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## The Impact of Medication Donation Repositories: A Policy Analysis

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Lacey Brinegar, Student

Dr. Sarah Wackerbarth, Committee Chair

Dr. Sarah Wackerbarth, Director of Graduate Studies

# **The Impact of Medication Donation Repositories: A Policy Analysis**

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the  
requirements for the degree of  
Master of Public Health  
in the  
University of Kentucky College of Public Health  
By  
Lacey Brinegar  
Paoli, IN

Final Examination  
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Sarah Wackerbarth, PhD (Chair)  
Kathi Harp, PhD  
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## **ABSTRACT**

Two major issues surround the U.S. healthcare system: waste and inaccessibility of prescription drug medication. This paper primarily examines the financial impact medication donation repositories have on individuals and the healthcare system overall. Healthcare facilities may act as repositories for donated medications to be dispensed to those otherwise unable to afford them. The specifics of each policy vary from state to state with some policies covering a wider array of acceptable donations than others. Although Kentucky enacted a policy in 2005, the state still lacks any operational programs. By analyzing the policies of multiple states, this paper elucidates the more comprehensive impact medication donation repositories have on the healthcare system. The Georgia program includes a wider array of medications while serving geographic areas and demographics similar to those of Kentucky. Alternatively, the longer existing programs in Iowa and Wyoming paint a more complete picture regarding the sustainability and effect of repository policies. While policies and programs exist separately pertaining to both medication donation and waste, like drug disposal and medication assistance programs, medication donation repository policies tackle multiple problems in the U.S. healthcare system. Instead of wasting unused medications that could benefit others, the medications can be donated for redistribution, which reduces environmental waste and the financial expenditures associated with healthcare.

## **KEYWORDS**

Medication donation repository, Georgia, Iowa, Kentucky, Wyoming

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## **ACRONYMS AND ABBREVIATIONS**

CDC – Centers for Disease Control and Prevention

CFR – Code of Federal Regulations

CHFS – Cabinet for Health and Family Services

DEA – Drug Enforcement Administration

EPA – Environmental Protection Agency

IAC – Iowa Administrative Code

KRS – Kentucky Revised Statutes

NCHS – National Center for Health Statistics

OCGA – Official Code of Georgia Annotated

SIRUM – Supporting Initiatives to Redistribute Unused Medicine

UNITE – Unlawful Narcotics Investigations, Treatment and Education

WDH – Wyoming Department of Health

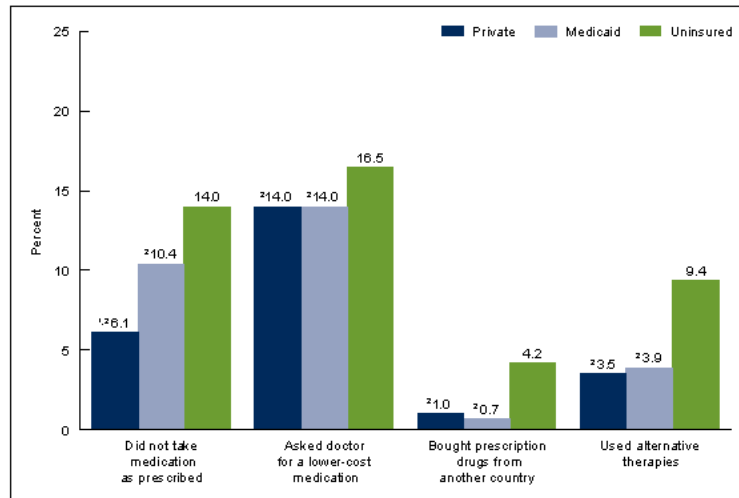
WMDP – Wyoming Medication Donation Program



## INTRODUCTION

In Kentucky alone, medication costs total more than \$5 billion annually, which is just a fraction of the more than \$354 billion spent by the entire United States.<sup>1</sup> Almost one-fifth of the billions of dollars spent on prescription medications comes directly out of patients' pockets.<sup>2</sup> Additionally, the World Health Organization reports that only 50% of people in developed countries take their chronic disease medications as prescribed.<sup>3</sup> In fact, 7.8% of adults in the U.S. admit to taking prescription medications incorrectly as a way to save money.<sup>4</sup> The incidence of nonadherence to prescription medications varies based on insurance coverage. Incidence of nonadherence, as well as other cost-saving methods, increases from private insurance holders to Medicaid beneficiaries to the uninsured (Figure 1).<sup>5</sup> Along with other reasons like prescribing too large of quantities and changes to therapies due to ineffectiveness or intolerability, nonadherence to medications results in increased waste and healthcare expenditures.<sup>6</sup>

Figure 1: Percent of Adults Using Cost-Saving Strategies Due to Prescription Drug Costs, 2013



<sup>1</sup>Significantly different from those with Medicaid coverage ( $p < 0.05$ ).

<sup>2</sup>Significantly different from those who were uninsured ( $p < 0.05$ ).

NOTES: "Did not take medication as prescribed" is a composite measure that includes adults who "skipped medication doses," "took less medicine," or "delayed filling a prescription." See the Definitions section for further details. A person may use more than one strategy to reduce prescription drug costs.

Source: CDC/NCHS, National Health Interview Survey, 2013.

When considering waste generated by pharmaceuticals, there are two perspectives to consider: the physical pollution resulting from disposal and the inefficiency of prescribing resulting in unused medication. From a pollution standpoint, lack of knowledge regarding proper disposal practices may lead to environmental harm. Specifically, the U.S. regularly disposes of medications via the wastewater system, whether by toilet or sink.<sup>7</sup> An analysis of fifty wastewater plants revealed at least 90% of samples contained various pharmaceutical products including multiple blood pressure medications and a mood stabilizing and antiepileptic medication.<sup>8</sup> From sewage and septic systems, pharmaceutical compounds enter bodies of water and groundwater supplies. Not only do humans face harm from contaminated water supplies, but aquatic life is endangered by improper disposal practices. Similarly, medications disposed of via the trash also pose a threat to nearby aquifers.<sup>9</sup>

Due to water contamination, the Environmental Protection Agency (EPA) began looking at unused pharmaceutical disposal practices among healthcare facilities. To dispose of waste in a safer manner and reduce the overall amount of waste produced, the EPA created best management practice guidelines for healthcare facilities. The EPA first suggests various strategies to reduce waste: order smaller container sizes, utilize unit-dose packaging, and relocate medications that are close to expiring to an area of the facility where it will be used more frequently. Since it is illogical to expect a healthcare facility to operate with no waste, the EPA recognizes various ways for unused medications to be disposed of safely. From most to least preferred, the EPA endorses the following disposal methods: donation, reverse distribution, management as hazardous waste, solid waste incineration, and disposal in solid waste landfill after mixing with undesirable substance. However, the exact methods recommended for a specific product depend on the classification of the pharmaceutical product—hazardous,

nonhazardous, controlled substance, or chemotherapeutic agent.<sup>10</sup> While the EPA focuses on safe disposal practices, it also addresses the volume of unused medication that could be redistributed to conserve waste.

Moving toward the wastefulness of the distribution process, U.S. healthcare facilities and households alike contribute to the problem. Inefficient dispensing of medications cannot be separated from increased healthcare expenditures as the former contributes to the latter. According to a prospective study of Medicare Part D beneficiaries in various skilled nursing facilities, almost 7% of dispensed medications are returned only partially used, which accounts for 3.5% of the cost of dispensing. Although the percentage of cost appears low, the total cost of unused medications represents \$125 million in healthcare expenditures for a relatively small population sample when considering all healthcare consumers.<sup>11</sup> Additionally, a survey of 1,228 hospice nurses in Michigan reports that 44% of survey participants dispose of at least eleven doses of medication when a patient dies. Furthermore, the majority of these nurses feel it is either never acceptable, extremely unsafe, or unsafe to return medication to the hospice facility, further impeding a more sustainable system. Unfortunately, the survey did not inquire about the classes of medications that nurses typically discard.<sup>12</sup>

When looking at unused medications in U.S. households, a survey of healthcare consumers in Southern California reveals that 67% of prescription medications go completely unused. This study projects a national average of 42% of all prescriptions going unused, creating enough dispensed medication to total 3.9 billion unnecessary prescriptions annually. From the study sample alone, unused medications account for between \$59,264.20 and \$152,014.89 of healthcare expenditures—the exact cost varying depending on the use of average retail price or average wholesale price. National estimates for unused medication costs spans anywhere

between \$2.4 billion and \$5.4 billion. Lastly, the most common classes of unused prescriptions include acute medications, like antibiotics and pain medications, and chronic medications for high blood pressure, diabetes, high cholesterol, and heart disease.<sup>13</sup>

Overall, the U.S. healthcare system operates inefficiently. Prescription medications represent a significant cost to healthcare facilities, healthcare consumers, and insurance companies. Consumers able to afford medications may be spending more than necessary, while those unable to afford medications must sacrifice their health and wellbeing. To increase access and affordability of care, many states enacted medication donation repository policies. Medication repositories are legitimate healthcare sites serving to accept properly stored and unadulterated medications for distribution among those unable to otherwise afford treatment. While many states have enacted policies to operate medication repositories, fewer states actually have operational facilities. The purpose of this project was to assess the impact medication donation repositories can have on providing access to much needed treatment for those in need. To call attention to the benefits of developing operational sites in Kentucky, this study examined the effects other states' programs have had, specifically Georgia, Iowa, and Wyoming. Impacts of interest included the cost spared to both the healthcare system and those receiving the medication and the decrease in medication waste due to these programs.

## **METHODS**

### *Policy Framework*

To analyze medication donation repository policies, this study utilized the framework outlined in Eugene Bardach's *A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving*. The eight steps for appropriate analysis include 1) defining the

problem, 2) assembling evidence, 3) constructing alternatives, 4) selecting criteria, 5) projecting outcomes, 6) confronting trade-offs, 7) deciding, and 8) telling your story. Steps one and two consisted of a literature search to examine the extent of the problem regarding the affordability of, access to, and waste produced by medications in the U.S. healthcare system. The first two steps are addressed in the introduction and “Scope of the Problem” portion of the results section. While assembling evidence, alternative solutions related to step three surfaced that either concurrently exist in the U.S. or have been postulated, which are covered in the “Policy Alternatives” portion of the interpretation. Criteria selected for step four largely pertained to the main problems discovered in step one: access, affordability and sustainability, and waste. The selected criteria assisted in step five’s projecting the outcomes of medication donation repositories and alternative solutions by looking at increased patient reach, money saved to both patients and the healthcare system, and reduced waste. Step five is addressed in both the results section for repository programs and “Policy Alternatives” in the interpretation section for other solutions. Trade-offs of step six were accounted for by creating a list of possible benefits and shortcomings of medication donation repository programs in regards to other solutions, which is found in the “Implications of Medication Donation Repositories” portion of the interpretation section. Finally, the discussion and conclusion represent steps seven and eight of Bardach’s framework, which further outlines the benefits and shortcomings of proposed solutions.

Due to the economic and political ties healthcare has in the U.S., this study must consider, to an extent, the effect that current and future political climates may have on the impact of repository policies and programs. To assess any political considerations, this study also utilizes Beaufort Longest’s framework outlined in *Health Policymaking in the United States*. The “Implications of Medication Donation Repositories” subsection of the interpretation section

delves into the political considerations of repository programs. While increasing efficiency and reducing waste may not be a source of bipartisan discord, the undecided changes to the healthcare system can drastically determine the utility of repository programs. Furthermore, the political considerations presented in this study are of a speculative nature because of the uncertain future of healthcare coverage.

### *Literature Review Process*

Information related to the scope of this study was found via the Google search engine and PubMed, which is primarily controlled by the United States National Library of Medicine database. The following words and phrases used in various combinations led to the facts and results outlined in this policy analysis: medication donation repository, Georgia, Iowa, Kentucky, Wyoming, USA, unused medication, hospital, nursing home, drug disposal, drug waste, cost of medication, healthcare expenditures, insurance coverage, uninsured, medication recycling, economic impact, and financial burden of medications. Inclusion criteria for useful data included being published within the past ten years from a reputable source, which was limited to scholarly articles and reports. Information was also included from national and international organizations, such as the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Environmental Protection Agency, Kaiser Family Foundation, and World Health Organization. News articles were only utilized about Georgia's policy, as it is too new to have other impact studies or data. Information was excluded from the study if it pertained to data outside of the U.S.

### *Limitations*

Despite a thorough analysis of medication donation repository policies, this study had several limitations. The most prevalent limitation lies within the lack of evaluative information

that exists pertaining to repository programs. While many states have operational programs, the data assessing the impact of the programs is not always present. Combining the available data with the discrepancies among policies, it was not possible to consistently report on the same measures for each policy. The selection of state policies to analyze was largely decided based on which states had existing data, presenting potential selection bias. Additionally, any financial and conservatory effects of repository programs are conveyed by the operative program itself, which presents an opportunity for reporting bias. Furthermore, as this study partially serves as a call-to-action for Kentucky to implement operational programs, the effects of other states' policies were analyzed and are used as surrogates to show the potential—not definitive—impact of programs in Kentucky.

## RESULTS

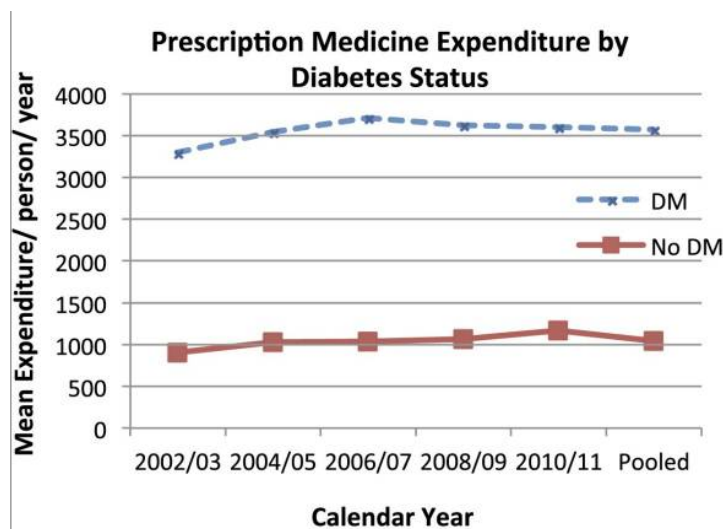
### *Scope of the Problem*

The ineffectiveness of the U.S. healthcare system cannot be boiled down to a single root cause. Due to differences in insurance coverage, patients face varying prices when paying for medications, if they can even afford their medications. In fact, individuals with multiple chronic conditions contribute over 80% of all prescription costs. Furthermore, of all individuals with multiple chronic conditions, 31.3% have private insurance, 25.5% have Medicaid, 87.4% have Medicare and Supplement, 80% have Medicare alone, 78% have Medicare and Medicaid, 58.6% have other government insurance, and 16% are uninsured.<sup>14</sup> Nationally speaking, 8.8% of U.S. citizens—28.5 million people—are uninsured.<sup>15</sup> Kentucky has a slightly lower uninsured rate of 7%.<sup>16</sup> In 2013, the average annual cost of prescription medications to individuals in the U.S. totaled \$858, which could vary drastically depending on insurance coverage and may be

infeasible for many.<sup>17</sup> Accordingly, a systematic review of various studies demonstrated that increased prescription drug insurance coverage simultaneously decreased the use of other healthcare resources while improving patient outcomes.<sup>18</sup>

Additionally, approximately 60% of U.S. adults currently suffer from at least one chronic disease, and about 40% of U.S. adults carry the diagnoses of multiple chronic conditions.<sup>19</sup> With the increase in chronic disease prevalence, the percentage of individuals taking prescription medication has subsequently increased. From 1999-2000 to 2011-2012, U.S. adults reporting the use of one prescription medication rose from 51% to 59%, and those reporting the use of five or more medications rose from 8% to 15%.<sup>20</sup> Not only does insurance coverage impact the out-of-pocket costs to patients, but costs also vary depending on the diagnosis and medications prescribed. As a leading driver of healthcare costs in the U.S., diabetes is one of the most common chronic conditions, affecting 29.1 million people.<sup>21,22</sup> This single condition increases prescription expenditure by approximately \$2,500 per person per year (Figure 2).<sup>23</sup>

Figure 2: Annual Cost of Prescription Medications Based on Diabetes Diagnosis



Source: Ozieh et. al., 2015.



Along with the role insurance coverage, increased incidence of disease, and growing treatment options have in expenditures, waste also largely contributes to the inefficiency of healthcare. Estimates reveal that ten million prescriptions dispensed in the U.S. could be recycled, potentially representing \$700 million in healthcare expenditure waste. Long-term healthcare facilities may waste as much as \$2 billion of unexpired medications every year, and all sources of unexpired medication waste may total as much as \$5 billion annually. Meanwhile, as many as 50 million individuals in the U.S. may be unable to afford needed medications.<sup>24</sup> Instead of wasting reusable medications that account for millions to billions in healthcare expenditures and leaving individuals undertreated and at-risk of further medical exacerbations, medication donation repositories help to bridge the gap of an unsustainable healthcare system.

#### *Policy Solution*

Over the past 22 years, states have developed policies pertaining to medication donation repositories. Since the inception of repository legislative action in 1997, 38 states enacted repository policies, and 21 states began operational repository programs.<sup>25</sup> Repository programs serve as a central hub for collecting donated, and previously dispensed, medications and redistributing it to qualified entities. If the program deems the donated medication unusable, then it is also responsible for properly disposing of it.<sup>26</sup> The specifics of each statewide policy differ among states, with some states allowing a wider scope of permissible donations than others. Main points of diversion among policies include who can donate medications, who can accept medications, who is eligible to receive donations, and what medications can be donated.

In regards to who can donate medications, some states require the donated medication come from other healthcare facilities, keeping the medications in a closed system to assure proper handling and storage techniques were used. Of these states, some policies narrow down

the types of healthcare facilities that can donate, such as only long-term care facilities. Alternatively, other states' policies use language that permit any individual with unused medications to donate. Qualified accepting facilities vary drastically: pharmacies that originally dispensed the medication, any healthcare facility complying with legal stipulations, charitable clinics, any hospital facility, board-approved drop-off sites, physician offices, and many other restricted examples. Eligible recipients of donated medication typically consist of needy residents, whether they are uninsured, underinsured, indigent, meet the income requirement, an eligible healthcare professional, or meet eligibility outlined by other laws. Though, some policies extend eligible recipient coverage to any resident of the state. Donated materials may be limited to solely cancer drugs or may encompass any prescription drug, over-the-counter drugs, and/or medical supplies. Finally, states may place certain restrictions within their policies—the most common being an exclusion on donating controlled substances.<sup>27</sup>

In Kentucky specifically, a policy pertaining to medication donation repositories was first enacted in 2005, and then repealed, reenacted, and renumbered in 2017.<sup>28</sup> Per the original policy, the Cabinet for Health and Family Services (CHFS) was responsible for establishing and maintaining repository programs (See Appendix A).<sup>29</sup> Since the CHFS oversees most human services and healthcare programs in Kentucky, like the Department of Medicaid and Department of Public Health, it was logical for repository programs to also fall under its regulation. However, the CHFS failed to promulgate administrative regulations, preventing the existence of operational programs. In 2017, the Board of Pharmacy assumed the role previously held by the CHFS. Much of the language remained the same after the policy was reenacted (See Appendix B).<sup>30</sup>

Currently, Kentucky’s policy extends to include any legend drug, which according to KRS 217.015 is “a drug defined by the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement ‘Caution: Federal law prohibits dispensing without prescription.’”<sup>31</sup> While the policy does not explicitly outline who can donate medications, KRS 315.454 states that the drug or supply be “in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened” and that it is neither adulterated nor misbranded “as determined by a pharmacist employed by, or under contract with, the health facility or pharmacy.”<sup>32</sup> Any health facility or pharmacy may act as a repository site, but involvement is strictly voluntary. Although a repository site may charge a set handling fee for dispensing the medication, the donated medication and supplies cannot be resold.<sup>33</sup> Furthermore, the donated medications cannot be controlled substances, and recipients must have a valid prescription for the medication.<sup>34</sup> Lastly, the repository facility determines its own eligibility criteria for recipients, which pertains to both individuals and healthcare facilities.<sup>35</sup>

In the 14 years of Kentucky’s existing policy, no repository programs have been established. To analyze the benefit of repository policies, the effects of existing programs in Georgia, Iowa, and Wyoming were examined. As policies vary state-to-state, the major points of each policy are outlined before delving into the number of redistributed prescriptions, number of people assisted, dollars saved to individuals and/or the healthcare system, and the amount of reduced waste. However, by looking at different policies in different states, many confounding variables present themselves: the ability of a repository program to get in contact with surplus materials, prescribing habits of surrounding providers, number of healthcare facilities in the area, and the constraints of the policy itself among others. To account for these differences, the impact

of SIRUM—Supporting Initiatives to Redistribute Unused Medicine, an intermediary organization connecting donors to repository programs—is also outlined.

### *Georgia*

In 1997, Georgia created the first state law allowing medication reuse in long-term health facilities. Over the next 20 years, the policy went through several amendments until it became what it is today under O.C.G.A. § 31-8-301 et.seq., which gives operational oversight to the Georgia Department of Public Health.<sup>36</sup> The most recent changes to the policy allow for over-the-counter medications to be donated to the program in addition to prescription medications, as long as the donated medications are in unopened packaging.<sup>37</sup> Due to the Department of Public Health's authority, more explicit eligibility criteria is outlined in Chapter 511-5-12 of the Rules of the Department of Public Health (See Appendix C).<sup>38</sup> Eligible donation repository sites consist of an array of healthcare facilities voluntarily participating in the program—pharmacies, clinics, hospitals, nursing homes and providers' offices—and non-healthcare related sites, like wholesalers, distributors, and other entities participating in the program. Georgia permits donations from any individual regardless of association with a healthcare facility, government entity, wholesaler, or manufacturer. Finally, any person in need of medication may be an eligible recipient, but priority consideration is given to the indigent, uninsured, underinsured, and those enrolled in public assistance health benefits program.<sup>39</sup>

In 2018, as many as 17% of Georgia's adults went without needed healthcare due to cost.<sup>40</sup> Currently, only three facilities in Georgia serve as donation sites: Good Pill Pharmacy, Charitable Returns, and Crossroads Pharmacy.<sup>41</sup> Of these entities, Good Pill Pharmacy is the first pharmacy to solely dispense surplus, donated medications. Most of the medications dispensed at Good Pill Pharmacy cost patients \$6 for a 90-day supply and are shipped for free to patients.

Since the pharmacy is fully stocked with surplus medication, the inventory is sporadic, and a real-time list of available medication is updated online.<sup>42</sup> In its first seven months of operation, Good Pill Pharmacy began providing medication to approximately 1,000 Georgians, with a monthly growth rate around 40%. Not only does Good Pill Pharmacy partner with SIRUM to acquire donations, but as of August 2018, local donations were garnered from around 20 nursing homes and five long-term care pharmacies. Well within its first year of operation, Good Pill Pharmacy estimates it dispensed more than \$2 million in medications to those in need.<sup>43</sup>

### *Iowa*

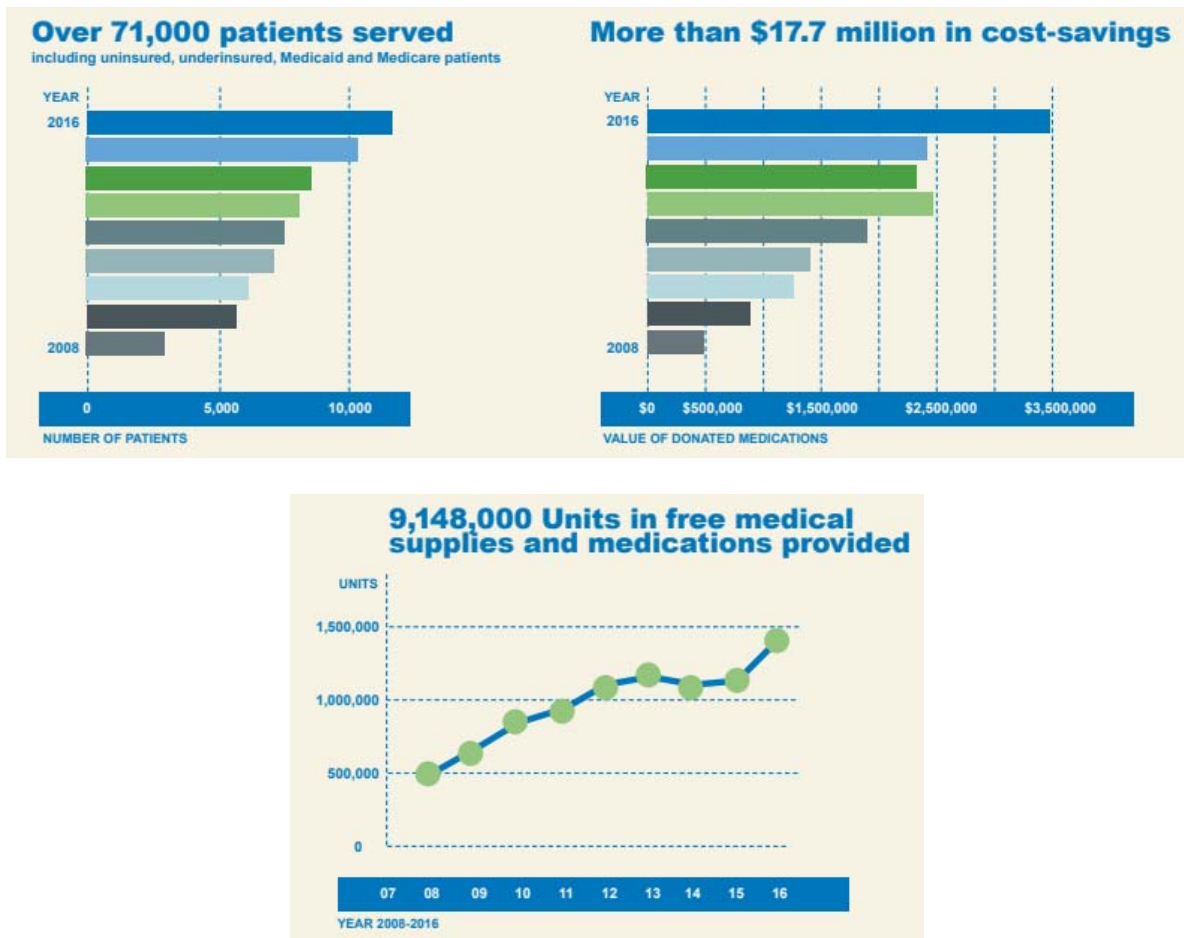
Similar to Kentucky, Iowa began legislative consideration of medication donation repositories in 2005.<sup>44</sup> Per Iowa Code § 135M, the Department of Public Health oversees the operations and regulates the specifics of repository programs via 641 IAC 109 (See Appendix D).<sup>45</sup> The Prescription Drug Donation Repository Program in Iowa accepts all types of non-controlled prescription medications, including cancer and anti-rejection medications and samples provided by manufacturers, and medical supplies. Any pharmacy or medical facility may act as a local repository: physician office, hospital, health clinic, and nursing facility. Additionally, any individual over the age of 18 may donate medications and supplies that a pharmacist inspects to ensure it is properly branded and unadulterated. Finally, recipients of donated materials must show proof of residence in Iowa and be either indigent, uninsured, or underinsured.<sup>46</sup>

Unlike Kentucky, a repository program began operating in Iowa in 2007, shortly after enacting the policy. The SafeNetRx program works with the Iowa Department of Public Health to provide medications and supplies to qualified individuals at the cost of a small handling fee if any fee at all.<sup>47</sup> SafeNetRx currently places receptacles at nine different cancer centers throughout Iowa to collect donated cancer medications. Furthermore, the program works with the

Iowa Safety Net Pharmacy, which ships affordable medications to individuals in need for free. Patients utilizing the Safety Net Pharmacy typically pay \$10 for a 30-day supply of their first prescription and \$3 for each subsequent prescription.<sup>48</sup>

After eight years of operation, SafeNetRx conducted a comprehensive performance report in 2016. In addition to the nine cancer centers who partner with the program to attain donations, more than 250 other healthcare centers act as repository sites for SafeNetRx. To justify the sustainability of the Iowa Drug Donation Repository, the program reports a return on investment of \$7 in free medications and supplies for every \$1 invested. From 2007 to 2016, SafeNetRx provided more than 71,000 Iowans with needed medications and medical supplies. Donations over the first nine years of operation total more than 9 million units in free medication and supplies to those in need, which corresponds to over \$17 million in cost-savings (Figure 3).<sup>49</sup> Whether patients meet the federal poverty level, are uninsured, or underinsured, SafeNetRx provides patient testimonials and financial data for each scenario. One beneficiary of Iowa's repository program has Medicare coverage and receives low-income subsidies, but none of the three medications she takes qualifies for any insurance coverage. Without insurance reimbursement, this patient faces a monthly cost over \$650 for her medications. Instead, the repository program provides the patient with these medications for a fraction of the price. Another beneficiary lost Medicaid coverage after receiving a \$1 raise and two consecutive \$250 bonuses. While she could reapply for Medicaid in three months, her raise and bonuses would be insufficient to cover her out-of-pocket prescription costs in the meantime. During her uninsured period, the repository program provided the patient with her prescriptions and saved her over \$1,700.<sup>50</sup>

Figure 3: Impact of SafeNetRx, 2008-2016



Source: SafeNetRx Performance Update, 2016.

### Wyoming

Wyoming’s drug donation repository history is akin to Iowa’s: legislative action occurring in 2005 that led to operational programs within the next few years.<sup>51</sup> The policy, WY Stat § 35-7-1601 et.seq., gives supervisory authority to the Wyoming Department of Health, which further describes the operational constraints of the state’s repository programs (See Appendix E).<sup>52</sup> Any prescription medication can be donated to the Wyoming Medication Donation Program (WMDP); however, all controlled substance medications are only to be collected for disposal, not redistribution. Healthcare facilities of all kinds may accept donations, ranging from hospitals to assisted living facilities. To maximize inventory and care to those in

need, any resident of Wyoming may donate medications regardless of their healthcare affiliations. Medications obtained at take-back events are also eligible for donation.<sup>53</sup> While the enacted policy does not explicitly outline eligible recipients of donated medications, the Wyoming Department of Health website states the program serves low-income, uninsured, and underinsured individuals.<sup>54</sup>

According to the most recent publishing, Wyoming offers 31 locations across the state where patients can donate their unused medications.<sup>55</sup> The WMDP has filled more than 150,000 prescriptions since its inception in 2007. These 150,000 prescriptions account for more than \$12.5 million, which, when divided evenly, translates to slightly over \$83 per prescription. In 2016 alone, over \$2.4 million worth of prescription medications were donated and redistributed to individuals in need.<sup>56</sup> Not only does the WMDP focus on the importance of donating unused medications, but it recognizes the environmental significance of proper disposal of unused medication. The 31 drug donation receptacles across the state also serve as disposal boxes for unacceptable donations, along with 34 other sites designated solely as disposal locations.<sup>57</sup> From mid-2008, the WMDP redistributed more than 88,000 pounds of donated medications and supplies that may have been improperly disposed of otherwise. Almost 20,000 pounds of unacceptable donated medications have been safely incinerated by the WMDP since 2009, reducing environmental waste and the potential for accidental poisonings and drug abuse.<sup>58</sup>

### *SIRUM*

Founded in California in 2011, SIRUM works to connect healthcare facilities with surplus medications to healthcare facilities in need of donated medications for patients unable to afford them. Operational sites associated with SIRUM exist in California, Colorado, Georgia, Iowa, and Ohio.<sup>59</sup> Additionally, SIRUM partners with the WMDP and accepts donations from



varying types of healthcare facilities, manufacturers, and wholesalers in other states.<sup>60</sup> In its eight years of operation, more than \$17 million in medications have been donated and dispensed to individuals in need, corresponding to a retail value greater than \$51 million and totaling more than 870,000 prescriptions.<sup>61</sup> Moreover, 150,000 patients unable to afford prescriptions benefit from SIRUM’s efforts. These donations prevent more than 240,000 pounds of waste that manufacturing new medications would create.<sup>62</sup> Figure 4 summarizes the main points of these states’ policies.

**Figure 4: Summary Table of States’ Repository Policies**

<b>State:</b>	<b>Who Can Accept:</b>	<b>Who Can Donate:</b>	<b>Who Is Eligible:</b>	<b>What Can Be Donated:</b>
Georgia	Various healthcare facilities, entities involved in the distribution process, and facilities choosing to participate in repository programs	Any individual or entity in lawful possession of donated materials	Primarily indigent individuals and then others in need of medication given that inventory is sufficient	Prescription and over-the-counter medications, excluding controlled substances
Iowa	Medical facilities (clinics, physician offices, hospitals) and pharmacies	Individuals 18 years of age and older in legal possession of medications	Indigent individuals	Prescription drugs, excluding controlled substances
Kentucky	Health facilities and pharmacies	<i>Not explicitly stated</i>	Specific eligibility criteria to be determined, prioritizing the uninsured and indigent	Legend drugs <sup>Y</sup> and supplies needed to administer them, excluding controlled substances
Wyoming	Healthcare facilities, pharmacies, take back events, and donation sites overseen by the WDH	Any individual or entity	Residents of Wyoming with limited resources	Prescription drugs
* <i>Indigent refers to those who are uninsured, underinsured, enrolled in a public assistance health benefits program, or meet income eligibility</i>				
Y Legend drugs are defined by the FDA as drugs that require a label stating "Caution: Federal law prohibits dispensing without prescription"				

## INTERPRETATION

### *Policy Alternatives*

With states considering repository programs for well over the past ten years, the inefficiencies plaguing the U.S. pharmaceutical healthcare industry are not newly realized.

Therefore, several other policies function to correct the imbalances of the healthcare system. One

of the most widespread and utilized programs is authorized by 21 CFR 1317, which deals with the disposal of unwanted, and perhaps expired, medications. Individuals needing to discard prescriptions may seek out various options: take-back events, mail-back programs, and collection receptacles placed at participating locations. Facilities authorized to act as collection sites include community pharmacies, hospitals and clinics with on-site pharmacies, manufacturers, distributors, reverse distributors, and narcotic treatment programs.<sup>63</sup>

Unlike repository programs, drugs brought to take-back events, mailed to registered locations, or left at receptacles are destroyed, not reused. Annually, the Drug Enforcement Administration (DEA) assigns at least one calendar day to be the National Prescription Drug Take-Back Day. These events also provide an opportunity to educate individuals about potential medication abuse and associated harms.<sup>64</sup> From 2010 to October 2018, the DEA and its partners safely disposed of almost ten million pounds of prescription medications at take-back events.<sup>65</sup> In Kentucky, more than 135,000 pounds of medication have been collected at take-back events alone since 2011. Apart from take-back events, Kentucky law enforcement and local government agencies offer 198 collection receptacles in 116 counties across the state.<sup>66</sup> Forty-one of these sites are associated with Operation UNITE, a non-profit organization in Southeastern Kentucky working to mitigate substance abuse.<sup>67</sup> Over the past seven years, Operation UNITE drop boxes have sequestered over 27,000 pounds of medications—3,700 pounds of which were obtained from the October 2018 Take-Back Day alone.<sup>68</sup> While this solution addresses issues of environmental contamination, waste, and potential misuse of medications, it fails to address the barriers blocking access to pharmaceutical care.

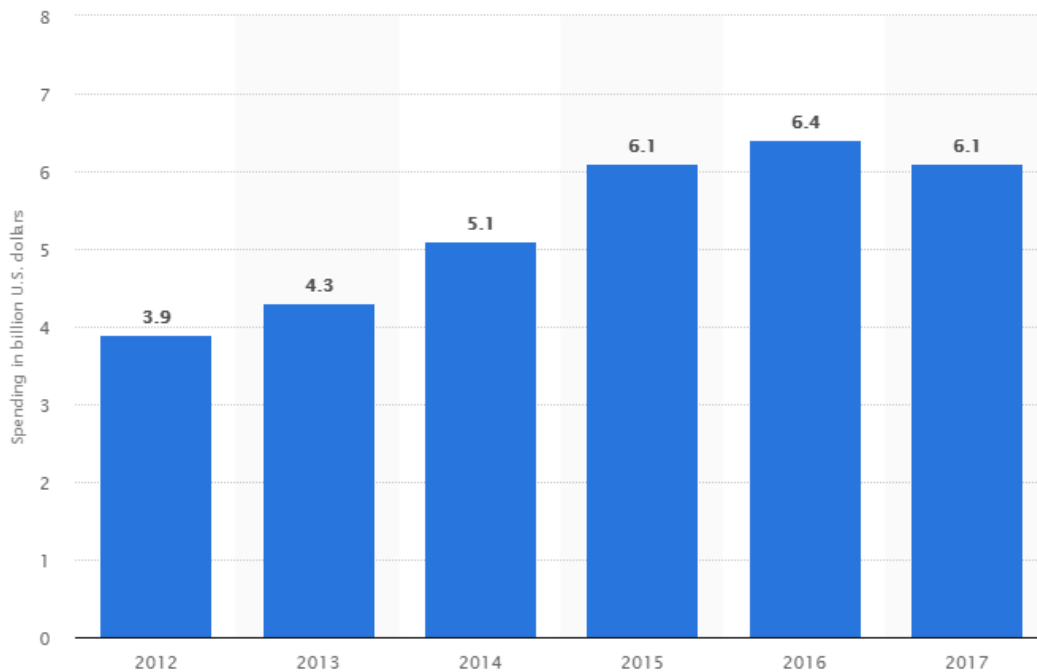
Alternatively, medication assistance programs alleviate the financial barriers that impede pharmaceutical care. Many medication assistance programs are offered by pharmaceutical

companies, and enrollment in these programs allows patients to receive needed medications at no or a very low cost. Although each program is unique, most require enrollees to provide in-depth medical and financial information, like disease states, medications, income statements, and any health insurance information. Furthermore, healthcare professionals typically have to attest for each patient trying to enroll because the medications will be sent to the professional for distribution to the patient.<sup>69</sup> A study out of Washington looked at the utilization rate of hospitals and emergency departments before and after patients enrolled in the Spokane Prescription Assistance Network program. Enrollment in this program correlated with a 51% decrease in emergency department and hospital utilization rate. Patient prescription coordinators connect patients in need with prescriptions they can afford, which further enables patients and the healthcare system to save money on unnecessary hospital and emergency department visits.<sup>70</sup> To quantify the direct savings medication assistance programs produce, a retrospective study at two community health centers found the average prescription cost to be \$0.11, saving patients an average of \$617.36.<sup>71</sup> Once again, these programs only focus on one part of the problem by correcting the inaccessibility of medication without tackling the issue of waste.

Simultaneously, the ability of pharmaceutical companies to provide medication at a very reduced or free price brings another solution into play: more stringent regulations on pharmaceutical industry pricing and spending. Companies spend ten years to get one drug on the market, possibly making the cost of medications seem more reasonable. Direct expenses, like salaries, clinical trials, labs, and manufacturing costs, make up \$1.4 billion. Capital costs, or the money companies estimate they forego by pursuing an unproven drug, account for \$1.2 billion. Regardless of the breakdown, the research and development cost behind one new medication is approximately \$2.6 billion. Meanwhile, pharmaceutical companies annually spend \$24 billion in

marketing costs to healthcare professionals alone.<sup>72</sup> An additional \$6.1 billion was allocated to direct-to-consumer advertising in 2017 (Figure 5).<sup>73</sup>

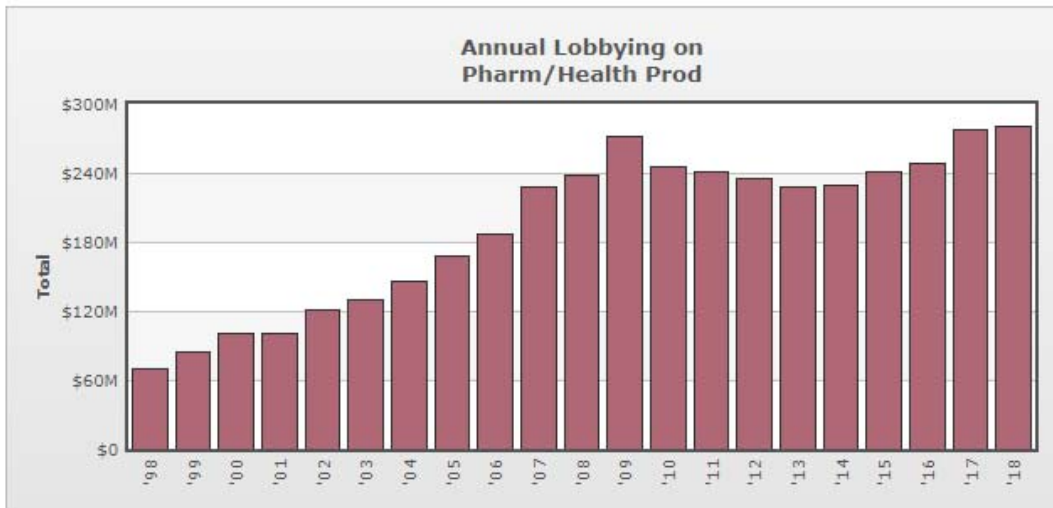
Figure 5: Direct-to-Consumer Spending of the U.S. Pharmaceutical Industry, 2012-2017



Source: Statista, 2018.

Significant spending by the pharmaceutical industry is also tied up in politics. As a whole, the pharmaceutical industry donated over \$41 million to political campaigns in 2018. The majority of donations usually go to Republicans, like in 2018, when 52% of contributions were to Republicans, and Democrats received the remaining 48%.<sup>74</sup> Annual lobbying expenses have grown significantly over the past 20 years, from \$69.1 million in 1998 to \$280.31 million in 2018 (Figure 6).<sup>75</sup> Ultimately, however, regulating drug prices only creates more affordable products, and price controls would likely remain insufficient for some. Regulating pharmaceutical pricing is one piece of the puzzle in correcting the inefficiencies of the U.S. healthcare system, but political affiliations pose a monumental barrier in implementing these regulations.

Figure 6: Annual Lobbying Expenses for Pharmaceutical and Health Products Industry



Source: Center for Responsive Politics, 2018.

### *Implications of Medication Donation Repositories*

Political climates also play a role in the efficacy and impact of medication donation repositories. The underlying principles of repository programs—to reduce waste in the healthcare system while increasing access to treatment—likely reap bipartisan approval, given that they are cost-effective. Therefore, the existence of repository programs is not largely threatened by changes in controlling political parties. Conversely, the utility of repository programs may drastically change depending on government actions pertaining to healthcare policy changes and spending. President Trump’s 2020 budget proposal suggests increasing healthcare spending for veterans, enforcing price transparency for prescription drug prices, decreasing funding for the Department of Health and Human Services, and revamping Medicare and Medicaid, which would result in budget cuts.<sup>76,77</sup> However, a budget proposal is indefinite, and the true effects of funding changes cannot be extrapolated accurately. Meanwhile, in late February 2019, House Democrats proposed a Medicare for All bill, expanding the demographic covered and replacing Medicaid. This bill recreates the U.S. healthcare system as a federally-funded entity while

providing insurance to all citizens.<sup>78</sup> Overall, politics play a significant role in the utility of repository programs.

Like any intervention, the benefits must be weighed against the costs. To continue operating repository programs, they must prove to be cost-effective, especially to comply with reducing healthcare expenditure waste. Most of the programs discussed in this paper have pharmacies that strictly dispense donated medications. Operating pharmacies incur many different expenses: the cost of the physical facility and utilities; salaries of employees; equipment, like computers, software, refrigerators, shelving, printers, and paper; materials needed for dispensing medications, like vials, bottles, and blister packs. If these pharmacies only distribute donated medication and only charge a handling fee in some cases, then the revenue generated to sustain itself is much lower than that of a traditional community pharmacy.

The Texas Department of State Health Services issued a request for information regarding drug donation programs. A nonprofit organization associated with drug donation programs responded with funding estimates broken down by year. For the first year, the program would likely require \$750,000, which would then decrease to \$500,000, \$300,000, and \$150,000 for each additional year of operation. By year five, the program should be self-sustaining from its own revenues. Furthermore, significant reductions in expenses are possible if programs exist as multistate centralized repositories. Both the size of the repository facility and the number of employees needed depend on the potential population served. While the size of the facility may vary drastically from a few hundred square feet to several thousand square feet, three is the lowest number of employees necessary for operations: a pharmacist, technician, and staff member to manage partnerships. Other suggestions for creating revenue include charging

recipients a handling or administrative fee and charging donors a fee that they likely incur at a higher rate for disposing of unused medications.<sup>79</sup>

Alternatively, if the repository program operates under an existing and traditional pharmacy, costs may be sustained due to an increased workload. Technicians must spend more time sorting, preparing, and dispensing medications, and pharmacists must take time to confirm that the medication is safe to be redistributed. Also, if donated medications prove unacceptable for distribution, the accepting facility must pay the price for disposing of the medications as no reimbursement codes exist for donated medications. While most programs likely work diligently to connect patients to needed medications, the inconsistency in the inventory of repository programs increases the likelihood of patients going without medications and experiencing discontinuity of care. At the same time it should be noted that repository programs were never designed to be long-term solutions for patients.

Additional concerns surround the legitimacy of donated medications being unadulterated. Restricting donations from healthcare sources alone better ensures the appropriate handling and storage of drugs, but definitive practices cannot be guaranteed upon disbursement. Although policies prohibit legal action against parties affiliated with repository programs in regard to harm, healthcare professionals may remain hesitant to risk their license by recommending or assisting in repository programs. Lastly, awareness of repository programs poses a barrier in their potential impact. To connect patients in need with medications, various entities and individuals—healthcare professionals, homeless shelters, insurance companies, government offices, health departments, and more—must be aware of existing programs and advocate for their use.

## DISCUSSION

Overall, inefficiencies plaguing the U.S. healthcare system are multifaceted and require multiple interventions for complete resolution. Excessive physical and financial waste and inaccessibility of needed medications comprise two major inefficiencies of the system. The purpose of this study was to evaluate the impact of one solution, medication donation repository programs. Through the analysis of multiple operating repository programs, data revealed these programs prevent hundreds of thousands of pounds in pharmaceutical waste, dispense millions of dollars in medication that would otherwise go unused, provide medications to tens to hundreds of thousands of individuals in need, and save patients hundreds to thousands of dollars in prescription medication costs annually. However, many expenses follow the implementation of a repository program, perhaps negating its cost-saving effects. Unfortunately, the true financial impact of repository programs cannot be assessed as the down-stream effects of improved access to medication and continuity of care are unable to be definitively deduced.

Other solutions vary both in their impacts and feasibilities. Drug disposal programs and DEA take-back events greatly reduce the physical waste and environmental pollution produced by consumer disposal practices but fail to address financial waste and inaccessibility of care. Moreover, these interventions are well-established and practical in their implementation. Conversely, medication assistance programs offer affordable care options to those in need without tackling the issue of waste, and the lack of clarity and consistency among programs inhibits their utility. Least feasible of solutions is the restructuring of the U.S. healthcare system by political intervention. Although this solution would largely tackle the issue of inaccessibility, it could potentially touch on the aspect of waste depending on the depth of the restructuring and restrictions placed on the pharmaceutical industry.



## CONCLUSION

Ultimately, medication donation repository programs provide feasible solutions to waste and lack of access to care—two major public health concerns. Additionally, barriers preventing implementation in Kentucky were eliminated with the 2017 reenactment giving regulatory authority to the Board of Pharmacy, making repository programs even more feasible solutions. Still, repository programs represent a downstream intervention. In other words, they treat the symptoms of the problem without correcting the problem. Considering the time, money, and hesitations associated with implementing and using repository programs, more evaluations and data must be compiled regarding the potential impact of the programs. In the meantime, the efforts of repository programs are insufficient and, therefore, need to be paired with other interventions until a permanent solution is reached. A major barrier to alleviating these issues is a lack of knowledge about available resources. Healthcare and public health professionals must act as conduits of information to connect patients and entities to resources, whether for the purposes of donating excess medication or receiving needed treatment. As a country, the U.S. must do more to protect our land, natural resources, and the health of our people.

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## **APPENDIX A: Kentucky Drug Repository Policy, 2005**

### **194A.450 Definitions for KRS 194A.450 to 194A.458.**

For the purposes of KRS 194A.450 to 194A.458:

- 1) "Controlled substance" has the same meaning as in KRS 218A.010;
- 2) "Dispense" has the same meaning as in KRS 217.015;
- 3) "Health care provider" has the same meaning as in KRS 304.17A-005;
- 4) "Health facility" has the same meaning as in KRS 216B.015;
- 5) "Legend drug" has the same meaning as in KRS 217.015;
- 6) "Pharmacist" has the same meaning as in KRS 315.010; and
- 7) "Prescription drug" has the same meaning as in KRS 315.010.

### **194A.452 Legend Drug Repository Program to be established -- Purpose -- Permitted donations -- Voluntary participation -- Handling fee -- Distribution.**

- (1) The Cabinet for Health and Family Services shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the cabinet. The repository program shall not accept any controlled substance.
- (2) Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requirements specified by the cabinet by an administrative regulation promulgated by the cabinet.
- (3) The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program established under this section, except that the fee shall not exceed the amount established by an administrative regulation promulgated by the cabinet.
- (4) A health facility or pharmacy that receives a donated legend drug under this section may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program created under this section.
- (5) Nothing in this section or KRS 194A.454 shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.

### **194A.454 Requirements for accepting and dispensing legend drug or administration supplies.**

- (1) A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in KRS 194A.452 only if the following requirements are met:
  - (a) The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;
  - (b) The legend drug is not classified as a controlled substance;
  - (c) The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the health

facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug or supplies are dispensed; and

(d) The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.

(2) No legend drug or supplies needed to administer a legend drug that are donated for use under this section may be resold.

**194A.456 Immunity from civil liability -- Exceptions.**

(1) Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under KRS 194A.452, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(2) Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under KRS 194A.450 to 194A.458, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.

**194A.458 Required administrative regulations.**

The Cabinet for Health and Family Services shall promulgate administrative regulations to establish:

(1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under KRS 194A.452 and 194A.454, including all of the following:

(a) Eligibility criteria for health facilities;

(b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;

(c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and

(d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under KRS 194A.452 and 194A.454;

(3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;

- (4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;
- (5) Necessary forms for administration of the legend drug repository program;
- (6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;
- (7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and
- (8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.

## **APPENDIX B: Kentucky Drug Repository Policy, 2017**

### **315.450 Definitions for KRS 315.450 to 315.460.**

For the purposes of KRS 315.450 to 315.460:

- 1) "Controlled substance" has the same meaning as in KRS 218A.010;
- 2) "Dispense" has the same meaning as in KRS 217.015;
- 3) "Health care provider" has the same meaning as in KRS 304.17A-005;
- 4) "Health facility" has the same meaning as in KRS 216B.015;
- 5) "Legend drug" has the same meaning as in KRS 217.015;
- 6) "Pharmacist" has the same meaning as in KRS 315.010; and
- 7) "Prescription drug" has the same meaning as in KRS 315.010.

### **315.452 Legend Drug Repository Program to be established -- Purpose -- Permitted donations -- Voluntary participation -- Handling fee -- Distribution.**

(1) The board shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the board. The repository program shall not accept any controlled substance.

(2) Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requirements specified by the board by an administrative regulation promulgated by the board.

(3) The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program established under this section, except that the fee shall not exceed the amount established by an administrative regulation promulgated by the board.

(4) A health facility or pharmacy that receives a donated legend drug under this section may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program created under this section.

(5) Nothing in this section or KRS 315.454 shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.

### **315.454 Requirements for accepting and dispensing legend drug or administration supplies.**

(1) A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in KRS 315.452 only if the following requirements are met:

- (a) The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;
- (b) The legend drug is not classified as a controlled substance;
- (c) The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the health

facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug or supplies are dispensed; and

(d) The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.

(2) No legend drug or supplies needed to administer a legend drug that are donated for use under this section may be resold.

### **315.456 Immunity from civil liability -- Exceptions.**

(1) Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under KRS 315.452, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(2) Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under KRS 315.450 to 315.460, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.

### **315.458 Required administrative regulations.**

The board shall promulgate administrative regulations to establish:

(1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under KRS 315.452 and 315.454, including all of the following:

(a) Eligibility criteria for health facilities;

(b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;

(c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and

(c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under KRS 315.452 and 315.454;

(3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;

(4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;

(5) Necessary forms for administration of the legend drug repository program;

(6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;

(7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and

(8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.

**315.460 Restriction on acceptance or distribution of certain drugs.**

Drugs that shall only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements shall not be accepted or distributed under the provisions of the program.



## **APPENDIX C: Georgia Donated Drug Repository Policy**

### **Subject 511-5-12 DONATED DRUG REPOSITORY PROGRAM**

#### Rule 511-5-12-.01 Definitions

As used in this Chapter, the term:

- 1) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 CFR Part 1308.
- 2) "Donor" shall mean any person, including an individual member of the public, or any entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation centers, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor shall also mean government agencies and entities that are federally authorized to possess drugs including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, and prisons.
- 3) "Drugs" means both prescription and non-prescription ("over-the-counter") drugs.
- 4) "Eligible patient" means an indigent person; provided, however, that if the recipient's supply of donated drugs exceed the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.
- 5) "Eligible recipient" means a pharmacy, wholesaler, reverse distributor, hospital, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or private office of a healthcare professional which has been authorized by the Office of Pharmacy of the Department of Public Health as provided in DPH Rule 511-5-12-.04.
- 6) "Healthcare facility" means a facility licensed by the Georgia Department of Community Health in accordance with Title 31, Chapter 7 as a:
  - a. Nursing home;
  - b. Personal care home;
  - c. Assisted living community;
  - d. Residential care facility for the elderly;
  - e. Hospice;
  - f. Hospital;
  - g. Home health agency; or
  - h. A similar entity licensed in the state in which it is located.
- 7) "Health care professional" means a person who is licensed by the State of Georgia to practice as a:
  - a. Physician;
  - b. Registered nurse or licensed practical nurse;
  - c. Physician assistant;
  - d. Dentist or dental hygienist;
  - e. Optometrist; or
  - f. Pharmacist
- 8) "Indigent patient" means a patient whose income is at or below the income eligibility requirements of the Georgia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.
- 9) "Program" means the donated drug repository program established by this Department pursuant to Code Section 31-8-301.
- 10) "Transaction date" means the date on which ownership of the drugs is transferred between two participants of the program as established by contract or other arrangement. If no such contract or

arrangement exists, the transaction date shall be the date the drug was accepted into inventory by the recipient.

#### Rule 511-5-12-.02 Authority and waivers

- 1) A donor or eligible recipient may request a waiver or variance from the Department with regard to any regulation related to this program in accordance with DPH Rule 511-1-1-.05. Notwithstanding DPH Rule 511-1-1-.05(2)(a), a donor or eligible recipient may request a waiver or variance from any provision of Title 31, Chapter 8, Article 10, upon a showing that such action would be in the interest of public health and safety.
- 2) Pursuant to Code Section 31-8-304, this Department and its rules have sole regulatory authority over the program. Notwithstanding any other administrative regulation, including but not limited to Ga. R. & Regs.
  - a. 480-10-.17, 480-24-.05 (2)(b), and 480-24-.06, a person or entity may dispose of an eligible drug by donating it to an eligible recipient in accordance with the rules of this program.
  - b. 480-10-.21 and 480-16-.08, an eligible recipient including but not limited to a pharmacy may receive drugs from a donor as defined in 511-5-12-.01 (2) in accordance with the rules of this program.
  - c. 480-7-.03 (7)(e)(1), an eligible recipient may accept donated drugs that are in tamper-evident packaging in accordance with DPH Rule 511-5-12-.03(1)(b), including but not limited to drugs that have a tamper-evident seal on either their immediate, outer, secondary, or shipping container.
  - d. 480-7.02(1)(d), an eligible recipient, including but not limited to a pharmacy, may receive, accept, replenish, repackage, and store donated drug samples in accordance with the rules of this program.

#### Rule 511-5-12-.03 Eligible drugs

- 1) Drugs shall only be dispensed pursuant to the program if:
  - a. For prescription drugs, they do not expire before the completion of the medication by the eligible patient based on the prescribing health care professional's directions for use and, for over-the-counter drugs, they do not expire before use by the eligible patient based on the directions for use on the manufacturer's label; and
  - b. The drugs were donated in unopened tamper-evident packaging as defined by United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including but not limited to unopened unit-dose and multiple-dose packaging.
- 2) The following drugs shall not be donated to the program:
  - a. Controlled substances;
  - b. Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 if inventory transfer is prohibited by such strategy; or
  - c. Drugs that there is reason to believe are adulterated pursuant to Code Section 26-3-7.

#### Rule 511-5-12-.04 Eligible recipients

- 1) A pharmacy, hospital, wholesaler, reverse distributor, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or healthcare professional that is otherwise legally authorized to possess prescription drugs may become an eligible recipient for a period of one year by giving written notice to the Office of Pharmacy of the Department of Public Health. That notice shall serve as authority for the recipient to participate in the program for a period of one year, unless revoked by the Department. An eligible recipient may renew its authority by sending written notice in subsequent years.

- 2) The Department of Public Health shall publish on its website the list of authorized recipients.
- 3) An entity which chooses to participate in the program shall comply with this Chapter, and shall make all records available for audit by this Department within five business days. Failure to comply with any provision of this Chapter or statutes governing prescription drugs may result in revocation of authority to participate in the program. Such revocation shall be provided as a written notice to the recipient and shall include the specific requirements that were violated and the corrective actions necessary for the recipient to reinstate its authority to participate in the program.

Rule 511-5-12-.05 Receipt, storage, and handling of donated drugs by an eligible recipient

- 1) A donor may donate drugs to an eligible recipient.
- 2) An eligible recipient may receive, accept, donate, dispose, replenish, and store drugs that were either donated or repackaged as provided in paragraph (6) of this Rule.
- 3) Prior to the first donation from a new donor, a recipient must verify and record the following:
  - a. The donor meets the definition provided in DPH Rule 511-5-12-.01(2);
  - b. The donor's name, address, phone number, and license number if applicable;
  - c. The donor will only make donations of drugs in accordance with Code Section 31-8-301;
  - d. The donor will insure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by enclosing in the drug's packaging a USP-recognized method by which the eligible recipient can easily detect improper storage or temperature variations; and
  - e. If applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the eligible recipient.
- 4) An eligible recipient must store and maintain donated drugs in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) standards.
- 5) A participating eligible recipient shall keep all donated drugs physically or electronically separated from other inventory. Donated inventory may be used to replenish purchased inventory with the same drug name and strength that was previously dispensed or administered to an eligible patient. Replenishment shall follow applicable federal 340B statute and Health Resources and Services Administration guidance.
- 6) Drugs may be repackaged as necessary for storage, replenishment, dispensing, administration, or further donation. Repackaged drugs shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a health care professional authorized to dispense.
- 7) All donations received but not yet accepted into inventory shall be kept in a separate designated area.
- 8) Prior to or upon accepting a donation into inventory, an eligible recipient shall maintain a written or electronic inventory of the donation, including:
  - a. The transaction date;
  - b. The name, strength, and quantity of each accepted drug; and
  - c. The name, address and phone number of the donor.
- 9) No record of a donation other than as described in paragraph (8) of this Rule shall be required.
- 10) All records required by this Chapter shall be retained in physical or electronic format, on or off the recipient's premise for a period of six years.
- 11) A donor or eligible recipient may contract with one another or a third-party to create and/or maintain records on each other's behalf.
- 12) An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to this Chapter if it allows for such information to be readily retrievable. Upon audit by the Department of Public Health the identifier on requested

records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

- 13) Pursuant to Code Section 26-4-115(b)(3)(A), a drug wholesaler, distributor, supplier, or outsourcing facility registered as provided in Chapter 13 of Title 16 or in Code Section 26-4-115(a), except reverse distributors, shall comply with the requirements of 21 U.S.C. Sections 360ee e-1 through 360eee-4 relating to drug supply chain security. If a donation's transaction history is required, the record of transaction history shall begin with the donor of the drugs, shall include all prior donations, and, if the drug was previously dispensed, shall not include drug information that is not required to be on the drug's label pursuant to Code Section 26-4-80(k)(1).

#### Rule 511-5-12-.06 Dispensing and distribution of donated drugs

- 1) An eligible recipient may only dispense or administer prescription drugs if otherwise permitted by law.
- 2) Donation and the brokering or other facilitation of a donation of a drug pursuant to this program shall not be considered wholesale distribution and shall not require licensure as a wholesaler.
- 3) Donated prescription drugs may only be dispensed to eligible patients pursuant to a valid prescription drug order in accordance with Title 26, Chapter 4. That patient shall be provided with appropriate counseling on the use of the prescription drug, including any potential side effects and the fact that the drug was donated.
- 4) An eligible recipient may further donate unused prescription drugs to or receive unused prescription drugs from another eligible recipient in the program when one has the need for a drug and another has it available. An inventory of such donations shall be created in accordance with DPH Rule 511-5-12-.05(8) unless both eligible recipients are under common ownership or common control.
- 5) An eligible recipient shall dispose of any drug that does not meet all of the requirements of Code Section 31-8-301 in one of the following ways:
  - a. Return the drug to the donor;
  - b. Destroy the drug through an incinerator licensed with the Environmental Protection Agency or other lawful method; or
  - c. Transfer the drug to a reverse distributor.
- 6) All such donated drugs to be disposed shall be quarantined in a separately designated area
- 7) An eligible recipient shall maintain a written or electronic record of disposal, including:
  - a. The disposal method as described in paragraph (5) of this Rule;
  - b. The date of disposal or quarantine; and
  - c. The name, strength, and quantity of each drug disposed.
- 8) No record of disposal other than as described in paragraph (7) of this Rule shall be required.
- 9) Donated drugs shall not be resold and shall be considered nonsaleable; provided, however, that reimbursement for any handling fee authorized pursuant to this Chapter shall not constitute reselling.
- 10) Before dispensing a donated drug, an eligible recipient shall inspect the drug to determine that it has not adulterated. The drug must be repackaged into a new container or all previous patient information and pharmacy labeling must be redacted or removed from the donated container.
- 11) Dispensed drugs must clearly indicate the final dispenser's information and current patient information, and shall be properly labeled in accordance with the regulations of the Georgia Board of Pharmacy.
- 12) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic records in accordance with Georgia law and the regulations of the Board of Pharmacy. If also providing patients with purchased drugs, the eligible recipient shall also note, either on the face of a written prescription or in the electronic record of prescription, that a donated drug was dispensed to the patient.

- 13) An expiration date is required on all donated drugs dispensed. The expiration date shall be brought forward to the filled prescription. If multiple packaged donated drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date shall be used for the dispensed prescription.
- 14) Dispensed drugs shall not expire before the use by the patient based on the prescribing practitioner's directions for use or, for over-the-counter medicine not dispensed pursuant to a prescription, the directions for use on the package's label.
- 15) Dispensed drugs subject to a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 shall be managed and dispensed according to the requirements of that strategy.

Rule 511-5-12-.07 Handling fees

- 1) An eligible recipient may not charge or collect any fees from an eligible patient for drugs dispensed pursuant to this program; provided, however that an eligible recipient may charge a handling fee for each donated drug that is dispensed. Such a handling fee shall not exceed the reasonable costs of participating in the program including but not limited to the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies and equipment.
- 2) Nothing in the preceding paragraph shall limit an eligible recipient from charging fees, including but not limited to a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefit managers, and other entities.

## **APPENDIX D: Iowa Prescription Drug Donation Repository Policy**

### **CHAPTER 109**

#### **PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM**

##### **641—109.1(135M) Definitions. For purposes of this chapter, the following definitions apply:**

- 1) “Centralized repository” means a distributor approved by the contractor and licensed pursuant to 657 IAC Chapter 17 that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, rules and regulations.
- 2) “Contractor” means the third party approved by the department to implement and administer the prescription drug donation repository program.
- 3) “Controlled substance” means the same as defined in Iowa Code section 124.101.
- 4) “Department” means the Iowa department of public health.
- 5) “Indigent” means a person with an income that is below 200 percent of the federal poverty level (FPL) as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.
- 6) “Local repository” means a pharmacy or medical facility that elects to accept and dispense donated drugs and that meets the eligibility requirements of rule 641—109.3(135M).
- 7) “Medical facility” means any of the following:
  - a. A physician’s office.
  - b. A hospital.
  - c. A health clinic.
  - d. A nonprofit health clinic, including a federally qualified health center as defined in 42 U.S.C. § 1396d(1)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(1)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.
  - e. A free clinic as defined in Iowa Code section 135.24.
  - f. A charitable organization as defined in Iowa Code section 135.24.
  - g. A nursing facility as defined in Iowa Code section 135C.1.
- 8) “NDC #” means the unique national drug code number that identifies a specific approved drug.
- 9) “Nurse practitioner” means an advanced registered nurse practitioner as defined in 655 IAC Chapter 7.
- 10) “Pharmacist” means a pharmacist as defined in Iowa Code section 155A.3.
- 11) “Pharmacy” means a pharmacy as defined in Iowa Code section 155A.3.
- 12) “Physician” means an individual licensed under Iowa Code chapter 148, 150, or 150A.
- 13) “Prescription drug” means the same as defined in Iowa Code section 155A.3 and includes cancer drugs and antirejection drugs, but does not include controlled substances.
- 14) “Supplies” means the supplies necessary to administer the prescription drugs donated.
- 15) “USP” means United States Pharmacopoeia.

##### **641—109.2(135M) Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with Iowa Code chapter 135M relative to the following:**

- 1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies.
- 2) Eligibility criteria for individuals to receive donated prescription drugs and supplies.

##### **641—109.3(135M) Eligibility criteria for program participation by medical facilities and pharmacies.**

**109.3(1)** To be eligible for participation in the prescription drug donation repository program, a medical facility or pharmacy shall be in compliance with all applicable federal and state laws,

including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, nonrestricted, state-issued licenses or registrations in good standing.

**109.3(2)** Participation in the prescription drug donation repository program is voluntary.

**109.3(3)** A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the program's Web page, written notification to the centralized repository of all of the following:

- a. The name, street address, and telephone number of the pharmacy or medical facility, and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency.
- b. The name and telephone number of the responsible pharmacist, physician or nurse practitioner who is employed by or under contract with the pharmacy or medical facility.
- c. A statement, signed and dated by the responsible pharmacist, physician or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

**109.3(4)** Withdrawal from participation. A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the centralized repository on a form prescribed by the department and available on the program's Web page.

#### **641—109.4(135M) Standards and procedures for accepting donated prescription drugs and supplies.**

**109.4(1)** Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to the centralized repository or a local repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a drug repository.

**109.4(2)** No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia shall be donated or accepted as part of the prescription drug donation repository program. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

**109.4(3)** Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

**109.4(4)** The centralized repository or a local repository may accept a prescription drug only if all of the following requirements are met:

- a. The drug is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed;
- b. The drug has been stored according to manufacturer or USP storage requirements;
- c. The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall, pursuant to Iowa board of pharmacy rules;
- d. The drug has an expiration date that is more than six months after the date that the drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;
- e. The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

- f. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and
- g. All drugs shall be inventoried at the centralized repository or a local repository. The inventory shall include the name of the drug, strength of the drug, quantity of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

**109.4(5)** A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

- a. The supplies are in their original, unopened, sealed packaging;
- b. The supplies are not adulterated or misbranded; and
- c. All supplies shall be inventoried at the centralized repository or a local repository. The inventory shall include a description of the supplies and the date donated. Such inventory shall be recorded on a form provided by the prescription drug donation repository program.

**109.4(6)** Drugs and supplies may be donated on the premises of a participating centralized repository or a local repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.

**641—109.5(135M) Standards and procedures for inspecting and storing donated prescription drugs and supplies.**

**109.5(1)** A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs. If a local repository receives drugs and supplies from the centralized repository, the local repository does not need to reinspect the drugs and supplies.

**109.5(2)** The centralized repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

**109.5(3)** Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to board of pharmacy rule 657—8.8(124,155A). The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.5(4).

**109.5(4)** Controlled substances shall not be accepted for donation.

- a. Controlled substances submitted for donation shall be documented and returned immediately to the donor or the donor's representative that provided the drugs.
- b. In the event controlled substances enter the centralized repository or a local repository and it is not possible or practicable to return the controlled substances to the donor or the donor's representative due to inability to identify the donor or the donor's representative or due to refusal by the donor or the donor's representative to receive them, abandoned controlled substances shall be documented and destroyed beyond reclamation pursuant to rules of the board of pharmacy examiners. Such destruction shall be performed by a



pharmacist or other person that has authority to dispense controlled substances and shall be witnessed by another responsible adult employee of the repository.

**109.5(5)** If a repository receives a recall notification, the repository shall perform a uniform destruction of all of the recalled prescription drugs in the repository and complete the destruction information form for all donated drugs destroyed. If a recalled drug has been dispensed, the repository shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

**641—109.6(135M) Standards and procedures for dispensing donated prescription drugs and supplies.**

**109.6(1)** Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist, physician or nurse practitioner.

**109.6(2)** A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

- a. First, to an indigent individual;
- b. Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed; and
- c. Third, to any other individual if an indigent or uninsured individual is unavailable.

**109.6(3)** A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

**109.6(4)** The centralized repository and a local repository shall remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs or supplies.

**109.6(5)** The centralized repository and a local repository shall be responsible for drug recalls and shall have an established mechanism to notify recipients in the event of a drug recall.

**109.6(6)** Prescription drugs or supplies donated under this program shall not be resold.

**109.6(7)** The participating centralized repository and local repositories may distribute drugs and supplies donated under this program to other participating repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form.

**641—109.7(135M) Eligibility criteria for individuals to receive donated prescription drugs and supplies.**

**109.7(1)** An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Iowa and meets one or both of the following criteria:

- a. Is indigent;
- b. Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

**109.7(2)** The local repository shall collect from each individual recipient a signed intake collection form provided by the department or its contractor.

- a. The intake collection form shall attest that:
  1. The individual is a resident of the state of Iowa;
  2. The individual's income does not exceed 200 percent of the FPL;
  3. The individual is uninsured and has no prescription coverage or is underinsured and has no prescription coverage;
  4. The individual acknowledges that the drugs may have been donated; and
  5. The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act.

- b. The intake collection form will include an identification card to be given to the recipient for continued use for one year.

**109.7(3)** The identification card is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

**109.7(4)** A summary of data taken from the intake collection form is to be sent via regular mail, E-mail or facsimile to the centralized repository for data collection.

**641—109.8(135M) Forms and record keeping.**

**109.8(1)** The following forms developed for the administration of this program shall be utilized by participants of the program and are available on the program's Web page on the department's Web site, [www.idph.state.ia.us](http://www.idph.state.ia.us).

- a. Prescription drug donation repository program notice of participation or withdrawal.
- b. Prescription drug donation repository program donation, transfer, inventory or destruction record.
- c. A record of medications dispensed.

**109.8(2)** The prescription drug donation repository program recipient data collection form and identification card are given to the recipient by the local repository, and the completed data collection form is collected from the recipient by the local repository.

**109.8(3)** Record-keeping requirements.

- a. All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five years by participating pharmacies and medical facilities.
- b. Records required as part of this program shall be maintained pursuant to all current applicable practice acts.
- c. Data collected by the prescription drug donation repository program from all participating repositories shall be submitted quarterly or upon request to the centralized repository. The data will consist of the information collected in accordance with 641—109.8(135M), Forms and record keeping.
- d. The centralized repository and the contractor shall submit reports to the department as required by the contract or upon request of the department.

**641—109.9(135M) Handling fee.** A repository may charge the recipient of a donated drug a handling fee, not to exceed a maximum of 200 percent of the Medicaid professional dispensing fee as established by rule of the department of human services, to cover stocking and dispensing costs. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

**641—109.10(135M) List of drugs and supplies program will accept.** All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these rules may be accepted for donation under the prescription drug donation repository program.

**641—109.11(135M) Exemption from disciplinary action, civil liability and criminal prosecution.**

**109.11(1)** A drug manufacturer acting reasonably and in good faith is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this chapter, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

**109.11(2)** Except as provided in subrule 109.11(3), a person other than a drug manufacturer subject to subrule 109.11(1), acting reasonably and in good faith, is immune from civil liability

and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this chapter and shall be exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter.

**109.11(3)** The immunity and exemption provided in subrule 109.11(2) does not extend to any of the following:

- a. The donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter by a person if the person's acts or omissions are not performed reasonably and in good faith.
- b. Acts or omissions outside the scope of the program.

**641—109.12 and 109.13 Reserved.**

**641—109.14(135M) Prescription drug donation repository in disaster emergencies.** The following are the requirements for the department to receive and distribute prescription drugs and supplies in preparation for a disaster emergency proclaimed by the governor or in preparation for a public health disaster.

**109.14(1)** The department may receive prescription drugs and supplies directly from the prescription drug donation repository contractor and dispense prescription drugs and supplies through licensed personnel during or in preparation for a disaster emergency proclaimed by the governor pursuant to Iowa Code section 29C.6 or during or in preparation for a public health disaster as defined in 2009 Iowa Code Supplement section 135.140, subsection 6.

**109.14(2)** The department may receive and distribute prescription drugs and supplies as defined in Iowa Code section 135.142 to any Iowan who has been a victim of a disaster emergency proclaimed by the governor.

[ARC 8983B, IAB 8/11/10, effective 9/15/10]

These rules are intended to implement Iowa Code chapter 135M

## **APPENDIX E: Wyoming Drug Donation Policy**

### **ARTICLE 16 - DRUG DONATION PROGRAM**

#### **Wyoming Statutes as of September 2009**

##### **35-7-1601. Short title.**

This act shall be known and may be cited as the "Drug Donation Program Act".

##### **35-7-1602. Definitions.**

- a. For purposes of this act:
  1. "Prescription drug" means a pharmaceutical drug which is required by any applicable federal or state law to be dispensed only pursuant to a health care provider's prescription; and
  2. "Health care facility" means as defined in W.S. 35-2-901(a)(x) and that is additionally authorized to maintain an inventory of pharmaceutical drugs for dispensing to the facility's patients or residents.

##### **35-7-1603. Drug donation, redispensing and disposal program established; minimum requirements.**

- a. The department shall establish pursuant to its rules and regulations a voluntary drug donation and disposal program as provided in this section.
- b. The drug donation and redispensing program shall have the following features:
  1. Any person or entity, including but not limited to a drug manufacturer, physician or health care facility, may donate drugs to the drug donation program;
  2. Drugs may be donated at a donation site maintained by the department, a take back event approved by the United States drug enforcement agency or at a physician's office, a pharmacy or a health care facility that elects to participate in the program and meets criteria established by the department;
  3. Drugs shall be redispensed under the drug donation program only if they are in their original, unopened, sealed packaging or, if the outside packaging is opened, the contents are single unit doses that are individually contained in unopened, tamper evident packaging;
  4. A drug shall not be redispensed within two (2) months of its expiration date or if the drug appears to be adulterated or misbranded in any way;
  5. Drugs in the donation program may be dispensed under the Medical Assistance and Services Act;
  6. Drugs shall be delivered either to the department's central collection facility, a take back event approved by the United States drug enforcement agency or one (1) of its regional collection facilities;
  7. Drugs available for redispensing shall be inventoried and posted on a list of drugs available for redispensing on the department's internet website.
- c. The drug drop off and disposal program shall have the following features:
  1. Drop off locations shall be located with donation sites as provided in paragraph (b)(ii) of this section or local law enforcement agencies approved by the United States drug enforcement agency to the extent necessary under federal law;
  2. Procedures shall be maintained for the documentation of all collected unused medication;
  3. Procedures shall be maintained for the environmentally safe disposal of unused medications;
  4. The department shall provide for public education of potential participating consumers about the availability of the drug disposal program and proper and effective disposal of unused medications;

5. The department shall cooperate with law enforcement agencies to the extent required for the collection under law enforcement supervision or the secure collection, storage, transport and destruction of controlled substances.

**35-7-1604. Program participants.**

- a. A physician, pharmacy or health care facility that accepts donated drugs under the drug donation program shall comply with all applicable provisions of state and federal law relating to the storage, distribution and dispensing of such drugs and shall inspect all donated drugs prior to dispensing to determine if they appear to be adulterated or misbranded in any way.
- b. Donated drugs may be distributed to another participating physician, pharmacy or health care facility for dispensing.
- c. Donated drugs shall only be dispensed to a patient pursuant to prescription as required by law.
- d. A physician, pharmacy or health care facility may charge a handling fee for distributing or dispensing drugs under the drug donation program, as established by department rules and regulations, but shall not otherwise resell or charge for donated drugs.

**35-7-1605. Participant immunity.**

- a. In the absence of bad faith, any person who participates in donating, accepting, distributing or dispensing drugs under this act shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss. No person, in the absence of bad faith, shall be liable for the bad faith of another relating to the provisions of this act.
- b. The immunity provided by this section shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributor or dispenser that would have existed but for the donation.

**35-7-1606. Rules and regulations; agency cooperation.**

- a. The department, in cooperation with the Wyoming board of pharmacy, shall promulgate rules and regulations implementing the drug donation program established by this act. Initial rules shall be promulgated within ninety (90) days after the effective date of this act and shall include:
  1. Eligibility criteria and other standards and procedures for participating physicians and health care facilities;
  2. Necessary forms for administration of the drug donation program, including forms for persons donating, accepting, distributing or dispensing drugs under the program;
  3. Maximum handling fees;
  4. Categories of drugs that the program will and will not accept.

## **BIOGRAPHICAL SKETCH**

This capstone project was completed by Lacey Brinegar. She earned her Bachelor of Science degree from Indiana State University in Terre Haute, Indiana in May of 2015 with a major in chemistry and minor in Spanish. During her undergraduate career, she became involved in Timmy Global Health, a non-profit organization headquartered in Indianapolis. Through this organization, she developed an interest in and passion for both pharmacy and public health. In May 2019, she graduated with her Master of Public Health degree from the University of Kentucky with a Population Health and Policy Management concentration, as well as a Doctor of Pharmacy degree. Lacey will be pursuing a pharmacy residency at Blake Medical Center in Bradenton, Florida with long-term aspirations of integrating public health practices into her pharmacy career. Lacey can be contacted via email at [laceybrinegar@gmail.com](mailto:laceybrinegar@gmail.com).