



# Report of the Task Force on Drug Return and Reuse Programs

## Members Present:

Ron Klein (VT), *chair*; Lois Anderson (LA); Phil Burgess (IL); Trish D'Antonio (DC); Benjamin Fry (TX); Bob Goetz (MN); Suzan Kedron (TX); Nichole Penny (MI); Joyce Tipton (TX).

## Others Present:

Edward G. McGinley, *Executive Committee liaison*; Eileen Lewalski, Sarah Fowle, Emily Shaffer, Deborah Zak, *NABP staff*.

## Introduction:

The Task Force on Drug Return and Reuse Programs met October 9-10, 2012, at NABP Headquarters. This task force was established in response to Resolution 108-9-12, Drug Return and Reuse Programs, which was approved by the NABP membership at the Association's 108<sup>th</sup> Annual Meeting in May 2012.

## Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review available data and studies to determine if medications returned through acceptable means, as presented in the National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications in the Community Pharmacy Setting, are safe for reuse;
2. Consider revising, if necessary, the position statement; and/or
3. Recommend amendments, if necessary, to the *Model Act* to address drug return and reuse programs.

## **Recommendation 1: NABP Should Collaborate with Healthcare Providers, Payers, and Patients to Develop Strategies to Minimize Quantities of Unused Medications**

The task force recommends that NABP assist in developing strategies that will minimize the quantities of unused medications by collaborating with healthcare providers including prescribers and pharmacists; payers, including employer groups and third-party administrators; legislators; regulatory and professional associations; advocacy groups; educators; and patients and/or caregivers.

## Background:

Task force members began focusing on their charge by discussing the causes of unused medications and determined that the obvious source is over-prescribing and over-dispensing. Members decided that it is critical to address the front end of the supply chain at the prescribing and dispensing level and that the most effective means to accomplish this would be to collaborate with other healthcare providers and payers to develop strategies to decrease the amount that may potentially become unused. As these causes are due to a variety of reasons, the task force agreed that it is necessary to collaborate with as many stakeholders as possible to discuss the issue and develop solutions.

While discussing the causes and possible effective strategies, the task force agreed that demonstrating the decrease in costs for the overall healthcare system should be a major factor. One suggested strategy included the development of an incentive program that encourages sensible dispensing and discourages the automatic dispensing of three months at a time until a patient is stabilized on a particular regimen. Another strategy was to define the pharmacist's role in solving this problem, demonstrate positive outcomes that substantiate modifying dispensing practices, therefore decreasing costs and the amount of unused medications. Members discussed the recent policy change regarding reimbursements to hospitals for readmissions as a good analogy to implement change in the current practice. Ultimately, the task force agreed that collaborating with stakeholders and demonstrating the total cost savings for the patient and healthcare system could incentivize stakeholders to effectuate change that will result in decreased costs and unused medications.

## **Recommendation 2: NABP Should Amend the Position Statement on the Return and Reuse of Prescription Medications in the Community Pharmacy Setting**

The task force recommends the following changes to the *Position Statement*, including revising the existing language and adding a section to address repository programs. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.



## **National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications ~~in the Community Pharmacy Setting~~ 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 increasingly frequent question issue of whether previously dispensed prescription medications<sup>1</sup>, in the community pharmacy setting, 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 may approve, and have already enacted regulations approved for return and reuse programs and NABP strongly encourages those members and members yet to enact regulations to require such programs when it is 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 the dispensing of safe medications to patients.

This issue has come to the forefront due to the increase in 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 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

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<sup>1</sup> 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.

and/or return of prescription medication from a healthcare or other institutional facility, which is maintained in a controlled environment under 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, where the medication is returned in its original packaging, 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 ~~A safe return and reuse protocol in the community pharmacy setting may 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. ~~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
    - 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 indicate ~~demonstrate~~ that the product's integrity and stability has 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 redispensing.~~

### **Repository Programs**

NABP does not endorse the reuse of medications that have left the closed distribution system due to the inability to ensure integrity of such drugs and the possibility of placing 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 environmental regulations. NABP strongly encourages currently operated, state-mandated repository programs and repository programs yet to be implemented to require the following:

- Repository programs should be registered 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
    - inspected and determined to be:
      - unadulterated

- unexpired; and
- in unopened unit dose or manufacturer's tamper-resistant original packaging; and
- Maintenance of a separate physical inventory;
- Completion of monthly review for all medications ;
- Prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;
- Dispensing 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, ~~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. 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.”<sup>2</sup> 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

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

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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup> 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.

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<sup>3</sup> NABP Newsletter; April 2009.

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

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



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 inspection authority. 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 the Position Statement.

~~Much research needs to be done. In the meantime,~~ Overall, 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.

### **Recommendation 3: NABP Should Amend the *Model Act***

NABP should amend the *Model Act* to reflect the revisions to the *National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications* and address the return and reuse of medications in both the community and repository settings.

#### **Background**

The task force agreed that language, reflective of what is contained in the Position Statement, should be added to the *Model Act* to address the return and reuse of medications. Members discussed the number of states that have already implemented and that have yet to implement legislatively mandated repository programs and determined that NABP should provide specific *Model Act* language for guidance as to how to regulate and oversee such programs.