October 30, 2017

James Arnold, Chief
Liaison and Policy Section, Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Arnold:

The undersigned local and state officials are writing today to request clarification regarding two issues related to DEA's 2014 guidance and regulation pertaining to medication take-back programs. Our goal is to enhance implementation of our existing medicine take-back programs to better serve our residents.

**Background**

As you know, in September 2014, DEA issued a final rule to provide increased options for consumers to safely and securely dispose of unwanted and expired medications that are controlled substances. To maximize the amount of controlled substance medications collected, DEA allowed for commingled collection and disposal of all medications. This is an important allowance since most consumers are unaware of the difference between controlled and non-controlled medications. DEA's 2014 regulations also allow collections at locations other than law enforcement offices, including retail pharmacies and hospitals, which are convenient locations for consumers to bring back their unwanted and expired medications. Immediately following issuance of the 2014 regulations, DEA provided a series of three fact sheets on its website (www.usdoj.gov) for registrants, the general public, and long-term care facilities.

Since 2014, 20 local and state governments in California, Washington, New York, Vermont, and Massachusetts have passed laws requiring pharmaceutical producers to create and fund permanent medicine collection programs, which are in various stages of implementation. MED-Project, a non-profit LLC, implements the take-back programs on behalf of the Pharmaceutical Product Stewardship Work Group (PPSWG), which describes itself as "…a U.S. membership association of major manufacturers of prescription and over-the-counter medicines formed to address household disposal regulations."

**Issue #1: Products and Dosage Forms "Prohibited" from Commingled Disposal**

MED-Project has informed our jurisdictions that four products or dosage forms cannot be commingled with other medications in collection kiosks due to information provided in Question 12 of the 2014 DEA General Public Fact Sheet

(see addendum to this letter). These four items are inhalers, aerosol products, iodine-containing medicines, and preloaded auto-injectors.

**Request**
We would like DEA to revise its General Public Fact Sheet to state that kiosk collection of inhalers, aerosol products, iodine-containing medicines, and unused preloaded auto-injectors in original packaging (e.g., expired unused epi-pens) is allowed when in accordance with local, state, and federal law, including but not limited to Department of Transportation requirements. Alternatively, DEA could eliminate Question 12 on the General Public Fact Sheet.

**Rationale**
We believe that DEA Fact Sheets, such as the General Public Fact Sheet attached, are not formal DEA policy guidance. We understand the fact sheet to be based, in part, on DEA's experience hosting medication take-backs starting in 2011. Since this time, collection and transportation best practices have advanced. The U.S. Department of Transportation (DOT) has issued Special Permits that allow for commingled transportation of all medicine collected under 21 CFR 1317 in all dosage forms. We understand this to mean that inhalers, aerosol products, iodine-containing medicine and medicine in auto-injector devices can be co-mingled with other medications in kiosks. Despite the issuance of DOT Special Permits, including a Special Permit issued to their collection vendor, Stericycle, MED-Project has stated to us that they cannot accept these four products in the take-back programs they offer while item 12 of the DEA General Public Fact Sheet remains in place.

**Issue #2: Placement of Collection Kiosks in Hospitals**
The DEA rules inform that collection kiosks located in hospitals with an on-site pharmacy can be placed in areas regularly monitored by employees. The rules do not inform, however, that the only acceptable location envisioned for a collection kiosk is within or in proximity to a hospital's on-site pharmacy. Some hospitals are comprised of multi-building campuses that could provide several convenient kiosk locations for our residents to safely and securely dispose of their unwanted and expired medications.

**Request:** Please clarify how Sec. 1317.75(d)(2)(i) applies to modern multi-building campus hospitals where a "Place of Business" address may be an administration building, while patient care and public access occur in multiple buildings on the campus. In addition, since DEA rules reference a practitioner's "registered location" in the context of establishing collection kiosks, we seek clarification whether "registered location" refers to the hospital complex in general or something more specific and limiting for the purpose of collection.

**Rationale:** DEA rule Sec. 1300.01 (Definitions) defines the term *collector* as "a registered manufacturer, distributor,…..*hospital/clinic with on-site pharmacy*….authorized under this chapter to so receive a controlled substance for the purpose of destruction.*"* Further, DEA rule Sec. 1317.75(d)(2)(i) states "…*At a hospital/clinic: a collection receptacle shall be located in an area regularly monitored by employees*…"

DEA form 224's "Place of Business" line does not capture the complexity of today's multi-building hospital campus, which may comprise multiple buildings with different street

addresses, although located on a contiguous property and under common management. For example, a single on-site inpatient-only pharmacy inaccessible to the public may serve the entire multi-building campus. Further, Sec. 1317.75(d)(2)(i) gives broad authorization to locate a collection kiosk in an area regularly monitored by hospital employees exclusive of emergency room waiting areas and urgent care clinics. Finally, Sec. 1317.75(d)(2)(i) does not inform of the intent that a collection kiosk must be associated only with the on-site pharmacy or the building where the on-site pharmacy is located.

We would appreciate a response in writing. We would also welcome the opportunity to have a conference call to discuss these issues. To arrange a call, or for any questions, please contact Scott Cassel, Chief Executive Officer, Product Stewardship Institute, at (617) 236-4822, or scott@productstewardship.us. Mr. Cassel is working with us on these issues.

Thank you for assisting us to clarify the above issues, which are critical to the success of our pharmaceutical take-back programs and the provision of safe and secure medication disposal for our residents.

Sincerely,

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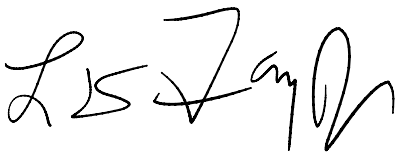

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**ADDENDUM**

**DISPOSAL ACT: GENERAL PUBLIC FACT SHEET**

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"). The final rule is available for public view at http://www.federalregister.gov/public-inspection. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on http://www.regulations.gov, and our website, http://www.DEAdiversion.usdoj.gov.
This General Public Fact Sheet contains a general summary of some of the effects of the new rule on the general public. For detailed information, please visit our website or contact your local DEA office.

**1. What is the Disposal Act?**
The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

**2. Who is an "ultimate user"?**
The CSA defines an "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

**3. Are my options for disposing of pharmaceuticals more limited now?**
No. These regulations don't limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expand them. The DEA's new regulations outline the methods by which pharmaceutical controlled substances may be transferred to authorized collectors for disposal. Ultimate users now have expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances: through collection receptacles, mail-back packages, and take-back events.

**4. May I continue to dispose of pharmaceutical controlled substances using methods that were valid prior to this final rule?**
Yes. Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.

For example, ultimate users may continue to utilize the FDA and EPA guidelines for the disposal of medicines, available through the DEA website at http://www.deadiversion.usdoj.gov/drug_disposal/index.html.

**5. Will there still be take-back events every six months?**
Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events. The DEA encourages communities to partner with law enforcement to continue to conduct take-back events.

The DEA will continue to sponsor nationwide take-back events in the spring and fall. DEA will continue to encourage local law enforcement to implement additional take-back efforts conducted in accordance with the new regulations.

**6. Can I dispose of a friend or family member's pharmaceutical controlled substances for them?**
You may dispose of a member of your household's unused or unwanted pharmaceutical controlled substances. But, if they are *not* a member of your household, you may not dispose of their pharmaceutical controlled substances on their behalf. Only ultimate users may dispose of pharmaceutical controlled substances. An ultimate user, which includes a household member of the person or pet who was prescribed the medication, may transfer pharmaceutical controlled substances to authorized collectors or law enforcement via a collection receptacle, mail-back package, or take-back event.

Exceptions:
- If someone dies while in lawful possession of pharmaceutical controlled substances, any person lawfully entitled to dispose of the decedent's property may dispose of the pharmaceutical controlled substances; and
- A long-term-care facility may dispose of a current or former resident's pharmaceutical controlled substances.

**7. My mother has pharmaceutical controlled substances delivered to her home. She passed away, and I would like to dispose of her unused pharmaceutical controlled substances. I did not live with her. Can I dispose of them?**
Yes, so long as you are lawfully entitled to dispose of her property, you may dispose of her unused pharmaceutical controlled substances.

**8. How can I find a collection receptacle location near me?**
Members of the public may call the DEA's Registration Call Center at 1-800-882-9539 to find a collection receptacle location near them.

**9. I live in a rural location. There are no collection receptacles, mail-back programs, or take-back events in the vicinity. How can I safely and securely dispose of my unwanted pharmaceutical controlled substances?**
There are no restrictions on using a mail-back package obtained from another state. You may dispose of your unwanted pharmaceutical controlled substances in a mail-back package that you received from another state, even if the mail-back package is delivered to a location outside of your state.

Additionally, these regulations expand—not limit—the options that ultimate users have to dispose of unwanted pharmaceutical controlled substances. You may continue to dispose of your unwanted pharmaceutical controlled substances using the lawful methods you used prior to the effective date of the new regulations, as long as those methods are consistent with Federal, State, tribal, or local laws and regulations, including surrendering pharmaceutical controlled substances to law enforcement.

**10. Can I dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event? How can I safely and securely dispose of my unwanted marijuana?**
No. Persons may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

Persons may not dispose of any controlled substances that they do not legally possess. This includes schedules II-V controlled substances that are illegally obtained and possessed.

**11. I don't have a mail-back package, but I remember the address from the last mail-back package I used. Can I mail pharmaceutical controlled substances to that address without an official mail-back package?**
No. Persons must use the mail-back package that was provided by an authorized collector or one of their partners. The mail-back package must meet certain specifications, to include having a unique identification number. If an authorized collector receives a sealed mail-back package that they did not provide, the collector must reject it, or if they inadvertently accept it, they must notify the DEA.

If persons would like to use a mail-back package and don't possess one, they may contact an authorized collector to obtain one.

**12. Can I dispose of my insulin syringes through one of the disposal methods? What about my child's asthma inhaler?**
No. Persons may not dispose of any dangerous, hazardous, or non-compliant items in a collection receptacle or a mail-back package. This includes medical sharps and needles (*e.g.*, insulin syringes & injectable).

Other non-compliant items that may not be placed into a collection receptacle or mail-back package include iodine-containing medications and mercury-containing thermometers.

Accepting these materials places the collector at risk, and might cause a dangerous situation. You should continue to use any valid methods you currently utilize to dispose of those medications and medical implements.

Carefully review the authorized collector's instructions for what is and is not acceptable to place into the collection receptacle or mail-back package. If you have any questions, you should ask an employee of the authorized collector.

**13. Can my pharmacy or other collector force me to give personal information, like my name, my prescription information, or my physician information?**
No. A collector may not force anyone to provide any personal information about themselves, their prescription, or their physician.

In order to protect personally identifiable information, the DEA encourages persons not to place prescription bottles in collection receptacles or mail-back packages.

**14. What happens to my pharmaceuticals after I dispose of them? Can they be sold, given away, re-packaged, or re-dispensed for use by another patient? Can they be otherwise recycled?**
Pharmaceutical controlled substances transferred from ultimate users to authorized collectors via either collection receptacles or mail-back programs shall be securely stored or transferred until rendered non-retrievable. They may not be re-sold, donated, repackaged, or re-dispensed. Currently, the most common method of rendering pharmaceutical controlled substances non-retrievable is incineration.

**15. Are there environmental impacts?**
Disposed pharmaceuticals must be rendered non-retrievable in compliance with all applicable Federal, State, tribal, and local laws, including those relating to environmental protection. By expanding options on how ultimate users may dispose of their pharmaceutical controlled substances, fewer of these substances may end up in our nation's water system.