MINNESOTA BOARD OF PHARMACY

Prescription Drug Waste Reduction Report. (In compliance with Minnesota Session Laws, 2010 First Special Session, Chapter 1, section 21)

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COST OF REPORT

Minnesota Statutes §3.197 states that a "report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government". The estimated cost of preparing this report was **$300.00**. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent preparing the report.

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Introduction

The Board of Pharmacy (Board) is submitting this report to the Legislature in compliance with Minnesota Session Laws, 2010 First Special Session, Chapter 1, section 21. That section states:

> "Sec. 21. PRESCRIPTION DRUG WASTE REDUCTION.
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> The Minnesota Board of Pharmacy, in cooperation with the commissioners of human services, pollution control, health, veterans affairs, and corrections, shall study prescription drug waste reduction techniques and technologies applicable to long-term care facilities, veterans nursing homes, and correctional facilities. In conducting the study, the commissioners shall consult with the Minnesota Pharmacists Association, the University Of Minnesota College Of Pharmacy, University of Minnesota's Minnesota Technical Assistance Project, consumers, long-term care providers, and other interested parties. The board shall evaluate the extent to which new prescription drug waste reduction techniques and technologies can reduce the amount of prescription drugs that enter the waste stream and reduce state prescription drug costs. The techniques and technologies studied must include, but are not limited to, daily, weekly, and automated dose dispensing. The study must provide an estimate of the cost of adopting these and other techniques and technologies, and an estimate of waste reduction and state prescription drug savings that would result from adoption. The study must also evaluate methods of encouraging the adoption of effective drug waste reduction techniques and technologies. The board shall present recommendations on the adoption of new prescription drug waste reduction techniques and technologies to the legislature by December 15, 2011.

The Board's Executive Director acknowledges, and accepts responsibility for, the late submission of this report. One of the reasons that this report was not completed in a timely manner is that the Board has done extensive work on the issue of pharmaceutical waste. For example, the Board has done much work involving the use of automated dispensing devices in long-term care facilities. Board staff helped draft legislation, passed by the Legislature during the 2012 Session, which allows pharmacies to operate such devices in skilled nursing facilities, Class F assisted-living facilities and DHS-operated Minnesota sex offender program facilities. Based on this work, and the other considerations discussed below, the Board believes that further study in this area is no longer necessary.

Developments in the Area of Pharmaceutical Waste

Impact of the federal Affordable Care Act

Among the many provisions of the Patient Protection and Affordable Care Act of 2010 (ACA) is one that directly addresses the issue of pharmaceutical waste in long-term care facilities. Section 3310 of the ACA reads as follows:

> REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES UNDER PRESCRIPTION DRUG PLANS AND MA–PD PLANS.
> (a) IN GENERAL.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended by adding at the end the following new paragraph:
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> "(3) REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES.—The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities,

pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.''
(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to plan years beginning on or after January 1, 2012.

The Center for Medicare and Medicaid Services (CMS) has adopted regulations to effectuate this section of the ACA. (See 42 CFR §423.154). These regulations state, in part (emphasis added):

> "Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—
>
> (1) **Require all pharmacies servicing long-term care facilities**, as defined in §423.100 **to**—
>
> (i) **Dispense solid oral doses of brand-name drugs**, as defined in §423.4, **to enrollees in such facilities in no greater than 14-day increments at a time**;

In the past, it was common for pharmacies to dispense 30-day supplies of medications to residents of long-term care facilities. With the adoption of 42 CFR §423.154, some pharmacies have switched to dispensing 14-day supplies. Another way in which pharmacies can meet the requirements of this federal regulation is to place automated drug distribution devices in long-term care facilities. Some of these devices package the drugs that will be administered to patients shortly before the administration occurs. In essence, the drugs are being packaged right when they are needed.

When compared to the traditional 30-day dispensing cycles, the use of either 14-day dispensing cycles or an ADDS reduces the amount of drug that is wasted. When a drug is dispensed to a resident of a long-term care facility, it often cannot be returned to the pharmacy if it is discontinued, the dosage changes or the resident dies. This has been particularly true for controlled substance medications, such as narcotic pain relievers. Use of a 14-day dispensing cycle reduces the amount of drug wasted compared to the use of a 30-day cycle because over 50% fewer doses are dispensed. Since an ADD packages drugs in the facility as they are needed, the waste reduction is potentially even greater. This reduction in waste should help reduce costs for health care payers, including Medicare and Medicaid. It should also help reduce the amount of pharmaceuticals that end up in the waste stream.

Automated drug distribution devices (ADD)

Around the time that CMS adopted the above-mentioned regulation, the Board received a request from a specialty long-term care (LTC) pharmacy for approval to use an ADD in a nursing home. After working with the pharmacy to ensure that adequate safeguards were in place, the Board approved the request in 2011. However, language in the state's Pharmacy Practice Act (Chapter151) required that the pharmacy obtain Board approval for each subsequent placement of an ADD in nursing homes. Each room in which an ADD was placed also needed to be licensed as a pharmacy.

During the 2012 session, the Board worked with the LTC pharmacy on proposed legislation, reaching a compromise on language that was enacted as MN Stats. §151.58. Pharmacies are now allowed to place ADDs in skilled nursing facilities and Class F assisted living facilities without having to license a room in each facility as a pharmacy. The Board must approve an ADD before pharmacies can use it in these facilities. The Board must also approve the policies and procedures used by the pharmacy. However, once the ADD and the related

policies and procedures are approved, a pharmacy only needs to notify the Board of the subsequent facilities in which ADDs are placed. (Rather than having each placement approved by the Board). Since the enactment of MN Stats. §151.58, nearly 100 ADDs have been placed in LTC facilities around the state. Several dozen of them are used to dispense the majority of drugs that are used by residents of the facilities. The others are used to dispense the first doses of newly ordered drugs or other urgently needed drugs. The Board will work during the 2015 Session to allow the use of ADDs in certain boarding care facilities.

Potential Impact of federal Secure and Responsible Drug Disposal Act of 2010

Until very recently, health care providers who held registrations from the U.S. Drug Enforcement Administration (DEA) were not allowed to take back unused and unwanted controlled substance medications from "end users", such as patients. Therefore, pharmacies were not allowed to accept any returns of controlled substances from patients or from LTC facilities – not even for the purpose of having them disposed of properly.

In recognition of the growing epidemic of prescription drug abuse, and in light of the fact that many people obtain the drugs they abuse from unused prescription supplies, Congress passed the Secure and Responsible Drug Disposal Act of 2010. As stated by the DEA, the act "authorized DEA to develop and implement regulations that outline methods to transfer unused or unwanted pharmaceutical controlled substances to authorized collectors for the purpose of disposal. **The Act also permits long-term-care facilities to do the same on behalf of residents or former residents of their facilities**." The hope is that people will bring unwanted controlled substance medications back to certain DEA registrants to have them destroyed, thus reducing the supply of such drugs that are available to be abused.

On September 9, 2014, the DEA published a Final Rule, implementing the Secure and Responsible Drug Disposal Act. Among other provisions, the Final Rule:

- Authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors.
- Allows these authorized collectors to operate a collection receptacle at their registered location. (Collectors with an on-site means of destruction are allowed to operate a mail-back program).
- **Allows retail pharmacies and hospitals/clinics with an on-site pharmacy to operate collection receptacles at long-term care facilities.**

In order for DEA registrants located within Minnesota to begin collecting controlled substances from end users, the state's statutes would need to be amended. The statutes do not currently allow health care facilities or professionals of any sort to collect drugs from end users for the purpose of having them disposed of properly. Specifically, Minnesota Statutes §151.37 would need to be amended to allow such registrants to collect drugs from end users for that purpose.

The Board recommends that pharmacies, including pharmacies located within hospitals or clinics, be allowed to collect drugs for the purpose of having them disposed of properly, provided that they follow the new DEA Final Rule for all drugs collected. That would allow pharmacies to collect unwanted pharmaceuticals from the general public and to place receptacles in long-term care facilities. Assuming that the Minnesota Department of Human Services has no objections, the Board further recommends that narcotic treatment programs that are licensed by DHS, and also licensed by the Board as pharmacies, be allowed to collect drugs from end users for the same purpose and in the same manner. The Board will submit draft legislation to the Office of the Revisor of Statutes for possible introduction during the 2015 Session.

Allowing pharmacies and narcotic treatment programs to collect drugs from the public for disposal purposes would complement the existing "Take It to the Box" program of the Minnesota Pollution Control Agency. There are currently over 150 permanent collection receptacles located throughout Minnesota in the offices of law enforcement agencies. Allowing pharmacies and narcotic treatment programs to also operate collection receptacles will most likely increase the number of sites to which members of the public can bring unwanted pharmaceuticals for disposal. That may have a positive impact by keeping such drugs out of the waste stream. It might also help reduce prescription drug abuse, which could result in reducing costs associated with the treatment of addiction and overdoses.

Summary

When the Legislature directed the Board to complete this study in 2010, there were still unanswered questions about the proper disposal of pharmaceutical waste. However, the developments described above have actually addressed many of those questions. Short-cycle dispensing is now a reality and the use of ADDs effectively means that daily "dispensing" occurs in many long-term care facilities. If the Legislature amends MN Stats. §151.37 to allow pharmacies and narcotic treatment programs to collect unwanted pharmaceuticals from "end users", the general public and long-term care facilities will have additional sites through which they can dispose of their unwanted medications.