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406.401: Introduction

All pharmacies participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to MassHealth regulations set forth in 130 CMR 406.000 and 450.000: *Administrative and Billing Regulations*.

406.402: Definitions

The following terms used in 130 CMR 406.000 have the meanings given in 130 CMR 406.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 406.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 406.000 and in 130 CMR 450.000: *Administrative and Billing Regulations*

340B-covered Entities. Facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Care Act of 1992.

340B Drug Pricing Program. A program established by Section 340B of Public Health Law 102-585, the Veterans Health Care Act of 1992.

Compounded Drug. Any drug, excluding cough preparations, in which two or more active ingredients, at least one of which is a drug, are extemporaneously mixed by a registered pharmacist.

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

Durable Medical Equipment Specialty. A designation by the MassHealth agency for pharmacy providers whose primary business is not providing durable medical equipment but that nevertheless are qualified pursuant to the applicable requirements of 130 CMR 409.000: *Durable Medical Equipment Services* to provide durable medical equipment not listed on the Non-drug Product List to MassHealth Members.

Drug. A substance as defined by the Food, Drug, and Cosmetic Act, containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Electronic Prescription. A prescription transmitted electronically in compliance with applicable state and federal law.

~~Gross Cost Per Utilizer Per Year. Annual cost per utilizer projected by EOHHS based on factors including actual or expected utilization, dosing information, duration of therapy, and the National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) (when NADAC is not available) of the covered drug prior to any federal or supplemental rebate.~~

Health Insurer. A private or public entity, including Medicare, that has a health plan or policy under which it pays for medical services provided to a member. An endorsed discount card issued in accordance with Section 1860D-31(a) of the Social Security Act is not considered a health insurance plan or policy.

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 Center for Drug Evaluation and Research (FDA CDER), or by the

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Massachusetts Drug Formulary Commission.

MassHealth Drug List. A list of commonly prescribed drugs and therapeutic class tables published by MassHealth. 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 406.413(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 406.000.

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.

Non-drug Product List. A section of the MassHealth Drug List comprised of those products not classified as drugs (~~i.e.g.~~, blood testing supplies) that are payable by the MassHealth agency through the Pharmacy Program. Except as designated by Pharmacy Facts, provider bulletin, or other written issuance from the MassHealth agency, payment for these items is in accordance with rates published in EOHHS regulations at 101 CMR 322.00: *Rates for Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment* and 101 CMR 317.00: *Rates for Medicine Services*. The MassHealth Non-~~d~~Drug Product List also specifies which of the included products require prior authorization.

Over-the-counter Drug. Any drug for which no prescription is required by federal or state law. These drugs are sometimes referred to as nonlegend drugs. The MassHealth agency requires a prescription for both prescription drugs and over-the-counter drugs (*see* 130 CMR 406.411(A)).

Oxygen and Respiratory Therapy Equipment Specialty. Designation by the MassHealth agency for pharmacy providers whose primary business is not the provision of oxygen and respiratory therapy equipment but that nonetheless are qualified pursuant to the applicable requirements of 130 CMR 427.000: *Oxygen and Respiratory Therapy Equipment* (excepting any requirement that the provider primarily engage in the ~~in the~~ business of supplying oxygen and respiratory therapy equipment to the public) to provide oxygen and respiratory therapy equipment not listed on the Non-drug Product List to MassHealth Members.

Pharmacy Covered Professional Services List. A section of the MassHealth Drug List comprised of those professional services that are payable by the MassHealth agency through the Pharmacy Program.

Pharmacy Online Processing System (POPS). The online, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Prescription Drug. Any drug for which a prescription is required by applicable federal or state law or regulation, other than MassHealth regulations. These drugs are sometimes referred to as legend drugs.

Retail Establishment. A physical place of business at which the provider dispenses prescription and over-the-counter drugs; a business conducted by mail, telephone, the internet, or any other remote means does not constitute a “retail establishment.”

Step Therapy Protocol. A utilization management policy or program that establishes the specific sequence in which a prescription drug for a specified medical condition is covered by the MassHealth agency.

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406.403: Eligible Members

- (A) (1) MassHealth Members. The MassHealth agency covers pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105: Coverage Types specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
- (2) Recipients of the 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: Emergency Aid to the Elderly, Disabled and Children Program.
- (B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107: Eligible Members and the MassHealth Card.

406.404: Provider Eligibility

- (A) All Providers. A pharmacy must be a participant in MassHealth on the date of service in order to be eligible for payment.
- (B) In-state Providers. To be eligible for participation as a MassHealth provider, a pharmacy must
- (1) have a retail establishment located and doing business in the Commonwealth of Massachusetts;
 - (2) be licensed by the Massachusetts Board of Registration in Pharmacy in accordance with M.G.L. c. 112 and 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department Licensure of Pharmacies, or be licensed by the Massachusetts Department of Public Health and dispensing as a pharmacy in a clinic or hospital setting in accordance with M.G.L. c. 111 and 105 CMR 722.000: Dispensing Procedures for Clinic and Hospital Pharmacies;
 - (3) be licensed by the federal Drug Enforcement Administration (DEA) and possess a DEA registration number (if a pharmacy is licensed to dispense only Schedule VI drugs, the pharmacy may possess a Massachusetts Controlled Substance Registration number instead of a DEA registration number); and
 - (4) agree to use the MassHealth Pharmacy Online Processing System (POPS) in real-time mode to submit claims.
- (C) Out-of-state Providers.
- (1) All Out-of-state Providers. A provider that does not meet the requirements of 130 CMR 406.404(B) may participate in MassHealth only if the provider meets the following requirements of 130 CMR 450.109: Out-of-state Services; and
 - (a) is licensed by the Board of Registration in Pharmacy (or the equivalent) in the state in which the provider primarily conducts business and in accordance with applicable provisions of 247 CMR 6.00: Licensure of Pharmacies Registration, Management and Operation of a Pharmacy or Pharmacy Department;
 - (b) possesses a DEA registration number;

- (c) participates in the Medicaid program or equivalent of the state in which the provider primarily conducts business; and
- (d) agrees to use the MassHealth agency Pharmacy Online Processing System (POPS) in real-time mode to submit claims.

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(2) Limited Purpose Out-of-state Providers.

- (a) If a pharmaceutical manufacturer supplies a drug only to a pharmacy that is located outside of Massachusetts, and the drug is medically necessary for a MassHealth member, the MassHealth agency may enroll such a provider for the limited purpose of dispensing the drug, and may only reimburse the pharmacy for the dispensing of that drug. The provider must agree to this restriction as a condition of enrollment and meet the requirements of 130 CMR 406.404(C)(1)(a) through (d).
- (b) If a member is covered by other primary insurance and that carrier requires use of an out-of-state pharmacy, MassHealth may enroll that pharmacy for the purpose of submitting secondary claims only.
- (c) If the drug later becomes readily available within Massachusetts, the MassHealth agency may disenroll the limited purpose out-of-state pharmacy.

(D) Participation in the 340B Drug Pricing Program for Outpatient Pharmacy Services. ~~The MassHealth agency does not cover drugs billed through pharmacy point-of-sale adjudication when these drugs are acquired through the 340B Drug Pricing Program.~~

~~(1) Notification of Participation. Except for drugs that cost \$100,000 or more (gross cost per utilizer per year) that are designated as excluded from coverage for MassHealth members through the 340B Drug Pricing Program, 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 in writing that the 340B-covered entity is registered and approved by the federal Office of Pharmacy Affairs (OPA). Any high cost drug designated for exclusion from coverage for MassHealth members through the 340B drug pricing program will be communicated by provider bulletin or other written issuance from the MassHealth agency, be consistent with all requirements of M.G.L. c. 118E, §13L, and include an opportunity for eligible providers to provide input regarding the designation. The MassHealth agency may designate up to 25 drugs for exclusion from coverage for MassHealth members through the 340B Drug Pricing Program. will DAny exclusion from coverage for MassHealth members through the 340B Drug Pricing Program does not apply to claims paid using the adjudicated payment amount per discharge (APAD) or adjudicated payment per episode of care (APEC) methodology, other than for drugs listed on the Acute Hospital Carve-Out Drugs List section in the MassHealth Drug List.~~

~~(2) Subcontracting for 340B Outpatient Pharmacy Services.~~

- ~~(a) 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 340B-covered entity 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 agency approval.~~
- ~~(b) The 340B-covered entity is legally responsible to the MassHealth agency for the performance of any subcontractor. The 340B-covered entity must ensure that every pharmacy subcontractor is licensed by the Massachusetts Board of Registration in~~

~~Pharmacy and 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: *Administrative and Billing Regulations*.~~

~~(3) Termination or Changes in 340B Drug Pricing Program Participation. A 340B-covered entity 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.~~

~~(4) Payment for 340B Outpatient Pharmacy Services. The MassHealth agency pays the 340B-covered entity for eligible pharmacy services, whether provided and billed directly or through a subcontractor, at the rates established in EOHHS regulations at 101 CMR 331.00: *Prescribed Drugs*.~~

406.405: Drugs and Medical Supplies Provided ~~to Members Who are Temporarily~~ Outside of Massachusetts

When provided out of state, drugs and medical supplies are reimbursable only if the member is temporarily out of state and requires drugs or medical supplies under the circumstances described in 130 CMR 450.109: *Out-of-state Services*.

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406.411: Prescription Requirements

(A) Legal Prescription Requirements. The MassHealth agency pays for prescription drugs, over-the-counter drugs, and items on the Non-~~d~~ Drug Product List 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 for drugs in Schedules II through V must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber's Massachusetts Controlled Substance Registration number must appear on the prescription.

(B) Emergencies. When the pharmacist determines that an emergency exists, the MassHealth agency will pay the 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 Substances Management Program (CSMP) must comply with 130 CMR 406.442(C)(2).

(C) Refills.

~~(1) T~~

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

~~(2) The MassHealth agency pays for a maximum of 11 monthly refills, except in circumstances described in 130 CMR 406.411(C)(3), or where federal or state law prohibits, or where the MassHealth Drug List or Pharmacy Facts or other written issuance from the MassHealth agency specifically limits the number of refills, duration of the prescription, or both.~~

~~(3) The MassHealth agency 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 406.411(D).~~

~~(24)~~ -The MassHealth agency 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.

~~(63)~~ -The MassHealth agency does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

(D) Quantities.

(1) Days' Supply Limitations.

(a) The MassHealth agency requires that all drugs be dispensed in a 30-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 406.411(D)(1)(b) and 130 CMR 406.411(D)(2).

(b) 90-day supplies. The MassHealth agency requires or allows that drugs be dispensed in a 90-day supply in the following circumstances, except as specified in 130 CMR 406.411(D)(2):

1. Required 90-day Supplies. The MassHealth agency requires certain designated generic drugs, other designated low-net-cost drugs, and drugs listed as preferred in the Brand Name Preferred section of the MassHealth Drug List to be dispensed in a 90-day supply after a trial supply is dispensed in up to a 30-day supply. Drugs subject to this requirement will be designated in the MassHealth Drug List. This requirement

does not apply to drugs dispensed to members in certain long term care facilities, hospices, and group homes, or as specified by law or regulation.

2. Allowed 90-day Supplies. MassHealth allows that drugs be dispensed in up to a 90-day supply in the following circumstances:

- a. Drugs designated in the MassHealth Drug List as allowed to be dispensed in 90-day supplies.
- b. Drugs for which the MassHealth agency is not the primary payer but for which payment is available from the MassHealth agency for any portion of the claim (including any copayment or deductible), provided that the primary payer will pay for the drug when dispensed in up to a 90-day supply.

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Exceptions prohibiting the dispensing of a drug in a 90-day supply set forth in 130 CMR 406.411(D)(2) do not apply if the primary payer will pay for the drug when dispensed up to a 90-day supply.

(c) The MassHealth Drug List 90-day Supply Page. This page on the MassHealth Drug List describes the types of drugs that are allowed or required to be dispensed in a 90-day supply. This page also notes exclusions to the 90-day supply program which are at the discretion of the MassHealth agency.

(2) Exceptions to Days' Supply Limitations.

(a) The MassHealth agency allows exceptions to the limitations described in 130 CMR 406.411(D)(1) for the following products:

(1) drugs in therapeutic classes that are commonly prescribed for less than a 30-day or 90-day supply (as applicable), including but not limited to antibiotics and analgesics;

(2) drugs that, in the prescriber's professional judgment, are not clinically appropriate for the member in a 30-day or 90-day supply (as applicable);

(3) 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;

(4) drugs packaged in such a way that the smallest quantity that may be dispensed is larger than a 30-day or 90-day supply, as applicable (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);

(5) 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);

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

~~(7) methylphenidate and amphetamine prescribed in 60-day supplies;~~

~~(8) drugs designated by MassHealth as required to be dispensed in less than 30-day or 90-day supplies (as applicable) in order to limit potential fraud, waste, or abuse;~~

~~(9) opioid substances in Schedule II if the patient requests less than the prescribed quantity as provided in M.G.L. c. 94, -§ 18(d3/4); and~~

~~(10) drugs designated for reporting to the Department of Public Health's Prescription Monitoring Program, 105 CMR 700.012(A): Pharmacy Reporting Requirements, are not eligible to be dispensed in a 90-day supply; and~~

~~(11) as designated in a Pharmacy Facts, provider bulletin, or other written issuance from the MassHealth agency.~~

(b) Drugs used for family planning may be dispensed in up to a 365-day supply.

(E) Prescription-splitting. Providers must not split prescriptions by filling them for a period or

quantity less than that specified by the prescriber. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. The MassHealth agency considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).) Partial fills of prescriptions pursuant to an exception to days' supply limitations described above in 130 CMR 406.411(D)(2)(a) are not considered prescription-splitting for purposes of 130 CMR 406.411(E).

(F) Excluded, Suspended, or Terminated Clinicians. The MassHealth agency does not pay for prescriptions written by clinicians

- (1) who have been excluded from participation based on a notice by the U.S. Department of Health and Human Services Office of Inspector General; or
- (2) whom the MassHealth agency has suspended, terminated, or denied admission into its program for any other reason.

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406.412: Covered Drugs and Medical Supplies

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

- (1) Prescription Drugs. The MassHealth agency pays only for prescription 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. Payment is calculated in accordance with 101 CMR 331.00: *Prescribed Drugs*.
- (2) Over-the-counter Drugs. Payment by the MassHealth agency for over-the-counter drugs is calculated in accordance with 101 CMR 331.00: *Prescribed Drugs*.
- (3) Compounded Drugs. MassHealth pays for compounded drugs specified in the MassHealth Drug List. Payment for compounded drugs is calculated in accordance with 101 CMR 331.00: *Prescribed Drugs*.

(B) Non-drug Products Paid through POPS.

- (1) The MassHealth agency pays through POPS for products not classified as drugs only if such products are listed in the Non-drug Product List section of the MassHealth Drug List.
- (2) Non-drug Product List. Except as designated by Pharmacy Facts, provider bulletin, or other written issuance from the MassHealth agency, payment for items listed in the Non-drug Product List is in accordance with rates published in the EOHHS regulations at 101 CMR 322.00: *Rates for Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment* and 101 CMR 317.00: *Rates for Medicine Services*. The MassHealth Non-~~d~~Drug Product List also specifies which of the included products require prior authorization.

(C) Non-Drug Products that Require Certification by Other MassHealth Programs.

- (1) Durable Medical Equipment. Pharmacy providers who intend to provide durable medical equipment and medical supplies that are not listed in the Non-~~d~~Drug Product List section of the MassHealth Drug List to MassHealth members must meet the applicable requirements of 130 CMR 409.000: *Durable Medical Equipment Services*, and must obtain a durable medical equipment specialty designation from the MassHealth agency.
- (2) Oxygen and Respiratory Therapy Equipment. Pharmacy providers who intend to provide oxygen and respiratory therapy equipment and supplies that are not listed in the Non-drug Product List to MassHealth members must meet the applicable requirements of 130 CMR 427.000: *Oxygen and Respiratory Therapy Equipment* and must obtain an oxygen and respiratory therapy equipment specialty designation from the MassHealth agency.

(D) Covered Professional Services Paid Through POPS. The MassHealth Pharmacy Covered Professional Services List specifies certain services that may be provided by a pharmacy provider and payable through POPS (e.g., the administration of a particular vaccine). The service must be provided by a properly trained and certified pharmacist or other appropriately certified health care professional in accordance with Massachusetts Department of Public Health regulations and employed or contracted by a MassHealth pharmacy provider. Services must be provided in accordance with applicable Department of Public Health regulations including those at 105 CMR 700.000: Implementation of M.G.L. c. 94C and 247 CMR 16.00: Collaborative Drug Therapy Management.

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406.413: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The MassHealth agency 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 MassHealth agency for a nongeneric multiple-source drug (*see* 130 CMR 406.422); and
- (2) the prescriber certified on the prescription that the brand-name drug is
 - (a) medically necessary and may not be substituted in a manner consistent with Massachusetts Department of Public Health regulations, and with all other applicable state and federal regulations; and
 - (b) is prescribed in the appropriate manner (e.g., written or electronic) and consistent with Massachusetts Department of Public Health regulations; or
- (3) the MassHealth agency designates the brand-name drug as preferred in the Brand-name Preferred section of the MassHealth Drug List because the net cost of the brand-name drug after consideration of all rebates, is less than the cost of the generic equivalent.

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

- (1) Cosmetic. The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth, unless medically necessary.
- (2) Cough and Cold. The MassHealth agency does not pay for any drug 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 a member who is a resident in a nursing facility or an intermediate care facility for individuals with intellectual disabilities (ICF/IID).~~
- (3) Fertility. The MassHealth agency does not pay for any drug used to promote fertility.
- (4) Less-than-effective Drugs. The MassHealth agency does not pay for any 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.
- (5) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (6) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction.
- (7) Obesity and Overweight Management. ~~The MassHealth agency does not pay for any drug used for the treatment of obesity or overweight.~~

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B). The limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for MassHealth Standard and CommonHealth enrollees ~~under age younger than 21 years old~~. The MassHealth Drug List specifies those 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 406.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. See 130 CMR 450.303: *Prior Authorization*.

(2) The MassHealth agency does not pay for the following types of drugs, or drug therapies or non-drug products without prior authorization:

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

(b) any drug, drug therapy, or non-drug product designated in the MassHealth Drug List as requiring prior authorization.

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(3) 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.

(4) The MassHealth agency does not pay for any 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: *Unacceptable Billing Practices*.

406.414: Insurance Coverage

(A) 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 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~~their 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: *Eligible Members and the MassHealth Card* and 450.117: *Managed Care Participation*.

(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 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 406.413(C)(2)(a). 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: *Definitions*.

(C) Medicare Part D.

(1) 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.

(2) 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), 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. 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. The MassHealth agency pays for a one-time 72-hour supply of prescribed medications.

(3) Cost-sharing Assistance for MassHealth Members Enrolled in a Medicare Part D Prescription Drug Plan. For the purpose of 130 CMR 406.414(C)(3), the “applicable

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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. 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, must pay 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.

(130 CMR 406.415 through 406.420 Reserved)

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406.421: Drugs and Medical Supplies for Institutionalized Members

- (A) MassHealth pays for prescription drugs provided to institutionalized members.
- (B) MassHealth does not pay for over-the-counter drugs or medical supplies provided to institutionalized members, except in circumstances described in 130 CMR 406.421(C).
- (C) MassHealth pays for insulin prescribed for members who are residents of a nursing facility or rest home.

406.422: Prior Authorization

- (A) Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303: *Prior Authorization*. If the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(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 130 CMR 450.303: *Prior Authorization*, and the instructions for requesting prior authorization in the Pharmacy Online Processing System (POPS) billing guide, the MassHealth Drug List, and any other applicable guidance. The MassHealth agency will notify the requesting provider and the member, in writing, of its decision.
- (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 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 and designates which drugs require prior authorization. Any drug that does not appear on the MassHealth Drug List requires prior authorization. The MassHealth agency evaluates the prior authorization status of drugs on an ongoing basis, and updates the MassHealth Drug List accordingly.
- (F) If the pharmacy does not dispense a drug or non-drug product because the prescriber did not submit a request for prior authorization, the pharmacy must take reasonable steps to notify both the patient and prescriber of the need for prior authorization, and make a contemporaneous record of having done so.
- (G) The MassHealth agency allows exceptions to its step therapy protocol consistent with M.G.L. c.118E, § 51A. The MassHealth Drug List details the specific process for members or their prescriber seeking an exception to step therapy.
 - (1) The MassHealth agency will grant or deny a request for an exception to the step therapy protocol or a request to appeal a denial of an exception not more than three business days after the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If additional delay would result in significant risk to the enrollee's health or well-being, then this three-business day period will be reduced to

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24 hours after the receipt of all necessary information to establish the medical necessity of the prescribed treatment.

(2) For purposes of 130 CMR 406.422(G)(1) above, an appeal of a denial of a step therapy exception will occur through informal consultation with a clinical pharmacist with the MassHealth program or its utilization review organization.

(3) Nothing in this section shall limit a member’s right to a fair hearing consistent with the timing and requirements under 130 CMR 610.000: *MassHealth: Fair Hearing Rules*.

(4) For purposes of granting exceptions to step therapy consistent with M.G.L. c. 118E, § 51A(c)(1)(iv)(a), MassHealth is not required to consider samples provided to members absent a prescription to be a “prescription drug prescribed by the health care provider” or otherwise sufficient to establish stability.

(5) Requests for exceptions to step therapy require such documentation as MassHealth requires to establish the medical necessity of the treatment or otherwise specifies on the MassHealth Drug List.

406.423: 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 prescription or over-the-counter) covered by MassHealth. The copayment requirements are detailed in 130 CMR 450.130: *Copayments Required by the MassHealth Agency*.

406.424: Cash Payments

(A) No pharmacy provider may solicit, charge, receive, or accept any money, gift, or other consideration (including cash payments) from a member, or from any other person on behalf of the member, for any drug for which payment is available under MassHealth in accordance with 130 CMR 450.203: *Payment in Full*, and nothing in this Section 406.424 will relieve pharmacy providers of their obligations under 130 CMR 450.203. Payment is considered to be available under MassHealth even if a drug is subject to a quantity limit, dose limit, or prior authorization requirement, or prospective drug utilization review (PRO-DUR) edit, unless the prescriber has made diligent efforts to secure prior authorization or the pharmacy or prescriber has sought a PRO-DUR certification as applicable, and the MassHealth agency has denied prior authorization for the drug as not medically necessary or denied PRO-DUR certification.

(B) On the date of service and prior to accepting any money, gift, or other consideration (including cash payments) from a member, or from any other person on behalf of the member, for any Schedule II-V drug (or other drug designated for reporting to the Department of Public Health’s Prescription Monitoring Program, 105 CMR 700.012(A): *Pharmacy Reporting Requirements*;) listed on the MassHealth Drug List for which payment is not available under MassHealth, a pharmacy must

(1) verify that payment is not available from MassHealth in at least one of the following ways:

(a) request and obtain verification from the MassHealth agency Drug Utilization Review (DUR) Program that payment is not available under MassHealth; or

(b) request and obtain verification from the prescriber certifying that:

1. the prescriber made diligent efforts to obtain prior authorization for the drug from the MassHealth agency; and
2. the prescriber’s prior authorization request was denied by the MassHealth agency as not medically necessary; or

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(c) verify that the drug is excluded from MassHealth coverage under 130 CMR 406.413(B);

(2) verify that the member is not enrolled in the Controlled Substances Management Program (CMSP) described in 130 CMR 406.442 by utilizing the Eligibility Verification System (EVS);

(3) use the Massachusetts Prescription Awareness Tool (MassPAT) to run a patient search on the member; and

(4) document compliance with the requirements outlined in 130 CMR 406.424(B)(1) through (3).

(C) A pharmacy that accepts any money, gift, or other consideration (including cash payments) from a member, or from any other person on behalf of the member, under 130 CMR 406.424(B) must thereafter monitor the prescription utilization pattern of the member at the pharmacy and maintain documentation of such pattern in a readily accessible form. In the event the member's utilization pattern would indicate overutilization or improper utilization of prescribed drugs to a pharmacist exercising sound professional judgment, the pharmacy must refer the member to the MassHealth agency for potential enrollment in the CSMP.

(D) A pharmacy may not solicit, charge, receive, or accept any money, gift, or other consideration (including cash payments) from a member enrolled in the CSMP, or from any other person on behalf of the member, for any drug for which payment is not available under MassHealth unless

(1) the pharmacy is the member's primary pharmacy as designated by the MassHealth agency;

(2) the pharmacy has satisfied the requirements set forth in both 130 CMR 406.424(B)(1) and 130 CMR 406.424(B)(3);

(3) the dispensing pharmacist certifies that in ~~his or her~~their professional judgment, the prescription is appropriate for the member's medical condition and the member's utilization pattern does not otherwise indicate that acceptance of any money, gift, or other consideration (including cash payment) from a member, or from any other person on behalf of the member, would be inappropriate or inconsistent with any professional standards; and

(4) the pharmacy documents compliance with the requirements outlined in 130 CMR 406.424(C)(1) through (3).

(E) The pharmacy must maintain the documentation described in 130 CMR 406.424(B)(4), 130 CMR 406.424(C), and 130 CMR 406.424(D)(4) in a readily accessible form, and must provide such documentation to the MassHealth agency, the Attorney General's Medicaid Fraud Division, the State Auditor, and the United States Department of Health and Human Services on request.

(F) For purposes of 130 CMR 406.424, the term “diligent efforts” means the submission, after review of all other therapeutic alternatives, of a complete and timely prior authorization request for a drug in accordance with 130 CMR 450.303: *Prior Authorization* and the instructions for requesting prior authorization in the Pharmacy Online Processing System (POPS) billing guide, the MassHealth Drug List, and any other applicable guidance. A prior authorization request denied by the MassHealth agency for any other reason than as not medically necessary (e.g., missing or incomplete documentation) will not be deemed to have satisfied this requirement. The pharmacy is responsible for verifying that the prescriber undertook diligent efforts to obtain prior authorization.

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(G) Failure to comply with any provision of 130 CMR 406.424 may result in the imposition of sanctions against a pharmacy provider in accordance with the provisions of 130 CMR 450.000: *Administrative and Billing Regulations*.

(130 CMR 406.425 through 406.430 Reserved)

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406.431: Payment Rates

Except as to drugs designated by Pharmacy Facts, provider bulletin, or other written issuance from the MassHealth agency, the methods for determining payment of drugs are contained in 101 CMR 331.00: *Prescribed Drugs*. The methods for determining payment for medical supplies described in 130 CMR 406.412 are contained in 101 CMR 322.00: *Rates for Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment* and 101 CMR 317.00: *Rates for Medicine Services*. The methods for determining payment for services listed on the MassHealth Pharmacy Covered Professional Services List are contained in 101 CMR 317.00: *Rates for Medicine Services*. In the event of conflict between 130 CMR 406.000 and 101 CMR 331.00: *Prescribed Drugs*, 101 CMR 331.00: *Prescribed Drugs* ~~shall~~will govern.

(130 CMR 406.432 through 406.435 Reserved)

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406.436: Disclosure of Information

In order for the MassHealth agency to verify a pharmacy's compliance with 101 CMR 331.00: *Prescribed Drugs*, a pharmacy must, upon request, make available to the MassHealth agency for inspection and copying the following documentation:

(A) all prescriptions (for both members and nonmembers) filled during the time period specified by the MassHealth agency with the names of the patients and all other identifying information blocked out;

(B) all documentation of a drug's cost to the pharmacy provider, all documentation regarding the amount the pharmacy provider has charged any entity, and the amount any purchaser or reimbursor has paid the pharmacy provider for any drug covered by MassHealth. This must include, but is not limited to, all documentation used to calculate charges billed to the MassHealth agency for any given date. In addition, all reports, books, and records related to its operation must be available for audit.

(130 CMR 406.437 through 406.441 Reserved)

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406.442: Controlled Substances Management Program

(A) Introduction. The MassHealth agency has established a Controlled Substances Management Program for MassHealth members who over-utilize or improperly utilize prescribed drugs. Members in the Controlled Substances Management Program are restricted to obtaining prescribed drugs only from the provider that the MassHealth agency designates as the member's primary pharmacy.

(B) Criteria for Member Enrollment. The MassHealth agency may enroll in the Controlled Substances Management Program those MassHealth members who meet one of the following criteria:

- (1) members whom the MassHealth agency determines over-utilize or improperly utilize medications in certain therapeutic classes, receive duplicative therapy from multiple physicians, or frequently visit the hospital emergency department seeking pain medications. The MassHealth Drug Utilization Program will identify criteria to identify members for the Controlled Substances Management Program. These criteria will be listed in the MassHealth Drug List; or
- (2) members who were enrolled in the Controlled Substances Management Program of a MassHealth-contracted managed care organization (MCO) at the time the member disenrolled from the MCO. When the MassHealth agency enrolls a member in the Controlled Substances Management Program it notifies the member accordingly.

(C) Service Restriction.

- (1) Except as outlined in 130 CMR 406.442(B), members enrolled in the Controlled Substances Management Program may obtain prescribed drugs only from the member's primary pharmacy as designated by the MassHealth agency, and only the member's primary pharmacy may receive payment from the MassHealth agency. Members who are enrolled in this program will be identified by the Eligibility Verification System (EVS) as participants in the Controlled Substances Management Program.
- (2) The MassHealth agency authorizes a pharmacy other than the primary pharmacy to dispense a nonrefillable supply of a drug to a restricted member when the pharmacist has determined that the member's health or safety would be jeopardized without immediate access to that drug or if the prescription is for family planning.

(D) Responsibilities of Primary Pharmacy. The primary pharmacy must monitor the prescription utilization pattern of each member, and must exercise sound professional judgment when dispensing all prescription drugs. When the pharmacist reasonably believes that the member is presenting a prescription that is inappropriate for ~~his or her~~their medical condition, the pharmacist must contact the prescriber to verify the authenticity and accuracy of the prescription presented. Primary pharmacies that are found on review to be dispensing drugs in a manner that is inconsistent with professional standards may be subject to administrative action by the MassHealth agency, including the recovery of payments and the imposition of sanctions in accordance with 130 CMR 450.000: *Administrative and Billing Regulations*.

(E) Change in Primary Pharmacy and Member Status.

- (1) The member may ask the MassHealth agency to change the member's primary pharmacy designation only once per calendar year, unless the member can demonstrate that the designated primary pharmacy is unable to address the member's pharmacy needs due to a change in
 - (a) the member's residence;

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- (b) the member’s medical condition; or
- (c) the primary pharmacy’s business practices.

(2) The MassHealth agency may disenroll or transfer a member from a primary pharmacy if the pharmacy requests the change.

(3) MassHealth will periodically review the member’s drug utilization on its own initiative, or upon the member’s request, but no earlier than 12 months after the date on which the MassHealth agency enrolled the member in the Controlled Substances Management Program. If, after such review, the MassHealth agency determines that the member has not used excessive quantities of prescribed drugs for at least that 12-month period, the MassHealth agency will disenroll the member from the Controlled Substances Management Program and the member will no longer be subject to the restrictions of that program. However, the MassHealth agency may reenroll a member in that program at any time in accordance with the provisions of 130 CMR 406.442(B).

406.443: Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary ~~acute-outpatient hospital~~pharmacy services for EPSDT-eligible members in accordance with 130 CMR 450.140 through 450.149, without regard to service limitations described in 130 CMR 406.000, and with prior authorization.

(130 CMR 406.444 through 406.445 Reserved)

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406.446: Prospective Drug Review and Counseling

Pharmacies must offer prospective drug review and counseling consistent with the requirements in M.G.L. c. 94C, § 21A and 247 CMR 9.07. Only a patient's refusal of counseling must be documented, except as otherwise required under applicable state law.

REGULATORY AUTHORITY

130 CMR 406.000: M.G.L. c. 118E, §§7 and 12.

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