



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

July 2009, Revised October 2012

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 issue of whether previously dispensed prescription medications¹ can be safely returned and reused. The position statement separates this issue by addressing the circumstances in both the community setting and in state-mandated repository programs under which previously dispensed medications may be redispensed to patients. Some of NABP's member state boards of pharmacy have already enacted regulations for return and reuse programs and NABP strongly encourages those members and members yet to enact regulations to require such programs to demonstrate that the integrity and stability of the medication is maintained, that the medication has not been tampered with, and that the process results in dispensing safe medications to patients.

This issue has come to the forefront due to the increase in the quantities of prescription medications that have been prescribed and dispensed and that, ultimately, are not used by patients. As the integrity of previously dispensed prescription medications must always be scrutinized, NABP encourages stakeholders to develop methods that will minimize the amount of unused medications. Collaboration among health care providers and payers is key to this initiative. Equally vital is educating health care providers on the importance of prescribing and dispensing appropriate quantities, particularly limiting quantities for acute therapy and in the

¹ At this time, controlled substances may not be included in any return and reuse program in order 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.

initiation of chronic therapy. As today's pharmacists are taking a greater role in their patients' health care regimens, utilizing medication therapy management as a tool to closely monitor and control the use of automatic refills is extremely important. By reviewing the necessity of and quantities dispensed for automatic refills, as well as effectually interacting with patients to determine the appropriateness of whether a prescription should be automatically refilled, pharmacists can play a significant role in decreasing the amount of unused prescription medication that is dispensed.

Community Setting

NABP endorses the return and reuse of medications that have been maintained in a closed system that ensures the integrity of the medication. A closed system is defined as the delivery to and/or the return of prescription medication from a health care or other institutional facility, which is maintained in a controlled environment under the control of a health care practitioner and not the patient.

A closed distribution system enables the pharmacy to ensure that the integrity of the medications dispensed is intact, as they have not left the control of the pharmacy or institutional facility, and the control of the medication is under the direction of a health care practitioner.

The components of a closed distribution system in a community pharmacy setting for the return and reuse of medications include but are 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.
- 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
 - the dispensing pharmacy’s original packaging; and
 - returned to the pharmacy on the same day 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, that maintains the product quality as per United States Pharmacopeia (USP) standards; and
 - returned to the pharmacy on the same day after the unsuccessful delivery attempt.
- All returned packaging must indicate that the product’s integrity and stability has been maintained.
- 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.

^{*}Unit-of-use is not intended to include co-mingled, multi-medication unit of use packages also known as compliance packs.

Repository Programs

NABP does not endorse the reuse of medications that have left the closed distribution system as there is an inability to ensure the integrity of such drugs, which may place the public at risk.

Repository program, for the purposes of this position statement, is defined as a program that is established to receive previously dispensed medications and redispense such to qualified individuals and/or to facilitate proper disposal of unacceptable medications in compliance with state and federal regulations. NABP strongly encourages all repository programs to require the following:

- Repository programs should be registered with and under the jurisdiction of the board of pharmacy and should be subject to inspection;

- Repository programs must have written policies and procedures, which include at a minimum:
 - Qualifications of acceptable medications for reuse must include:
 - only non-controlled medications; and
 - were inspected and determined to be:
 - unadulterated;
 - unexpired; and
 - in unopened unit dose-or manufacturer’s tamper-resistant original packaging;
 - Maintenance of a separate physical inventory;
 - Completion of a monthly expiration date review for all medications;
 - Prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;
 - Dispensation by a pharmacist or a practitioner within the practitioner’s scope of practice; and
 - Record keeping including the source and dispensation of all medication.

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 or with some repository programs, however, this has not been the case.

In recent years, 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. As of December 2009, the program served 5,372 patients, dispensing a total of 795,752 units valuing \$1,141,777.

- 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 "[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

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

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

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.

The task force also recommended that NABP revise the *Model Act* to include language in the patient counseling section that requires pharmacists to discuss appropriate medication disposal 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.

In October 2012, NABP convened the Task Force on Drug Return and Reuse Programs. This task force was charged with reviewing available data and studies to determine if medications returned through acceptable means, as presented in the original Position Statement, are safe for reuse; considering revising, if necessary, the position statement; and/or recommending amendments, if necessary, to the *Model Act* to address drug return and reuse programs.

This task force recognized that the amount of unused medications is a major issue and recommended that NABP collaborate with stakeholders to develop strategies that will minimize the amount of unused medications. Additionally, the task force reviewed the existing Position Statement and determined that it should be revised to address the causes of unused prescription medications and to add collaboration and education of health care practitioners as integral solutions to the problem. Task force members also agreed that a section devoted to repository programs, both existing and those yet to be implemented, should be added to differentiate those types of programs from medications being returned and reused in the community setting. The task force discussed what should be included in these programs and strongly agreed that the board of pharmacy should have direct oversight of such programs by requiring registration and having inspection authority over them. Lastly, the task force recommended that the *Model Act* be revised to add language to address return and reuse programs that reflects the language in this Position Statement.

Overall, NABP acknowledges the societal value that return and reuse programs 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.