
# Controlled Substances: Return and Disposal

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Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010 ("SRDDA"), consumers lawfully possessing unused or expired pharmaceutical controlled substances had three options for proper disposal: (1) dispose by flushing or trashing pursuant to Drug Enforcement Administration ("DEA") guidelines; (2) turn the substances over to law enforcement; or (3) seek assistance from DEA. Under SRDDA, consumers' options expanded to allow the return of controlled substances to other entities in accordance with regulations, once developed. On September 9, 2014, DEA published these final regulations in the Federal Register. 79 FR 53520-70 (amending 21 CFR §§ 1300-01, 1304-05, 1307, and 1317) (available at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf). The regulations became effective on October 9, 2014.

In this document, NAMSDL details some of the major elements of the new DEA controlled substance regulations (the "October 2014 DEA regulations"). This document then provides a look at several statewide and locality-based disposal programs in existence as of November 2014, particularly ones that allow for collection of controlled substances.

## October 2014 DEA Regulations

The October 2014 DEA regulations explicitly describe three return options for "ultimate users," *i.e.*, persons who lawfully possess controlled substances for their use, or use by another person (or animal) in the household. The options are: (1) take back events; (2) mail back programs; and (3) collection receptacles. 79 FR at 53521. The regulations apply only to Schedule II through V controlled substances and therefore do not allow for the collection of Schedule I substances. Although the DEA notes that the new regulations do not prohibit consumers from "using existing lawful methods" for disposal, a clear stated purpose of the regulations is to reduce the volume of controlled substances entering the environment through current disposal methods, particularly through waterways. *Id.* Another stated purpose of the regulations is to reduce the risk of diversion to illegal activity or accidental harm that can occur if stockpiles of unwanted controlled substances remain in homes. *Id.*

The new regulations allow certain non-law enforcement "registrants," *i.e.*, entities already authorized by DEA to handle controlled substances, to amend their DEA registration to become controlled substance "collectors." *Id*. at 53561 (21 CFR § 1301.51). "Collectors" are registered manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics

with an on-site pharmacy, and retail pharmacies that are authorized by DEA to manage collection receptacles and/or mail back programs.[1]

With respect to collection receptacles, the regulations provide a number of specific requirements, including:

- Only ultimate users and non-registrants may deposit substances into the receptacles, preventing registrants from using the receptacles for their own unused inventory. *Id.* at 53568 (21 CFR § 1317.75(c)).
- Registrants may not physically handle the controlled substances either prior to, or after, drop off by the consumer. *Id.*
- Receptacles must be securely locked inside of a registrant's premises, securely fastened to a permanent structure, and consist of a permanent outer container with a removable inner liner. *Id.* at 53569 (21 CFR § 1317.75(e)).
- At least two registrant employees must be present when removing and sealing the inner liner. *Id.*
- Inner liners must be waterproof, tamper-proof, opaque, tear resistant, seal-able, and marked with a unique ID number that can be tracked. *Id.* at 53567 (21 CFR § 1317.60).

The regulations allow a retail pharmacy or a hospital/clinic with an on-site pharmacy to manage a receptacle inside of a long-term care facility ("LTCF"). *Id.* at 53569 (21 CFR § 1317.80). In those cases, the LTCF can store removed and sealed inner liners for up to three business days before the liners must be picked up for disposal. *Id.* Moreover, although they are not ultimate users under the regulation, employees at LTCFs are allowed to dispose of controlled substances on behalf of current/former residents of the facility. *Id.*

In terms of mail back programs, collectors may operate programs (for free or a fee) only if they have an on-site method to destroy the returned packages. *Id.* at 53566, 53568 (21 CFR §§ 1317.05(c)(1) & 1317.70). Collectors without an on-site method of destruction, *i.e.*, most retail pharmacies, cannot receive packages and have them transported off-site for disposal. Therefore, a retail pharmacy wishing to manage a mail back program likely will need to partner with a reverse distributor, utilizing the return mailing address of the reverse distributor. As with the collection receptacles, the regulations provide minimum specifications for the mail back envelopes that are intended to reduce the possibility of diversion. *Id.* at 53568 (21 CFR § 1317.70).

[1] Under the regulations, a "reverse distributor" is a registrant that acquires a controlled substance from another registrant or law enforcement agency for the purpose of either destroying the substance or returning it to the manufacturer. *Id.* at 53560 (21 CFR § 1300.01).

Collectors are not authorized to hold controlled substance take back events on their own. *Id.* at 53568 (21 CFR § 1317.65(a)). Collectors wishing to be involved in such events must do it in conjunction with a law enforcement agency. The regulations provide that law enforcement must maintain "control and custody" of the collected items from "the time the substances are collected . . . until secure transfer, storage, or destruction of the controlled substances has occurred." *Id.* (21 CFR § 1317.65(b)).

According to DEA, the use of "should" instead of "shall" in the provisions about law enforcement mean that the regulations are suggestions for law enforcement procedure, not requirements. *Id*. at 53531. Indeed, in public teleconferences since the publishing of the regulations, DEA continues to give law enforcement substantial discretion on their handling of controlled substances. The regulations do require, however, that law enforcement collection receptacles be "inside law enforcement's physical location." *Id.* at 53569 (21 CFR § 1317.75 (d)(1)).

The regulations do not specify the method for destruction of controlled substances; rather, they require that the method used render the controlled substances "non-retrievable." *Id.* at 53569 (21 CFR § 1317.90(a)). The term "non-retrievable" is defined as a method that alters the physical or chemical condition irreversibly, so as to "[render] the controlled substance unavailable and unusable for all practical purposes." *Id.* at 53560 (21 CFR § 1300.05(b)). DEA notes that disposing of the substance by flushing or trash/landfill does not meet the "non-retrievable" standard and thus is not an allowed method for collectors. *Id.* at 53548.

Absent from the October 2014 DEA regulations is any discussion about funding mechanisms for disposal programs. Likewise, the regulations do not address the existing differences between states in how household pharmaceutical drug waste is regulated under state hazardous waste and other environmental heath laws. Finally, the regulations do not allow collectors an "in hand" method of collecting data about the types of substances that ultimate users dispose. Instead, data can be collected only if ultimate users voluntarily: (1) answer questions; or (2) allow visual inspection of drugs prior to drop-off.

## Statewide Legislation Addressing Disposal of Pharmaceutical Controlled Substances

As of the effective date of the October 2014 DEA regulations, several state legislatures have enacted laws/regulations addressing disposal options for pharmaceutical drugs, including controlled substances. As discussed below, these laws and regulations differ greatly in how regulatory oversight is assigned and the amount of guidance provided to stakeholders. The laws are presented alphabetically by state.

*California's Senate Bill 966 and Model Guidelines*

Enacted in 2007, California Senate Bill 966 required the California Department of Resources, Recycling and Recovery ("CalRecycle," formerly the California Integrated Waste Management Board) to adopt model guidelines for pharmaceutical waste collection by December 2008, evaluate programs in other domestic and foreign jurisdictions, and prepare a report to the legislature by December 2010. The law, codified at Ca. Public Resources Code §§ 47120-26, was repealed on January 1, 2013, under its own sunset provision.

CalRecycle's model guidelines were finalized in February 2009 and focused on three types of collection activity: (1) permanent collection programs; (2) one-time or periodic events; and (3) mail back programs. *CalRecycle Report to the Legislature*, Recommendations for Home-Generated Pharmaceutical Collection Programs in California, App. D (December 2010) (available at http://www.calrecycle.ca.gov/HomeHazWaste/Medications/LegReport.htm). The guidelines contained a stated preference for permanent collection programs. *Id.* at App. D, p.2.

The main recommendations for each type of collection activity were as follows:

Model Permanent Collection Programs

- No cost to pubic;
- Collection sites at pharmacies, law enforcement stations, public/environmental health agencies, physicians' offices, household hazardous waste facilities, and healthcare facilities;
- Program approved in advance by relevant government agencies and approved medical waste transporters;
- Collection of prescription and non-prescription drugs along with medical sharps, so long as sharps are not comingled with drugs and the collection site is approved as a sharps collection point;
- Controlled substance collection only if law enforcement presence on site;

- No comingling of waste with expired, recalled or quarantined drugs;
- On-site secure storage of waste limited to 90 days, but once materials are removed from container they must be taken for disposal immediately;
- Chain of custody requirements for transportation and disposal;
- Secure containers in all locations with a "two- key" system required at pharmacies, where one of the keys is possessed by the waste transporter;
- Educational information available at drop-off locations; and
- Suggestions for data collection, including the types of materials collected.

*Id.* at App. D, pp. 2-7.

Periodic/One-Time Events (many of the same recommendations as above, except where noted)

- Access to site limited to consumers dropping off waste;
- Pharmacist's presence regardless of collection location;
- Law enforcement presence required if controlled substances collected;
- Waste removed from collection site the day of event but can be stored securely for 90 days prior to disposal; and
- Recommended equipment includes gloves for all staff and facemasks for some.

*Id.* at App. D, pp. 7-13.

Mail Back Programs

- Use DEA approved locations for return of waste;
- Disposal locations should be approved to handle controlled substances and provide information on amount received and destroyed;
- Use traceable, self-sealing, pre-addressed, pre-stamped envelopes that are approved by USPS to contain/transport pharmaceutical waste; and
- Distribute envelopes at pharmacies, periodic events, physicians' offices, and post offices.

*Id.* at App. D, pp. 13-14.

Senate Bill 966 required CalRecycle: (1) to assess both the model guidelines and out-of-state programs' ability to attain four goals: efficacy, safety, statewide accessibility and cost effectiveness; and (2) to make recommendations about implementing a statewide program and/or statutory changes. The evaluation was detailed in the December 2010 report to the legislature. *Id.* at 9. In the report, CalRecycle identified numerous challenges to disposal programs generally, including high costs to collect/destroy, lack of public awareness of the problem, locating funding, and regulatory complexity. *Id.* at 22-27. CalRecycle also described four options for future programs:

- Keep the status quo and encourage local programs to use the (voluntary) model guidelines;
- Establish clear agency responsibilities, improve the guidelines, and convert the guidelines to mandatory regulations;
- Implement product stewardship legislation requiring the private sector to develop and fund a disposal program with some state oversight; and/or
- Fund state program(s) through a disposal fee paid at time of purchase.

*Id.* at 50.

Ultimately, CalRecycle recommended a combination of the second and third options—a private-sector stewardship program with clearer governmental roles and oversight. *Id.* at 57. CalRecycle noted that its recommendation did not address the difficulties of collection/disposal of controlled substances under pre-SRDDA federal requirements, but hoped—correctly, it appears—that the then-still-to-be-developed federal regulations would make collection of the substances easier and its recommendation more plausible. *Id.*

*District of Columbia Unused Pharmaceutical Disposal Act (DC ST §§ 48-851)*

In late 2009, the D.C. Council enacted The Unused Pharmaceutical Safe Disposal Act of 2009 (the "Act"), codified at DC ST §§ 48-851.01-851.04. The Act directs the D.C. Board of Pharmacy: (1) to design a public education campaign implemented by retail pharmacies regarding the proper disposal of unused pharmaceuticals; and (2) to make recommendations to the Mayor, by July 2010, about establishing an unused pharmaceutical disposal program that includes controlled substances. *Id.* at § 48-851.02.

The statute expressly provides that the Board "shall give consideration to a mail-in program" in which prepaid envelopes are made available to the public at various locations, including all retail pharmacies. *Id.* The Mayor may issue rules to implement the program, but is not required to do so. *Id.* at § 48-851.04. To date, no regulations have been promulgated. Moreover, the D.C. Water and Sewer Authority website current states that "[a]t this time, the District of Columbia has no public drug take-back or collection programs." *Drinking Water Quality FAQs*, DC Water and Sewer Authority website (available at http://www.dcwater.com/waterquality/faqs.cfm) (last accessed December 2, 2014).

The Act also prohibits a "health care facility," defined as a "hospital, assisted living facility, nursing home, or institutional pharmacy," from disposing of any used or unused pharmaceuticals through flushing or other use of the public sewer "except as authorized by the

Mayor through rulemaking." *Id.* at §§ 48-851.01(1) & 48-851.03. The regulations required by this part of the statute were adopted in June 2013.

The regulations provide that except in certain cases, pharmaceutical products must be disposed of through: (1) waste to energy programs; (2) pharmaceutical waste containers with appropriate procedures for disposal; or (3) recommended procedures published by the FDA and DEA. D.C. Mun. Regs. Subt. 22-B, § 502 (exceptions are listed in § 501). Any facility that violates the regulations is subject to a fine of up to $1,000 per occurrence and it must submit a mitigation plan to prevent future violations to the Board. *Id.* at § 500.2. The health care facilities are directed to maintain: (1) records of the disposal for three years after disposal; and (2) written policies and procedures that are updated at least every two years and are a part of staff orientation and continuing education. *Id.* at § 503.

*Maine Unused Pharmaceutical Disposal Program (22 M.R.S.A. § 2700)*

The Maine Unused Pharmaceutical Disposal Program (the "Program") was created by statute in May 2004, with a targeted July 2005 effective date. 22 M.R.S.A. § 2700, et seq. As originally enacted, the Program created a means to return unused pharmaceuticals to the state Drug Enforcement Agency ("Maine DEA") through the use of prepaid mailing envelopes made available at pharmacies, physicians' offices and post offices. *Id.* at (2)-(3) (as enacted). The statute provided that funding for the program would come from an "Unused Pharmaceutical Disposal Fund" (the "Fund") created within the Maine DEA. Originally, Maine DEA was authorized to accept contributions to the Fund from "any non-General Fund, nonpublic fund source, including grants or contributions of money." *Id.* at (5) (as enacted). Shortly after enactment, the starting date of the program was moved from July 2005 to July 2006 and the restriction against public funds was removed. 2005 Me. Legis. Serv. Ch. 297 (S.P. 609) (emergency action by legislature).

As enacted, the law established the Maine Drug Return Implementation Group (the "Group") to study several implementation issues including: postal regulations, requirements for packaging, drug diversion and theft, public education, and local drop-off programs. 22 M.R.S.A. at § 2700 (Sec. 2) (as enacted). In a March 2005 report, the Group recommended that Maine establish a product stewardship approach for collecting unwanted pharmaceuticals, with a manufacturer-funded program to begin by July 2007. *Implementing Product Stewardship in Maine,* Maine Department of Environmental Protection, 16-17 (January 2011 Report to the Joint Standing Committee on Natural Resources). No legislative action was taken at that time, however.

In 2007, the U.S. Environmental Protection Agency ("EPA") provided start-up funding for a pilot mail back program, administered by the University of Maine's Center on Aging, called the Safe Medicine Disposal for ME Program. *Id.* The program provided prepaid envelopes and participant surveys to interested individuals, allowing researchers to analyze the type and quantity of accumulating medicine. *Information for Researchers and Collaborators*, Safe Medicine Disposal for ME Program (available at http://umaine.edu/safemeddisposal/information-for-researchers-and-collaborators/) (last accessed December 2, 2014). The envelopes with the unused medicine and completed surveys were returned to Maine DEA, who also oversaw the cataloging and disposal of returned medicine. *Id.* As of December 2012, over 8,000 pounds of unused and unwanted medications, including controlled substances, had been disposed of through the program. *Id.* Subsequent funding for the program came from a state public health fund. According to the Center on Aging, the program ended in 2012. *Safe Medicine Disposal for ME 2008-2012*, UMaine Center on Aging (http://mainecenteronaging.umaine.edu/safe_medicine_disposal_for_me_2008present) (last accessed December 2, 2014).

In 2010, while the mail back program was ongoing, a Maine state representative introduced legislation calling for a permanent disposal program, designed and funded by the pharmaceutical industry. This product stewardship legislation was opposed by the pharmaceutical companies and it died between houses in March 2010. *Implementing Product Stewardship in Maine* at 17.

Maine's Governor established the Maine Prescription Drug Abuse Task Force (the "Task Force") in February 2012. In the Task Force's interim July 2012 report, the disposal subcommittee noted that Maine's Department of Environmental Protection recently had "clarified the requirements of waste disposal options for collection programs to follow" allowing many collected medicines to be incinerated within Maine, thereby lowering disposal costs. *July 2012 Interim Report*, Maine Prescription Drug Task Force, 6 (available at ttp://www.maine.gov/tools/whatsnew/attach.php?id=409705&an=1).

In the report, the Task Force also recommended that the Program be amended to make other types of programs eligible for funding "if and when it becomes available." *Id*. 6-7. This suggested change to the statutory language was enacted in October 2013. Today, the statute no longer requires a mail back program and the Program's purpose is expanded to "the safe, effective and proper disposal of unused pharmaceuticals" and not just their return. 22 M.R.S.A § 2700(3).

NAMSDL has not located any regulations or rules promulgated by Maine DEA pursuant to 22 M.R.S.A. § 2700.

*New Hampshire Pharmaceutical Drug Take Back Program (N.H. Rev. Stat. § 318-E:1)*

Enacted in 2011, § 318-E:1 of the New Hampshire statutes, Pharmaceutical Drug Take-Back Program Authorized (the "Program"), allows governmental entities and private parties to establish controlled and non-controlled pharmaceutical drug take-back programs in conjunction with law enforcement officers for the "collection, storage, and disposal" of pharmaceuticals "in accordance with applicable state and federal statutes and regulations." N.H. Rev. Stat. § 318-E:1(II).

Under the statute's original terms, the New Hampshire Department of Justice, Pharmacy Board, Department of Safety, and Department of Environmental Services were to establish rules/regulations for communities and private entities to follow. The statute was amended in 2014 to make the Department of Justice solely responsible for creating regulations, in consultation with the other entities. *Id.* at (III). The statute does not provide a method of funding, but notes that a program "may accept public and private grants and donations" including "a fee from participating individuals returning unused pharmaceuticals." *Id.* at (VI).

Rules and regulations for the program were adopted in August 2012. N.H. Code Admin. R. Ch. Jus 1600, et seq. The regulations address two types of collection options: (1) permanent drop boxes; and (2) take back ("collection") events. Unlike the October 2014 DEA regulations, the New Hampshire rules provide that drop boxes can be located only at police stations in areas under constant video surveillance. *Id.* at § 1603.01. Moreover, signage on the boxes must indicate that drugs are to be placed in original containers or sealed plastic bags. As for collection events, law enforcement is required to receive authorization in advance from DEA to hold the event. *Id.* at § 1604.01(c). The regulations instruct that two law enforcement officers must be present at all times to supervise and to remove the collection receptacle on the day of the event. *Id.* at §§ 1604.02(a) & 1604.03(a).

The regulations provide that collected drugs "shall be destroyed via incineration at a solid waste disposal facility that is authorized to accept the waste under the destination state's laws and rules." *Id*. at § 1605.01(a). The destruction is to be witnessed by a designated law enforcement officer who shall document: (1) date/location of the collection event; (2) weight of collected drugs; (3) date/location of destruction; and (4) the names of the participating law enforcement

officers. *Id.* at §§ 1605.01(b) & 1605.02. Agencies taking part in disposal activities are also required to develop and maintain written policies and procedures. *Id.* at § 1606.01(b).

The regulations provide that requests for waivers of specific rules for a take back event can be submitted in writing to the state's Department of Justice. *Id.* at § 1607.01. Moreover, a periodic collection event is exempt from the rules entirely if within 30 days before the event the chief law enforcement officer requests the exemption from DEA and:

> [C]ertifies in writing to the attorney general that the…event shall be compliant with the Northeast Recycling Council "Best Management Practices Operating Unwanted Medication Collections – A Legal & Safe Approach", November 2008 edition; "Holding an Unwanted Medication Collection as Part of a Household Hazardous Waste Event – A Legal and Safe Approach", September 2006 edition; and "Operating Unwanted Medication Collections - A Legal & Safe Approach", September 2006 edition.

*Id.* at § 1608.01.

*New York Drug Management and Disposal (ECL § 27-2701, et seq.)*

Enacted in 2009, § 27–2703 of New York's Environmental Conservation law provides that the state's Department of Environmental Conservation shall "develop and implement a public information program on the proper disposal of drugs" along with the Department of Health. ECL § 27-2703(1). The law also provides that the Department of Environmental Conservation shall establish a public notice regarding the proper storage and disposal of drugs which must be "conspicuously displayed in every pharmacy . . . and in every other retail business authorized to sell drugs." *Id.* at § 27-2703(2).

By its original terms, the law provided that the Commissioner of Environmental Conservation, in consultation with the Commissioner of the Department of Health, could establish "a demonstration program to determine the most effective method for the disposal of drugs." 2008 Sess. Law News of N.Y. Ch. 625 (S. 7560–A). This part of the statute expired in December 2010.

*Ohio Drug Take-Back Program (R.C. § 4729.69)*

Enacted in 2011, § 4729.69 of the Ohio Code provides that the state Board of Pharmacy, in conjunction with the state Attorney General and Director of Mental Health and Addiction Services, "shall establish and administer a drug take-back program under which drugs are collected from the community for the purpose of destruction or disposal of the drugs." *Id.* at § 4729.69(A). The statute provides that the board must establish rules and regulations that specify at a minimum: (1) participating entities; (2) drugs that may be collected; (3) record-keeping requirements; (4) proper methods to destroy unused drugs; (5) privacy and security standards; and (6) drug transportation procedures. *Id.* at (C).

At the same time, the statute prohibits future rules and regulations requiring any entity to establish, operate or fund the program or requiring a new licensing requirement or fee to participate. *Id.* at (D). The board, the Department of Mental Health and Addiction Services, and the Attorney General's office are authorized to accept grants, gifts and/or donations for the program, which are to be set aside in a separate fund and used only for purposes of the program. *Id.* at §§ 109.90, 4729.69(I) & 5119.49.

The regulations were first published by the Board of Pharmacy in August 2014 and took effect in October 2014. OAC § 4729-8-01, et seq. These regulations addressed: (1) permanent collection boxes, to be located only at law enforcement locations, unless allowed elsewhere by DEA regulations; (2) periodic collection events with at least one law enforcement officer present; and (3) disposal. *Id.* In early November 2014, however, the board proposed to rescind the recent regulations and implement others (with the same section numbers) that more closely track the October 2014 DEA regulations. (The proposed new regulations are available at http://pharmacy.ohio.gov/Documents/LawsRules/ProposedRules/CommonSense/4729-8,%204729-12,%204729-15,%204729-21,%204729-22,%204729-25%20&%204729-29%20CSI%20BIA%20-%20Comments%20Due%2011.20.2014.pdf) (last accessed December 2, 2014). Public comment on the new regulations was due November 20, 2014.

The November 2014 regulations allow non-law enforcement "authorized collectors" (*i.e.*, "collectors" under the October 2014 DEA regulations) to operate permanent collection receptacles and mail back programs so long as DEA's controlled substance requirements are met, regardless of whether or not the collection includes controlled substances. Proposed OAC § 4729-8-02(A-E). As with the federal regulations, collectors are not authorized to operate periodic take-back events on their own. *Id.* at (H). The regulations also prohibit collection of

items such as medical sharps/needles, iodine containing medications, mercury thermometers, aerosols, Schedule I controlled substances, and inventory/stock. *Id.* at (F).

Under the proposed Ohio regulations, law enforcement agencies are authorized to operate collection receptacles, free or fee-based mail back programs, and take back events. *Id.* at § 4729-08-03. Law enforcement may also take possession of drugs collected in an authorized collector's receptacle. *Id.* at § 4729-08-02(I). In each case, the law enforcement agency must handle the receptacle, collection event, mail back program, or drugs collected in a manner consistent with the October 2014 DEA regulations. The Ohio regulations direct that mail back envelopes be addressed to the law enforcement agency's address. *Id.* at § 4729-08-03(B)(2)(c). At take back events, the regulations allow for a separate container for bulk sharps disposal. *Id*. at § 4729-08-03(C)(4).

All drugs collected pursuant to the regulations are to be rendered non-retrievable through destruction in compliance with Federal, State, tribal and local laws that maintains the confidentiality of the drug's user. *Id.* at § 4729-08-04.

*Wisconsin Drug Disposal Program (W.S.A. § 165.65)*

Enacted in April 2014, but not effective until July 2015, §165.65 of the Wisconsin Code authorizes "drug disposal programs" for "household pharmaceutical items" ("HPIs") to be overseen by the state Department of Justice. W.S.A. § 165.65(1)(c). Under the statute, no entity can accept HPIs as part of a disposal program unless: (1) the program is authorized in writing by the Department of Justice; (2) the program is authorized under federal law; or (3) the entity is a political subdivision operating the program within its geographic limits and the HPIs will be delivered in person by individuals authorized to possess them. *Id.* at § 165.65(2)-(3). According to the Department of Justice, the purpose of the law is "to ensure that any person or municipality operating a drug disposal program has the clear legal authority to do so, and to ensure that such programs are developed with appropriate guidelines and oversight." *Statement from Attorney General J.B. Van Hollen Regarding the U.S. Drug Enforcement Administration's (DEA's) Final Rule for the Disposal of Controlled Substances* (September 9, 2014) (available at http://www.doj.state.wi.us/media-center/2014-news-releases/september-9-2014-2) (last accessed December 2, 2014).

As defined, a "drug disposal program" is a program to recycle, destroy or otherwise dispose of HPIs but "does not include a sharps collection station operated in compliance with rules promulgated by the department of natural resources." *Id.* at § 165.65(1)(c). HPIs include

pharmaceutical drugs, controlled substances, and medical devices, so long as the device "is located in or comes from a place where the individual, a member of the individual's household, an in-home hospice service, or an adult family home serving fewer than 5 adult members manages the use." *Id.* at § 165.65(1)(d). HPIs do not include items contaminated by chemotherapy drugs or mercury. *Id.*

In order for a disposal program to be authorized, the person wishing to operate must establish written policies and procedures that, at a minimum, identify: (1) the kinds of HPIs covered by the program (and if it covers controlled substances); (2) whether or not HPIs will be transferred by mail; (3) collection locations; (4) the person(s) responsible for the program; and (5) how the program complies with state/federal medical waste, solid waste or hazardous waste laws. *Id.* at § 165.65(5).

The statute does not require that the state Department of Justice or any other agency develop regulations to govern operation of the statute.

**Local Legislation Addressing Disposal of Pharmaceutical Controlled Substances**

*Alameda County (CA) Safe Drug Disposal Program*

In July 2012, the Board of Supervisors of Alameda County (CA) passed an "extended producer responsibility" ("EPR") ordinance requiring any pharmaceutical "Producer" whose prescription drugs are sold or distributed in the county to operate a product stewardship program, or have a stewardship organization operate one on its behalf. Alameda County Health and Safety Code, § 6.53.040(A) (available at http://www.acgov.org/sustain/documents/ac_safe_drug_ disposal_ordinance.pdf). A "Producer" is defined as a person who manufactures a drug covered by the ordinance and who "sells, offers for sale, or distributes" the drug in Alameda County. *Id.* at § 6.53.030(14). A "product stewardship program" is a program "financed and operated by Producers to collect, transport, and dispose of" unused pharmaceuticals regardless of maker. *Id.* at § 6.053.030(15). This legislation was the first EPR law in the United States related to the collection/disposal of pharmaceutical drugs.

The program does not cover non-prescription drugs, medical devices or their component parts, but does include controlled substances. *Id.* at §§ 6.53.030(3) & (6). Under the ordinance, the producers "must pay all administrative and operational fees" associated with their program, including "all costs incurred by the County of Alameda" in administering the program. *Id.* at § 6.53.040(B). The ordinance provides that producers cannot charge consumers a point-of-sale or

point-of-service fee to recoup its costs for covering the program, but it does not address whether producers can increase prices generally to cover costs. *Id.* The ordinance suggests that producers will establish collection sites for the pharmaceuticals but also notes the possibility of mail back envelopes. *Id.* at § 6.53.050(A)(5).

Producers are required to develop product stewardship plans outlining the scope and manner of the programs and submit them to the County's Department of Environmental Health (the "Department"), which has general oversight of the program. *Id.* at § 6.53.050)(A). This plan must also include public education about the program and outreach to retailers of the covered drugs. The ordinance directs that the collected drugs be disposed of "by incineration at a medical waste or hazardous waste facility." *Id.* at § 6.53.060(B). As originally enacted, stewardship plans were due to be submitted to the Department by July 2013 with first reports on program activities due to the department by July 2014. *Id.* at §§ 6.53.050(B) & 6.53.080. Violations of the ordinance subject the producers to fines of up to $1,000 per day. *Id.* at § 6.53.110.

Regulations governing the program were adopted in February 2013 and amended in October 2013. The amended regulations push back the deadline for submitting plans to May 2014. Alameda County Safe Drug Disposal Regulations, § 6 (available at http://www.acgov.org /aceh/safedisposal/documents/SDD-Regulations.pdf) (last accessed December 2, 2014). The regulations do not appear to require collection receptacles, instead indicating that a plan can propose multiple collection components which may include collection sites, mail back envelopes, and take back events. *Id.* at § 7.D. The plans must contain, among other things: contact information, website address, collection goals, collection components, transporter information, and disposal information. *Id.* at § 7. The plans will be judged by the Department on the following basis: (1) adequate collection and collection points; (2) management practices; (3) how controlled substances are handled; (4) education and public outreach; (5) educational materials; and (6) cost. *Id.* at § 8. Once approved, plans are valid for three years, unless the Department sets up a different term. *Id.* at § 16.

The regulations provide that the Department can require the entity submitting a plan (the "Plan Owner") to pay an initial deposit of up to $10,000 to cover the cost of administration by the Department. *Id.* at § 3. Moreover, the Plan Owner may be required to pay additional amounts to the Department should expected costs exceed deposits. *Id.*

Certain non-profit trade organizations representing the manufacturers and distributors of pharmaceutical products brought suit against Alameda County in 2012 alleging that the

ordinance violated constitutional Commerce Clause protections. The United States District Court for the Northern District of California rejected this argument and granted summary judgment for the county in 2013. *Pharmaceutical Research and Manufacturers of America, et al., v. County of Alameda*, 967 F.Supp.2d 1339 (N.D. Ca. 2013). This decision was upheld by the U.S. Court of Appeals for the Ninth Circuit in September 2014. *Pharmaceutical Research and Manufacturers of America, et al., v. County of Alameda*, 2014 WL 4814407 (9th Cir. Sept. 30, 2014).

*King County (WA) Board of Health Secure Medicine Return Regulations*

In June 2013, the King County Board of Health enacted regulations establishing the second EPR program for pharmaceutical disposal in the U.S. Code of King County Board of Health, § 11.50. As with the Alameda County program, pharmaceutical organizations brought suit against King County alleging that the regulations are unconstitutional. *Pharmaceutical Research and Manufacturers of America, et al., v. King County*, No. 2:13-cv-02151 (W.D. Wash. Nov. 27, 2013). The case is still pending at the trial court level as of December 2, 2014.

Although very similar to the Alameda County program, there are some differences in program coverage and additional requirements in the regulations, such as:

- Oversight by the County Department of Public Health. *Id.* at § 11.50.020(A);
- Non-prescription drugs are included. *Id.*, at § 11.50.030(B.1);
- There is a stated "service convenience goal" of "a system of drop-off sites distributed to provide reasonably convenient and equitable access for all residents" with preference given to "having retail pharmacies and law enforcement agencies serve as drop-off sites." *Id.*, at § 11.50.060(D.1-2);
- Specifications that in any locality with a pharmacy or law enforcement facility there must be "one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents." *Id.*, at § 11.50.060(D.3);
- If "service convenience" cannot be achieved in an area via drop-off sites alone, then "those areas shall be served through periodic collection events or mail back services, or a combination of these collection methods." *Id.*, at § 11.50.060(D.4);
- Mail back programs shall be free of charge. *Id.*, at § 11.50.060(F); and
- Proposed stewardship plans are to be submitted by June 20, 2014. *Id.*, at § 11.50.120(A).

## Conclusion

With the release of the October 2014 DEA regulations, NAMSDL expects to see more states and localities passing legislation regarding safe disposal of controlled substances. NAMSDL will continue to monitor legislative activities and keep abreast of any private entities, including chain pharmacies and pharmaceutical manufacturers, who opt to begin drug disposal programs and will update this memorandum as needed.