



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Division of Medical Assistance
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MASSHEALTH
TRANSMITTAL LETTER PHM-45
June 2002

TO: Pharmacies Participating in MassHealth
FROM: Wendy E. Warring, Commissioner
RE: *Pharmacy Manual* (Unit Dose Return for Certain Drugs)

In an effort to reduce pharmaceutical waste in nursing facilities, the Division has developed a unit-dose-dispensing and return requirement of certain drugs for pharmacies and nursing facilities. This letter transmits revisions to the pharmacy regulations. Under these regulations, the pharmacy must fill prescriptions for certain drugs in unit-dose packaging when they are dispensed to MassHealth members residing in a skilled nursing facility. The pharmacy must also credit to the Division amounts paid by the Division for certain unused unit-dose-packaged drugs that have been returned by the nursing facility.

These new requirements apply only to the eight drugs listed in Appendix D of the *Pharmacy Manual*. The Division may update this appendix to include additional drugs at a later date. Pharmacies should refer to 130 CMR 406.446 for specific requirements related to the dispensing and crediting of returned unit-dose-packaged drugs.

The Division will pay the pharmacy a unit-dose return fee in accordance with the rate established by the Massachusetts Division of Health Care Finance and Policy (DHCFP), for each returned prescription credited to the Division. This rate will be adopted in early July, and will be effective July 1, 2002. The Division is recommending the amount of the return fee to be \$5 per prescription. Providers may check the DHCFP Web site at www.mass.gov/dhcfp in early July to confirm the amount of the adopted fee.

Updated Billing Guides

Under separate cover, pharmacies will receive updated billing guides from ACS, the Division's Pharmacy On-line Processing vendor, that will describe how to credit the amount of the returned drugs to the Division and receive the return fee. Once the returned drugs are credited to the Division, the pharmacy may redispense the drugs in accordance with guidelines established by the Department of Public Health.

Department of Public Health Guidelines

The Department of Public Health has issued two documents about unit-dose dispensing and return:

- Policy on Return for Redispensing of Medications from Long Term Care Facilities
- Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities.

Pharmacies must adhere to these guidelines when dispensing drugs in unit-dose packaging, and when redispensing returned unit-dose-packaged drugs. A copy of each of these documents is included with this transmittal letter.

Best Practices

The Division, in concert with nursing facility and pharmacy stakeholders, has also prepared “Best Practices” guidelines. These guidelines advise pharmacies and nursing facilities on how to best manage the unit-dose return and redispense policy described in the attached regulations. The “Best Practices” guidelines are also included with this mailing for your information.

Updates to Controlled Substance Management Program

The attached regulations also include minor clarifications to the Controlled Substance Management Program, previously known as the Medical Services Control Program. The revisions define “excessive quantities” of drugs as “11 or more prescriptions of one or more controlled substances from Schedule II, III, or IV over a three-month period, and obtained from four or more prescribers and/or filled by four or more pharmacies without written confirmation from a licensed physician.” This new language defines how a MassHealth member will be selected for enrollment into the Controlled Substance Management Program. Under these revised provisions, the Division will conduct a review of a member’s enrollment into the Controlled Substance Management Program upon the request of the member after the member has participated in the program for at least 12 months.

Questions or Comments

Pharmacies may contact ACS at 1-866-246-8505 if they have questions related to the unit-dose dispensing or return requirements. Pharmacies may e-mail comments and questions about this new policy to medreturn@nt.dma.state.ma.us. All questions submitted through this electronic mailbox will be summarized and presented to the Long Term Care Pharmacy Unit Dose Return and Redispense Policy Workgroup. This workgroup will provide responses and updates to the pharmacies through the e-mail system operated by the Massachusetts American Society of Consultant Pharmacists. An information sheet about submitting inquiries through this electronic mailbox is also included with this letter.

These regulations are effective July 1, 2002.

NEW MATERIAL

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

Pharmacy Manual

Pages iv, vi, 4-1 through 4-14, D-1, and D-2

OBSOLETE MATERIAL

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

Pharmacy Manual

Pages iv, vi, and 4-1 through 4-12 — transmitted by Transmittal Letter PHM-43

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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). The FULP is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia of cost information on drugs) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size most commonly listed) or, in the case of liquids, the most commonly listed size.

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, as listed in the current edition of the *Massachusetts List of Interchangeable Drug Products* (105 CMR 720.000) or any supplement thereof.

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

Massachusetts Upper-Limit Price (MULP) — for multiple-source drugs that do not appear on the federal upper-limit price (FULP) list, an amount equal to 150 percent of the published price for the least costly therapeutic equivalent as listed in national price compendia such as the Red Book and First Data Bank for the most frequently purchased package size.

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.

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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 reimbursor, including those with contracts that represent less than one percent of the pharmacy's total prescription revenue. If the provider can demonstrate to the Division that a particular contract represents less than one percent of its total prescription revenue, the Division may eliminate that contract from consideration in determining the lowest 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;

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- (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)

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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(C) 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. The Division does not pay for prescription refills that exceed the specific number authorized by the prescriber up to a maximum of 11 refills. The Division does not pay for any refill dispensed after one year from the date of the original prescription. The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(D) Quantities.

(1) Quantity 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. 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 90-day supply may not be split into three 30-day supplies. The Division considers prescription splitting to be fraudulent.

(2) Exceptions to Quantity Limitations. The Division allows exceptions to the limitations described in 130 CMR 406.411(D)(1) for:

- (a) those 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; and
- (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.

406.412: Covered Drugs and Medical Supplies

(A) 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 Section 4401 of the Omnibus Budget Reconciliation Act of 1990. Payment is calculated in accordance with 130 CMR 406.432.

(B) 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.

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(C) 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: Service Limitations

(A) Interchangeable Drug Products. For drugs listed in the current edition of the *Massachusetts List of Interchangeable Drug Products* (105 CMR 720.000) or any supplement thereof, the Division pays no more than the FULP or MULP, whichever applies, 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) Insurance Coverage.

- (1) Managed Care Organizations. The Division does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.
- (2) Other Health Insurance. The Division will pay for pharmacy claims for services to MassHealth members who have health insurance other than through a MassHealth MCO only if the services were provided in accordance with the regulations, including any prior-authorization requirements, and billing rules of the member's other insurance carrier.

(C) 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.

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(D) Experimental and Investigational Drugs.

- (1) The Division does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (2) 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.

(E) Specific Drug Limitations.

- (1) Cosmetic Drugs. The Division does not pay for drugs used for cosmetic purposes or for hair growth.
- (2) Cough and Cold Preparations. The Division does not pay for legend or nonlegend preparations that contain an antitussive or expectorant as a major ingredient, or any drug used for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized member.
- (3) Fertility Drugs. The Division does not pay for any drugs used to treat male or female infertility (specifically including, but not limited to, A.P.L., chorionic gonadotropins, Clomid, clomiphenes, HCG, menotropins, Milphene, Pergonal, Pregnyl, Profasi, Profasi HP, and Serophene).
- (4) Immunizing Biologicals and Tubercular Drugs. Immunizing biologicals and tubercular (TB) drugs available free of charge through local boards of public health or through the Massachusetts Department of Public Health are not reimbursable. If the member has a prescription, however, the Division pays for the following drugs for a nonambulatory member who cannot attend one of the Department of Public Health clinics: Isoniazid, Myambutal, and P.A.S. All other such drugs require prior authorization (see 130 CMR 406.422).
- (5) Nongeneric Multiple-Source Drugs. Prescribers must obtain prior authorization from the Division for any nongeneric multiple-source drug identified by the Division in accordance with 130 CMR 450.303.
- (6) Obesity Management. The Division does not pay for any drug used for the treatment of obesity.
- (7) Sexual Dysfunction Therapy. The Division does not pay for the treatment of male or female sexual dysfunction.
- (8) Sex-Reassignment Hormone Therapy. The Division does not pay for drugs related to sex-reassignment surgery. This specifically includes, but is 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.
- (9) Smoking Cessation. The Division does not pay for any drug used for smoking cessation.
- (10) Topical Acne Drugs. The Division pays only for topical acne products for members aged 25 years and under who have cases of acne documented to be Grade II or higher.
- (11) Unit-Dose Distribution System. 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.

(130 CMR 406.414 through 406.419 Reserved)

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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. In addition, if the limitations on payment specified in 130 CMR 406.412 and 406.413 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 or medical supply.

(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 and assigns a prior-authorization number that must be written on the prescription.

(C) The Division will authorize at least a 72-hour 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.

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)

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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 drugs listed in the current edition of the *Massachusetts List of Interchangeable Drug Products* (105 CMR 720.000) or any supplement thereof, 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.

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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 reimbursor 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)

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406.442: Controlled Substance Management Program

(A) Introduction.

(1) The Division's Controlled Substance Management Program was established to prevent MassHealth members from obtaining excessive quantities of prescribed drugs. For purposes of 130 CMR 406.442, "excessive quantities" is defined as 11 or more prescriptions of one or more controlled substances from Schedule II, III, or IV over a three-month period, and obtained from four or more prescribers or filled by four or more pharmacies without written confirmation from a licensed physician.

(2) Members who are enrolled in the Controlled Substance Management Program may obtain drugs from their primary pharmacy only. The primary pharmacy is responsible for dispensing all prescription drugs for the member. 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.

(B) Enrollment of Members.

(1) The Division identifies members who have a documented history of obtaining excessive quantities of controlled substances under MassHealth for enrollment in the Controlled Substance Management Program. The Division issues a notice to the member requesting that the member choose a primary pharmacy as the single source for all prescription drugs.

(2) If the member does not choose a primary pharmacy within 30 days, the pharmacy identified on the member's notice becomes the member's primary pharmacy.

(3) The Division notifies the primary pharmacy of the identity of members restricted to that pharmacy.

(C) Service Restriction.

(1) Except as outlined in 130 CMR 406.442(C)(2), no pharmacy except the member's primary pharmacy may receive payment from the Division for drugs dispensed to a member with this restriction.

(2) In a life-threatening emergency or other emergency verified by the treating prescriber, the Division will authorize a pharmacy other than the primary pharmacy to dispense a maximum of a 72-hour supply of a drug to a restricted member. The pharmacy must obtain an original prescription from the prescriber stating that an emergency exists.

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(D) Responsibilities of Primary Pharmacy. The primary pharmacy must monitor the drug use of each member, and must exercise sound professional judgment when dispensing drugs. When the pharmacist reasonably believes that the member is attempting to obtain excessive quantities of drugs, the pharmacist must contact the prescriber to verify the authenticity and accuracy of questionable 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 not change pharmacies more than once per calendar year, unless there is a change that significantly impedes the member's access to pharmacy services. For the second and subsequent changes in a member's primary pharmacy in the same calendar year, the member must demonstrate that the pharmacy is no longer able 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) If, after review of the member's drug-usage profile, the Division determines that restriction of the member to the primary pharmacy is no longer appropriate, the restriction will be removed. The Division will conduct such a review upon the request of the member after the member has participated in the program for at least 12 months.

(130 CMR 406.443 through 406.445 Reserved)

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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, and must be available for review by the Division upon request, and 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;

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- (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.

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Unit-Dose Drugs

This appendix lists the unit-dose-packaged drugs that the dispensing pharmacy must credit to the Division when they have been dispensed to a MassHealth member in a nursing facility and have been returned by the nursing facility in accordance with 130 CMR 406.446. Beside each drug is the minimum quantity of the doses of the drug that the Division will accept for return.

Drug	Minimum Quantity
Depakote	3
Neurontin	3
Paxil	3
Prevacid	3
Remeron	3
Risperdal	3
Zoloft	3
Zyprexa	3

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This page is reserved.

Department of Public Health
Division of Health Care Quality
and
Drug Control Program

Policy on Return for Redispensing of Medications from Long Term Care Facilities

Background

In accordance with M.G.L. c. 111, §25I, the Department of Public Health (Department), permits long term care facilities (LTCFs) licensed by the Department to return unused unit-dose packaged¹ and certain other unused Schedule VI² and over-the-counter medications to pharmacies for the purpose of redispensing to patients or residents. Department policy also permits LTCFs to utilize a unit-dose packaging for management and administration of pharmaceuticals to patients or residents.³

The Department, working with the Board of Registration in Pharmacy⁴, has determined that the return for redispensing of unit-dose packaged medications can be a safe and effective method of pharmaceutical distribution. The return for redispensing of unit-dose packaged medications may contribute to the reduction of medication waste.⁵

Department regulations and this policy govern only the return for redispensing of medications from LTCFs to pharmacies. Regulations of the Board of Registration in Pharmacy govern the receipt and redispensing of such returned medications.

¹ Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form. Labeling is in accordance with United States Pharmacopeia standards compendia and federal and state law. For purposes of this policy traditional "bingo cards" or "bubble packs" are considered an assemblage of multiple, unlabeled, single doses and are not considered to be unit-dose packaging.

² Schedule VI medications refers to all prescription medications that are not in federal Schedules II - V.

³ Department of Public Health *Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities*.

⁴ Board of Registration in Pharmacy, 239 Causeway St., Boston 02114.

⁵ Department of Public Health Report, May 31, 1996, *Special Project: Dispensing of Unit Dose Medications in LTCFs*.

Requirements

- 1) The LTCF must have a written policy regarding the return for redispensing of Schedule VI and over-the-counter medications. The policy must address patient or resident safety issues including but not limited to:
 - A) ensuring the integrity of drugs subjected to extended and repeated handling, storage and transportation;
 - B) ensuring dispensers, repackagers and ultimate users can be identified and notified in the event of a recall;
 - C) minimizing opportunities for tampering and diversion; and
 - D) ensuring that all medications are stored in accordance with the standards of the United States Pharmacopeia (USP);
- 2) Drug products that may be returned are limited to:
 - A) intact, solid oral dosage forms, in unit-dose packaging and packaged as follows:
 - i) by the original manufacturer; or
 - ii) by the pharmacy in accordance with industry standards;
 - B) ampules;
 - C) suppositories;
 - D) parenteral medications in single-dose sealed containers; and
 - E) medications in multi-dose sealed containers⁶, that are dispensed pursuant to an order for an individual patient or resident and from which no doses have been withdrawn;
- 3) The following must be indicated clearly on each individual unit:
 - A) if a single active ingredient, the established name of the drug and the quantity of the active ingredient per dosage unit;
 - B) if a combination drug, the established name and quantity of each active ingredient per dosage unit;
 - C) lot or control number;
 - D) expiration or beyond use date;
 - E) NDC number or equivalent information; and
 - F) any special storage and handling instructions required by USP standards or state or federal law;
- 4) The following drug products may not be returned to a pharmacy for redispensing:
 - A) compounded or reconstituted drugs;
 - B) drugs that require refrigeration;
 - C) drugs that are adulterated or misbranded;
 - D) drugs which have had their integrity, packaging or labeling compromised (e.g., through environmental damage such as water damage, crushing, a broken seal, a torn or marked label); and
 - E) drugs designated as Schedule II - V controlled substances in accordance with M.G.L. c. 94C, §3.

⁶ Injectables, ophthalmics and topicals packaged and sealed by the original manufacturer.

- 5) Medications must be returned to the pharmacy (including location) from which they were originally dispensed;
- 6) Drug products must be returned within 30 days of discontinuation of use by a patient or resident;
- 7) Drug products must be returned no less than 90 days prior to the beyond use date or expiration date, whichever is earlier;
- 8) The LTCF must establish tracking and recordkeeping systems for returned medications:
 - A) Records must include:
 - i) the date returned to the pharmacy;
 - ii) prescription number under which the unused medication was originally dispensed;
 - iii) identity and strength of drug product;
 - B) This information must be made available to the Department upon request; and
 - C) These records shall be kept on file for a period of two years; and
- 9) In accordance with M.G.L. c. 111, §25I, the pharmacy to which such medication is returned shall reimburse or credit the purchaser for any such returned medication.

Massachusetts Department of Public Health

Division of Health Care Quality and Drug Control Program

Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities

In accordance with Department of Public Health (Department) regulations at 105 CMR 150.000 *et seq.* and 105 CMR 700.000 *et seq.*, long term care facilities (facilities) may use unit-dose packaging for management and administration of pharmaceuticals in accordance with the following guidelines.

Definition(s)

Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form.

Guidelines

1. Written policies and procedures must be developed and implemented that describe the procurement, administration, storage, security, disposal and record-keeping necessary to assure accountability throughout the system, prevent medication errors, impede drug diversion and facilitate the recall of prescription drug products.
2. Policies must include the manner in which provisions for alternate deliveries will be made in the event of an emergency situation (such as daily delivery not possible), new admissions to the facility or a patient or resident choosing an alternate pharmacy provider.
3. Policies and procedures must comply with all applicable state and federal laws. The Department does not require a waiver or advance approval for use of unit-dose packaging.
4. The policies and procedures must be approved by the facility's administration, nursing and medical staffs.
5. Appropriate training must be provided to the nursing staff as part of orientation and whenever significant system changes are made.
6. The system must be periodically evaluated as part of the facility's quality assurance/continuous quality improvement program.

Additional Information

This policy only covers utilization of unitdose packaging for medication management and administration. There are separate requirements for the implementation of a system of return for redispensing of unit-dose medications.

There are additional requirements that apply to the use of automated dispensing machines in long term care facilities¹.

¹ Department of Public Health, Circular Letter DHCQ 3-98-380.

BEST PRACTICES
FOR
MEDICATION RETURN AND RE-DISPENSING
OF SCHEDULE VI DRUGS
IN
PHARMACIES



Prepared by:
Massachusetts Division of Medical Assistance
in partnership with
Massachusetts Extended Care Federation

July 2002

ACKNOWLEDGEMENTS

The development of the Best Practices for Medication Return and Redispense of Schedule VI Drugs is a result of a collaborative effort among representatives from various state agencies, pharmacy groups, long term care nursing facilities, as well as other industry stakeholders who share a common goal of reducing medication waste.

The following individuals deserve acknowledgement for their generous input and work in bringing together the content of these best practices:

Albert C. Sivo, Regional Director of Client Services, Omnicare, Inc.

William J. Donatelli, B.S., R. Ph, Director of Operations – Braintree, NeighborCare,
and President, Massachusetts Chapter of the American Society of Consultant
Pharmacists (MASCP)

Paul Sardagnola, Manager of Operations, Kindred Pharmacy Services

Greg Laham, Owner, Sullivan Pharmacy

David D. Lozier, R. Ph, Chief Operating Officer, Omnicare, Inc.

Ken MacAskill, Director, Sunscript Pharmacy

BEST PRACTICES FOR PHARMACIES WHOSE BUSINESS ACTIVITIES INVOLVE PROVIDING PHARMACEUTICALS TO NURSING FACILITIES

In order to work towards the goal of reducing and eventually eliminating pharmaceutical waste, the Division of Medical Assistance (DMA) will implement a policy and regulations that mandate the return and redispensing of certain Schedule VI medications for MassHealth members in skilled nursing facilities (not applicable to assisted living facilities or rest homes).

In the updated pharmacy and nursing facility regulations relating to the return and redispensing of Schedule VI medications dated July 1, 2002, DMA is requiring each pharmacy to develop policies and procedures to implement its new return and redispense policy. Nursing facilities served by these pharmacies are also required to develop policy and procedures. Pharmacy policy and procedures must address the following topics related to medication return and redispensing:

- I. Systems Management Oversight
- II. Medication Ordering Practices
- III. Managing the Delivery of Medications to the Nursing Facility
- IV. Medication Storage Practices
- V. Managing the Dispensing of Medications
- VI. Medication Return Practices
- VII. Pharmacy and Nursing Facility Agreements
- VIII. Training

In order to facilitate pharmacies in writing policies and procedures, the Division, together with a small design group, composed of representatives of pharmacy owners (independent and chain) and the Massachusetts Chapter of the American Society of Consultant Pharmacists (MASCP) and the Long Term Care Pharmacy

Alliance, have provided significant input in the development of these Best Practices.

The group encourages pharmacies to use the Best Practices for a year. The design group will then evaluate their effectiveness, review and edit the practices, and formally publish them if they are, in fact, helpful and useful.

ELEMENTS OF BEST PRACTICE

I. Systems Management Oversight

It is recommended that one or more individuals be designated to oversee the medication return and redispense program in the pharmacy.

II. Medication Ordering Practices

1. The pharmacy should consider having a stated policy for that provides for trial amounts of medications new to the patient, and considers the nursing facility's policy requirements and DMA regulations.
2. It is recommended that the pharmacy's clinical pharmacist work with the nursing facility in the following situations:
 - When trial amounts of medications that are new to the resident are being considered, consider providing guidance to the nursing facility about how soon to expect adverse reactions.
 - When a patient is at the end stage of an illness, the LTCF should consult with the LTC Pharmacy on the amount of drug that should be ordered.
 - When a patient is experiencing side effects, consider identifying different ways the pharmacy can assist the nursing facility in managing the side effects. Ensure that the pharmacy educational insert/brochure that documents side effects/adverse reactions and symptom improvement accompanies the medication for trial medications.
 - When there is sufficient evidence to establish the patient's tolerance and that the medication is effective, consider reminding the nursing facility that they should be ordering a maintenance supply of medication.
 - When a dosage of a particular medication has changed, pharmacies should supply the facility with auxiliary labels stating, "directions have changed, refer to patient's medication record for the proper dose" in a timely manner.
3. Pharmacies should support the practice that when a MassHealth patient leaves the nursing facility to go home or to another nursing facility, as specified in Nursing Facility Bulletin 120 (see Appendix A) the facility is encouraged to consider reminding the prescriber to write an order allowing the patient's medication to accompany him/her.

III. Managing the Delivery of Medications to the Nursing Facility

1. It is recommended that the pharmacy, in conjunction with the nursing facility, establish a turnaround time that allows the nursing facility to compare the delivery manifest with the patient census. Identifying ordering errors or problems and patients who have died or have moved out of the facility before drugs are accepted reduces the documentation mandated when returning or destroying drugs. It is suggested that pharmacies negotiate with the nursing facility about accepting partial cards.
2. It is suggested that pharmacies work together with nursing facility to develop a delivery and pick-up schedule that is efficient and cost-effective and that will not result in any added cost to the pharmacy or nursing facility.

IV. Medication Storage Practices

1. It is suggested that the pharmacy encourage the consultant pharmacist to oversee/recommend to the nursing facility, the establishment of practices about drug safety, security, and integrity. (See Appendix B.)
2. It is recommended that the pharmacy consider coordinating training with the consultant pharmacist and nursing facility about storage issues.

V. Managing the Dispensing of Medications

Consider working with the nursing facility on a system that will help you identify what drugs are subject to return, including a unique unit-dose card to identify drugs to be returned.

VI. Medication Return Practices

1. The pharmacy should consider working with the nursing facility on a system that will help identify what drugs are subject to return (see Appendix C), including:
 - A unique unit-dose card to identify drugs to be returned, and
 - Using the existing re-order label to be affixed to the unit-dose card, which can then be affixed to the pharmacy/facility manifest.
2. Consider working with the nursing facility to fax a copy of **the manifest for drugs to be returned** (see Appendix D) the night prior to the scheduled pick-up day. The pharmacy can use the fax information to assure that that the medications listed are appropriate for the return. A faxed signoff back to the facility can assure that the facility removes non-returnable drugs from the return process and manifest.
3. Consider working with the nursing facility to determine in what type of package or container the returned drugs will be placed and stored for pickup.

4. Consider developing a system to document returned and destroyed medications and maintaining periodic auditing of the system (see Appendix E).
5. The pharmacy should have system in place to accept unused mandatory Schedule VI unit dose-packaged drugs for return.

VII. Pharmacy and Nursing Facility Agreements

The pharmacy is encouraged to work with the nursing facility to have a written policy and procedures that cover the tasks identified in the regulations and these Best Practices.

A. Managing the Packaging of Medications

1. The pharmacy must set up a system that identifies the mandated drugs and supplies those drugs in a modified unit-dose packaging.
2. It is recommended that the pharmacy develop, document, and test, a system for organizing the returned drugs for repackaging.
3. It is recommended that the pharmacy develop, document, and test an efficient system for crediting the returned drugs to the Division.
4. Identify specific workflow methods to accommodate safe handling of returned medications, i.e. designate specific areas.

B. Repackaging

1. In order to comply with regulations, it is suggested that the pharmacy develop, document, and test, a system to repackage and redispense returned drugs.
2. Although an infrequent occurrence, drug recalls will require all unit-dose packages of the recalled medication to be recalled.
3. It is suggested that pharmacists visually check reassembled unit-dose package for errors; technology should not be relied on to ensure accuracy.

C. Auditing

1. DMA's auditing principles include:
 - An auditing process based on examining **patterns** of behavior rather than documenting individual, infrequent errors or inconsistencies.
 - ✓ It is suggested that pharmacies' have clear, precise, and simple documentation of return transactions that provide a paper trail for audits for both the pharmacy and the nursing facility. Options for such a system include among other things:
 - ✓ Individual written agreements between nursing facilities and pharmacies that create instruments that can be used to establish a paper trail.
 - ✓ Use of the attached manifest that has sign-off for both parties including the date of signoff. The manifest could be

in duplicate: one for the pharmacy, and one for the nursing facility.

- ✓ Use of the attached manifest that has signoff for both parties, including the date of signoff. The signoff document would then be faxed to the pharmacy.
2. Discrepancies between the nursing facility count of returned medications and the pharmacy count received should be resolved by the individuals designated to oversee the return system.
 - It is suggested that pharmacies have a system in place to determine if the return/reuse system is working properly. The pharmacy should establish a self-audit process to document changes that promote continuous improvement that will result in efficiency when performing the necessary tasks.

VIII. Training

1. Consider holding initial and ongoing training sessions on the new DMA policy, the facility's policies and procedures, and medication return/re-use best practices.
2. Consider involving the director of nursing, medication nurses, and the consultant pharmacists in reviewing the policies and procedures.
3. Appropriate training should be provided to pharmacy staff whenever significant changes are made in agreements between the pharmacy organization and the nursing facility.

Appendices

The appendices cited throughout this document are intended to provide examples to assist pharmacies in implementation of best practices of new policy for medication return/redispense. Pharmacies are encouraged to modify forms in accordance with pharmacy and nursing facility agreements.



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Division of Medical Assistance
600 Washington Street
Boston, MA 02111
www.state.ma.us/dma

MassHealth
Nursing Facility Bulletin 120
July 2001

TO: Nursing Facilities Participating in MassHealth
FROM: Wendy E. Warring, Commissioner
RE: **Handling Schedule VI Medications in Nursing Facilities**

Background

Medication waste is a significant problem for nursing facilities. The Division of Medical Assistance is collaborating with the Department of Public Health to help nursing facilities reduce medication waste.

Reference Chart

The accompanying chart reviews relevant Division of Medical Assistance and Department of Public Health policies and procedures nursing facilities should follow to ensure the appropriate handling of residents' Schedule VI medications.

Questions

If you have any questions about the information on this chart, contact the MassHealth Provider Relations Department at (617) 628-4141 or 1-800-325-5231 or the DPH Division of Health Care Quality at (617) 753-8106. You may also access the DPH Web site at www.state.ma.us/dph.

Nursing Facility Responsibilities in Handling Schedule VI Medications

Resident admissions	The Massachusetts Department of Public Health (DPH) allows nursing facilities to administer medications that residents bring either from home or from another nursing facility with prescriber orders.
Amount of Medication to Be Ordered	<p>Order only the amount of medication prescribed: for example, a quantity sufficient for 10 days or less for medications new to the resident, for medications that require monitoring (for example, psychotropic or cardiac medications), or for medications that require frequent dosage adjustments (for example, anticoagulants or antibiotics).</p> <p>Order prescribed maintenance medications in 30-to-60 day quantities.</p>
Medical and Non-Medical Leaves of Absence	<p>Hold medications for the duration of a resident's medical leave of absence (MLOA) up to 20 days.</p> <p>Hold medications for the duration of a resident's non-medical leave of absence (NMLOA) up to 15 days.</p> <p>When the resident returns from MLOA or NMLOA, follow the current Department of Public Health procedures for handling the medication.</p>
Changes in Medication Labeling	<p>Affix an auxiliary label to the medication to signify a change in the prescriber's order. The label must state, in effect, that the directions have changed; refer to the resident's medication record for proper dose.</p> <p>Request that the pharmacy provider affix a new label when there is a dosage change.</p>
Resident Discharges	<p>See DPH regulations at 105 CMR 150.008 (B)(4), (B)(13), and (G)(1).</p> <p>When the doctor's orders state the member is to be discharged with his or her medications, send the medications with the resident to another nursing facility or community setting.</p>
Disposal of Schedule VI Medications	Dispose of Schedule VI medications when the resident expires, the prescriber discontinues the drug, or the medication reaches its expiration date.
Change of Pharmacy	The Division will not pay for new prescriptions solely because of a change in the pharmacy provider. Re-order medication only when the current supply is about to be exhausted.

Quality Assurance Checklist
for
Maintaining Drug Safety, Security & Integrity

1. Store medications at the appropriate temperature.
 2. Protect medications from exposure to excessive light.
 3. Protect medications from exposure to excessive heat.
 4. Prevent medications and or packaging from being exposed to spills.
 5. Prevent medication from being crushed or damaged.
 6. Examine medications for alteration or tampering.
 7. Be sure medications have been locked appropriately according to facility policy.
 8. Be sure medications are in the appropriate packaging.
-
-

MassHealth Schedule VI Top 8 Drugs
Return and Redispense
Dosage Forms and Storage Requirements

DRUG NAME	DOSAGE FORMS	STORAGE	TEMPERATURE	QUANTITY TO BE RETURNED
Depakote (divalproex sodium)		below 30°C (86°F)		
		below 30°C (86°F)		
Neurontin (gabapentin)		Controlled room temperature	15-30°C (59-86°F)	
	ALL	Controlled room temperature	15-30°C (59-86°F)	3
Paxil (paroxetine hydrochloride)			15-30°C (59-86°F)	
Prevacid (lansoprazole)	SOLID	Controlled room temperature	15-30°C (59-86°F)	OR
Remeron (mirtazapine)		Dark and dry	2 - 30°C	
Risperdal (risperidone)	FORMS	Controlled room temperature	15°-25°C (59°-77°F)	MORE
Zoloft (sertraline hydrochloride)		Controlled room temperature	15-30°C (59-86°F)	
		Controlled room temperature 15°-30°C (59°-86°F), protect from light and moisture.	excursions permitted to 15°-30°C (59°-86°F)	
Zyprexa (olanzapine)		Controlled room temperature 15°-30°C (59°-86°F), protect from light and moisture.	excursions permitted to 15°-30°C (59°-86°F)	

Clinical Sources: Manufacturer's information - package inserts and Physician's Desk Reference published information

Sample
Medication Return/Destruction Log

Appendix D
July 1, 2002

Name of Facility _____

Name of Pharmacy _____ Date Returned: _____

PLACE REORDER LABEL HERE IF AVAILABLE
Prescription #: _____
Patient Name: _____
Name of Drug: _____
Dose: _____
Strength: _____
FOR NURSING FACILITY ONLY
Date Discontinued: _____
Quantity Returned: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Date Destroyed: _____ Reason Destroyed: _____
FOR PHARMACY USE ONLY
Date Received: _____ Initials: _____
Quantity Returned to Inventory: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Reason Destroyed: _____

PLACE REORDER LABEL HERE IF AVAILABLE
Prescription #: _____
Patient Name: _____
Name of Drug: _____
Dose: _____
Strength: _____
FOR NURSING FACILITY ONLY
Date Discontinued: _____
Quantity Returned: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Date Destroyed: _____ Reason Destroyed: _____
FOR PHARMACY USE ONLY
Date Received: _____ Initials: _____
Quantity Returned to Inventory: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Reason Destroyed: _____

PLACE REORDER LABEL HERE IF AVAILABLE
Prescription #: _____
Patient Name: _____
Name of Drug: _____
Dose: _____
Strength: _____
FOR NURSING FACILITY ONLY
Date Discontinued: _____
Quantity Returned: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Date Destroyed: _____ Reason Destroyed: _____
FOR PHARMACY USE ONLY
Date Received: _____ Initials: _____
Quantity Returned to Inventory: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Reason Destroyed: _____

PLACE REORDER LABEL HERE IF AVAILABLE
Prescription #: _____
Patient Name: _____
Name of Drug: _____
Dose: _____
Strength: _____
FOR NURSING FACILITY ONLY
Date Discontinued: _____
Quantity Returned: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Date Destroyed: _____ Reason Destroyed: _____
FOR PHARMACY USE ONLY
Date Received: _____ Initials: _____
Quantity Returned to Inventory: _____ Initials: _____
Quantity Destroyed: _____ Initials: _____
Reason Destroyed: _____

Shaded area does not need to be filled out if a label is available.

Destruction Reason: 01-Broken/Crushed ; 02- Wet; 03-Temperature Compromised; 04-Broken Seal; 05-Med Expired; 06-Uncreditable; 07-Other (Explain)

SELF-AUDIT OF MEDICATION RETURN/REUSE SYSTEMS

To determine if medication return/reuse systems are working properly nursing facility and pharmacists can conduct a self-audit of at 30, 60 and 90-day intervals from the date the process begins. The emphasis can be placed on the following areas:

NURSING FACILITY	YES	NO	Comments/Notes
1. Are prescribers writing for initial new medications in smaller quantities?			
2. When directions change, are pharmacies supplying corrected labels as requested?			
3. Is nursing staff isolating returnable unit-dose cards according to policy (within 30 days)?			
4. If drug integrity in question, is nursing staff isolating the unit-dose cards for destruction?			
5. Are drugs with less than 90 days remaining on the beyond use /expiration date being isolated for destruction?			
6. Is the drug delivery manifest system working correctly, if not why?			
7. Is the labeling of each dose in the unit-dose card properly labeled with lot # exp. date, and NDC number?			
8. Is the LTCF tracking system working properly, if not why?			
PHARMACY	YES	NO	Comments/Notes
1. Are unit-dose cards being returned by the LTCF according to the following regulations: a: At least 90 days remaining on beyond use/expiration date? b: Within 30 days of being discontinued by practitioner? c: With questionable packaging integrity problems?			
2. Are only the required drugs being returned pursuant to regulations?			
3. Are LTCF only returning unit-dose cards pursuant to regulations. If not what has been done to correct the problem?			
4. Is the crediting system working according to regulations, if not why?			
5. Is the LTCF only returning unit-dose prescription drugs dispensed by this pharmacy? (must be returned to dispensing pharmacy only)			
6. Is the pharmacy recall system working to identify dispensers, re-packers and ultimate users, pursuant to Board of Pharmacy Policy?			
7. Is the quality assurance repacking records systems working properly in conformance with Board of Pharmacy Policy? If not why?			
8. Is the packing manifest which accompanies each returned unit-dose card being stored properly where it can readily be retrieved for seven years?			



INSTRUCTIONS FOR USE OF ELECTRONIC MAILBOX

The Massachusetts Division of Medical Assistance is providing an option for long term care pharmacies (LTCP) to submit questions and input about issues related to the implementation of the new policy on medication return & re-dispense.

LTC pharmacies can submit questions via email to a dedicated electronic mailbox. This mailbox will be active *May 15, 2002 through December 30, 2002*. The following email address has been designated for LTC Pharmacies:

medreturn@nt.dma.state.ma.us

The following conditions apply to electronic inquiries:

- a) You must include the Pharmacy name in the “**subject line**” of the email correspondence. The message should also your **name, title, phone number, and fax number**. This will be the method for identifying your pharmacy.
- b) The dedicated email account is to be used **only** for submitting questions that are specific to implementation of policy and best practices for the medication return and re-dispense policy. Please be specific when submitting your questions.
- c) The dedicated mailbox **should not** be used for questions on other aspects of the provider contracting, such as billing or crediting.
- d) This mailbox address is **not** intended to serve as a source of interactive technical assistance support for implementation of policy changes. For specific questions about nursing facility policy and procedures talk to your facility.
- e) When you submit your inquiry you will receive an automated response message that acknowledges receipt of your email.
- f) The Division cannot be responsible for the damage or destruction of information due to external computer viruses. If you do not receive an automated reply message please resubmit your inquiry.

All questions and inquiries submitted through this medium will be reviewed weekly by Massachusetts Division of Medical Assistance staff. Inquiries will be summarized and presented to Massachusetts Chapter of the American Society of Consultant Pharmacists (MASCP) and the Unit-Dose Return and Redispense Policy Workgroup. MASCP will be responsible for disseminating or providing responses and/or periodic updates to the LTC pharmacy industry via newsletters, Web site and existing workgroups.