PERMANENT MEDICATION DISPOSAL BOX IMPLEMENTATION

REDUCE THE RISK OF UNUSED MEDICATIONS IN OUR COMMUNITY THROUGH INSTALLATION OF A SUSTAINABLE DISPOSAL OPTION.

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THE OPIOID EPIDEMIC

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Each day 136 Americans die from opioid overdose.[1] A recent systematic literature review found that up to 77% of patients who filled their post-surgical opioid prescriptions stored them in unlocked areas and approximately 71% of dispensed pills went unused, concluding that an excessive amount of unused prescription opioids pose a threat to our community.[2]

Unused opioids are an opportunity for medication diversion, misuse, and overdose. Of the 12.5 million people (age 12 and up) surveyed in the 2015 National Survey on Drug Use and Health, 53.7% of those who used a prescription medication for non-medical purposes obtained the medication from a friend or relative. This finding demonstrates that unused prescription opioids are being diverted to others and used beyond the intended purpose.[3,4]

In addition to the societal cost of the opioid epidemic, in 2007 Michigan's combined cost of opioid-use disorders (OUD) and fatal opioid overdoses was $41,396.1 (million) while the per capita combined costs were $4,155.[3]

OPIOID MISUSE FAST FACTS

- 2/3 of teens who misuse opioids obtained them from family, friends, and acquaintances.[5]
- 1 in 4 teens will misuse a prescription drug at least once in their lifetime.[6]
- Leftover prescription opioids place older adults and seniors at risk of harmful drug interactions and side effects.[7]
- Up to 40% of prescription medications are left over in homes where the storage of these medications may not be secure, posing a risk for unintentional poisoning or diversion.[8]
- Individuals suffering from mental health issues may be susceptible to using opioids as a coping mechanism.[9]
- The top two pet toxins are commonly prescribed opioids and other human prescription medications respectively.[10]

INCREASED URGENCY: IMPACT OF THE COVID-19 PANDEMIC

IN MICHIGAN, **FATAL OVERDOSES WERE 15% HIGHER** DURING THE COVID-19 PANDEMIC COMPARED TO THE SAME PERIOD OF TIME PRE-PANDEMIC IN 2019.[4]

Prior to the COVID-19 pandemic, OUD treatment options were limited and the pandemic only further exacerbated challenges with access to treatment.

The pandemic also placed individuals in recovery at risk of relapse, as OUD, a chronic brain disorder, can manifest with "…a hypersensitivity to stress and a diminished capacity to experience normal levels of reward," contends Dr. John Kelly, professor of Psychiatry in Addiction Medicine at Harvard Medical School.[11]

The long-term impact of the COVID-19 pandemic on the opioid epidemic makes this fight even more urgent today. While turning the tide on the opioid epidemic requires a multidisciplinary approach from policy advisors, healthcare, and the public, the medical community must play a key part, given their role in opioid prescribing.

CURRENT OPIOID DISPOSAL OPTIONS

DEA-authorized opioid collectors are found in select law enforcement agencies, pharmacies, and organized community take-back events, yet many patients remain unaware of these available options within their communities or do not use them on a consistent basis.[3] Many disposal options may present challenges to convenient use.

TAKE-BACK EVENTS

- While bi-annual community take-back events are excellent options for medication disposal, they remain temporary solutions, which can inadvertently lead to stockpiling excess medications in anticipation of the event. Should the event be canceled (e.g., COVID) or an individual is unable to attend, the medications remain in households in larger quantities and available for diversion.
    - These community events have both financial and resource costs to ensure they are successful. Although nominal, there is a financial cost for promotional advertising as well as paying law enforcement salaries to both supervise the event and to transport the medications to DEA incineration sites. The DEA-mandated law enforcement support may be unavailable due to conflicting priorities or limited staffing. Lastly, volunteer hours for planning and hosting the events are critical to a successful community take-back event.

POLICE STATIONS

- Several police stations currently provide permanent medication disposal boxes. These may not be ideal for individuals who have had a previous negative encounter with law enforcement. This resistance may be exacerbated by stations that require that the individual's name appear on the prescription label or other rules which discourage anonymous disposal. Additionally, some police substations have instituted specific hours for disposal, which may also limit access.

HOME DISPOSAL

- Home disposal products present a convenient and environmentally considerate option.
- These products are becoming more readily available, however they can be difficult to get or costly.

ENVIRONMENTAL DISPOSAL

- Disposal of excess opioids by flushing unused medication down the toilet or disposing in the household trash is not recommended as a permanent solution.
    - Flushing opioids is not an environmentally safe option. While the FDA's list of flushable medications[13] does include opioids, this is due to the belief that in some situations, immediate removal of opioids can avert potential misuse or diversion.
    - Disposing of opioids in household trash can lead to accidental ingestion by pets or children and can be removed for misuse, as the medications remain intact and have not been neutralized.
        - Household trash turns environmentally toxic when opioids leak into the environment.

HEALTHCARE'S RESPONSIBILITY TO PREVENT OPIOID MISUSE

NORMALIZING MEDICATION DISPOSAL

Hospitals are uniquely poised to address the issue of safe and convenient opioid disposal. With the installation of permanent medication disposal boxes—ideally located in surgery clinics, ambulatory care centers, or on-site retail pharmacies—unused medications can be properly disposed of during routine or postoperative follow-up appointments.

A recent study found that 85% of patients would likely dispose of unused medications if the take-back box was conveniently located, while the number-one contributing factor to disposal was adopting a disposal routine.[15] This finding speaks to the importance of normalizing the practice of medication disposal and making it easy and convenient.

Clinicians can be instrumental to educating patients to dispose of unused opioids and incorporating disposal as part of follow-up care. While clinicians play a key role in patient education, encouragement, and adoption of the disposal process, institutional support is critical to the success of a disposal initiative.

DISPOSAL AS PREVENTION

The societal impact of the opioid epidemic can be seen throughout the community, and can have a profound effect on youth - with potentially lifelong trauma and generational substance misuse.[16] A recent study found that among those diagnosed with OUD, over 80% had experienced some form of an adverse childhood experience (ACE), with physical neglect or parents with substance use being the most reported.[17]

Providing a take-back box can remove unused opioids from the home to interrupt the potential early exposure and intergenerational aspect of substance misuse. Healthcare, and specifically surgery, is oftentimes the first introduction to opioid use, which may progress into misuse as a coping mechanism for youth struggling with ACEs and other mental health disorders.

FINANCIAL IMPACT

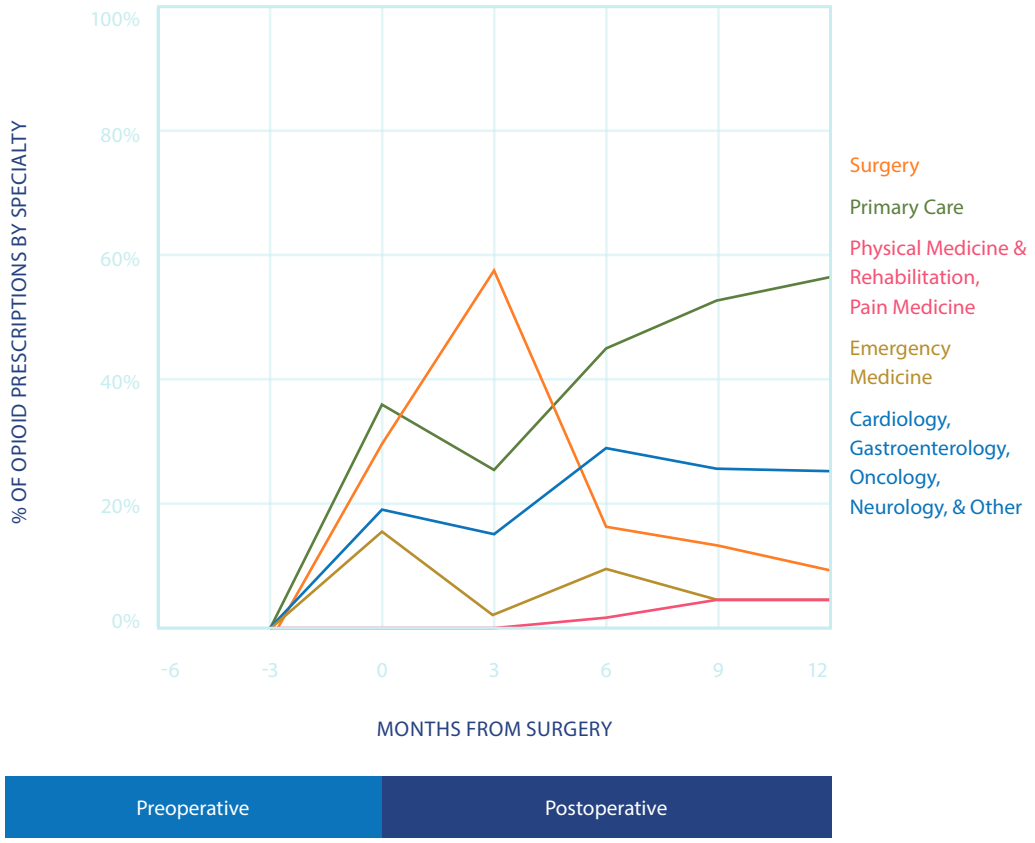
The epidemic's financial burden to the healthcare system is substantial. The evidence found that 6 to 10% of previously opioid-naive surgical patients developed new persistent opioid use (NPOU), or the continued use of opioids long after resolution of the surgical pain.[18] The risk of developing NPOU is a significant surgical complication fueled by an overabundance of prescribed opioid medications.[19] However, many surgeons may remain unaware of patients developing NPOU or OUD as the surgeon's episodic care likely ends long before these downstream disorders have manifested.

The opioid epidemic's financial burden to hospital systems can be seen in the following costs:

- In 2018 the total cost of OUD to the healthcare system was $89.1 billion.[21]
- Increased ED visits for fatal and non-fatal ODs resulted in costly hospital admissions.[22]
- The financial cost to hospitals for Neonatal Abstinence Syndrome (NAS) in 2016 was $572.7 million.[23]

HEALTHCARE'S RESPONSIBILITY TO PREVENT OPIOID MISUSE

POSTOPERATIVE OPIOID PRESCRIBING BY SPECIALTY



PRESCRIBERS BEYOND SURGERY

Surgery is not the only contributing factor to ongoing opioid prescribing.[20] While surgeons accounted for 69% of opioid prescribing in the initial months after surgery, their prescribing decreased to 11% at 9 months postoperatively, then other specialties continued opioid prescribing.[20]

Excessive prescribing resulting in unused opioids contributed to 2.4M cases of OUD. This does not include the thousands of other individuals not yet diagnosed, developing NPOU, or engaging in other risky drug use behaviors.[24, 25]

Implementation of a permanent take-back box is a complementary step to a larger opioid stewardship plan including patient counseling, education, and evidence-based prescribing recommendations.

DISPOSAL BOX IMPLEMENTATION

SUCCESSFUL IMPLEMENTATION OF A PERMANENT MEDICATION DISPOSAL BOX COMPONENTS:

- Understanding financing and developing a process.
- Establishing governance according to the Code of Federal Regulations.
- Spread awareness of the disposal box through employee and patient education.
- Demonstrate impact of the box through evaluation.

FINANCING

FINANCING

Funding a medication disposal box has a start up cost and an ongoing operational cost. Unique ways to financially support a take-back box initiative can be found by seeking grants through environmental groups or local or federal government agencies; accessing available hospital foundations that allocate funding for specific initiatives; or introducing a box as a pilot initiative.

Starting as a pilot may be a way to gauge the feasibility and acceptability of this initiative, increase buy-in, and perform continuous quality improvement checks prior to hardwiring the process. Consider potential partnerships with take-back box companies in your area, community coalitions, or grant organizations focused on prevention. These organizations may be willing to share the cost in return for co-branding or sharing in the pilot outcomes analysis.

The Affordable Care Act provision allows non-profit hospitals to accept tax-deductible charitable donations and receive federal, state, and local tax-exempt status in return for providing "community benefits."[26] These community benefits, determined by completing a community health needs assessment every three years, include input from the non-profit hospitals' communities and their public health officials.

Notably, many of Michigan hospitals' community health needs assessments cite the opioid epidemic as a critical issue in most communities. Providing a permanent take-back box as a community benefit can begin addressing the community's health needs specific to the opioid epidemic.

TIP: Check with your pharmacy reverse distribution vendor. If your hospital has a credit, it may be an option for financing the box and program.

FINANCING

INITIAL COSTS

One-time purchase of the take-back box and initial liners.

- Construction costs to secure the box (hospital-specific).
- Reinforcement, or placement of required security measures (e.g., locked area - doors, security gates, etc.).

  TIP: seek an already secured location.

- Additional hospital-mandated upgrades beyond Code of Federal Regulations (CFR) requirements (e.g., security cameras, panic buttons at clerical stations, etc.).
- There is no cost associated with modifying an existing DEA license.

Permanent Medication Disposal Box	Price
Stainless Steel Drug Take-back Box Per Unit (33 Gallon) with 4 Anchor Lag Bolts	$ 1,600.00
Return Liner*	$ 100.00
Regulatory and Compliance Fee Per Unit	$ 0.00
Custom Artwork/Powder Coating (OPTIONAL)	$ 350.00
Total (approximate) Cost Per Unit	$ 2,050.00
No additional fee for pickups *Additional Liner Kits purchased for $400.00/pack of 4 liners, or $100/per liner	

ONGOING COSTS:

- Continued supply of liners.
- Pickup of containers for incineration.
- Patient education brochures, cards, etc.

TIP: consider modifying pharmacy contract with current reverse distribution vendor and incorporating the pickup into their current cadence of pickups at no additional costs.

ESTABLISHING GOVERNANCE

It is important to have a clear understanding of how decisions related to take-back boxes will work. Experience shows that developing a committee can help ensure the success of this initiative.

SAMPLE COMMITTEE

- Program manager leads the team to successful launch by managing timeline; liaises between leadership and the committee and the Office of General Counsel, ensuring legal compliance.
- Pharmacy ensures compliance with pharmacy rules and regulations; liaises with current pharmacy reverse distributor.
- Security anticipates and advises on potentially adverse situations; addresses leadership security concerns; informs policy development.
- Nursing develops and disseminates patient education materials, processes, and patient scripting.
- Physician/Advance Practice Provider (APP) Champion supports, leads, and encourages disposal plans with all patients receiving opioid prescriptions.
- Facilities (Plant Operations) verifies specifications for permanently securing the box, camera, or panic button placement if hospital mandated. NOTE: CFR does not require cameras or panic buttons.
- Public Relations (Communications) as needed for external announcement of launch.

TIP: Check with your contracted vendor as some may allow the disposal of liquids if they are deposited in their originally prescribed container. This is important if your facility sees pediatric patients.

DECISIONS TO CONSIDER

- How to ensure federal regulation and institutional compliance.
- Insitutional protocol for implementation.
- Assigning team member roles and responsibilities.
- Timelines for implementation and supply orders.
- Exploring potential box site location per CFR requirements.
  - Regularly monitored by employees with direct line of sight.
  - Not located in the proximity of areas providing emergency or urgent care.
  - TIP: Physically visit the identified location prior to finalizing, to ensure an ideal take-back site.
- Obtaining approval from identified site's leadership for box placement.
- Type of available take-back box vendors and products, including style, material, logos, signage, availability, and cost.
- Purchasing box in collaboration with funders and hospital finance.

CODE OF FEDERAL REGULATIONS (CFR) REQUIREMENTS

Institutions desiring to be an authorized collector of controlled substances must comply with all federal regulations governing medication disposal. The items below are excerpted from the Title 21 of the Code of Federal Regulations (CFR). The registrant is ultimately responsible for ensuring adherence to all regulations, including registering each hospital and pharmacy within the system separately. In many institutions, this is held and managed by the Department of Pharmacy.

NOTE: This guide is not intended to replace a thorough review of the CFR.

SCAN TO VISIT CODE OF FEDERAL REGULATIONS WEBPAGE

CFR HIGHLIGHTS - CLICK TITLE TO VISIT SPECIFIC CFR POLICY

21 CFR §1317.40 Becoming an authorized collector

Eligible registrants must be registered with the DEA and, therefore, have authority to handle Schedule II controlled substances.

21 CFR §1301.51 Modification in registration

Institutions must modify their existing DEA registration to become an "authorized collector." This can be done online at https://www.deadiversion.usdoj.gov/.

21 CFR §1317.75 Collection receptacles must be:

- Securely fastened to a permanent structure.
- Locked and substantially constructed with a removable inner liner inside the permanent outer container.
- The outer container shall include a small opening such that only medications can be added. The opening must be lockable or otherwise inaccessible when an employee is not present to monitor the box .
- A sign noting acceptable items must be visibly displayed on the box. Only Schedule II–V controlled substances and non-controlled substances are permitted. No illicit drugs are permitted.

NOTE: MI requires all sites to have a controlled substance (CS) license, in addition to a DEA license.

21 CFR §1317.80 Collection receptacles at long-term care facilities

Long-term care facilities (LTCF) may have a take-back box located on the premises if partnered with an authorized retail pharmacy or hospital/clinic (with an on-site pharmacy) to install, manage, and maintain the receptacle. (see 21 CFR §1301.51)

- All previous design specifications apply (21 CFR §1317.75).
- Disposal of substances, on behalf of the LTCF current or previous residence, must occur: (§ 1317.80).
    - No longer than 3 business days after discontinuation of use by the resident (i.e., discontinued prescription; resident transfer or deceased).
- Installation and removal of the take-back box's inner liner:
    - Shall be performed by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the LTCF (e.g., a charge nurse or supervisor) or two employees of the authorized collector. (§ 1317.05)
    - Sealed inner liners may only be stored at the LTCF for up to 3 business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer.

EDUCATION

EMPLOYEE COMMUNICATION:

Share the news! Ensure institutional awareness by using established communication options such as staff huddles, emails, and newsletters. Be sure to include the location, hours, and accepted items.

NOTE: Display posters to remind staff to discuss medication disposal plans with patients.

PATIENT EDUCATION:

Healthcare providers play an integral role in patient pain management education. Disposal plans must be part of the conversation, normalizing prescription opioid disposal at patient care visits. Departments can collaborate on creating one unified message for patients on the why and where to dispose of unused opioids. An educated, well-informed patient will be more likely to adopt the disposal recommendations.

Review current processes for clinic appointment reminders and modify to incorporate patient reminders to bring in unused prescription opioids at the next scheduled clinic visit.

Consider placing patient disposal education stock cards at the discharge desk, on the box, or at the on-site retail pharmacy. On-site retail pharmacies may consider including disposal information with each filled opioid prescription, in addition to verbally reminding patients. Look for creative ways to disseminate this important information to patients, utilizing hospital resources. Many inpatient hospital rooms offer informational videos, which can be mandatory patient viewing. This is an excellent option for highlighting the importance of the opioid disposal initiative.

Scan the QR code to see posters and patient educational materials about the importance of disposal.

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EVALUATION

Ongoing evaluations are important to determine process improvement needs and ensure the overall success of the take-back box initiative. Determining both short- and long-term goals at the onset facilitates the evaluation process by identifying metrics to be measured.

METRICS TO CONSIDER:

- Monthly disposed medication weights, or volumes, as evidence of patient and community need, acceptance, and use.
- Patient and community satisfaction as evidenced by anecdotal patient comments or optional patient satisfaction surveys specific to box initiative.
- Staff acceptance of process as evidenced by minimal to no additional work impact.
- Financial sustainability as evidenced by available funding sources or minimal additional pharmacy costs if merged into current pharmacy budget.
- Widespread internal knowledge of take-back box and adoption of disposal process into patient education and follow-up visits as proof of excellent internal communication and implementation processes

TERMINATING PERMANENT MEDICATION DROP BOX USE

Should the decision be made to end the permanent medication disposal box initiative, federal regulations require that the registrant (i.e., hospital) notify the DEA, either in writing or online at www.DEAdiversion.usdoj.gov.

MAKING A DIFFERENCE

While it may prove difficult to assess the full impact of a permanent medication disposal box in relation to the overall opioid epidemic, your institution is providing a valuable service to patients and the surrounding community. The overarching goals of providing this service are not only to remove unused opioids from households where they can be misused or cause an accidental ingestion or overdose, but also to normalize the disposal process as an important safety feature of a patient's pain management plan and to educate on safe use, storage, and disposal of opioids. Education is key to prevention, and prevention will help turn the tide of the opioid epidemic saving innocent lives.

FREQUENTLY ASKED QUESTIONS

Why are we taking back unused medications and controlled substances?

Returning unwanted medicines to a take-back program is the safest and most environmentally protective way to dispose of unused medication.

Is the disposal box only for our organization?

No, anyone can use the disposal box as long as they are disposing acceptable items.

What items can be collected?

Any prescription medication including controlled substances, in tablets, pills, or liquid form. Liquids must be sealed and fit into the disposal box's opening. Check the label on the box if unsure.

Can illicit (illegal) drugs be collected in the disposal box?

No. The disposal box is not for disposal of any illicit drugs.

How should medications be deposited into the disposal box?

Medications can be deposited in their original prescription containers. The collector is required to keep all information confidential.

Can we place medications in the disposal box for a patient?

No. Staff should never accept medications from another person. A person must dispose of the medication themselves.

Do we need to collect or retain any information about persons utilizing the disposal box?

No. A collector shall not collect any personally identifying information.

How often should the disposal box be emptied?

The disposal box should be emptied when the kiosk system indicates the box is full. This varies based on how quickly medications are deposited.

What happens if someone accidentally places the wrong medication or loses a valuable item in the disposal box?

Medications and items deposited within the disposal box are not retrievable.

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