



Report of the Task Force on

MEDICATION REUSE

***Note:** The Report of the Task Force on Medication Reuse was approved by the NABP Executive Committee with the exception to the allowance for the return of controlled substances to align with federal regulations*



Members Present

Brenda McCrady (AR), *chair*; Mike Bertagnolli (MT), Katie Busroe (KY), Kim Caldwell (TX), Traci Collier (SC), Donna Horn (MA), John Marraffa (NY), Dennis McAllister (AZ), Rich Palombo (NJ), Ed Taglieri (MA), Cynthia “Cindy” Warriner (VA), Linda Witzal (NJ).

Others Present

Fred M. Weaver, Executive Committee liaison; Lemrey “Al” Carter, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Cameron Orr, Andrea Busch, *NABP staff*.

Introduction

The task force met virtually on October 29, 2020. This task force was established pursuant to Resolution 116-4-20, Task Force on Medication Reuse, which was approved by the NABP membership during the Association’s 116th Annual Meeting that was held virtually in May 2020.

Review of the Task Force Charge

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

1. Review current state laws and regulations related to the reuse of medications.
2. Review existing NABP policy on the reuse of medications.
3. Recommend the best mechanisms to enable the transfer of unused medications to persons in need of financial assistance to ensure access to lifesaving therapies.

Background and Discussion

Task force members reviewed the charge and the sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* pertaining to the return and reuse of medications, as well as those pertaining to repository programs. The task force opened the discussion noting the vast number of medications, many of which are expensive, that are discarded every year and addressed the question of whether medications could be reused, and if so, how to best accomplish this in the interest of patient care and public protection. In addressing the overarching question of whether it is ever appropriate to redispense unused drugs to individuals who are unable to afford them, members were adamant that it is crucial that pharmacists use their best professional judgment to ensure that any returned and/or donated medication is an unadulterated product, and therefore can be reused. The task force concurred that there is a very delicate balance in deciding if a patient in need of a possibly life-saving medication should receive a previously dispensed product, realizing it is impossible to guarantee its integrity, versus the patient not receiving it at all.

In discussing how this might be accomplished, members stressed the need for a minimum standard for medication return and reuse. The task force reviewed various state models and



noted that Arizona's and Ohio's have been operational for many years without reported incidents of patient harm. The member from Arizona indicated that the program in that state has been in place for 17 years; and the standards limit accepting returns from only long-term care (LTC) and mail-order pharmacies and only allow for medications that: 1) are in tamper-evident packaging; 2) have a verifiable chain of custody; 3) are not temperature sensitive; and 4) have the ability to validate for recalls. The task force applauded the efforts of these existing charitable clinics and repository programs that have helped so many individuals and pondered how best to expand such care to more people.

In attempting to develop model minimum standards, the task force agreed that such standards must incorporate the pharmacist's professional judgment in order to determine a medication's integrity and whether it is appropriate to reuse. This issue ensued in an in-depth discussion by the members regarding chain of custody, as well as the time frame in which medications needed to be returned, as that plays an integral role in determining any medication's integrity. When discussing the time frame issue, it was recognized that the length of time a medication remained in a delivery vehicle, especially if it was temperature sensitive like many specialty medications, was of importance. After some discussion, the task force, rather than dictate that specific time frames, temperature variation indicators, or tamper-evident mechanisms be used, agreed that the pharmacist, using professional judgment, should make the final determination regarding appropriateness for reuse.

The task force also contemplated whether medications that were secured from community pharmacies (as opposed to LTC pharmacies) were of the same integrity and safe to reuse. Members spent a significant amount of time discussing this issue and ultimately decided to recognize that, if the medication has been determined to be unadulterated based on a pharmacist's professional judgment, it could be obtained from any practice setting. The issue of whether controlled substances (CS) could be reused was also discussed and members quickly decided to allow for this, as they may be used to treat patients with substance use disorders.

Members were also mindful that fraud prevention must be considered when it comes to the return and reuse of prescription drugs. Any charges to third-party payers should be reversed prior to reuse. In addition, donated drugs must not be allowed to reenter the commercial supply chain.

Members also discussed possible barriers for the return and reuse of medications. Several members indicated that many LTC facilities are reluctant to participate in return or repository programs due to the amount of work necessary to process the medications, although an inordinate amount of resources is also spent preparing drugs for destruction. It was also noted that destroying unused medications has environmental concerns that also need to be considered. Task force members wondered if there was a means to make donating medications more palatable to LTC facilities by informing them that the medications will be used to help others. Additionally, it was noted that the federal Drug Supply Chain Security Act may pose barriers to providing medications to patients if the lot numbers are unavailable; however,

Section 581(24)(B)(viii) of the Act addresses transaction exemptions for charitable organizations and alleviates that concern.

Lastly, while reviewing the *Model Act* language members joined in a spirited discussion regarding the topic of requiring patients to sign liability waivers. It was noted that it may appear demeaning to some patients if they must waive their rights to recourse in the case of product adulteration. Whereas, the task force was uncomfortable with allowing a pharmacy to use a waiver to avoid liability for dispensing previously used medications, members compromised and agreed that patients who receive medications from a repository program should be fully informed about the fact their medications had been previously dispensed and acknowledge that they have been provided with the repository program’s qualifications for acceptable medications for reuse.

After careful review and deliberation, the task force recommended the following:

1. NABP retain the current *Model Act* definition of “repository program” and amend Section 10. Return and Reuse of Prescription Drugs by removing language pertaining to delivery attempts. Additionally, amend Section 11. Prescription Drug Repository Programs to allow for the reuse of CS, as well as adding a requirement for the provision of a patient acknowledgement.
2. NABP review the *National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications* and revise accordingly to reflect the task force’s recommended amendments to the *Model Act*.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

...

- (f6) “Repository Program” means a program that is established to receive previously dispensed medications and redispense such to qualified individuals and/or to

facilitate the proper disposal of unacceptable medications in compliance with state and environmental regulations.

Model Rules for the Practice of Pharmacy

...

Section 10. Return and Reuse of Prescription Drugs.

- (a) Prescription Drugs may only be returned and reused providing that the Prescription Drugs:
- ~~(1) were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and~~
 - ~~(1)(2) Prescription Drugs were packaged in:~~
 - (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
 - (ii) the dispensing pharmacy's original packaging; ~~and~~
 - ~~(iii) returned to the pharmacy immediately after the unsuccessful delivery attempt.~~
 - ~~(2)(3) If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:~~
 - (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use¹, or unit-dose packaging; or
 - (ii) the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the Product quality as per United States Pharmacopeia (USP) standards.
- (b) All returned packaging must indicate that the Prescription Drug's integrity and stability has been maintained.
- (c) All returned Prescription Drugs ~~must have been returned on the same day as the attempted delivery and~~ must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.
- (d) A state-licensed Pharmacist must verify compliance with all of the above elements.

Section 11. Prescription Drug Repository Programs.

- (a) Repository Programs must have written policies and procedures, which include, at a minimum:
- (1) Qualifications of acceptable medications for reuse. Such qualifications must include the following provisions:
 - ~~(i) only non-controlled medications will be accepted~~

¹Unit-of-use is not intended to include co-mingled, multi-medication unit-of-use packages also known as compliance packs.

- ~~(ii)(i)~~ all medications will be inspected and determined to be:
 - (A) unadulterated;
 - (B) unexpired; and
 - (C) in unopened unit dose or manufacturer's tamper-resistant original packaging, or otherwise approved by the board of pharmacy
 - ~~(iii)(ii)~~ maintenance of a separate physical inventory;
 - ~~(iv)(iii)~~ completion of a monthly expiration date review for all medications;
 - ~~(v)(iv)~~ prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;
 - ~~(vi)(v)~~ dispensing by a pharmacist or a practitioner within the practitioner's scope of practice; and
 - ~~(vii)(vi)~~ record keeping, including the source and dispensation of all medication.
- (2) A requirement that the patient acknowledge that he or she understands that the medication is being dispensed by a repository program and that he or she has been provided with the program's qualifications for acceptable medications for reuse.