractor is licensed by the Massachusetts Board of Registration in Pharmacy, is a MassHealth pharmacy provider, and that services are furnished in accordance with MassHealth pharmacy regulations at 130 CMR 406.000 and all other applicable MassHealth requirements, including but not limited to, those set forth in 130 CMR 450.000.

(C) Termination or Changes in 340B Drug-Pricing Program Participation. A hospital outpatient department or hospital-licensed health center must provide the MassHealth agency 30 days' advance written notice of its intent to discontinue, or change in any way material to the MassHealth agency, the manner in which it provides 340B outpatient drugs for its MassHealth patients.

(D) Payment for 340B Outpatient Pharmacy Services. The MassHealth agency pays the 340B-covered entity for outpatient hospital pharmacy services, whether provided and billed directly or through a subcontractor, at the rates established in DHCFP regulations at 114.3 CMR 31.00.

(130 CMR 410.469 through 410.470 Reserved)

410.471: Mental Health Services: Introduction

A mental health program is a comprehensive group of diagnostic and treatment services, as outlined in 130 CMR 410.474, furnished to mentally or emotionally disabled persons and their families under the direction of a licensed psychiatrist. The MassHealth agency pays for mental health services provided in hospital outpatient departments subject to the restrictions and limitations in 130 CMR 410.472 through 410.479.

410.472: Mental Health Services: Noncovered Services

(A) Nonmedical Services. The MassHealth agency does not pay for nonmedical mental health services. These services include, but are not limited to, the following:
(1) vocational rehabilitation services;
(2) sheltered workshops;
(3) educational services;
(4) recreational services (play therapy, the use of play activities with a child in an identified treatment setting as an alternative to strictly verbal expression of conflicts and feelings, is not considered a recreational service and is covered);
(5) life-enrichment services (ego-enhancing services such as workshops or educational courses provided to functioning persons); and
(6) telephone conversations.

(B) Nonmedical Programs. The MassHealth agency does not pay for diagnostic and treatment services that are provided as an integral part of a planned and comprehensive program that is organized to provide primarily nonmedical or other nonreimbursable services. Such programs include alcohol or drug drop-in centers.

(130 CMR 410.473 Reserved)