



POLICY STATEMENT

Statement on the Return and Reuse of Medications in Long-term Care Facilities

Preamble

Long-term care (LTC) facilities regularly discard medications that have been dispensed but cannot be subsequently used for the intended resident due to a number of reasons, including:

- The medication was discontinued
- The medication became outdated
- The resident was discharged by the facility

Because of the expense associated with unused medications, policymakers have expressed interest in finding ways to reduce medication waste. The purpose of this statement is to address considerations related to the legitimate return and reuse of unused medications as allowed by federal and state laws and regulations, and when reasonable mechanisms are in place to accurately account for medication tracking, billing, and crediting.

Background

Throughout the United States, the pharmacist is charged with the responsibility to ensure that medications are safely and accurately dispensed to patients who need them. Patients and payers also expect accurate billing and accountability (i.e., tracking) for dispensed medications. As such, the return and reuse of unused medications presents a number of regulatory and logistical challenges that must be addressed for the pharmacist to fulfill the expected duties.

First, it should be noted that medications classified as controlled substances by the Drug Enforcement Administration (DEA) (e.g., morphine, lorazepam) may not be returned for credit under the Controlled Substances Act and DEA regulations. According to these laws and regulations, controlled substances may only be returned or transferred between DEA registrants. Because LTC facilities are not DEA registrants, the facility may not return controlled medications to the contracted LTC pharmacy.

The integrity of the medications must also be maintained according to appropriate federal and state guidelines. Medications that require refrigeration are generally not returned because of the difficulty of ensuring appropriate storage throughout the life cycle of the product.

The ability to assure integrity of the medications varies with the type of packaging used. U. S. Pharmacopeial (USP) Official Standards include these statements:

“If a product is known to be oxygen sensitive or if it exhibits extreme moisture or light sensitivity, it shall not be repackaged.”

“Reprocessing of repackaged unit-dose containers (e.g., removal of medication from one unit-dose container and placing it into another unit-dose container) shall not be done.”

However, USP guidelines do allow for “reprocessing of the secondary packaging (e.g., removing the blister card from the cardboard carrier and placing the blister card into another cardboard carrier).” This may be done if the original beyond-use date is maintained and if the integrity of the blister is ensured.

Unfortunately, the technology and equipment necessary to comply with these USP standards is not common in the LTC pharmacy industry and the expense to acquire this technology is overly burdensome for most pharmacy operations. As a result, these guidelines have the practical result of limiting pharmacies to accepting for return and reuse only those medications provided by the product manufacturer in unit-dose or tamper-evident packaging; or unused packages of medications that have been repackaged by the pharmacy.

Return and reuse of medications is also a labor-intensive process and the pharmacy must be compensated for the related costs. Activities associated with the return and reuse of medications include:

- Retrieving the unused medication from the facility to which it was delivered
- Inventory and record keeping costs to account for returned medications
- Crediting the original payer for the returned medications
- Proper discarding and/or destruction of medications that are returned to the dispensing LTC pharmacy but that cannot be reused (e.g. use of a reverse distributor)

Re-stocking fees, similar to dispensing fees, must be provided to cover the costs of the services highlighted above. For many medications, especially generic drugs, the cost of returning and reusing the medication is far greater than the cost of the returned medication. For these medications, return and reuse makes no economic sense.

Position

ASCP will only support the return and reuse of medications to the original dispensing pharmacy if the following criteria are met:

1. Organization policies for return and reuse of medications must meet federal and state laws and regulations (e.g. USP standards, DEA regulations, EPA standards)
2. An electronic mechanism (reasonable for both the payer and the dispensing LTC pharmacy) is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source.
3. The pharmacy is adequately compensated for the costs associated with the return and reuse of medications.
4. A system is in place to track re-stocking and reuse to allow medications to be recalled if required.
5. The medications are dispensed in tamper-evident packaging and returned with packaging intact.
6. Policies and procedures are followed for the appropriate storage and handling of medications at the long-term care facility and for the transfer, receipt, and security of medications returned to the dispensing pharmacy.
7. In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity.
8. The returned medications are not controlled substances.

References:

1. Paone RP, Vogenberg FR, Caporello E, et al. Medication destruction and waste measurement and management in long-term care facilities. *Consult Pharm.* 1996; 11:32-40.
2. Shinavier BD, Kirk KW. Medication waste in selected central Texas long-term care facilities under the same corporate ownership. *Consult Pharm.* 1992; 7:415-422.
3. Kidder SW. Review of drug waste in long-term care facilities 1976-1983. *J Geriatr Drug Ther.* 1987; 1(3):35-47.
4. Mathieson DR, Rawlings JL. Evaluation of a unit dose system in nursing homes as implemented by a community pharmacy. *Am J Hosp Pharm.* 1971; 28:254-259.
5. United States Pharmacopoeia and National Formulary, USP 26-NF 21. 2003; Section <1146> Packaging Practice— Repackaging a Single Solid Oral Drug Product Into a Unit-Dose Container.

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