Minnesota Medication Repository NGA

A. Public Safety and Well-Being

1) Describe, using evidence to the extent possible, how the proposed scope and regulation may improve or may harm the health, safety, and welfare of the public?

Medication repository programs have the ability to

1. Lower the cost of medications for indigents for Minnesota.
2. Improve health outcomes of Minnesota residents due to increased medication adherence due to higher medication availability and lower costs.
3. Lower the overall healthcare cost to the state by reducing healthcare problems related to adherence (saves taxpayer funding).
4. Removes pollutants from environment.

Medication repository program vs Current practice

In 2014 researchers at the University of Chicago estimated that as much as two billion dollars of medications are wasted every year at long term care facilities.[1] Colorado officials have said the state's 220 long-term care facilities throw away a whopping 17.5 tons of potentially reusable drugs every year, with a price tag of about $10 million. The Environmental Protection Agency estimated in 2015 that about 740 tons of drugs are wasted by nursing homes each year.[2] Mark Coggins, who oversees the pharmacy services for Diversicare, a chain of more than 70 nursing homes in 10 states, "It would not surprise me if as much as 20 percent of the medications we receive we end up having to destroy." Billions of dollars of medication, *millions of real-life saving- medications*, are being disposed of. At the same time many Americans can not take the medications the need because of cost.

If legislation was modified as currently recommended it would allow medications to be received from long-term care dispensing pharmacies, retail pharmacies, and health providers.Currently this can only be done with cancer medications.

Medications at long term care (LTC) facilities are often prepared for a patient in single use doses or in a monthly blister pack. Once a medication is repackaged Minnesota law states "Unused drugs repackaged according to this section that are returned to any pharmacy shall not be redispensed.[3]" A repackaged medication does not lose any of its efficacy or safety measures if it was kept in a controlled setting, to be defined below. These medications are still usable, and safe for patients, and we are having to waste them because of the current legislation. Medication repository, programs help connect these two

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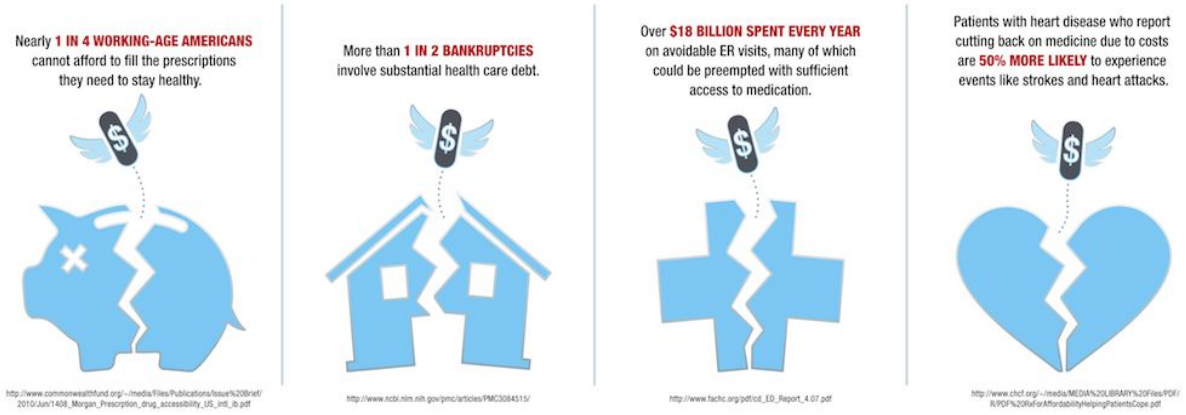
[1] "The shocking cost of wasted prescription pills - Marketplace." 10 Dec. 2014, https://www.marketplace.org/2014/12/10/health-care/shocking-cost-wasted-prescription-pills. Accessed 23 Oct. 2017.
[2] "America's Other Drug Problem — ProPublica." 27 Apr. 2017, https://www.propublica.org/article/americas-other-drug-problem. Accessed 13 Nov. 2017.
[3] "151.415 - 2017 Minnesota Statutes - Revisor of Statutes." https://www.revisor.mn.gov/statutes/?id=151.415. Accessed 23 Oct. 2017.

problems into a win-win situation.

Adam Kircher, SIRUM co-founder, on medication donation, "For a midsize nursing home with 50 to 75 beds, we'll typically see $6,000 in medications donated each year, usually once per quarter," Kircher said. "It costs us $10 in shipping to get that $1,500 donation to a clinic. If we could do this across the country, it would prevent many needless deaths and emergency room visits and the savings could be astronomical."[4]



2) Is there any research evidence that the proposed change(s) might have a risk to the public? Please cite.

There is no evidence that the proposed change might have a risk to the public.

Strict safety rules and regulations would be applied to the medication repository program. This protects the patients that ultimately obtains and takes the drug. The following rules would be in place for medication to be successfully allowed into inventory within the medication repository program:

1. Is in unopened, tamper-evident packaging;
2. The medications are not adulterated or misbranded;
3. Controlled substances and drugs and supplies that do not meet the criteria under this subdivision are not eligible for donation or acceptance under the prescription drug repository program.
4. Expired prescription drugs shall not be accepted.
5. The medication has been maintained in accordance with the federal Food and Drug Administration risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 if applicable; and has a USP-recognized method to detect improper temperature variations if the medicine requires temperature control other than "room temperature storage"

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[4] "Recycling Unused Medicines to Save Money and Lives - Opinionator." 20 Mar. 2015, https://opinionator.blogs.nytimes.com/2015/03/20/recycling-unused-medicines-to-save-money-and-lives/. Accessed 13 Nov. 2017.

B. Access, Cost, Quality, Care Transformation Implications

1) Describe how the proposed change(s) will affect the availability, accessibility, cost, delivery, and quality of health care.

There are 365 Nursing homes within Minnesota.[5] This proposal could help improve patient health within Minnesota by expanding access of care to patients in economic need. Medication recycling programs allow for more patients to receive the medications they need but can't afford. When patients can't take their medications as prescribed it leads to increased health care problems, and increased health care costs for the state due to ER visits. [6]

An additional feature of employing medication repository programs is that it removed pollutants from the water and landfills. Many LCT facilities in Minnesota specifically are often mixing unwanted non-scheduled medications with coffee grounds, this is an ineffective measure which ultimately still results in detrimental environmental effects through landfills and water supply Some LTC facilities dispose of their unwanted medications by having them incinerated, having more active medication repository programs allow for energy to be saved because less products are having to be incinerated. The Environmental Protection Agency estimated in 2015 that about 740 tons of drugs are wasted by nursing homes each year.

2) Describe the unmet healthcare needs of the population (including health disparities) that can be served under this proposal and how the proposal will contribute to meeting these needs.

Medication cost vs Adherence:

An analysis of the data from the National Health Interview Survey from 1999-2015 showed that the proportion of all Americans who did not fill a prescription in the previous 12 months because they could not afford the cost of the medication(s) grew from 1999 to 2009, peaking at 8.3% at the height of the Great Recession and dropping to 5.2% by 2015.[7] In 2015 the United States population was 320.9 million, that means that over 1 million americans could not receive the medications they needed.[8] One survey of 10,000 patients showed that 17% of patients did not adhere to their prescriptions because of high drug costs. Another study of 14,464 patients showed that 55.5% did not fill at least one prescription because they "thought it would cost too much," and another 20.2% because their "medicine was not covered by insurance." [9] Another study from the National Health Interview Survey estimated [10]that 8% of

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[5] "begin searching - Minnesota Nursing Home Report Card." http://nhreportcard.dhs.mn.gov/Search.aspx. Accessed 12 Nov. 2017.
[6] "SIRUM – Saving Medicine : Saving Lives." https://www.sirum.org/. Accessed 23 Oct. 2017.
[7] "Medication Costs and Adherence of Treatment Before and After the ...." http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2016.303269. Accessed 23 Oct. 2017.
[8] "Population Clock - Census Bureau." https://www.census.gov/popclock/. Accessed 23 Oct. 2017.
[9] "Adherence and health care costs - NCBI - NIH." 20 Feb. 2014, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/. Accessed 23 Oct. 2017.
[10] "Adherence to Medication — NEJM - New England Journal of Medicine." http://www.nejm.org/doi/full/10.1056/NEJMra050100. Accessed 12 Nov. 2017.

Americans do not take their medications as prescribed due to costs. [11] These values are not just statistics, they are real people who are unable to receive proper medical care because of medication costs.

Medication adherence vs Cost to the state

Nonadherence is said to cost the United States health care system $100-290 billion every year[12],[13]. A systematic literature review of 25 studies found that, "that higher medication adherence significantly improved primary and secondary prevention of coronary artery disease outcomes. Studies of secondary coronary artery disease prevention show 10.1%-17.8% cost reductions ($294 and $868 per patient) between high- and low-adherence patients." It has been shown that individuals who do not take their prescription medication as prescribed have poorer health status and increased emergency room use, hospitalizations, and cardiovascular events.[14]

3) Please describe whether the proposed scope includes provisions to encourage or require practitioners to serve underserved populations.

This proposed legislation would encourage service to underserved populations. It would allow practitioners an opportunity to help their patients receive the medications they need but otherwise couldn't afford. The practitioners and providers could refer the patient to appropriate pharmacies or clinicians that have partnerships with the program. The medications and supplies will all be required to be inspected by a pharmacist. From there they can distributed to medical providers or pharmacies, and dispensed to Minnesotans in need.

4) Describe how this proposal is intended to contribute to an evolving health care delivery and payment system (e.g. interprofessional and collaborative practice, innovations in technology, ensuring cultural agility and competence in the profession, value based payment etc.)
N/A

C. Regulation

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3) Is there model legislation for the profession available at the national level? If so, from what organization? Which states have adopted it? Briefly describe any

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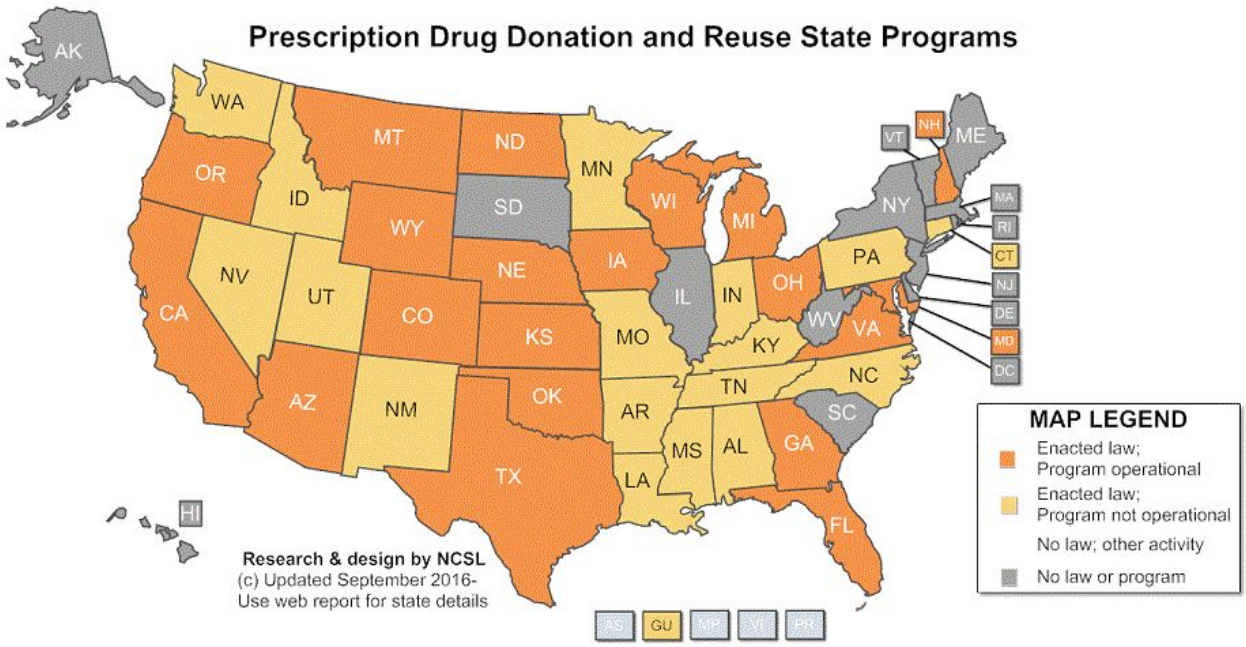
[11] "Products - Data Briefs - Number 184 - January 2015." 29 Jan. 2015, http://www.cdc.gov/nchs/data/databriefs/db184.htm. Accessed 12 Nov. 2017.
[12] "Thinking Outside the Pillbox." https://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf. Accessed 12 Nov. 2017.
[13] "Thinking Outside the Pillbox." https://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf. Accessed 12 Nov. 2017.
[14] "Strategies used by adults to reduce their prescription drug costs - NCBI." https://www.ncbi.nlm.nih.gov/pubmed/25633356. Accessed 23 Oct. 2017.

relevant implementation information.

The following information was obtained from the National Conference of State Legislators:



- **As of mid-2016, 42 states had passed laws establishing drug redistribution programs.** Many of these programs are not operational or small, but successful programs are growing. A few measures have been repealed.
- **Twenty states currently have enacted laws with operational repository programs.**
- **Nineteen additional states are categorized as having non-operational enacted laws**. New York's Nov. 2016 law is the latest.
    - **Cancer-Specific Programs**: The enacted laws in 13 states—Colorado, Florida, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin—allows them to accept and distribute cancer-related prescription drugs.

SIRUM runs 4 states medication repository programs: California, Colorado, Ohio, Oregon [15]

Medication Donation Administrative Process

Using SIRUM, other nonprofit administration company (this is how Colorado, California run)

1. Donation site has medications that they are ready to donate.
2. Donation site fills out form (medication name, number, lot, etc…) and emails/fax SIRUM
3. SIRUM verifies all information and sends the donation site shipping supplies, including labels, boxes, and orders the delivery service to come pick up the medications.

[15] "State Prescription Drug Return, Reuse and Recycling Laws." http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx. Accessed 12 Nov. 2017.

4. Donation site packs medication and the medications are then sent to the charitable clinic
5. The charitable clinic pharmacy staff verifies medication and repackages medication for recipients.

Using a central repository, which has to be an FDA certified wholesaler, (this is how Iowa runs)

1. Donation site has medications that they are ready to donate
2. Donation site sends medications to central repository for the state
3. Central repository verifies and repackages medication
4. Repackaged medication is sent to pharmacies, and clinics for recipients.

Successful Medication Donation Program

Wyoming Medication Donation Program:

- Since beginning in 2007, the program has helped Wyoming residents fill over 150,000 prescriptions (worth over $12.5 million) they could not have afforded otherwise.
- In 2016, WMDP provided over $2.4 million worth of donated prescription medications free of charge.[16]
- Since July 2008, the program has processed over 88,000 pounds of donated medications and medical supplies for redistribution. Thus keeping 88,000 pounds of medications from polluting their water and landfills.

Iowa Medication Repository Program "SafetyNetRx":

- Since 2008 More than $17.7 million in cost-savings and over 71,000 patients served including uninsured, underinsured, Medicaid and Medicare patients.
- Return in investment high with every $1 used to administer the Iowa Drug Donation Repository generates over $7 in free medications and supplies.[17]
- Works with 200 facilities that either donate or distribute the 5 million dollars' worth of drugs redistributed every year.[18]

Oklahoma Medication Repository Program

- In 2017 Drug Recycling through September, 13,821 prescriptions filled-$1,333,642 Average Wholesale Price value
- From November 2004 to September 2017, 218,313 prescriptions filled- $21,559,065 Average Wholesale Price of medication

4) Does the proposal overlap with the current scope of practice for other professions/practitioners? If so, describe the areas of overlap. (This question is not intended to imply that overlap between professions is negative.)

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[16] "Wyoming Medication Donation Program - Wyoming Department of ...." https://health.wyo.gov/healthcarefin/medicationdonation/. Accessed 28 Oct. 2017.

[17] "Drug Donation Repository - SafeNetRX.org." https://safenetrx.org/drug-donation/. Accessed 28 Oct. 2017.

[18] "Saving medicines, saving money, saving lives." 27 Apr. 2017, http://www.desmoinesregister.com/story/opinion/columnists/rekha-basu/2017/04/27/iowa-leads-u-s-redistributing-meds/307211001/. Accessed 12 Nov. 2017.

N/A

D. Education and Professional Supervision

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E. Finance Issues – Reimbursement, Fiscal Impact to state, etc.

1) Describe how and by whom will the new or expanded services be compensated (e.g., Medical Assistance, health plans, etc.)? What costs and what savings would accrue and to whom (patients, insurers, payers, employers)?

A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

1. First, to an indigent individual;
2. Second, to individuals who are enrolled in medical assistance, general assistance medical care, MinnesotaCare, Medicare, or other public assistance health care; and
3. Third, to any other individual if an indigent or uninsured individual is unavailable.

3) What are the projected regulatory costs to the state government, and how does the proposal include revenue to offset those costs?

If the government went with SIRUM, or another nonprofit, to run the administrative side of this project the state should not have any projected costs.

If the state decided to set up a central repository program like Iowa's that could cost the state. In Iowa the state funds the program for about $600,000 a year, says SafeNetRx CEO Jon Rosmann, who calls it a "common sense" solution. In fiscal 2016 the program recovered and distributed drugs valued at about $3.4 million. For 2017 it is on pace to top $5 million.[19]

4) Do you anticipate a state fiscal impact of the proposed bill?

X No ☐ Yes

If, yes, describe briefly and complete table below to the extent possible:

Fund (specify)	FY2017	FY2018	FY2019	FY2020
Expenditure				

[19] "America's unused drug problem finds possible solution in Iowa." 28 Apr. 2017, http://www.desmoinesregister.com/story/news/health/2017/04/28/safenetrx-iowas-unused-drugs/307677001/. Accessed 13 Nov. 2017.

F. Workforce Impacts

1) Describe what is known about the **projected supply/how many individuals are expected to practice under the proposed scope**? If possible, also note geographic availability of proposed providers/services. Cite any sources used.

N/A

2) Describe, with evidence where possible, how the new/modified proposal will impact the overall supply of the proposed services with the current/projected demand for these services.

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G. Proposal Supporters/Opponents

(Sponsor should understand and attempt to address the concerns of the opposition before submitting the document)

1) What organizations and groups have developed or reviewed the proposal?

The Minnesota Board of Pharmacy has helped draft this proposal. SIRUM has also helped with the drafting of this proposal.
The Minnesota Nursing Association, Minnesota Organization of Leaders in Nursing, Care Providers, LeadingAge Minnesota, SIEU Healthcare, School Nurses of Minnesota, Minnesota Licensed Practical Nurses Association,Minnesota Association of Community Health Centers, Minnesota Home Care Association, Minnesota Organization of Registered Nurses, Minnesota Public Health Association, Minnesota Pharmacist Association, have all been approached and have had discussions about this proposal.

2) Please describe the anticipated or already documented position professional associations of the impacted professions (including opponents) will/have taken regarding the proposal.

The Minnesota Board of Pharmacy, the Minnesota Nursing Association (MNA) and the Minnesota Public Health Association (MPHA) supports this proposal.

3) What consumer and advocacy groups support/oppose the proposal and why?

No organization opposes the proposal at this time.

H. Report to the Legislature

1) Please describe any plans to submit a report to the legislature describing the progress made in the implementation and the subsequent impacts (if measureable) of

the scope of practice changes for regulated health professions/occupations. Describe the proposed report's focus and timeline. Any proposed report schedule should provide sufficient time for the change to be implemented and for impacts to appear.

N/A