



National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications in the Community Pharmacy Setting

July 2009

The National Association of Boards of Pharmacy[®] (NABP[®]) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP, in keeping with its mission statement, is addressing the increasingly frequent question of whether prescription medications,¹ in the community pharmacy setting, can be safely returned and reused. NABP's member state boards of pharmacy may approve, and have approved, when it is demonstrated that the integrity and stability of the medication is maintained, that the medication has not been tampered with, and the process results in the dispensing of safe medication to patients.

A safe return and reuse protocol in the community pharmacy setting may include, but is not limited to, the following elements:

- Returned and reused medications refer to those medications that have been removed from the pharmacy for delivery by pharmacy staff, a pharmacy contracted delivery service, or an approved common carrier and returned because the product is not deliverable or the patient refuses delivery and such medications have not left the control of the pharmacy staff, pharmacy contracted delivery service, or approved common carrier. Medications that have been delivered to the patient cannot be returned and reused.
- If a pharmacy attempts, but is not able, to deliver prescription medications using its own staff or its own local delivery service, then such prescription medications may be returned and reused by the pharmacy if:
 - packaged in:
 - the manufacturer's original, sealed, and tamper-evident bulk, unit of use, or unit dose packaging; or

¹ At this time, controlled substances may not be included in any return and reuse program to comply with existing federal and/or state laws that prohibit the transfer of controlled substances to any person other than for whom it was prescribed.

- the dispensing pharmacy's original packaging; and
 - returned to the pharmacy immediately after the unsuccessful delivery attempt.
- If a pharmacy attempts, but is not able, to deliver prescription medications using an approved common carrier, then such prescription medications may be returned and reused by the pharmacy if:
 - packaged in:
 - the manufacturer's original, sealed, and tamper-evident bulk, unit of use, or unit dose packaging; or
 - the dispensing pharmacy's original, sealed, and tamper-evident packaging, if the pharmacy demonstrated to the board of pharmacy that such packaging maintains the product quality as per United States Pharmacopeia (USP) standards; and
 - returned to the pharmacy within 14 days of the unsuccessful delivery attempt.
- All returned packaging must demonstrate that the products integrity and stability have been maintained (the pharmacy must furnish data from studies affirming the integrity and stability).
- All returned prescription medications must have an expiration of at least six months from the date of return.
- All returned prescription medications must be evaluated by appropriate pharmacy staff to ensure such medications are not adulterated or misbranded.

A state-licensed pharmacist must verify compliance with all of the above elements prior to dispensing.

Background

The return and reuse of prescription drugs in institutional pharmacy settings is legal in most, if not all, states and is a very common and safe practice. In the community pharmacy setting, however, this has not been the case.

In recent years, however, a number of states began legalizing and even implementing a charitable form of return and reuse “prescription drug repository” or “prescription drug donation” programs, which reuse donated drugs obtained from outpatients. Examples include the following:

- The Iowa Prescription Drug Donation Repository was implemented in 2005 by the Iowa State Legislature and authorizes medical facilities and pharmacies to redispense prescription drugs and supplies to low-income individuals. As of December 2007, the majority of the donated medications were supplied by long-term care pharmacy providers who had previously dispensed the medications in sealed unit-dose systems. Other sources included samples from physician offices and sealed or unit-dose medications from private individuals.
- North Dakota enacted a Prescription Drug Repository Program that became effective July 1, 2007. The program allows for donated drugs in the original, unopened package, or unopened single-unit dose pack to be donated for redispensing for those in need.
- Ohio’s Drug Repository Program was enacted in 2004 and also allows for the redispensing of unopened drugs in their original sealed and tamper-evident unit dose packaging and unopened single unit doses. It also requires drugs to have been in the possession of a licensed health care professional and stored according to federal Food and Drug Administration (FDA) storage requirements.

Most recently, and of increased concern to boards of pharmacy, are procedures established in retail and mail-order pharmacy settings that result in medications being redispensed if they have been removed from the pharmacy for delivery by pharmacy staff or common carrier and returned because the product was not deliverable or the patient refused delivery. Because such procedures are not legal in most, if not all, states they must receive approval from the board of pharmacy prior to implementation. Often, the board requires the pharmacy to demonstrate that the returned product is safe for redispensing.

These programs, however, are contrary to most state pharmacy practice acts and regulations, as well as laws, regulations, and policies enacted at the federal level. In fact, FDA’s Compliance Policy Guide on the Return of Unused Prescription Drugs to Pharmacy Stock directly states that

Return and Reuse: NABP Position Paper

“[a] pharmacist should not return drug products to his stock once they have been out of his possession” because of the inability to assure drug “strength, quality, purity or identity.”²

In an attempt to determine consensus on this issue, NABP convened the Task Force on Medication Collection Programs in December 2008. The charge of the task force was to evaluate the status of medication collection programs throughout the country; review state and federal laws and regulations, including those administered by the United States Drug Enforcement Administration, applicable to medication collection programs; suggest possible medication collection program protocols compliant with current, applicable state and federal laws and regulations; and recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing this issue.

The task force recommended that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as FDA, to research programs for the reuse of previously dispensed prescription medications to determine whether safe and legally compliant methods can be established. Task force members acknowledged that medications dispensed in institutional settings within a closed distribution system may be appropriate for reuse; however, members concluded that, because the medications leave the closed distribution system, programs based in the community pharmacy setting necessitate different requirements to ensure patient safety. Members concurred that any medication reuse program must comply with all state and federal regulations, including standards of the USP.³

In addition, the task force recommended that NABP work with key stakeholders to research the feasibility of establishing methods to reduce the amount of unused prescription medications that require disposal. Unused medications may account for as much as \$1 billion each year in wasted drug costs among elderly Americans alone.⁴ A 2004 study indicated that more than 90% of wasted medications are due to a change in the prescription, death, or transfer of the resident.⁵ The task force also recommended that NABP revise the *Model Act* to include in the patient counseling section language that requires pharmacists to discuss appropriate medication disposal

² Food and Drug Administration. Sec. 460.300 Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09).

³ NABP Newsletter; April 2009.

⁴ Morgan, Thomas. The Economic Impact of Wasted Prescription Medication in an Outpatient Population of Older Adults. *Journal of Family Practice*; September 2001.

⁵ Wang, Joseph. Unopened, Unused Prescription Drugs Destroyed at Taxpayer Expense. Health Law and Policy Institute. University of Houston Law Center; 2004.

Return and Reuse: NABP Position Paper

methods with patients. Along with this educational component, it was also agreed that there should be a shift to incentivize involved stakeholders to help reduce the quantities of medications that are dispensed, and that further research is necessary.

Much research needs to be done. In the meantime, NABP acknowledges the societal value that return and reuse programs in the community pharmacy setting may have and could endorse such programs if they demonstrate and incorporate a safe return and reuse protocol for accepting and dispensing previously dispensed prescription medications and comply with applicable state and federal laws and regulations.