

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-A-18

Subject: Prescription Drug Donation
(Resolution 207-I-17 and Resolution 525-A-17)

Presented by: Robert A. Gilchick, MD, MPH, Chair

Referred to: Reference Committee E
(Douglas Martin, MD, Chair)

1 Resolution 207-I-17, “Redistribution of Unused Prescription Drugs to Pharmaceutical Donation
2 and Reuse Programs,” introduced by the Medical Student Section and referred by the House of
3 Delegates asked:

4
5 That our American Medical Association work with appropriate stakeholders to draft and
6 promote model legislation aimed at developing better funding for drug donation programs on
7 the state level provided these programs follow the quality assurance guidelines set by existing
8 AMA Policy H-280.959.

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10 Resolution 525-A-17, “Providing for Prescription Drug Donation,” introduced by the Organized
11 Medical Staff Section and referred by the House of Delegates asked:

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13 That our American Medical Association advocate for new federal legislation that would allow:
14 1) nursing homes to recycle prescription drugs that are unused, sealed, and dated; 2) physician
15 offices and clinics to donate prescription drugs that are unused, sealed, and dated to patients in
16 need who are uninsured or underinsured; and, 3) cancer programs and clinics to accept and
17 recycle cancer-specific drugs to patients in need who are uninsured or underinsured.

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19 Both of these resolutions reflect concerns about the intersection of rising drug costs, wastage and
20 expiration of unused pharmaceutical products prompting their disposal, and existing problems with
21 patient access and their ability to pay for needed therapies.

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23 The Council previously examined the issue of pharmaceutical expiration (and beyond use) dates
24 and their clinical and fiscal consequences.¹ Expiration and beyond use dates are tangentially related
25 to prescription drug donation and/or recycling because they are fundamental criteria used to
26 establish or reaffirm the integrity of returned products.

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28 A fundamental goal expressed by both resolutions is minimizing the quantity of unused
29 prescription medications while decreasing healthcare costs. A prevailing issue is how unused
30 prescription medications that have been dispensed can be safely returned and reused. One way to
31 lessen prescription drug waste on the front end is for physicians and other prescribers to limit
32 quantities of prescription medications for acute therapy and/or during the initiation (trial phase) of
33 drug treatment for a chronic condition when the safety and efficacy of such treatment is being

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1 evaluated. The other approach, which is the focus of this report, is to recycle and re-dispense
2 unused medications.

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4 **CURRENT AMA POLICY**

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6 The AMA has well developed policy on the recycling of nursing home drugs based on a Council
7 report issued in 1997.² At the time, it was estimated that nearly 7% of monthly medication costs
8 were going to waste in this setting due to patient death, discontinuation of medication, a change in
9 medication, patient transfer or hospitalization. Policy H-280.959, "Recycling of Nursing Home
10 Drugs," supports the return and reuse of medications to the dispensing pharmacy to reduce waste
11 associated with unused medications in long-term care facilities (LTCFs) provided the following
12 conditions are satisfied:

- 13 • The returned medications are not controlled substances.
- 14 • The medications are dispensed in tamper-evident packaging and returned with packaging
15 intact (e.g., unit dose, unused injectable vials and ampules).
- 16 • In the professional judgment of the pharmacist, the medications meet all federal and state
17 standards for product integrity.
- 18 • Policies and procedures are followed for the appropriate storage and handling of
19 medications at the LTCF and for the transfer, receipt, and security of medications returned
20 to the dispensing pharmacy.
- 21 • A system is in place to track re-stocking and reuse to allow medications to be recalled if
22 required.

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24 **CURRENT STATUS OF PRESCRIPTION DRUG DONATION/REUSE PROGRAMS**

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26 Complicating the issue of recycling or medication reuse is guidance from the U.S. Food and Drug
27 Administration (FDA) (CPG Sec. 460.300, "Return of Unused Prescription Drugs to Pharmacy
28 Stock") that states:

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30 "A pharmacist should not return drugs products to his stock once they have been out of his
31 possession. It could be a dangerous practice for pharmacists to accept and return to stock the
32 unused portions of prescriptions that are returned by patrons, because he would no longer have
33 any assurance of the strength, quality, purity or identity of the articles."

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35 Furthermore,

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37 "The pharmacist or doctor dispensing a drug is legally responsible for all hazards of
38 contamination or adulteration that may arise, should he mix returned portions of drugs to his
39 shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons
40 and subsequently resold by the pharmacist were responsible for injuries."

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42 The language from the compliance guide is advisory in nature.

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44 While Resolution 525-A-17 seeks federal legislation to support the recycling of "nursing home
45 drugs," both medical and pharmacy practice are regulated by the states. Our AMA supports state
46 regulated medical and pharmacy practice. Increasingly state legislation, federal legislation, and
47 regulations affecting activities of the FDA (e.g., risk evaluation and mitigation strategies) and
48 certain policies implemented by payers, pharmaceutical benefit management companies, and
49 pharmacy chains are restricting prescriber behavior, especially with respect to the use of opioid
50 analgesics and other controlled substances. With respect to the specific issues raised in this report,

1 states regulate such activities, therefore the federal approach advocated for in Resolution 525-A-17
2 is not further evaluated or recommended.

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4 *National Association of Boards of Pharmacy Position Statement and Model Legislation*

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6 Resolution 207-I-17 seeks to draft and promote model legislation aimed at developing better
7 funding for drug donation programs on the state level, as long as such programs follow the quality
8 assurance guidelines described in Policy H-280.959. In October 2012, the National Association of
9 Boards of Pharmacy (NABP) convened a task force on “Drug Return and Reuse Programs” to
10 develop a position statement and revise its model act that addresses “the circumstances in both the
11 community setting and in state-mandated-repository programs under which previously dispensed
12 medications may be re-dispensed to patients.”³

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14 Return and Reuse of Prescription Drugs. NABP “endorses the return and reuse of medications that
15 have been maintained in a closed system.” A closed system is defined as the “delivery to and/or
16 return of prescription medication from a healthcare or other institutional facility, which is
17 maintained in a controlled environment under a health care practitioner and not the patient.” This
18 approach helps ensure the integrity of the medication. Prescription drugs should only be returned
19 and reused when the drugs were removed from the pharmacy for delivery by pharmacy staff, a
20 pharmacy contracted delivery service, or approved common carrier and the drugs were returned
21 immediately, either because they were “not deliverable” or the patient refused to accept the
22 delivery. Additionally, the returned product must remain packaged in the manufacturer’s original,
23 sealed, and tamper-evident packaging, or the dispensing pharmacy’s original packaging. If an
24 approved common carrier is used, product quality also must meet United States Pharmacopeia
25 (USP) standards. Additional criteria that must be met for return and reuse include:

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- All returned packaging must indicate that product integrity and stability has been
27 maintained.
 - All returned packaging must have been returned on the same day as the attempted delivery
28 and must be evaluated to ensure it is not adulterated or could be considered misbranded.
 - A state-licensed pharmacist must verify compliance with all of the above elements.
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32 Prescription Drug Repository Programs. In contrast to the limited and unique circumstances
33 described for a “return and reuse” program, a prescription drug repository program would be able
34 to accept drugs that are not confined to a delivery service. Although NABP “does not endorse the
35 reuse of medications that have left closed distribution systems,” for states that establish
36 repositories, such programs should be registered and under the jurisdiction of the Board of
37 Pharmacy and be subject to inspection. Strict criteria would apply to the policies, procedures and
38 qualification of acceptable medications for reuse. Controlled substances are not accepted, and the
39 medication must be judged to be unadulterated, unexpired, and in unopened unit dose or
40 manufacturer’s tamper-resistant original packaging. Additionally, such drugs must have been
41 originally dispensed by a pharmacist or practitioner acting within their scope of practice, and upon
42 return be kept in a separate inventory and undergo monthly expiration date review with record
43 keeping.

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45 In recent years, several states have legalized and implemented charitable return and reuse programs
46 involving drugs obtained from various donation sources. According to the 2018 Survey of
47 Pharmacy Law, 42 states currently have authorized prescription drug repository programs.⁴ A few
48 states that have not authorized repository programs allow return and reuse; with few exceptions,
49 states that have authorized repositories also allow return and reuse. In some cases repositories are
50 operational only for long term care facilities and/or correctional institutions, or charitable
51 recipients, or the program only accepts products directly from wholesalers, distributors, or

1 hospitals; in some cases medications are accepted from outpatients. In general, the provisions in
 2 enacted legislation are comparable to the requirements contained in the NABP model legislation.
 3 Differences may exist regarding which non-controlled drugs are accepted, criteria for eligible
 4 donors and recipients, protocols for transfer and repackaging, whether the program is centralized or
 5 de-centralized, and how it is funded. A 2016 summary of state prescription drug return, reuse, and
 6 recycling laws compiled by the National Conference of State Legislatures (NCSL) concluded that
 7 nearly half of the enacted laws were not operational. Some “common obstacles are the lack of
 8 awareness about the programs, no central agency or entity designated to operate and fund the
 9 program, and added responsibilities for repository sites that accept donations.”⁵ A summary of
 10 relevant state laws with links to their operational sites is maintained by NCSL.⁵

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 12 A sampling of reports that are available on the success of such programs includes the following:

- 13 • Established in 2007, the Iowa program has served 70,000 patients and redistributed \$15
 14 million in free medications and supplies over the last decade.⁶ Recipients at or below 200%
 15 of the federal poverty level as well as individuals who are uninsured or under-insured are
 16 eligible to receive donated drugs in their original sealed container or in tamper-evident
 17 packaging.
- 18 • Since beginning in 2007, the Wyoming program has helped residents fill more than
 19 150,000 prescriptions (worth more than \$12.5 million).^{7,8} In 2016, the program provided
 20 more than \$2.4 million worth of donated prescription medications free of charge on a short
 21 term basis.
- 22 • Oklahoma law allows the transfer of drugs from nursing homes to the Tulsa County
 23 Pharmacy. Since the start of the program in 2004 through January 2018, more than 223,000
 24 prescriptions at a savings of \$22 million have been dispensed.⁹
- 25 • In California, Supporting Initiatives to Redistribute Unused Medicine (SIRUM) was
 26 established. SIRUM is an online community matching drug donations with low-income
 27 safety-net health clinics whose patients could benefit from the medications.¹⁰ Unexpired
 28 drugs are collected from manufacturers, wholesalers, pharmacies and health facilities.
 29 Medicines go to clinics and pharmacies and are dispensed to low-income patients; more
 30 than 150,000 patients have been helped. SIRUM also operates the Colorado program
 31 which focuses on oncologic products. A few other states also either focus on
 32 cancer/immunosuppressant drugs or allow them in their repositories.

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 34 **DISCUSSION**

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 36 A substantial majority of states have authorized drug repository and/or return and reuse programs
 37 for prescription medications that are unexpired and in their original container or tamper proof
 38 packaging. Repository programs must address concerns with allowing donation and reuse of
 39 medications that have left controlled environments such as a pharmacy or institutional facility.
 40 Such concerns may include storage conditions affecting product integrity and issues specific to
 41 accepting drugs back into the supply chain that have left licensed entities that are part of the normal
 42 supply chain with track and trace requirements (i.e., possible counterfeiting or other substandard
 43 drug sources). Nearly half of the authorized programs in existence do not appear to be operational.
 44 Model state legislation to establish “return and reuse” or drug repository programs is available
 45 from the NABP. Such programs have the potential to provide pharmaceutical care to patients who
 46 cannot afford their medications, reduce waste and environmental disposal, and reduce healthcare
 47 costs. Several states have demonstrated measurable success in implementing these types of
 48 programs.

1 RECOMMENDATIONS

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3 The Council on Science and Public Health recommends that the following statements be adopted in
4 lieu of Resolution 207-I-17 and Resolution 525-A-17 and the remainder of the report be filed:

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6 Our AMA encourages:

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1. States with laws establishing prescription drug repository and/or “return and reuse”
programs to implement such laws and to consider integrating them with existing recycling
or disposal programs. (New AMA Policy)

2. States that lack drug repository and/or “return and reuse” programs to enact such laws in
consultation with their state board of pharmacy. (New AMA Policy).

3. State medical associations in states where there is a prescription drug repository or a
“return and reuse” program for unused medication supplies to educate physicians in their
state regarding the existence of such programs. (New AMA Policy).

Fiscal Note: less than \$500

REFERENCES

1. Council on Scientific Affairs. Report 1-Pharmaceutical Expiration Dates. Annual Meeting of the House of Delegates. American Medical Association. Chicago, Il. June 2001.
2. Council on Scientific Affairs. Report 2-Recycling of Nursing Home Drugs. Interim Meeting of the House of Delegates. American Medical Association. Dallas, Tx. December, 1997.
3. Report of the Task Force on Drug Return and Reuse Programs. National Association of Boards of Pharmacy. October 12, 2012.
4. National Association of Boards of Pharmacy. Survey of Pharmacy Law. 2018
5. National Conference of State Legislatures. State prescription drug return, reuse, and recycling laws. <http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx>. Accessed March 21, 2018.
6. Iowa Prescription Drug Donation Repository. <http://safenetrx.org/drug-donation/>. Accessed March 21, 2018.
7. Wyoming Medication Donation Program. <https://health.wyo.gov/healthcarefin/medicationdonation/>. Accessed March 20, 2018.
8. Fiscally challenged drug-donation program helps needy Wyoming residents. *Am J Health-Syst Pharm.* 66;2009:1688-89.
9. Oklahoma Drug Recycling – Utilization of Unused Prescription Drugs Act. <http://tmsok.org/drug-recycling/>. Accessed March 20, 2018
10. California Drug Donation Program. <https://www.sirum.org/>. Accessed March 21, 2018.