



Missouri Product Stewardship Council
Pharmaceuticals Stewardship Summit
Briefing Summary - DRAFT
October 6, 2020

Purpose of this Briefing Summary

The intent of this briefing document is to prepare participants for the October 14-15, 2020 multi-stakeholder meeting on pharmaceuticals stewardship, convened by the Missouri Product Stewardship Council (MO PSC) and the Product Stewardship Institute (PSI). The problem, focus, goals, barriers, and solutions outlined below are a starting point presented to stimulate discussion prior to, and at, the meeting. The aim of the meeting is to define the problems; identify opportunities, barriers, and potential solutions; and develop specific next steps that stakeholders can take collaboratively toward pharmaceuticals stewardship implementation in Missouri.

Problem

More people die each year from overdoses involving prescription painkillers than from heroin and cocaine combined, which has prompted federal and state governments to declare this growing public health threat an epidemic.^{i,ii} In 2018, there were 1,132 opioid overdose deaths in Missouri – 1 in every 56 deaths in the state.ⁱⁱⁱ This rate represents an increase from 1 in 65 deaths in 2017.^{iv} While deaths involving heroin and prescription opioids have remained steady in recent years at approximately 4 per year,^v deaths involving synthetic opioids (mainly fentanyl) have increased sharply. Between 2012 and 2017, deaths from synthetic opioids increased 11 times, from 56 deaths in 2012 to 618 in 2017.^{vi}

It is estimated that one in every three people statewide has been impacted by the opioid crisis either directly or through a loved one or family member.^{vii} This is due in part to drugs improperly stored in the home or disposed of in the trash, which can lead to accidental poisoning and abuse; almost half of all opioid misuse starts with a friend or family member's prescription.^{viii} Also, when medicines are disposed of in the garbage, poured down the drain, or flushed, they can contaminate our drinking water sources and harm the aquatic environment.

As the opioid epidemic has grown, so has the use of medical sharps (including syringes, pen needles, and lancets^{ix}). Sharps enable consumers to self-inject medications. Advances in needle design have made them extremely small, sharp, and relatively pain-free to enable administering life-saving medications quickly and easily, without the need to travel to a hospital or doctor's office. More than 7.8 billion injections are administered annually outside of healthcare facilities in the U.S.^x Seven percent of needles are flushed, and an estimated 3 billion sharps enter the U.S. municipal solid waste stream each

year as trash.^{xi} These disposal methods create the potential for injury or the transmission of infectious diseases to homeowners, sanitation workers, sewage treatment plant operators, and waste management personnel at transfer stations, recycling facilities, and disposal facilities. They are a potential hazard for hospitality workers when left at restaurants, hotels, airports, and other public locations. They also create costly maintenance problems when loose sharps become jammed in equipment, posing a risk to anyone trying to remove them, or to the equipment itself.^{xii}

Focus

Our meeting will focus on pharmaceutical waste—unwanted or expired drugs—generated in a residential setting. This waste is exempt from the U.S. Resource Conservation and Recovery Act (RCRA) “hazardous” designation.^{xiii} It should also be noted that household generated waste is exempt from disposal requirements of the Missouri Solid Waste Management Law. The priority drugs targeted for safe disposal are controlled substances—medications like Vicodin, Oxycontin, Percocet, Adderall, and Ritalin – that are addictive and most likely to be abused. The meeting will also include some discussion of medical sharps stewardship.

Goals

The goal of this meeting is to build support for a statewide pharmaceuticals stewardship program by finding consensus among stakeholders on a plan for Missouri. Specifically, the aims are to define the problems caused by leftover drugs; identify opportunities, barriers, and potential solutions for implementing a pharmaceuticals stewardship program; and develop specific next steps that stakeholders can take collaboratively toward implementing a statewide pharmaceuticals stewardship program that establishes the following:

- a safe and convenient pharmaceuticals disposal system for consumers;
- a clear/consistent message on safe pharmaceuticals disposal options for the public, including instructions and locations;
- a statewide strategy to disseminate this unified educational message, avoiding a patchwork of state and local programs; and
- a sustainable funding mechanism for this system that decreases or eliminates the cost to governments and taxpayers.

Participants and guest speakers will discuss these items:

- Current leftover drugs management practices, costs, and needs;
- A brief history of drug take-back programs and pharmaceuticals stewardship in the U.S.;
- Existing pharmaceuticals stewardship programs; and
- Steps to establishing a statewide drug take-back program.

Barriers

The barriers facing safe drug disposal include the following:

1. Lack of understanding and education about safe disposal;
2. Lack of convenient disposal options for the public; and
3. Lack of sustainable funding

A 2017 [report by the U.S. Government Accountability Office](#)^{xiv} found that only 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so, but this varied by state. Missouri had the second-lowest rate in the country, at 0.22%.^{xv} Overall, the most notable barrier to participation cited in this study was cost. However, another challenge was that in 2017 and prior, Missouri had no provisions to allow retail pharmacies to install collection bins for prescription drugs. In 2018, Missouri passed SB 826, which changed the rules for drug drop-offs; under this act, “a Drug Enforcement Agency-authorized collector, in accordance with federal regulations, may accept unused controlled substances from ultimate consumers, even if the authorized collector did not originally dispense the drug.”^{xvi} Since 2018, Missouri has allowed medication collection boxes to be placed in pharmacies, hospitals, long-term care facilities, and locations registered as narcotic treatment programs.^{xvii}

Mixed messaging from take-back programs regarding certain types of medication is another barrier in Missouri, with most programs run independently at the local level. For instance, some programs accept liquid medications for drop-off, while others do not. The federal Drug Enforcement Administration (DEA) does not accept liquid medications for its twice-yearly national take-back day.

It should also be noted that Missouri has no regulations that prohibit the disposal of pharmaceuticals in Missouri landfills.^{xviii} Since take-back programs are monitored and regulated by the DEA, state-level departments such as the Department of Natural Resources and the Department of Health and Senior Services do not have regulatory authority over medication take-backs.^{xix} Instead, state-level departments may only support and encourage best practices for stewardship and disposal of pharmaceuticals.

Solutions

Drug “take-back programs” are the preferred solution to the problems associated with improper drug storage and disposal. They can take three forms: an on-site collection receptacle (i.e., “kiosk” or “drop box”), a mail-back program with prepaid envelopes, or collection events. Drug take-back programs have been endorsed by most state environmental and public health agencies across the nation, and federal agencies including the Office of National Drug Control Policy, DEA, Food and Drug Administration, the Environmental Protection Agency, and [Missouri’s Attorney General, Eric Schmitt](#). Other supporters include law enforcement officials that see the effects of drug abuse on their communities and volunteer to host drug take-back programs; waste management companies responsible for transportation and destruction of collected materials; wastewater treatment plant operators concerned about effluents; the medical community that prescribes drugs and treats addiction; and activists concerned about impacts of pharmaceuticals on the environment, water quality, and public health.

Due in part to advocacy efforts of the [Product Stewardship Institute](#) (PSI) and others to amend the federal [Controlled Substances Act](#) and strengthen DEA’s final [rule](#) in 2014, there are now convenient options for collecting controlled substances. The new rule opened the door for retail pharmacies, which are most convenient for residents, and other entities to collect all unwanted medications. Today in Missouri, many law enforcement offices host a drug take-back program, as do several pharmacies. However, the cost of collecting and safely disposing of these drugs remains a considerable barrier, and these costs fall mainly on local and state government agencies.

Not only is it important for collection of unwanted pharmaceuticals to be convenient for the public, but it is also important that the public is made aware of take-back locations and best practices. PSI has worked with the Missouri Product Stewardship Council (MO PSC) and the Missouri Spatial Data Information Service to map existing locations serving as pharmaceutical take-back sites. A [draft of this map](#) is available online.

PSI and the MO PSC have also completed an [Analysis of Education Messaging on Pharmaceutical Disposal in Missouri](#). Upon analyzing 26 different websites and resources from MO organizations, governments, and agencies on the topic of pharmaceuticals, it was found that there is consensus that bringing medication to a take-back location or event is the preferred method of disposal. However, many organizations and local governments also suggested disposal in household trash as a legal, but less desirable, alternative. There was also mixed opinion about whether flushing is an acceptable last resort option for disposal. In order to have a clear, useful message for residents, educational resources on pharmaceutical disposal should ideally be consistent and employ the same type of language.

Costs

PSI estimates that the cost of a long-term, on-site drug take-back program starts at just \$2 per pound of drugs collected and safely destroyed. Collection receptacles (or “kiosks”) cost only \$2 - \$5 per pound, including liners and a vendor to transport and destroy collected materials. Pre-paid mail-back envelopes cost about four times more, at \$7 - \$22 per pound.^{xx} In-home disposal products claim to render drugs safe to dispose in household trash, but there is [little independent data available to support](#) this and they are the most expensive option, costing about \$130 per pound: 25 to 75 times more than kiosks.^{xxi} The [DEA sponsors twice-yearly events nationwide](#), and some state governments fund drug take-back programs paid for by their taxpayers, but the long-term prospect of government funding is tenuous.

Funding Drug Take-back Programs

There are [three basic drug take-back program types](#) that have developed in the U.S.: a voluntary industry program, a government/taxpayer-funded program, and a mandatory industry-funded program. We will discuss each of these options during our meeting.

Voluntary Program. Increasingly, large chain pharmacies— and even some smaller independent pharmacies— have set up collections and paid for the collection and disposal costs voluntarily; others have collected medications only if disposal costs are covered; and others are still exploring the implications of collecting under the DEA rule. Note: Drug companies do not promote drug take-back programs unless they are required by legislation or if others fund them.

Government Program. Some states and local governments have allocated funding to collect and dispose of pharmaceuticals.

Mandatory program. An increasing number of governments support having drug companies finance and manage drug take-back programs. Pharmaceuticals is the only product category for which manufacturer-funded take-back legislation has been proposed at the local, state, and federal levels. These EPR laws, sometimes referred to as “drug stewardship” laws, require that drug companies establish and fund take-back programs for unwanted medicine. Three pharmaceutical industry associations unsuccessfully challenged the first such law, Alameda County's Safe Drug Disposal Ordinance, ultimately filing a petition with the US Supreme Court in December 2014. The Supreme Court ruled on May 26, 2015 not to hear the industry’s petition.

Many drug companies that sell product in the U.S. participate in manufacturer-funded drug take-back programs in Canada, Europe, Australia, South America, and other countries. In the U.S., 29 pharmaceutical EPR laws have passed in 6 states (OR, MA, VT, WA, NY, and CA) and 23 local governments (in CA, WA, IL, and NY), 10 of which were combined EPR laws establishing separate programs for both pharmaceuticals and medical sharps. Many other states and counties are poised to do the same.

An increasing number of governments support producer-financed and managed sharps take-back programs as well, most in conjunction with medication take-back programs. There are currently 10 extended producer responsibility (EPR) laws for sharps stewardship in the U.S. – one at the state level, five at the county level, and four at the city level—all passed in California.

Additional Information:

The Missouri PSC: <https://missouripsc.org/initiatives/pharmaceuticals/>

PSI's website: <http://www.productstewardship.us/Pharmaceuticals.>

Stericycle: <https://www.stericycleenvironmental.com/category/pharmaceutical-takeback/>

Covanta: <https://www.covanta.com/In-Your-Community/Community-Engagement/Prescription-for-Safety>

MO DNR Proper Disposal of Household Pharmaceutical Waste: <https://dnr.mo.gov/pubs/pub2291.pdf>

ⁱ Kommenda, N., Durkin, E., Smears, L., 2018. Why are more Americans than ever dying from drug overdoses? The Guardian, 29 November 2018. Retrieved on Jan. 10, 2019 from www.theguardian.com/us-news/ng-interactive/2018/nov/29/usdrug-overdose-epidemic-opioids-crisis-getting-worse.

ⁱⁱ Centers for Disease Control and Prevention (CDC), 2012. CDC grand rounds: prescription drug overdoses - a U.S. epidemic, MMWR Morb Mortal Wkly Rep. 2012 Jan 13;61(1):10-3.

ⁱⁱⁱ Missouri Department of Health & Senior Services, 2020. Opioid Dashboard. Retrieved March 26 2020 from <https://health.mo.gov/data/opioids/>.

^{iv} *Ibid.*

^v National Institute on Drug Abuse, 2019. Missouri Opioid Summary. Retrieved 26 March 2020 from <https://www.drugabuse.gov/opioid-summaries-by-state/missouri-opioid-summary>.

^{vi} *Ibid.*

^{vii} State of Missouri, 2020. Time 2 Act Missouri. Retrieved 26 March 2020 from <https://time2actmissouri.com/>

^{viii} Center for Disease Control and Prevention (CDC), 2011. Policy Impact: Prescription Painkiller Overdoses. Retrieved 7 July 2013 from <http://www.cdc.gov/homeandrecreationalafety/rxbrief/>.

^{ix} A lancet is a surgical knife with a short, wide, pointed double-edged blade, used especially for making punctures and small incisions. It is widely used by diabetics to test blood.

^x Environmental Research & Education Foundation (EREF), Household Needles in Municipal Solid Waste (MWS) Report, 2018. <https://erefdn.org/product/household-needles-in-municipal-solid-waste-msw-report-pdf/>.

^{xi} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4414288/>.

^{xii} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4414288/>.

^{xiii} See the “household waste” exclusion at 40 CFR 261.4(b)(1) often referred to as the household hazardous waste exclusion.

^{xiv} United States Government Accountability Office (GAO), 2017. Report to Congressional Requesters: Preventing Drug Abuse. Retrieved 26 March 2020 from <https://www.gao.gov/assets/690/687719.pdf>.

^{xv} *Ibid.*

^{xvi} SB 826 – Modifies provisions relating to health care. 99th General Assembly, 2018. https://www.senate.mo.gov/18info/BTS_Web/Bill.aspx?SessionType=R&BillID=70365560

^{xvii} Bureau of Narcotics and Dangerous Drugs, 2019. Controlled Substance Guidelines for Missouri Pharmacies. Retrieved September 8 2020 from <https://health.mo.gov/safety/bnnd/doc/pharmaciesguidelines.doc>.

^{xviii} Mary Hopke, Missouri Department of Natural Resources. Personal Communication August 27, 2020.

^{xix} *Ibid.*

^{xx} Product Stewardship Institute, 2018. Drug Take-Back Saves Lives – and Money.

^{xxi} *Ibid.*