

ANOTHER BITE OF THE ELEPHANT: PRESCRIPTION MAILING REGULATIONS AND THE PRESCRIPTION DRUG EPIDEMIC

Seth Harrington*

INTRODUCTION

In 2011, a report issued by the Executive Office of the President described America's prescription drug addiction as an "epidemic."¹ The report found a staggering recent increase in prescription drug abuse among Americans: a 402% per person use increase of prescription opioids² from 1997 to 2007;³ a 48% increase in pharmacy-dispensed opioids from 2000 to 2009;⁴ a 313% increase in prescription opioid overdose deaths from 2000 to 2010.⁵ These dramatic increases prompted the Office of the President to "demand action . . . to reduce prescription drug abuse" in four areas: education, monitoring, proper disposal, and enforcement."⁶ However, in spite of such a government initiative, there are indicators that the prescription drug problem will persist.⁷

*J.D. Candidate 2016, William Mitchell College of Law.

¹ EXEC. OFFICE OF THE PRESIDENT OF THE U.S., EPIDEMIC: RESPONDING TO AM.'S PRESCRIPTION DRUG ABUSE CRISIS (2011), *available at* http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf. Congress also recognized this "epidemic," finding that the "nonmedical use of prescription drugs is a growing problem in the United States" and "the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years." 21 U.S.C. § 822 note (2010) (Secure and Responsible Drug Disposal Act of 2010).

² Prescription opioids, more commonly known as pain killers, are at the center of prescription drug abuse epidemic and represent a significant amount of prescription drug overdoses. *See generally* CTRS. FOR DISEASE CONTROL AND PREVENTION, POLICY IMPACT: PRESCRIPTION PAINKILLER OVERDOSES, <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/> (last visited February 13, 2014).

³ *Id.* at 1.

⁴ *Id.*

⁵ Congressional Testimony of Dr. Douglas Throckmorton, Examining the Federal Government's Response to the Prescription Drug Abuse Crisis (June 14, 2013), <http://www.fda.gov/NewsEvents/Testimony/ucm356674.htm>.

⁶ EPIDEMIC, *supra* note 1, at 1—2.

⁷ U.S. DEP'T OF HEALTH AND HUMAN SERVS., RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS (2013), *available at* <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch8.2>. (noting that nonmedical prescription drug use is rising among those age forty and over, likely due to teenage drugs use by the baby boom generation); *see generally* Julian Hattem, Lawmakers call for clampdown on prescription drug abuse, REGWATCH: THE HILL'S REGULATION BLOG (June 14, 2013, 4:39 PM),

States have further attempted to curb the epidemic with legislation.⁸ Such legislation has generally taken one of eight different forms:

- “Doctor-shopping” laws criminalizing the ability to seek and obtain multiple prescriptions from different health care practitioners;
- Immunity laws providing immunity to those who voluntarily seek help for themselves or others after an overdose;
- Pain management clinic oversight laws requiring specific oversight, licensure, registration or ownership of pain management clinics;
- Physical examination before prescribing laws requiring a patient examination, recitation of patient history, or other patient evaluation before providing a prescription;
- Prescription Drug Monitoring Programs (PDMP or PMP)⁹ enabling practitioners and pharmacies to track who is writing and filling prescriptions;
- Information sharing laws allowing interstate access to PMP data;
- Required identification before dispensing laws requiring pharmacies to review a valid photo identification before filling a prescription;
- Tamper-resistant form laws requiring pharmacies to only accept prescriptions written on tamper-resistant forms.¹⁰

<http://thehill.com/blogs/regwatch/healthcare/305623-lawmakers-want-clampdown-on-prescription-drug-abuse> (discussing how a prescription drug abuse problem is still prevalent in the United States).

⁸ CTRS. FOR DISEASE CONTROL AND PREVENTION, PRESCRIPTION DRUG OVERDOSE: STATE LAWS, <http://www.cdc.gov/HomeandRecreationalSafety/poisoning/laws/index.html> (last visited February 13, 2014).

⁹ For an example of a PMP website, visit <http://pmp.pharmacy.state.mn.us/>.

¹⁰ Nat’l Conference of State Legislatures, Prevention of Prescription Drug Overdose and Abuse (January 2014), <http://www.ncsl.org/research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx>.

Minnesota has enacted a doctor-shopping law,¹¹ patient identification law,¹² physical examination law,¹³ and a prescription limit law for medical assistance recipients.¹⁴ Minnesota has also created a PMP designed to identify and monitor prescription drug diversion, abuse, and misuse.¹⁵ These laws have a *direct impact* on the availability of prescription drugs in Minnesota and have undoubtedly helped limit the state's drug overdose mortality rate (when compared to the national average).¹⁶ But are these laws enough? Although Minnesota has succeeded in limiting its drug overdose mortality rate, the majority of such deaths are still caused by prescription drugs.¹⁷ Furthermore, from 2002 to 2011, the nonmedical use of pain relievers in Minnesota rose from 3.93% (2002-2003 report) to 4.57% (2010-2011 report).¹⁸ At the same time, the national average for nonmedical use of pain relievers dropped .22%, from 4.79% to 4.57%.¹⁹ Clearly there are gaps in the Minnesota legislation and policy aimed at combatting the prescription drug epidemic.

¹¹ MINN. STAT. § 152.126 (2013) (establishing a state prescription monitoring program (PMP)). The Minnesota PMP is designed to combat doctor-shopping by granting providers greater access to prescription fulfillment records. *See* EXEC. OFFICE OF THE PRESIDENT OF THE U.S., MINNESOTA DRUG CONTROL UPDATE 2 (2011), *available at* http://www.whitehouse.gov/sites/default/files/docs/state_profile_-_minnesota.pdf.

¹² MINN. STAT. § 152.11, subdiv. 2d. However, Minnesota's patient identification law only extends to Schedule II or III controlled substances and does not apply "to purchases of controlled substances that are [covered], in whole or in part, by a health plan company or third-party payor." *Id.* at subdiv. 2d(b).

¹³ MINN. STAT. § 151.37, subdiv. 2(d).

¹⁴ Minn. Stat. § 256B.0625, subdiv. 13.

¹⁵ MNPMP: Reducing Prescription Drug Abuse and Improving Patient Care, <http://pmp.pharmacy.state.mn.us/assets/files/PDFs/MNPMP%20Info%20Sheet%2010.1.13.pdf> (last visited April 7, 2014).

¹⁶ Trust for America's Health, *Minnesota has the Fifth Lowest Drug Overdose Mortality Rate in the United States*, TRUST FOR AMERICA'S HEALTH (Oct. 7, 2013), <http://healthyamericans.org/reports/drugabuse2013/release.php?stateid=MN>.

¹⁷ *Id.*

¹⁸ SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., NATIONAL SURVEY ON DRUG USE AND HEALTH: COMPARISON OF 2002-2003 AND 2010-2011 MODEL BASED PREVALENCE ESTIMATES (50 STATES AND THE DISTRICT OF COLUMBIA) 16 (2012), *available at* <http://www.samhsa.gov/data/NSDUH/2k11State/NSDUHsae2011/TrendTabs/NSDUHsaeTrendTabs2011.pdf>.

¹⁹ *Id.*

This paper addresses a lesser known gap, regulation of prescription drug mailings. Where receiving prescriptions through the mail is becoming increasingly popular,²⁰ what state or federal regulations work to ensure safe delivery? Part I of this paper begins with a brief discussion of a relevant bill that was prefiled in the Minnesota House of Representatives, recently introduced into the Minnesota Senate, and is slated to become law in August 2014. Part II then addresses the problem of mail theft generally, and the current federal and Minnesota regulations for mailing prescription drugs. Part III looks at how other states attempt to regulate such mailings. Finally, Part IV posits a recommendation for Minnesota's treatment of prescription drug mailings. In order to prevent prescription mail theft from contributing to the prescription abuse epidemic, Minnesota should adopt proactive legislation which seeks to stop the thefts before they occur.²¹ Furthermore, Minnesota should use existing data collection infrastructure to better track prescription mail theft.

I. MINNESOTA HOUSE FILE NO. 1872: RETAIL COMMUNITY PHARMACIES FILLING MAIL-ORDER PRESCRIPTIONS

In January 2014, a bill dealing with the treatment of mail-order pharmacies and retail community pharmacies was prefiled in the Minnesota House of Representatives.²² By March

²⁰ STATISTICAL BRIEF #200, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (2008), available at http://meps.ahrq.gov/mepsweb/data_files/publications/st200/stat200.shtml (noting that, from 2000 to 2005, use of mail order prescriptions increased from 8.8% to 13.2%).

²¹ Proactive legislation has generally meant legislation that seeks to predict future harms and stop such harms from occurring. Stuart Minor Benjamin, *Proactive Legislation and the First Amendment*, 99 MICH. L. REV. 281, 285 (2000). In the context of this paper, proactive legislation takes a slightly different definition because the problem of prescription drug mail theft is a present harm, not a future harm. See, e.g., *Mailbox theft on upswing: postal authorities peg drug users as culprits*, THE EXAMINER (Jan. 14, 2014), <http://www.examiner.com/article/mailbox-theft-on-the-upswing-postal-authorities-peg-drug-users-as-culprits>. Therefore, proactive legislation in this paper takes the opposite approach of reactive legislation. Reactive legislation reacts to a problem that has already occurred (for example, statutory criminal punishment for assault with a deadly weapon). Proactive legislation, on the other hand, seeks to limit access to the means by which a problem can occur (for example, statutory limits on who can possess a deadly weapon).

²² H.F. 1872, 88th Leg., 2d Reg. Sess. (Minn. 2014).

2013, the bill had been introduced into the Minnesota Senate as Senate File No. 2284.²³ As defined by the bill, a mail-order pharmacy conducts business primarily by mail or electronic means, dispenses drugs through the use of mail or private delivery services, and primarily consults with patients by mail or electronic means.²⁴ A retail community pharmacy is “open to the public, serves walk-in customers, and allows individuals to whom a prescription drug is being dispensed the opportunity to consult with a pharmacist face-to-face.”²⁵ However, it is important to note that many retail pharmacies also afford clients the opportunity to receive prescriptions through the mail.²⁶

The goal of this bill is to ensure that pharmacy benefit managers (PBMs)²⁷ do not favor mail-order (or, online) pharmacies over community retail pharmacies (think Walgreens or CVS).²⁸ Generally, PBMs favor mail-order pharmacies because such pharmacies are PBM-owned. According to James Langenfield and Robert Maness, “[e]ach of the four largest PBMs owns a mail order division, and these captive mail order houses account for 77 percent of all mail order prescription business.”²⁹ Therefore, if PBMs can require patient use of mail-order

²³ S.F. 2284, 88th Leg., 2d Reg. Sess. (Minn. 2014). Because the most recent bill activity has occurred in the Minnesota Senate, the senate file will be referenced in all subsequent text.

²⁴ *Id.* at § 3, subdiv. 1(c).

²⁵ *Id.* at subdiv. 1(e).

²⁶ *See, e.g.*, Walgreen’s Mail Service Pharmacy, <https://www.walgreens.com/topic/s/mail-service-pharmacy.jsp> (last visited February 24, 2014).

²⁷ For a description of the pharmacy benefit manager’s role in the prescription drug infrastructure, see Thomas Gryta, *What is a ‘Pharmacy Benefit Manager?’*, WALL STREET JOURNAL (July 21, 2011, 6:03 PM), <http://online.wsj.com/news/articles/SB10001424053111903554904576460322664055328>.

²⁸ Other states have enacted similar legislation designed to prevent PBMs from favoring mail-order pharmacies over retail community pharmacies. *See, e.g.*, N.Y. INS. LAW § 3216(i)(28) (McKinney 2014).

²⁹ JAMES LANGENFIELD & ROBERT MANESS, THE COST OF PBM “SELF-DEALING UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 1 (2003), available at http://www.ncpanet.org/assets/Federal_Bills_Pending_Legislation/asset_upload_file222_2891.pdf.

pharmacies, PBMs will likely participate in self-dealing, increasing their own sales at the expense of the consumer.³⁰

Senate File 2284 limits PBM self-dealing in three distinct ways: 1) the bill requires that PBMs allow individuals to fill prescriptions at mail-order *and* retail community pharmacies (assuming the retail community pharmacy agrees to fill the prescription and the cost to do so is “substantially the same” as if filled by a mail-order pharmacy), 2) the bill prohibits PBMs from imposing unequal cost-sharing requirements between individuals who fill prescriptions at a mail-order pharmacy or community retail pharmacy, and 3) the bill requires that PBMs “use the same pricing benchmarks, indices, formulas, and prescription drug codes” when reimbursing pharmacies, regardless of whether the prescription was filled at a mail-order or retail community pharmacy.³¹ These requirements will likely curb the use of mail-order pharmacies by allowing retail community pharmacies to fill identical prescriptions. Less use of mail-order pharmacies will in turn fight the prescription drug epidemic because such pharmacies, though now subject to strict federal regulations,³² are notorious for providing prescription drugs without valid prescriptions.³³

Although Senate File 2284 will likely combat the prescription drug problem in Minnesota, it is also noteworthy for what it lacks. That is, a law adopting the proper means by which online and retail community pharmacies can safely mail drugs to prescription recipients. Currently, Minnesota has no laws specifically tailored to mailing prescription drugs safely.

³⁰ *Id.* at 6—13 (noting that PBMs can inflate prescription drug costs to the consumer by dispensing less generic drugs and earning rebates from pharmaceutical companies on higher priced drugs).

³¹ S.F. 2284 at § 3, subdiv. 2(a)—(c).

³² *See, e.g.,* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. §§ 829, 831 (2009).

³³ Nat’l Ass’n of Bds. of Pharmacy, *NABP Issues Rogue Online Pharmacy Public Health Alert* (July 28, 2011, 8:57 AM), <http://www.nabp.net/news/nabp-issues-rogue-online-pharmacy-public-health-alert/> (noting that, in spite of new government regulations, online pharmacies remain a key contributor to the misuse and abuse of prescription drugs in the United States).

Furthermore, federal legislation on the topic lacks specificity. By implementing File 2284, the Minnesota Legislature is acknowledging that prescription drug abuse is a continuing problem, and that legislation plays an important role in combatting the problem. However, the bill does not go far enough in restricting non-patient access to prescription drugs, and could better accomplish its goals by including specific regulation of prescription drug mailings.

II. CURRENT MINNESOTA AND FEDERAL REGULATION OF PRESCRIPTION DRUG MAILINGS

Prescriptions delivered by mail are generally exposed to two key hazards which do not affect prescriptions received in person. First, prescriptions delivered by mail are subject to more diverse weather conditions (from time spent in a mail truck, to time spent in a mail carrier's bag, to time spent on a front stoop waiting for the recipient), which can adulterate the drugs. Second, prescriptions delivered by mail are subject to increased theft (it is much easier to take an unattended package from a front stoop than to rob someone leaving a local pharmacy). Current state law remedies the first hazard.³⁴ However, the second hazard is largely left untouched. Of course, criminal statutes are designed to combat mail theft. No statute, however, deals directly with the problem of increased accessibility to prescription theft posed by mailing prescriptions. In other words, existing statutes are designed to punish an act already committed, while neglecting a proactive approach which would prevent the theft from actually occurring.

³⁴ MINN. STAT. § 151.34 (1990). Section 151.34 makes it illegal for a pharmacy to manufacture, sell, deliver, hold, or offer for sale an adulterated or misbranded drug. *Id.* at (1). Generally, “[m]ost medications can be susceptible to losing some of their potency when exposed to environmental extremes [including heat, cold, and moisture].” Anahad O’Connor, *Ask Well: Can Weather Affect Mail Order Drugs?*, ASK WELL BLOG (Mar. 5, 2013, 12:42 PM), http://well.blogs.nytimes.com/2013/03/05/ask-well-can-weather-affect-mail-order-drugs/?_php=true&_type=blogs&_r=0. Furthermore, a drug is considered adulterated if its strength, quality, or purity differs from the official compendium (e.g., U.S. Pharmacopeial public drug standards). 21 U.S.C. § 351(b) (2012). Therefore, exposure to weather conditions, which can reduce a drug’s potency, may adulterate a drug. Pharmacies have generally responded to this liability with weather and light resistant packaging.

A. The mail theft problem

The federal government receives millions of mail theft complaints each year.³⁵ Based on sheer volume, mail theft has become the most popular white-collar crime in the United States.³⁶ However, though millions of complaints are filed each year, only a few thousand mail theft arrests are made, with even fewer convictions.³⁷ The large discrepancy between complaints and convictions can be attributed to the general characteristics of mail theft. Generally, thieves have access to home mailboxes; very few people lock their mailboxes.³⁸ Additionally, valuable items are regularly transported through the mail, including credit cards, prescriptions, and checks. Also, mail theft is a quick crime, not requiring extensive planning or time. Mail theft requires simply opening a mailbox, taking the contents, and walking away. Ease of crime, coupled with the potential for valuable gain, makes mail theft a popular crime in the United States.

B. Current Minnesota regulations impacting prescription drug mailings

Minnesota Statutes section 151.33 prohibits any person, “directly or indirectly, by agent or otherwise, [from] scatter[ing], distribut[ing], or giv[ing] away any samples of any medicine, drugs, or medical compounds . . . unless the same is delivered into the hands of an adult person.”³⁹ Arguably, a pharmacy that mails a prescription and then leaves that prescription on a front stoop or in a mailbox is distributing the prescription (drug) without delivering it into the

³⁵ U.S. POSTAL SERV., INFORMATION ABOUT RESTRICTIONS ON MAILBOX ACCESS 27 (1997) (noting that 2.4 million mail theft complaints were filed in 1996).

³⁶ Julie Knubley, *Mail Theft is the #1 White-Collar Crime in America Today*, EZINEARTICLES (Nov. 5, 2008), <http://ezinearticles.com/?Mail-Theft-is-the-1-White-Collar-Crime-in-America-Today&id=1635879>.

³⁷ U.S. POSTAL SERV., *supra* note 32, at 27; *see also* U.S. POSTAL INSPECTION SERV., ANNUAL REPORT OF INVESTIGATIONS, 2007 FY 56 (2008) (noting that, in the year 2007, only 3608 arrests were made for mail theft); U.S. POSTAL INSPECTION SERV., ANNUAL REPORT 2012 FY 45 (2013) (noting that, in the year 2012, 3158 mail theft arrests were made, with only 2321 convictions).

³⁸ U.S. POSTAL SERV., *supra* note 32, at 19 (noting that two-thirds of adults reported receiving mail in an unlocked mailbox).

³⁹ MINN. STAT. § 151.33 (1971).

hands of an adult person. Such an interpretation would increase the liability of pharmacies when mailing prescriptions, and would in turn likely restrict access to prescription drug theft.

However, two pieces of limiting language in the statute indicate this interpretation is unreasonable. First, section 151.33 refers specifically to drug or medicine samples.⁴⁰ A valid prescription for a drug is not a sample of the drug. Therefore the mailing of prescriptions likely does not apply to this statute. Furthermore, the statute carves out an unambiguous exception for drugs sent through the mail.⁴¹ This exception states that mailing prescription samples “to such persons through regular mail service” is not considered careless distribution of drugs.⁴²

Therefore, even if the statute was not limited to samples, mailing prescriptions would still be an acceptable practice, even without assurance that the patient actually receives the prescription.

As noted in section II.A, Minnesota has a statute designed to combat mail theft.⁴³ This statute criminalizes the taking of mail from a mail depository or the taking of mail that is left for collection near a mail depository.⁴⁴ This statute also provides for punishment of up to three years in prison, a fine of not more than \$5,000, or both.⁴⁵ However, this statute does not take a proactive approach in preventing mail theft. Instead, the statute reacts to a crime already committed. The presence of a criminal penalty does not, by itself, imply that no crime will take place. Furthermore, the presence of a criminal penalty does not imply that preventative measures should be neglected.⁴⁶

⁴⁰ *Id.* at subdiv. 1.

⁴¹ *Id.*

⁴² *Id.*

⁴³ MINN. STAT. § 609.529 (2003).

⁴⁴ *Id.* at subdiv. 2.

⁴⁵ *Id.* at subdiv. 3.

⁴⁶ For example, motor vehicle theft is criminalized. However, this does not stop individuals from installing car alarms in order to prevent such theft.

Overall, no Minnesota statute works to proactively prevent the theft of mailed prescription drugs. This is unfortunate because legislation specifically designed to combat the country's prescription drug abuse problem is likely necessary to cure the epidemic.

C. Current federal regulations impacting prescription drug mailings

The United States Postal Service (USPS) issues mailing regulations in accordance with Title 39 of the Code of Federal Regulations. Section 211.2 states that such regulations include: instructions, handbooks, delegations of authority, and other regulatory issuances or directives.⁴⁷ These regulations may or may not be published in the Federal Register or Code of Federal Regulations.⁴⁸ Regulations concerning the mailing of prescription drugs are found in the USPS document: "Publication 52 – Hazardous, Restricted, and Perishable Mail."⁴⁹

Section 453.31 of Publication 52 dictates the mailing requirements for prescriptions that contain controlled substances.⁵⁰ The section states: "[f]or prescription medicines containing mailable narcotic drugs (controlled substances), only a pharmacist or medical practitioner, etc., who dispenses the medicine may mail such substances to the patients under their care."⁵¹ When a pharmacist fills a prescription for a patient, that patient is under the pharmacist's care. Therefore, this regulation holds that a pharmacist may only mail prescriptions (which contain controlled substances) to the patients for whom the pharmacist has filled the prescriptions.

⁴⁷ 39 C.F.R. § 211.2(a)(3) (2005).

⁴⁸ *Id.*

⁴⁹ UNITED STATES POSTAL SERVICE, PUBLICATION 52 – HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL (Dec. 2013), *available at* <http://pe.usps.com/text/pub52/welcome.htm>.

⁵⁰ *Id.* at § 453.31.

⁵¹ *Id.* at § 453.31(b).

Section 453.32 of Publication 52 dictates the mailing requirements for prescriptions that do not contain controlled substances.⁵² The mailing regulations for “prescription medicines containing nonnarcotic drug(s),” however, are identical to those pertaining to prescriptions containing a controlled substance.⁵³ These regulations are partially designed to deter prescription theft by ensuring that pharmacists are only mailing prescriptions to their patients who possess a valid prescription. Arguably, if pharmacists are allowed to mail prescriptions to non-patients (implicitly without a proper prescription), the likelihood of theft would increase due to a lack of accountability and proper record-keeping.

Additionally, section 453.4 of Publication 52 dictates how a mailed prescription (whether containing or not containing a controlled substance) must be packaged.⁵⁴ For these prescriptions, “[n]o markings of any kind to indicate the nature of the contents may appear on the outside of the mailpiece.”⁵⁵ This regulation is designed to deter theft because it forces valuable contents into inconspicuous packaging. A potential thief may overlook the package due to its bland exterior or, in the alternative, not risk stealing a package if he or she does not know the contents.

Although the USPS regulations may help prevent some prescription drug theft, the overall impact is likely nominal. For instance, the first set of regulations merely displaces the location of the potential theft. While the regulation prevents a thief from receiving prescriptions directly from the pharmacist, the regulation has no impact on a thief stealing a prescription while it is either in route to a patient, or in a patient’s mailbox. Furthermore, although section 453.4 attempts to make prescription packaging inconspicuous, this will not, in and of itself, prevent

⁵² *Id.* at § 453.32.

⁵³ *Id.* at § 453.32(a).

⁵⁴ *Id.* at § 453.4.

⁵⁵ *Id.* at § 453.4(a) (referring to prescriptions containing a controlled substance; subsection (b) contains an identical provision with regards to prescriptions not containing a controlled substance).

theft. For instance, if a thief is aware that prescriptions come in inconspicuous packages, the thief may steal *any* such package in the hope that it will contain prescription drugs.

Lastly, like Minnesota state law, federal law criminalizes mail theft.⁵⁶ However, this prohibition is only reactive, and does not work to prevent theft from actually occurring. Overall – like current Minnesota regulations – pertinent federal regulations are not formulated to ensure prescription mailings are not stolen.

III. HOW OTHER STATES REGULATE PRESCRIPTION DRUG MAILINGS

Generally, other states regulate prescription drug mailings no more strictly than Minnesota. For example, like Minnesota, the state of Washington regulates the prescription supply to individuals on medical assistance.⁵⁷ Also like Minnesota, the state of New Hampshire prohibits the dispensation or sale of prescriptions which have been adulterated or misbranded.⁵⁸ However, neither of these states have statutes that take a proactive approach in preventing the theft of prescription drug mailings.

Other states take a slightly more proactive approach in preventing the theft of prescription drug mailings. The state of Iowa allows for delivery of prescriptions to a patient's residence, hospital or care facility where the patient is confined, outpatient medical care facility where the patient is receiving treatment, or the patient's place of employment.⁵⁹ However, unlike Minnesota law, Iowa also provides additional mailing requirements when the prescription is delivered to an outpatient care facility or the patient's place of employment. In order to mail a prescription to an outpatient facility or place of employment, a pharmacy must first obtain

⁵⁶ 18 U.S.C. § 1708 (1994).

⁵⁷ WASH. ADMIN. CODE § 182-530-6000 (2007).

⁵⁸ *See, e.g.*, N.H. CODE ADMIN. R. ANN. PH 907.01 (2008).

⁵⁹ IOWA ADMIN. CODE r. 657-8.15(155A)(1) (2009).

written authorization from the patient or patient’s caregiver and the prescription must be “delivered directly to . . . the patient, caregiver, or an authorized agent identified in the written authorization.”⁶⁰ Therefore, the state of Iowa takes a proactive approach in preventing prescription theft by requiring that a pharmacy directly deliver a prescription to a patient (or other authorized party). This statute implies that leaving a prescription in a patient’s work mailbox or outpatient facility mailbox is unlawful, and thus eliminates potential theft from such mailboxes. However, this approach is limited to a patient’s place of employment or an outpatient care facility, and the statutory in-person delivery requirement does not apply to the most likely of delivery destinations – a patient’s residence.

Another subset of states takes a stronger proactive approach, but such legislation tends to be limited in application. For example, the state of Texas requires that a mailing of peyote⁶¹ use “the United States Postal Service, certified mail, return receipt requested” or another delivery service that minimizes the risk of diversion.⁶² By requiring the use of return receipt (or similar service that minimizes the risk of diversion), Texas is limiting the potential for peyote theft by requiring that the peyote be delivered directly to the patient (as opposed to a mailbox or front stoop, where thieves may access the drug). However, such a requirement is limited to a single drug (peyote) and a single type of people requesting the drug (Indians).⁶³

Similarly, Pennsylvania requires that some prescription mailing recipients sign a document indicating receipt. Pennsylvania Code section 22.63(c) states that: “[a] prescription drug delivered by mail shall be accompanied, as a minimum by the following . . . A Universal

⁶⁰ *Id.* at r. 657-8.15(155A)(1)d.—e.

⁶¹ Generally, peyote is a cactus from which a hallucinogenic drug is derived. *See* PEYOTE, <http://medical-dictionary.thefreedictionary.com/peyote> (last visited Mar. 26, 2014).

⁶² 37 TEX. ADMIN. CODE § 13.51 (2001).

⁶³ *Id.*

Claim Form” which must be signed and returned within five days of receipt of the prescription.⁶⁴ This section applies specifically to patients who are enrolled in Pennsylvania’s PACE program (exclusively for those aged sixty-five or older and in financial need).⁶⁵ Furthermore, in order to qualify as an enrolled PACE provider of benefits by mail, a pharmacy must “have, or secure, and maintain on file a signature reference for each PACE claimant requesting services by mail from that provider.”⁶⁶ Although these requirements take steps to ensure the identity of the prescription recipient, they are not specifically designed to deter theft of prescription mailings. The Universal Claim Form – which must be signed by the prescription recipient – is included in the package itself, meaning that the form is signed *after* the package is delivered, as opposed to *before*, and as a condition of, delivery (required if return receipt requested). Therefore, Pennsylvania still exposes PACE prescription recipients to thefts occurring from the time of delivery to a residence to the time of actual acquisition by the recipient.

IV. A RECOMMENDATION FOR THE MINNESOTA LEGISLATURE

In order to properly subdue the prescription drug epidemic, the means by which abusers obtain drugs must be limited. Prescription drug mail theft represents one such means. However, both locally and nationally, little is being done to proactively prevent such thefts. In order to properly prevent prescription drug mail thefts, the Minnesota Legislature should adopt legislation which ensures a patient receives his or her prescription while minimizing the risk of theft. Two innovative steps can be taken to achieve this end.

⁶⁴ 6 PA. CODE § 22.63(c) (1985).

⁶⁵ See generally PACE, PACENET, AND PACE PLUS MEDICARE, <http://www.pahealthcoverage.com/pace.htm> (last visited Mar. 26, 2014).

⁶⁶ 6 PA. CODE § 22.62(g) (1990).

First, the Minnesota Legislature should require that Minnesota's PMP (MPMP) collect data related to prescription drug theft. Currently, MPMP data pertains specifically to prescription identification.⁶⁷ Such data allows pharmacists and physicians to view a patient's comprehensive prescription history with the hope of identifying individuals who forge or falsify prescriptions.⁶⁸ The data also allows the Board of Pharmacy to identify pharmacists and physicians who prescribe drugs at rates or dosages inconsistent with normal prescription practice.⁶⁹ The data is therefore designed to limit the potential for prescription drug abuse. Requiring the submission of data detailing prescription drug mail theft is consistent with this designation.

Access to mail theft data would benefit both pharmacists/practitioners and law enforcement agencies. Generally, if a prescription is lost or stolen, the intended recipient notifies the pharmacy and requests an early prescription refill. Each practitioner or pharmacy has its own protocol for dealing with stolen prescriptions.⁷⁰ Such protocols are rife with inconsistency.⁷¹ If providers are required to submit uniform data on prescription mailing theft, a prescribing

⁶⁷ Minn. Stat. § 152.126, subdiv. 4 (2013) (noting that prescriber name, dispenser name, date prescription filled, name and strength of substance, and patient name, among others, are required data submissions to the MPMP).

⁶⁸ *Id.* at subdiv. 5.

⁶⁹ *Id.*

⁷⁰ *See, e.g.*, Lost or Stolen Prescriptions, http://www.hmsa.com/PORTAL/PROVIDER/zav_pel.rx.LOS.500.htm (last visited April 7, 2014) (noting that the Hawaii Medical Service Association leaves the refilling of stolen prescriptions up to the discretion of the prescriber and pharmacists); Prescription Refill Policy, <http://coloradospineinstitute.com/forms/rx-refill-policy.pdf> (last visited April 7, 2014) (noting that the Colorado Comprehensive Spine Institute does not allow stolen prescriptions to be refilled); Lost or Stolen Prescription, http://www.hca.wa.gov/medicaid/healthyoptions/pages/faq_loststolenprescription.aspx (last visited April 7, 2014) (noting that Health Plans that contract with Washington Medicaid are required to replace stolen prescriptions at no cost to the patient). *But see*, MISS. ADMIN. CODE § 23-214:1.7 (2012) (noting that Mississippi Medicaid does not generally replace stolen prescriptions).

⁷¹ James L. Lindon, *When Can Controlled Substances Be Refilled Early?*, MEDSCAPE (Sept. 23, 2011), <http://www.medscape.com/viewarticle/749833> (noting that refilling a prescription early is generally up to the discretion of the pharmacist/practitioner).

practitioner or pharmacist is better equipped to identify prescription abuse as such abuse can be implicated by frequent prescription theft reports and the subsequent prescription requests.⁷²

Local law enforcement will also benefit from such data. Because some providers do not require the filing of a police report before a replacement prescription is mailed, it is possible that law enforcement will never be informed of the theft.⁷³ However, because a patient has an immediate need of the prescription, a practitioner or pharmacist is almost always notified of prescription theft. Therefore, if prescription providers are required to report prescription mail theft to the MPMP, a more complete picture of such theft will result, which will aid law enforcement efforts.

Step two involves instituting a return receipt requirement for prescription mailings. Requiring return receipt helps ensure both that the prescription is being directly delivered to the recipient (not just to the recipient's residence, where a prescription may be exposed to mail theft), and that the recipient acknowledges receipt of the package. Return receipt exhibits a proactive approach because it ensures a patient receives his or her prescription, thereby helping eliminate the opportunity for mail theft. Furthermore, requiring return receipt for important mailings is not foreign to legislation.⁷⁴ In fact, the federal government requires that a drug

⁷² An example of this trend has recently occurred in Gainesville, FL, where police apprehended numerous drug abusers who falsely filed prescription theft claims in order to acquire more pills. Cindy Swirko, *Police: Prescription abusers use theft reports to get more pills*, THE GAINESVILLE SUN (Apr. 18, 2011, 4:31 PM), <http://www.gainesville.com/article/20110418/articles/110419506>; see also THE MINNESOTA PRESCRIPTION MONITORING PROGRAM, http://www.mndental.org/features/2011/03/01/293/the_minnesota_prescription_monitoring_program (last visited April 10, 2014) (noting that "complaining that a prescription has been lost or stolen" is indicative of a patient seeking drugs for purposes of diversion or abuse).

⁷³ For example, California's Medicaid program, Medi-Cal, only requires the approval of the prescribing practitioner when a pharmacy is prematurely refilling a stolen prescription. PHARMACY BENEFITS FREQUENTLY ASKED QUESTIONS, <http://www.dhcs.ca.gov/services/Pages/PharmacyBenefitsFrequentlyAskedQuestions.aspx> (last visited April 10, 2014).

⁷⁴ See MINN. STAT. § 259.52 (2012) (stating that father's adoption registry documents must be sent to a putative father, return receipt requested); MINN. STAT. § 221.185 (1984) (stating that return receipt requested is required where specific motor carriers are being notified that their permit is being suspended).

sample recipient sign and acknowledge the receipt of the sample.⁷⁵ Where legislation helps ensure theft-free transaction of mailed prescription samples, why is there no legislation dealing with the actual prescription mailings? There seems to be a grave inconsistency in how prescription drug mailings are regulated.

Of course, requiring a prescription be mailed with return receipt requested will not end the prescription drug epidemic. However, ensuring the safe mailing of prescription drugs is a step toward preventing prescription drug theft, which will logically combat the accessibility and use of prescription drugs by individuals without prescriptions. This effect will in turn combat the prescription drug epidemic. There is a Twi proverb that says: you must eat an elephant one bite at a time.⁷⁶ Though proper regulation of prescription drug mailings may be just one bite, it is a bite necessary to finish the meal, and limit the prevalence of prescription drug abuse in Minnesota and the United States.

⁷⁵ 21 C.F.R. § 203.30(c) (1999).

⁷⁶ TRADITIONAL PROVERBS, <http://www.africanculture.dk/gambia/proverbsall.htm> (last visited Mar. 31, 2014).