Commonwealth of Massachusetts
Executive Office of Health and Human Services
Division of Medical Assistance
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MASSHEALTH
TRANSMITTAL LETTER PHM-46
March 2003

TO: Pharmacies Participating in MassHealth

FROM: Douglas S. Brown, Acting Commissioner

RE: *Pharmacy Manual* (Revised Regulations)

This letter transmits revised pharmacy regulations. The regulations have been revised to:

- modify the definition of interchangeable drug product;
- modify the definition of usual and customary charge to be consistent with state law;
- simplify the definition of Massachusetts upper-limit price to merely cite the Division of Health Care Finance and Policy regulations that define the term;
- simplify the definition of federal upper-limit price to merely cite the federal statute and the Centers for Medicare and Medicaid Services regulations that define the term;
- define the MassHealth Drug List;
- define wholesale acquisition cost;
- reduce the number of allowable refills from 11 to five;
- clarify specific drug limitations and prior-authorization requirements;
- clarify the impact of managed-care enrollment and insurance coverage on MassHealth pharmacy claims; and
- modify the requirements for the Controlled Substance Management Program.

These regulations are effective April 1, 2003.

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

Pharmacy Manual

Pages iv and 4-1 through 4-16

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(The pages listed here are no longer in effect.)

Pharmacy Manual

Pages iv and 4-1 through 4-14 — transmitted by Transmittal Letter PHM-45

4. PROGRAM REGULATIONS

406.401: Introduction

All pharmacies participating in MassHealth must comply with the regulations of the Division governing MassHealth, including but not limited to Division regulations set forth in 130 CMR 406.000 and 450.000.

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.

Actual Package Size – the package size of any drug for which the Massachusetts Division of Health Care Finance and Policy (DHCFP) has not determined the most frequently purchased package size is the actual package size as indicated by the National Drug Code (NDC) listed on the container from which the pharmacist dispenses the drug.

Compounded Drug – any drug, excluding cough preparations, in which two or more ingredients, at least one of which is a legend 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).

Dispensing Fee – the fee paid, over and above the ingredient cost of the drug, to a pharmacy for dispensing a prescribed drug to a member.

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.

Estimated Acquisition Cost – an estimate of the price generally and currently paid by pharmacies for the most frequently purchased package size of a drug, as determined in accordance with DHCFP regulations at 114.3 CMR 31.00.

Federal Upper-Limit Price (FULP) – a price established by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to 42 CFR 447.332 and U.S.C. §1396r-8(e).

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 Massachusetts Drug Formulary Commission.

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

Massachusetts Upper-Limit Price (MULP) – an upper-limit price for multiple source drugs as defined by the Division of Health Care Finance and Policy as specified in 114.3 CMR 31.00.

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 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.

Most Frequently Purchased Package Size – the package size of a drug most frequently purchased by pharmacy providers, based on utilization data compiled by the Division. The National Drug Code (NDC) that is most often paid by the Division and verified by audit, if determined necessary by the Division, is considered the most frequently purchased package size.

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.

Retail Establishment – a physical place of business at which the provider sells legend, nonlegend, and other pharmacy products and services to the general public; a business conducted by mail, telephone, the Internet, or any other remote means does not constitute a "retail establishment."

Single-Source Drug – a drug marketed or sold by one manufacturer or labeler under one proprietary name.

Unit-Dose Packaging – an individual drug product container usually consisting of foil, molded plastic, or laminate with indentations for a single solid oral dosage form, with any accompanying materials or components, including labeling. Each individual container fully identifies the drug and protects the integrity of the dosage. For purposes of 130 CMR 406.000, an assemblage of multiple, unlabeled single doses (traditional "bingo cards" or "bubble packs") is not unit-dose packaging.

Unit-Dose-Return Fee – a fee paid to the pharmacy for accepting returned drugs in unit-dose packaging in accordance with 130 CMR 406.446.

Unit-Dose Distribution System – a means of packaging and/or distributing drugs in unit doses, 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. Such unit doses may or may not be in unit-dose packaging.

Usual and Customary Charge – the lowest price for a given volume of drugs (legend or nonlegend) that a pharmacy charges to or accepts as payment from any purchaser or reimburser.

Wholesale Acquisition Cost (WAC) – a manufacturer's price published in a national price compendium or other publicly available source. Where no published price is identified as the WAC, the WAC is equal to the wholesale net unit price as published by First Data Bank. If no wholesale net unit price is published, the WAC is equal to the lower of the direct price or an adjusted average wholesale price.

406.403: Eligible Members

(A) (1) MassHealth Members. The Division covers pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, 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.

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

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 or be licensed by the Massachusetts Department of Public Health as a pharmacy in a clinic setting in accordance with M.G.L. c. 111;
(3) be licensed by the federal Drug Enforcement Administration (DEA) and possess a DEA registration number; and
(4) agree to use the Division's Pharmacy On-Line Processing System (POPS) in real-time mode to submit claims.

(C) 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 requirements of 130 CMR 450.109 and:
(1) is licensed by the Board of Registration in Pharmacy (or the equivalent) in the state in which the provider primarily conducts business;
(2) possesses a DEA registration number;

(3) participates in the medical assistance program or equivalent of the state in which the provider primarily conducts business; and
(4) agrees to use the Division's Pharmacy On-Line Processing System (POPS) in real-time mode to submit claims.

406.405: Drugs and Medical Supplies Provided 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.

(130 CMR 406.406 through 406.410 Reserved)

406.411: Prescription Requirements

(A) Legal Prescription Requirements. The Division pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 406.412(B) only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription, regardless of drug schedule, must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number on the prescription.

(B) Emergencies. When the pharmacist determines that an emergency exists, the Division will authorize the pharmacy to dispense at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations, except as provided in 130 CMR 406.442(C)(3).

(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 406.411(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 406.411(D)(2).

(2) Exceptions to Days' Supply Limitations. The Division allows exceptions to the limitations described in 130 CMR 406.411(D)(1) for the following products.

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

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

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

(d) drugs packaged 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 prescriber. 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).)

406.412: 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. Payment is calculated in accordance with 130 CMR 406.432.
(2) Nonlegend Drugs. The Division pays only for the nonlegend drugs listed in Appendix F of the *Pharmacy Manual* (Nonlegend Drug List). Payment is calculated in accordance with 130 CMR 406.433.

(B) Medical Supplies.
(1) The Division pays only for the following medical supplies through POPS:
(a) blood and urine testing reagent strips used for the management of diabetes;
(b) disposable insulin syringe and needle units;
(c) insulin cartridge delivery devices and needles (for example, pens);
(d) lancets; and
(e) drug delivery systems for use with metered dose inhalers (for example, aerochambers).
(2) Payment and coverage for all other medical supplies are described in the Division's durable medical equipment regulations at 130 CMR 409.000.

406.413: 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 406.422); 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 406.413(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 406.000. 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. The Division does, however, pay a unit-dose return fee in accordance with 130 CMR 406.446.
(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.

406.414: Insurance Coverage.

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

(B) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the Division for the primary insurer's copayment for the primary carrier's preferred drug without regard to whether the Division generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 406.413(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.

(130 CMR 406.415 through 406.419 Reserved)

406.420: Unit-Dose Packaging Requirement for Certain Drugs Dispensed in Nursing Facilities

For drugs listed in Appendix D of the *Pharmacy Manual*, the pharmacy must fill the prescription in unit-dose packaging when dispensed to MassHealth members residing in a nursing facility. See 130 CMR 406.446 for the pharmacy's requirements to accept unused unit-dose-packaged drugs returned by a nursing facility.

406.421: Drugs and Medical Supplies for Institutionalized Members

(A) The Division pays for legend drugs and ostomy supplies provided to institutionalized members.

(B) The Division does not pay for nonlegend drugs or medical supplies provided to institutionalized members.

406.422: 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 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 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 *Pharmacy Manual*. If the Division approves the request, the Division notifies 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 42 U.S.C. 1396r-8(d)(5).) The Division acts on requests for prior authorization for a prescribed drug within a time period consistent with federal regulations.

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

(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 406.000. The Division will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

406.423: 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.

(130 CMR 406.424 through 406.430 Reserved)

406.431: Payment Rates: Introduction

The methods for determining payment contained in 130 CMR 406.432 through 406.436 are based on regulations adopted by DHCFP (114.3 CMR 31.00: Prescribed Drugs). In the event of conflict between these Division regulations and DHCFP regulations, DHCFP regulations govern.

406.432: Payment Rates: Legend Drugs

(A) Payment Rate for Multiple-Source Drugs for Which a FULP or MULP Has Been Established.

(1) Payment to a pharmacy for a multiple-source drug dispensed to a member for which a FULP or MULP has been established does not exceed the lowest of:

(a) the FULP of the drug, if any, plus the appropriate dispensing fee (see 130 CMR 406.434);

(b) the MULP of the drug, if any, plus the appropriate dispensing fee (see 130 CMR 406.434); or

(c) the usual and customary charge.

(2) The payment limitation described in 130 CMR 406.432(A)(1) does not apply when:

(a) the prescriber has requested, and the Division has approved, prior authorization for the dispensing of a nongeneric multiple-source drug; and

(b) the prescriber has written on the face of the prescription in his or her 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) Payment Rate for All Other Drugs. Other drugs include multiple-source drugs for which a FULP or MULP has not been established, single-source drugs, and drugs that meet the requirements of 130 CMR 406.432(A)(2). Payment to a pharmacy for such a drug dispensed to a member does not exceed the lower of:

(1) the estimated acquisition cost of the drug, plus the appropriate dispensing fee (see 130 CMR 406.434); or

(2) the usual and customary charge.

(C) Payment Rate for Interchangeable Drug Products. For interchangeable drug products, payment does not exceed the rate of payment for a less expensive, reasonably available interchangeable drug product unless:

(1) the prescriber has requested, and the Division has approved, prior authorization for a nongeneric multiple-source drug; and

(2) the prescriber has written on the face of the prescription in his or her 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.

406.433: Payment Rates: Nonlegend Drugs

Payment to a pharmacy for a nonlegend drug dispensed to a member does not exceed the lower of:

(A) the estimated acquisition cost of the drug, plus the appropriate dispensing fee (see 130 CMR 406.434); or

(B) the usual and customary charge.

406.434: Payment Rates: Dispensing and Unit-Dose-Return Fees

The dispensing fee and unit-dose-return fee are paid in accordance with regulations adopted by DHCFP (114.3 CMR 31.00: Prescribed Drugs).

406.435: Payment Rates: Medical Supplies

The methods for determining payment for medical supplies contained in 130 CMR 406.435 are in accordance with regulations adopted by DHCFP (114.3 CMR 22.00: Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment).

406.436: Disclosure of Information

In order for the Division to verify a pharmacy's compliance with 130 CMR 406.432 and 406.433, a pharmacy must, upon request, make available to the Division for inspection and copying the following documentation:

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

(B) all documentation of returned unused drugs from nursing facilities pursuant to 130 CMR 406.446, including the manifest for each shipment of returned drugs from the nursing facility; and

(C) 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 reimburser has paid the pharmacy provider for any drug covered by the Division. This must include, but is not limited to, all documentation used to calculate charges billed to the Division 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)

406.442: Controlled Substance Management Program

(A) Introduction. The Division has established a Controlled Substance Management Program for MassHealth members who use excessive quantities of prescribed drugs. Members in the Controlled Substance Management Program are restricted to obtaining prescribed drugs only from the provider that the Division designates as the member's primary pharmacy.

(B) Criteria for Member Enrollment. The Division may enroll in the Controlled Substance Management Program those MassHealth members who the Division determines use excessive quantities of prescribed drugs. For purposes of 130 CMR 406.442, "excessive quantities of prescribed drugs" is defined as 11 or more prescriptions, including original fill and refills, of one or more controlled substances from Schedule II, III, or IV over a three-month period, obtained from four or more prescribers or filled by four or more pharmacies. Where the Division enrolls a member in the Controlled Substance Management Program upon a determination that the member uses excessive quantities of prescribed drugs, it will notify the member accordingly.

(C) Service Restriction.

(1) Except as outlined in 130 CMR 406.442(B)(2), members enrolled in the Controlled Substance Management Program may obtain prescribed drugs only from the member's primary pharmacy as designated by the Division, and only the member's primary pharmacy may receive payment from the Division. Members who are enrolled in this program will be identified by the Recipient Eligibility Verification System (REVS) as participants in the Controlled Substance Management Program.

(2) The Division will authorize 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.

(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 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 Division, including the recovery of payments and the imposition of sanctions.

(E) Change in Primary Pharmacy and Member Status.

(1) The member may request that the Division change the member's primary pharmacy designation only once per calendar year, except where the member can demonstrate that the designated primary pharmacy is unable to address the member's pharmacy needs due to a change in the:

(a) member's residence;
(b) member's medical condition; or
(c) primary pharmacy's business practices.

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

(3) The Division 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 Division enrolled the member in the Controlled Substance Management Program. If, after such review, the Division determines that the member has not used excessive quantities of prescribed drugs for at least that 12-month period, the Division will disenroll the member from the Controlled Substance Management Program and the member will no longer be subject to the restrictions of that program. However, the Division may reenroll a member in that program at any time in accordance with the provisions of 130 CMR 106.442(B).

(130 CMR 406.443 through 406.445 Reserved)

406.446: Return of Unused Unit-Dose-Packaged Drugs Dispensed in Nursing Facilities

(A) Creditable Drugs.

(1) Requirement. The pharmacy must accept those unused drugs in unit-dose packaging that are listed in Appendix D of the *Pharmacy Manual* and that were dispensed to a MassHealth member in a skilled nursing facility. The pharmacy must credit to the Division the amount paid for the quantity of such drugs pursuant to 130 CMR 406.446(D). Such credit enables the pharmacy to retain the original dispensing fee and receive a unit-dose-return fee. The pharmacy must credit to the Division within 15 days of receipt unit-dose-packaged drugs that meet the requirements of 130 CMR 406.446(A)(2), unless they are excluded under 130 CMR 406.446(B). The pharmacy may return the unused supply to inventory for redispensing as permitted by federal and state law.

(2) Creditable Drugs. The pharmacy must credit to the Division unit-dose-packaged drugs returned by a nursing facility if they comply with all applicable state and federal requirements, including but not limited to those related to the safety, labeling, handling, and storage of drugs.

(B) Excluded Drugs. Of the drugs described in 130 CMR 406.446(A), the pharmacy must not credit the Division for the following unit-dose-packaged drugs returned by a nursing facility:

(1) drugs that were dispensed to a member whose other insurance paid for part or all of the prescription;

(2) unused quantities of a prescription that are less than the minimum quantity identified in Appendix D of the *Pharmacy Manual*; and

(3) drugs with an expiration date of less than 90 days from the date of the return.

(C) Dosage Changes. When the prescriber changes the dosage of any drug described in 130 CMR 456.621(A), and the previously prescribed dosage of the drug can be used to accommodate the new dosage, the nursing facility will use up existing supplies of the drug dispensed to the member and will apply a change-of-directions sticker over the directions on the pharmacy prescription label. The pharmacy must provide a new label for the prescription when requested by the nursing facility.

(D) Crediting the Division for Returned Drugs. The pharmacy must use POPS to reverse the initial claim for the drug by the quantity of the returned drug. The pharmacy must submit the reversal through POPS within 15 days of receipt of the drug from the nursing facility. The amount of the payment will be recalculated based on the adjusted quantity and the inclusion of the unit-dose-return fee.

(E) Recordkeeping Requirements. The pharmacy must establish tracking and recordkeeping systems for all unit-dose-packaged drugs returned pursuant to 130 CMR 406.446(A). The records must reflect standard business accounting practices, must be available for review by the Division upon request, and must be kept for at least seven years from the date of the return. The records must include the:

(1) name of the member to whom the drugs were originally dispensed;

(2) date that the unused drugs were returned to the pharmacy;

(3) prescription number under which the unused drugs were originally dispensed;

(4) name and strength of the unused drugs;

(5) quantity of the doses returned;

(6) manifest from the nursing facility for each shipment of returned drugs; and
(7) name and quantity of drugs that were returned by the nursing facility, but are unacceptable for redispensing.

REGULATORY AUTHORITY

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