



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Division of Medical Assistance
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Boston, MA 02111
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MASSHEALTH
TRANSMITTAL LETTER NF-43
June 2002

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

In an effort to reduce pharmaceutical waste in nursing facilities, the Division has developed a unit-dose return requirement of certain drugs for nursing facilities and pharmacies. This letter transmits revisions to the nursing facility regulations. Under these regulations, the nursing facility must return to the dispensing pharmacy certain unused unit-dose-packaged drugs that were dispensed to MassHealth members.

These new requirements apply only to the eight drugs listed in Appendix F of the *Nursing Facility Manual*. The Division may update this appendix to include additional drugs at a later date. Nursing facilities should refer to 130 CMR 456.621 for specific requirements related to returning unit-dose-packaged drugs.

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.

Nursing facilities must adhere to these guidelines when returning drugs in unit-dose packaging. 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 nursing facilities and pharmacies on how to best manage the unit-dose return policy described in the attached regulations. The "Best Practices" guidelines are also included with this mailing for your information.

Questions or Comments

Nursing facilities may e-mail comments or 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 Massachusetts Extended Care Federation Unit-Dose Return and Redispense Policy Workgroup. This workgroup will provide responses and updates to the nursing facility industry through newsletters, the Internet, and existing workgroups. 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-a, vi, 4-1, 4-2, 4-21 through 4-26, F-1, and F-2

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Pharmacy Manual

Pages iv-a — transmitted by Transmittal Letter NF-36

Pages vi, 4-1, 4-2, and 4-21 through 4-24 — transmitted by Transmittal Letter NF-42

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456.401: Nursing Facility Services: Introduction

130 CMR 456.000 establishes the requirements for nursing-facility services under MassHealth. All nursing facilities participating in MassHealth must comply with the regulations of the Division of Medical Assistance governing MassHealth including, but not limited to, the regulations set forth in 130 CMR 456.000 and 130 CMR 450.000.

456.402: Definitions

Board of Hearings — the unit within the Division of Medical Assistance that is responsible for administering the fair-hearing process under 130 CMR 610.000 and claims for adjudication hearings under 130 CMR 450.241, including hearings about transfers and discharges of residents by nursing facilities.

Discharge — the removal from a nursing facility to a noninstitutional setting of an individual who is a resident where the discharging nursing facility ceases to be legally responsible for the care of that individual.

Fair Hearing — an administrative, adjudicatory proceeding conducted pursuant to 130 CMR 610.000 to determine the legal rights, duties, benefits, or privileges of applicants and members, or residents.

Hospital — an inpatient facility that is licensed as a hospital by the Massachusetts Department of Public Health.

Length of Stay — the duration of a member's inpatient hospital stay at a Medicare hospital level of care during a medical leave of absence.

Medical Leave of Absence — an inpatient hospital stay at a Medicare level by a member who is a resident of a nursing facility. The Division will pay the nursing facility for up to 10 consecutive medical leave-of-absence days in a hospital.

Medicare Hospital Level of Care — a level of care that meets all criteria, as determined by the Centers for Medicare and Medicaid Services or its agent, for MassHealth payment for hospital care.

Member — a person determined by the Division to be eligible for MassHealth.

Mobility System — any manual or motorized wheelchair or other wheeled device, such as a scooter, including its components, accessories, and modifications, that is prescribed by a physician.

Nursing Facility — an institution or a distinct part of an institution that meets the provider-eligibility and certification requirements of 130 CMR 456.404 or 456.405. For requirements related to the transfer and discharge of residents, the term nursing facility also includes a nursing facility participating in Medicare, whether or not it participates in MassHealth.

Patient-Paid Amount — The portion of monthly income that a member in a nursing facility must contribute to the cost of care.

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Personal Needs Allowance (PNA) — the designated portion of monthly income that a member in a facility is allowed to keep for personal expenses.

Personal Needs Allowance (PNA) Account — an account or accounts administered by a nursing facility on behalf of a member. The account may be used to deposit the PNA and any other money, such as a gift, belonging to the member.

Resident — an individual receiving care in a nursing facility regardless of whether the individual is a MassHealth member.

Transfer — movement of a resident from:

- (1) a Medicaid- or Medicare-certified bed to a noncertified bed;
- (2) a Medicaid-certified bed to a Medicare-certified bed;
- (3) a Medicare-certified bed to a Medicaid-certified bed;
- (4) one nursing facility to another nursing facility; or
- (5) a nursing facility to a hospital, or any other institutional setting.

Movement of a resident within the same facility from one certified bed to another bed with the same certification is not a transfer.

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 456.000, an assemblage of multiple, unlabeled single doses (traditional “bingo cards” or “bubble packs”) is not unit-dose packaging.

Working Days — Monday through Friday except for legal holidays.

456.403: Eligible Members

- (A) (1) MassHealth Members. The Division pays for nursing-facility services only when provided to eligible MassHealth members, subject to the restrictions and limitations in the Division’s regulations. The Division’s regulations at 130 CMR 450.105 specifically state which services are covered and which members are eligible to receive those services.
- (2) Recipients of Emergency Aid to the Elderly, Disabled and Children. For information on covered services for recipients of Emergency Aid to the Elderly, Disabled and Children, see 130 CMR 450.106.

- (B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

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456.615: Annual Accounting to the Division of the PNA Balance

(A) Annually, at least by each June 1, an accounting must be made to the Division of the balance of each PNA account. If the facility is not a trustee for any member's money, it must report this fact by each June 1 to the Division. The accounting to the Division must be submitted on the Statement of MassHealth Member's Personal Needs Account (PNA-1) and must be dated and signed under the pains and penalty of perjury by the administrator of the facility and mailed to the Division.

(B) The accounting must consist of the following:

- (1) the member's name;
- (2) the member's social security number;
- (3) the amount of petty cash held in the facility for the member;
- (4) the balance held in any individual bank account for the member;
- (5) the balance held in the trustee account for the member;
- (6) any other money being held by the facility for the member; and
- (7) if funds are held in an aggregate trustee bank account, then a copy of the bank statement for that account must be submitted with the accounting.

(130 CMR 456.616 through 456.620 Reserved)

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456.621: Return of Unused Unit-Dose Drugs

(A) Returnable Drugs.

(1) Requirement. The nursing facility must return to the dispensing pharmacy unused drugs in unit-dose packaging that are listed in Appendix F of the *Nursing Facility Manual* and that were dispensed to a MassHealth member, when the use of the drug for that member is discontinued. Such returns allow the pharmacy to credit the Division for unused doses, which reduces pharmaceutical waste. The nursing facility must return such drugs that meet the requirements of 130 CMR 456.621(A)(2), unless they are excluded under 130 CMR 456.621(B). The nursing facility must return such drugs as soon as possible, but no later than 30 days after the date that the drug is discontinued for the member, and no less than 90 days before the earliest expiration date printed on the drug's label.

(2) Returnable Drugs. Drug products that are returned must comply with all applicable state and federal requirements, including those related to the safety, labeling, handling, and storage of drugs.

(B) Excluded Drugs. Of the drugs described in 130 CMR 456.621(A), the following unit-dose-packaged drugs may not be returned to the pharmacy for credit to the Division:

- (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 F of the *Nursing Facility Manual*;
- (3) drugs prescribed to a member who has been discharged or transferred to another facility when a physician, physician's assistant, or nurse practitioner has authorized the release of the drug to the patient or an authorized custodian upon discharge; and
- (4) drugs with an expiration date of less than 90 days from the date of the discontinuation of the drug.

(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 must:

- (1) use up existing supplies of the drug dispensed to the member instead of returning the drug to the pharmacy;
- (2) document the dosage change in the member's record; and
- (3) apply a change-of-directions sticker over the directions on the pharmacy prescription label.

(D) Preparation of Manifest. The nursing facility must prepare a manifest of all drugs listed in Appendix F of the *Nursing Facility Manual* that are being returned to the pharmacy. This manifest must accompany the returned drugs to the pharmacy, account for drugs that have been destroyed because the integrity of the drug has been compromised, and must include:

- (1) the name of the member to whom the drugs were originally dispensed;
- (2) the date that the unused drugs were returned to the pharmacy;
- (3) the prescription number under which the unused drugs were originally dispensed;
- (4) the name and strength of the unused drugs;
- (5) the quantity of unit doses returned; and
- (6) if the drug was destroyed, the quantity, reason, and date of destruction; along with the initials of the person preparing the manifest.

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(E) Recordkeeping Requirements. The nursing facility must establish tracking and recordkeeping systems for all unit-dose-packaged drugs returned pursuant to 130 CMR 456.621. The records must reflect sound standard business accounting practices; 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:

- (1) a copy of the manifest described in 130 CMR 456.621(D) of each shipment of unused unit-dose-packaged drugs that has been returned to the pharmacy;
- (2) for unit-dose-packaged drugs that are not returned pursuant to 130 CMR 456.621(B), the reason that the drugs are not being returned; and
- (3) for unit-dose-packaged drugs that were destroyed, the quantity, reason, and date of destruction, along with the initials of the person who destroyed the drugs.

(130 CMR 456.622 through 456.700 Reserved)

456.701: Notice Requirements for Transfers and Discharges Initiated by a Nursing Facility

(A) A resident may be transferred or discharged from a nursing facility only when:

- (1) the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the nursing facility;
- (2) the transfer or discharge is appropriate because the resident's health has improved sufficiently so that the resident no longer needs the services provided by the nursing facility;
- (3) the safety of individuals in the nursing facility is endangered;
- (4) the health of individuals in the nursing facility would otherwise be endangered;
- (5) the resident has failed, after reasonable and appropriate notice, to pay for (or failed to have the Division or Medicare pay for) a stay at the nursing facility; or
- (6) the nursing facility ceases to operate.

(B) When the facility transfers or discharges a resident under any of the circumstances specified in 130 CMR 456.701(A)(1) through (5), the resident's clinical record must contain documentation to explain the transfer or discharge. The documentation must be made by:

- (1) the resident's physician when a transfer or discharge is necessary under 130 CMR 456.701(A)(1) or (2); and
- (2) a physician when the transfer or discharge is necessary under 130 CMR 456.701(A)(3) or (4).

(C) Before a nursing facility discharges or transfers any resident, the nursing facility must hand deliver to the resident and mail to a designated family member or legal representative a notice written in 12-point or larger type that contains, in a language the member understands, the following:

- (1) the action to be taken by the nursing facility;
- (2) the specific reason or reasons for the discharge or transfer;
- (3) the effective date of the discharge or transfer;
- (4) the location to which the resident is to be discharged or transferred;
- (5) a statement informing the resident of his or her right to request a hearing before the Division's Board of Hearings including:
 - (a) the address to send a request for a hearing;
 - (b) the time frame for requesting a hearing as provided for under 130 CMR 456.702; and
 - (c) the effect of requesting a hearing as provided for under 130 CMR 456.704;

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- (6) the name, address, and telephone number of the local long-term-care ombudsman office;
- (7) for nursing-facility residents with developmental disabilities, the address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. s. 6041 et seq.);
- (8) for nursing-facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act (42 U.S.C. s. 10801 et seq.);
- (9) a statement that all residents may seek legal assistance and that free legal assistance may be available through their local legal-services office. The notice should contain the address of the nearest legal-services office; and
- (10) the name of a person at the nursing facility who can answer any questions the resident has about the notice and who will be available to assist the resident in filing an appeal.

456.702: Time Frames for Notices Issued by Nursing Facilities

(A) The notice of discharge or transfer required under 130 CMR 456.701(C) must be made by the nursing facility at least 30 days prior to the date the resident is to be discharged or transferred, except as provided for under 130 CMR 456.702(B).

(B) Instead of the 30-day-notice requirement set forth in 130 CMR 456.702(A), the notice of discharge or transfer required under 130 CMR 456.701 must be made as soon as practicable before the discharge or transfer in any of the following circumstances, which are emergency discharges or emergency transfers.

- (1) The health or safety of individuals in the nursing facility would be endangered and this is documented in the resident's record by a physician.
- (2) The resident's health improves sufficiently to allow a more immediate transfer or discharge and the resident's attending physician documents this in the resident's record.
- (3) An immediate transfer or discharge is required by the resident's urgent medical needs and this is documented in the medical record by the resident's attending physician.
- (4) The resident has not resided in the nursing facility for 30 days immediately prior to receipt of the notice.

456.703: Time Frames for Submission of Requests for Fair Hearings

(A) Appeals of discharges and transfers will be handled by the Division's Board of Hearings (BOH).

(B) Time Limitation on the Right of Appeal. The date of request for a fair hearing is the date on which BOH receives such a request in writing. BOH must receive the request for a fair hearing within the following time limits:

- (1) 30 days after a resident receives written notice of a discharge or transfer pursuant to 130 CMR 456.702(A); or
- (2) 14 days after a resident receives written notice of an emergency discharge or emergency transfer pursuant to 130 CMR 456.702(B).

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456.704: Stay of a Transfer or Discharge from a Nursing Facility Pending Appeal

(A) If a request for a hearing regarding a discharge or transfer from a nursing facility is received by the Board of Hearings during the notice period described in 130 CMR 456.703(B)(1), the nursing facility must stay the planned discharge or transfer until 30 days after the decision is rendered. While this stay is in effect, the resident must not be transferred or discharged from the nursing facility.

(B) If a hearing is requested, in accordance with 130 CMR 456.703(B)(2), and the request is received prior to the discharge or transfer, then the nursing facility must stay the planned transfer or discharge until five days after the hearing decision. If the request for a hearing is received within the applicable time frame but after the transfer, the nursing facility must, upon receipt of the appeal decision favorable to the resident, promptly readmit the resident to the next available bed in the facility.

456.705: Scheduling by the Board of Hearings

(A) Upon receipt of a request for a fair hearing, BOH will register the appeal, set a date for a hearing, and so notify the appellant and the nursing facility.

(B) BOH will designate a site for the hearing accessible to the appellant. If the appellant has a handicap or disability that reasonably prevents his or her appearance at the designated site, he or she may request that the hearing be held by telephone or video conferencing, or at an accessible location.

REGULATORY AUTHORITY

130 CMR 456.000: M.G.L. c. 118E, §§ 7 and 12.

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Unit-Dose Drugs

This appendix lists the unit-dose-packaged drugs that a nursing facility must return to the dispensing pharmacy in accordance with 130 CMR 456.621, when the use of the drug for the member is discontinued. Beside each drug is the minimum quantity of the doses of the drug acceptable 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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