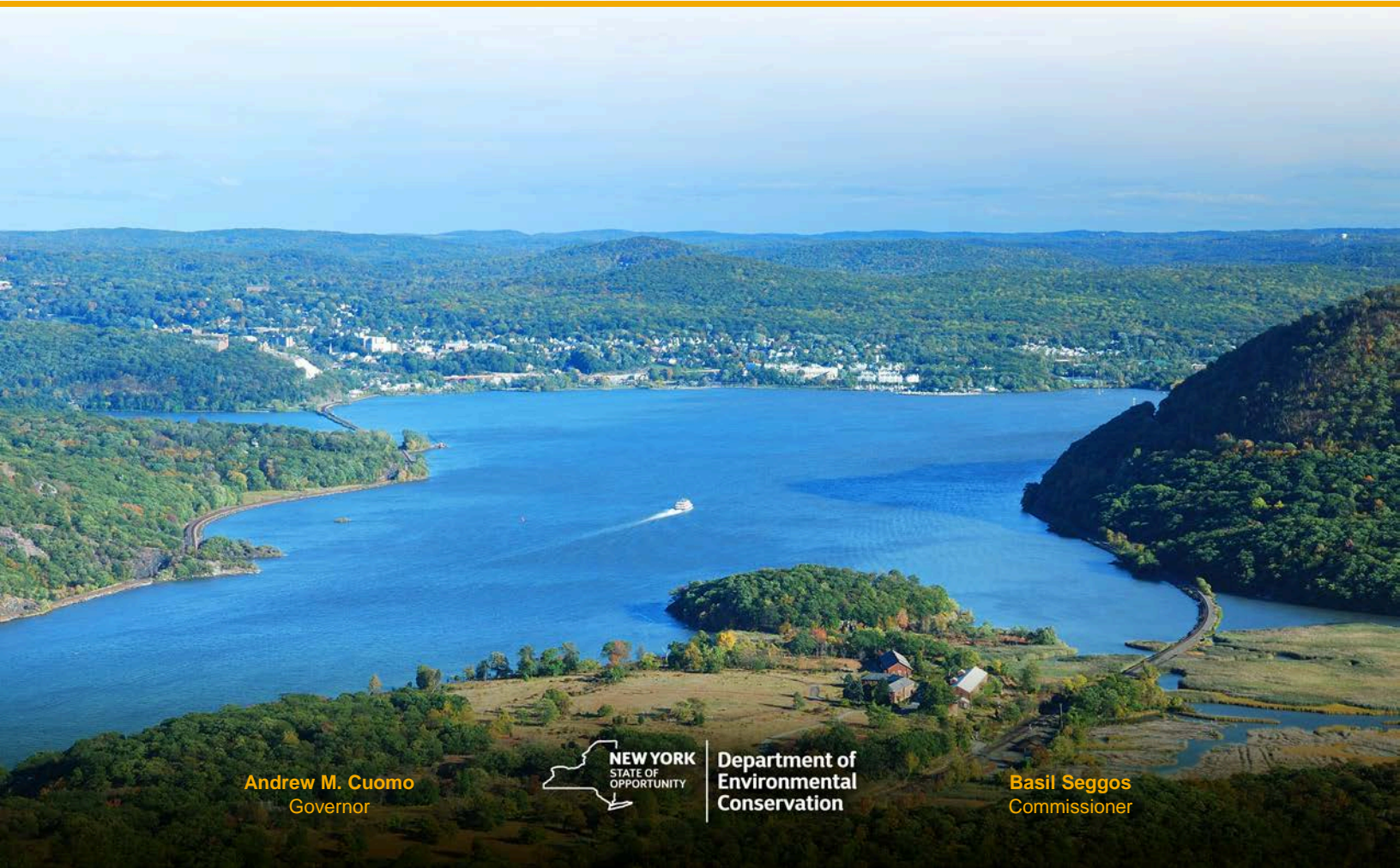




REPORT ON

The Feasibility of Creating and Implementing a
**Statewide Pharmaceutical
Stewardship Program**
in New York State



Andrew M. Cuomo
Governor



Department of
Environmental
Conservation

Basil Seggos
Commissioner

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Executive Summary

The New York Assembly and Senate both passed legislation to establish a statewide pharmaceutical stewardship program during the 2017 Legislative Session that required chain pharmacies with at least ten locations to offer mail-back envelopes to consumers for the return of unused and unwanted pharmaceuticals. While supporting the bill's objective of reducing the potential for opioid abuse by providing a mechanism for the public to properly dispose of unused drugs, the bill was vetoed by Governor Cuomo due to concerns over how the bill would be implemented. In his veto message (Appendix A), the Governor noted that the bill disproportionately burdened chain pharmacies with the costs associated with take-back and disposal and allowed a portion of those costs to be passed to consumers by authorizing chain pharmacies to charge up to a \$2 fee for a pre-addressed mail-back envelope. In the veto message, Governor Cuomo recognized that the bill's intent was laudable and directed the New York State Department of Environmental Conservation (DEC) to meet with stakeholders and investigate the feasibility of creating and implementing a statewide pharmaceutical stewardship program "provided by manufacturers, at no cost to consumers" (Appendix A). Based on characteristics unique to New York State, DEC's substantial experience with other product stewardship legislation, and the outcomes of other programs, DEC in partnership with the State Department of Health (DOH) to prepare this report and formulated its recommendation.



The Problem

Prescription drug abuse has become an epidemic in New York State and across the nation. Drug-related deaths in New York increased by 40% to 2,175 deaths between 2009 and 2013.¹ In 2016, approximately 64,000 Americans died of drug overdoses, with more than half of those involving prescription drugs.^{2,3} In addition, the increase in opioid prescriptions has been mirrored by a complementary increase in opioid-related child hospitalizations; the number requiring pediatric intensive care doubled between 2004 and 2015.⁴ Recent literature reports that removing unneeded pharmaceuticals from homes can reduce the risk of both intentional and accidental nonmedical use, overdose, and poisoning.⁵

The lack of an easily accessible, proper disposal method for pharmaceuticals has also affected our environment. Pharmaceuticals have been detected in waterbodies across the United States with recent studies finding pharmaceuticals in both the Niagara and Hudson Rivers.^{6,7} Pharmaceuticals enter the water in several ways, including through excretion after consumption by humans or animals, being flushed or put down the drain, and through leachate from landfills, but it is difficult to parse the share of contamination that comes through each pathway. Although both municipal wastewater and leachate are treated, many drugs pass through wastewater treatment plants fundamentally unadulterated and enter rivers, lakes, and drinking water sources. The environmental effects of this contamination include changes to the spawning ability of fish and the evolution of antibiotic resistant strains of bacteria.⁸ In addition, the long-term effects to humans from drinking water containing low levels of pharmaceuticals are not fully understood.

¹ (New York State Department of Health, 2015)

² (Hedegaard, Warner, & Minino, 2017)

³ (National Institutes of Health, 2017)

⁴ (Kane, Colvin, Bartlett, & Hall, 2018)

⁵ (SAMHSA's Center for the Application of Prevention Technologies, 2016)

⁶ (Arnnok, Singh, Burakham, Perez-Fuentetaja, & Aga, 2017)

⁷ (Cantwell, et al., 2017)

⁸ (Blazer, et al., 2014)

Efforts to Date

New York and other states have been working to combat improper pharmaceutical disposal in many ways. Working with the New York State Department of Health's Bureau of Narcotic Enforcement (BNE), the U.S. Drug Enforcement Administration (DEA) sponsors biannual National Prescription Drug Take-Back Days. Through a federal grant, BNE has also provided pharmaceutical drop boxes free of charge to law enforcement agencies. DEC adopted Commissioner Policy 66, in May 2017, which provides guidance for proper pharmaceutical disposal, established a pilot pharmaceutical take-back program funded by the state, and has made information about safe drug disposal readily available online (Appendix B). DEC has also developed, and is currently implementing, a Pilot Pharmaceutical Take-Back Program to provide collection receptacles to pharmacies, long-term care facilities, and hospitals and cover the cost of disposal for two years.

Across the country, 18 counties, including Rockland County in New York, four cities, and three states have adopted pharmaceutical stewardship laws that establish take-back programs to help ensure consumers' unwanted, expired, and excess drugs are disposed of safely (Appendix C). Many of the stewardship programs established by these laws are operated and financed differently.

Feasibility Study and Review of Legislation

To advance the Governor's directive, DEC held meetings in February 2018 with stakeholders representing New York's local governments and municipalities, retailers, manufacturers, waste management industry representatives, and environmental advocacy groups (Appendix D) to discuss the proper management and disposition of unused, expired, and unwanted pharmaceuticals. As a result of discussions with stakeholders and a review of proposed and existing laws (Appendix E), DEC and DOH identified the following elements critical to a comprehensive pharmaceutical stewardship program:

- Identification of entities required to participate and their respective roles
- Requirements for collection
- Requirements for disposal
- Public education and outreach
- Requirements for reporting
- Funding and cost allocation
- Uniform statewide application
- Compliance, enforcement, and penalties
- Implementation schedule



Recommendations

DEC, in consultation with DOH, recommends the establishment of a comprehensive pharmaceutical stewardship take-back program for all consumers across the state to dispose of their unused, expired, or unwanted pharmaceuticals in a safe and convenient manner. DEC and DOH recommend the following components be included in a New York State program:

- The program should cover prescription and nonprescription drugs, combination products, drugs in medical devices, and veterinary drugs. The program should not cover sharps collection, vitamins and supplements, homeopathic drugs, herbal remedies, or cosmetics or personal care products.
- The program must be fully funded by pharmaceutical manufacturers, as stated by Governor Cuomo in Veto #247 (Appendix A), and should be run by a single pharmaceutical stewardship organization, that will be established by and operate on behalf of all pharmaceutical manufacturers that sell covered drugs into New York State.
- The pharmaceutical stewardship organization should submit a plan outlining the features of the proposed program to DEC for approval. DEC should consult with DOH prior to approving a program plan.
- All pharmacies in New York should be required to house a collection receptacle as part of the manufacturer-run program and offer pre-paid mail-back envelopes at the time of sale. There should be a waiver to exempt pharmacies from housing a collection receptacle under certain circumstances, such as if their store does not have adequate space for a collection receptacle. If other authorized collectors voluntarily participate, the manufacturer-run program must include them in the program at no additional cost. Additionally, the manufacturer-run program must provide a collection receptacle to any authorized collector that volunteers to house one.
- Education and outreach requirements should, at a minimum, include: a website; a staffed, 24-hour toll free telephone number, and printed information detailing accepted materials.
- Collected pharmaceuticals should be disposed of at a municipal waste combustor, a hazardous waste facility, or by another method approved by DEC as allowed by DEA regulations.
- The lead regulatory agency should be DEC, in cooperation with DOH. DEC has experience implementing and enforcing stewardship programs and promoting the proper disposal of pharmaceuticals. DEC and DOH should coordinate the development of policy. DOH would provide expertise in the area of controlled substances as well as information on all bulk manufacturers licensed by BNE, and the New York State Education Department (NYSED) should provide information on licensed pharmacists and registered pharmacies in the state as well as wholesalers, repackagers, and drug manufacturers that sell into the state.
- The entity responsible for the pharmaceutical stewardship program should be required to report on program activities annually, and DEC and DOH should then report to the Governor and the legislature every three years.
- In order to provide regulatory certainty for all stakeholders, this program should apply statewide and establish full state jurisdiction on pharmaceutical stewardship.



Introduction

In 2017, in an effort to keep unused pharmaceuticals from being misused, the New York State legislature passed Senate Bill 6750/Assembly Bill 387-B. The bill required chain pharmacies and nonresident pharmacies (such as mail-order or internet-based pharmacies that fill prescriptions for delivery to New York residents) to provide pharmaceutical collection to their customers. Chain pharmacies, defined as those with 10 or more locations, could offer collection through collection receptacles, mail-back envelopes, or another option approved by the DEA. Nonresident pharmacies would have been required to offer mail-back envelopes to customers. Collection would have been free of charge to consumers, except in the case of mail-back envelopes, which could cost up to \$2.

In his veto message, Governor Cuomo expressed support for the legislative intent, to create a comprehensive product stewardship program for unused drugs, but vetoed the bill due to several critical shortcomings. The legislation would have placed the burden of organizing and funding collection and disposal on chain pharmacies and allowed some of the disposal costs to be passed to consumers. In addition, pharmaceutical manufacturers had no role. A true product stewardship program would ensure that all entities involved in the lifecycle of a product share the responsibility for reducing the health and environmental impacts that result from the production, use, and end-of-life management of the product. Pharmaceutical manufacturers must play a major role and take responsibility for proper disposal for pharmaceuticals at the end of their lives.

Therefore, Governor Cuomo directed DEC to research the issue by engaging stakeholders and local governments and prepare a report on the feasibility of creating and implementing a comprehensive statewide pharmaceutical stewardship program funded by pharmaceutical manufacturers.

This report summarizes the results of the state's research and analysis of this issue and provides recommendations for moving forward to provide a comprehensive stewardship solution for the collection and disposal of unwanted, unused, and expired pharmaceuticals throughout New York State.



Background

I. The Problem

Pharmaceuticals⁹ have been detected in waterbodies across the United States. A study conducted by the United States Geological Survey (USGS) in 1999 found low levels of pharmaceuticals in 80% of the streams sampled nationwide, including several sites in New York State.¹⁰ Two recent studies found pharmaceuticals in both the Niagara and Hudson Rivers.^{11,12} Pharmaceuticals enter waterbodies in several ways including excretion by humans or animals, flushing or being put down the drain, and through leachate from landfills.

Although both municipal wastewater and leachate are treated, many drugs pass through wastewater treatment plants (WWTPs) fundamentally unadulterated and ultimately enter rivers, lakes, and drinking water sources. This has been exacerbated by the increase in use of certain types of drugs over the past several decades, including antidepressants and pain relievers.¹³ In the 2017 study of the Hudson River, the highest concentrations of pharmaceuticals were measured near sewage outfalls, suggesting that these are major sources of contamination.¹⁴ It is difficult to parse the share of contamination that comes through each pathway.

In the past, best practices encouraged households and healthcare facilities to flush unused or expired drugs. However, there has been a general shift away from recommending flushing as a disposal method of unwanted and expired pharmaceuticals, including in New York State. The U.S. Food and Drug Administration (FDA) now recognizes that drug disposal via a take-back program or a DEA-authorized collector is the safest disposal method for both humans and the environment, and only recommends flushing for extremely potent pharmaceuticals or if preferred methods are not readily available.¹⁵ Despite this, little has been done at the federal level to ensure that take-back disposal methods are easily accessible.

The full range of health and environmental impacts of these pharmaceuticals is still unknown, but the primary concern is the biological risk to aquatic life. Studies have shown that common drugs, such as antidepressants, birth control, and beta-blockers, can affect spawning and fertility among fish living in contaminated waters.¹⁶ A 2017 study of the fish populations in the Niagara River found high concentrations of antidepressants in the brains of 10 species.¹⁷ These effects are seen even when the pharmaceuticals are expired. There is additional concern that long-term exposure to low concentrations of antibiotics may result in the evolution of antibiotic-resistant bacteria.¹⁸ A 2013 study measured the Hudson River estuary and found antibiotic resistant bacteria at all 10 sample sites, attributable to effluent from WWTPs.¹⁹

There is very limited research on the long-term impacts to humans of continuous exposure to low levels of these kinds of pharmaceuticals through treated drinking water. Pharmaceuticals are not generally present in concentrations that would affect human health and are unlikely to bioaccumulate in the human body over time.²⁰

⁹ Different governments, organizations, and legislations use a variety of terms to describe pharmaceuticals. To preempt any confusion, in this report, “pharmaceuticals”, “medications”, and “drugs” all refer to substances intended to diagnose, cure, treat, or prevent disease. Any reference to illicit drugs will be clearly indicated.

¹⁰ (Kolpin, et al., 2002)

¹¹ (Arnnok, Singh, Burakham, Perez-Fuentetaja, & Aga, 2017)

¹² (Cantwell, et al., 2017)

¹³ (Pratt, Brody, & Gu, 2017)

¹⁴ (Cantwell, et al., 2017)

¹⁵ (USFDA, 2018)

¹⁶ (Blazer, et al., 2014)

¹⁷ (Arnnok, Singh, Burakham, Perez-Fuentetaja, & Aga, 2017)

¹⁸ (DEC Pharmaceuticals Work Group)

¹⁹ (Young, Juhl, & O'Mullan, 2013)

²⁰ (DEC Pharmaceuticals Work Group)

However, there is significant risk to human health in keeping expired and unused pharmaceuticals in the home. A 2015 study estimated that, across the country, two of every three prescriptions were not fully consumed,²¹ leaving ample opportunity for misuse of prescriptions. More than half of all prescription drug misuse begins when individuals consume medication not prescribed for them; usually the drugs are prescribed for a friend or family member.²² This is true for adults as well as teens, for whom prescription drugs are the third most commonly misused substance, after marijuana and alcohol. About two-thirds of teens who misused prescription drugs reported getting them from friends and family, often without their knowledge.²³

Prescription drug abuse is both widespread and quickly increasing. In 2016, approximately 64,000 Americans died of drug overdoses (including overdoses involving illicit drugs), nearly double the number in 2006.²⁴ Over half of those, about 34,000, involved opioids and about 9,000 involved benzodiazepines.²⁵

In New York, drug overdose deaths increased 40% between 2009 and 2013.²⁶ The rate of opioid overdose deaths in New York doubled from 5.4 per 100,000 population in 2010 to 10.8 in 2015.²⁷ While drug-related deaths in New York have been lower than other parts of the U.S., pockets of the state mirror states with the greatest numbers of drug related deaths. The increase in drug-related deaths in New York has disproportionately affected upstate and suburban areas, rather than urban areas. The highest increases in per capita drug-related deaths were in Erie (256%), Onondaga (145%), and Westchester (122%) counties between 2010 and 2015.²⁸

In addition, pharmaceuticals are a common cause of poisonings in children, and are among the most dangerous.²⁹ The increase in opioid prescriptions has been mirrored by a complementary increase in opioid-related child hospitalizations. The number of opioid-related hospitalizations requiring pediatric intensive care doubled between 2004 and 2015.³⁰ Removing expired or unused pharmaceuticals from the home reduces the risk of off-label, nonmedical use, both intentional and accidental.

II. National, State, and Local Efforts

Federal, state, and local government, as well as non-governmental entities, have begun implementing options to mitigate the problems described above. These include education and outreach, pharmaceutical collection events, take-back programs, and comprehensive laws aimed at reducing pharmaceutical misuse.

There are currently pharmaceutical collection receptacles across New York State, but they are largely concentrated in cities and other population centers. Collection receptacles are primarily located in law enforcement agencies as provided by DOH, with smaller numbers in pharmacies and medical facilities. In addition, some municipalities hold pharmaceutical collection events, in partnership with law enforcement, throughout the year.

A. National Activities

National Prescription Drug Take-Back Days³¹ are biannual events sponsored by the DEA, which in New York coordinates with DOH's Bureau of Narcotics Enforcement. These events offer an opportunity for residents to drop off any unwanted pharmaceuticals that they may be storing in their homes, anonymously and without questions. There were 226 collection locations in New York on the most recent National Prescription Drug Take-Back Day, April 28, 2018, that collected a total of 39,940 pounds of drugs.³²

²¹ (Law, et al., 2015)

²² (Han, et al., 2017)

²³ (Volk, 2016)

²⁴ (Hedegaard, Warner, & Minino, 2017)

²⁵ (National Institutes of Health, 2017)

²⁶ (New York State Department of Health, 2015)

²⁷ (New York State Department of Health, 2015)

²⁸ (Malatras, 2017)

²⁹ (U.S. Poison Control Centers, 2015)

³⁰ (Kane, Colvin, Bartlett, & Hall, 2018)

³¹ (US Drug Enforcement Agency, n.d.)

³² (US Drug Enforcement Agency, 2018) (US Drug Enforcement Agency, 2017)

B. Nonprofit Activities in New York State

Several nonprofit organizations have operated pharmaceutical take-back pilot programs in New York over the last several years.

In 2016, The Product Stewardship Institute (PSI) and the New York Product Stewardship Council (NYPSC) conducted a six-month pilot program in rural Oneida and Lewis Counties, funded through a grant from the U.S. Department of Agriculture (USDA). Four independent pharmacies and one hospital pharmacy established a contract with Sharps Compliance Inc., whereby each received an 18-gallon pharmaceutical collection receptacle, pre-labeled cardboard box inserts, mail-back envelopes, and UPS shipping for disposal. At each retail pharmacy, receptacle boxes were replaced every two months. Additionally, each participating independent pharmacy maintained 250 mail-back envelopes for the duration of the program. At the hospital pharmacy, receptacle boxes were replaced twice a month and fifty mail-back envelopes were available. Promotion and outreach were mainly conducted by participating pharmacies, but funded through the program. The pilot collected approximately 300 pounds of pharmaceuticals. Four of the five participating pharmacies continued offering collection after the pilot ended.

In February 2018, PSI and NYPSC began a new pilot, funded by a USDA grant, at five New York hospitals in Delaware, Monroe, Otsego, and St. Lawrence counties. It is expected to run for six months and includes pharmaceutical collection receptacles and pre-paid mail-back envelopes, both of which are managed by the hospital pharmacies and obtained through Stericycle. The intent of the program is to focus on areas that are currently underserved by existing pharmaceutical collection locations.

Citizens Campaign for the Environment (CCE) has been supporting a program at King Kullen grocery stores on Long Island. A pilot began in 2014 and was continued with funding from a grant from DOH. Pharmaceutical collection receptacles and replacement inner containers are provided through a contract with Medsafe. When the containers are full, King Kullen ships them to Texas for incineration. Public outreach is ongoing and includes monthly ads in King Kullen's circular, ads in local papers, and social media promotion. The program has collected and destroyed more than 7,700 pounds of pharmaceuticals to date.

CCE also operated a pilot program through Stop & Shop grocery stores from December 2013 through December 2015. The program offered free, pre-paid mail-back envelopes upon request at participating locations and was promoted through Stop & Shop circulars, CCE tables at grocery store locations, and local media coverage. However, only 30% of the envelopes distributed were returned, and less than 300 pounds of pharmaceuticals were collected in the two years the program was in operation. CCE did not continue the program due to the relative lack of success. The failure of this program has been attributed, by CCE, to the lack of collection receptacles and the use of mail-back envelopes as the only option.

C. State Activities

The 2009 Drug Management and Disposal Act³³ mandated DEC and DOH, to develop and implement a public information program that included proper storage and disposal of drugs and drug disposal sites. The Act also required notices, from DEC in consultation with the NYSED, on safe drug storage and disposal be posted in every pharmacy and other retail business authorized to sell drugs. The resulting poster informs consumers not to flush drugs, and lists several options for safer disposal, as well as a website for more information. The current version of the poster is located below.

³³ (Drug Management and Disposal Act, 2009)

DOH's Bureau of Narcotic Enforcement (BNE) developed an approval process for community-sponsored pharmaceutical events and drop boxes located at law enforcement agencies that allow collected pharmaceuticals to be destroyed in a municipal solid waste combustor rather than a hazardous waste facility. The process requires the applicant to detail a collection and disposal plan. DOH currently operates the Medication Drop Box Program, which allows law enforcement agencies to operate an on-site drop box for pharmaceuticals. The box is available to members of the public, during hours of operation, who may drop off any unwanted pharmaceuticals. All costs associated with destruction of surrendered pharmaceuticals must be borne by the participating locations and a law enforcement officer must be involved in the transport and destruction. Currently, according to DOH, 41 counties have at least one drop box through DOH's program.



DEC also operated a collection program from 2009 to 2015 for health care facilities in Westchester, Putnam, Dutchess, and Delaware counties to reduce the amount of pharmaceuticals that enter the West and East of Hudson watersheds. From 2015 to 2017, DEC operated an annual collection program for certain long-term care facilities (LTCFs) without an on-site pharmacy in Nassau and Suffolk counties that have very few options for properly disposing of their waste drugs. The program was funded through a \$150,000 State legislative appropriation and was designed to reduce the amount of pharmaceuticals that are flushed and can end up in Long Island's groundwater, bays, and estuaries.

DEC Environmental Conservation Officers (ECOs) travelled to the LTCFs to collect controlled and non-controlled substances, which were then taken to Covanta for destruction via incineration. In 2015, 52 boxes of drugs of unknown weight were collected from 25 facilities; in 2016, 720 pounds of drugs were collected from 27 facilities; and in 2017, 660 pounds were collected from 24 facilities.

In May 2017, DEC released a Commissioner Policy, NYSDEC Guidance for Proper Pharmaceutical Disposal (CP-66),³⁴ as guidance for proper pharmaceutical disposal. The policy establishes a clear hierarchy for preferred pharmaceutical disposal methods. The most preferred method is authorized collection locations and in-pharmacy collection receptacles, followed by collection events. Least preferred is the mail-back option. If none of these disposal methods are available or reasonably convenient, the policy details how to safely dispose of pharmaceuticals in the trash and emphasizes that pharmaceuticals should not be flushed. The policy also contains steps for LTCFs to dispose of unused, unwanted, or expired pharmaceuticals via mail-back, collection receptacles, or by surrendering them to law enforcement. The policy also encourages all pharmacies to become authorized collectors, increased collection at LTCFs, and compliance with the Drug Management Disposal Act's posting requirements for all businesses where drugs are sold.

³⁴ (New York State Department of Environmental Conservation, 2017)

i. Current Pilot Pharmaceutical Take-Back Program

DEC has developed, and is currently implementing, a Pilot Pharmaceutical Take-Back Program³⁵, which was announced in February 2017 with collection receptacles being distributed beginning in April 2018. The pilot program is designed to increase New Yorkers' accessibility to pharmaceutical collection receptacles in pharmacies, LTCFs, and hospitals throughout the state. New York State is funding the program with \$2 million from the Environmental Protection Fund (EPF). An additional \$1 million in EPF funds has been added through the 2018-2019 State Budget to further expand the program.

Through the pilot program, DEC is purchasing DEA-compliant pharmaceutical collection receptacles (or kiosks), providing up to fifty replacement inner liners, and paying for the pick-up, transport, and destruction of waste pharmaceuticals for a period of two years at each location. Participants must commit to continue collection, at their own expense, for six months after the pilot period ends.

The program currently has 244 participants enrolled to date, consisting of 214 pharmacies, 20 LTCFs, and 10 hospitals throughout the state. Every effort was made to evenly distribute pharmaceutical collection receptacles across New York State and/or to cover gaps in existing kiosk coverage. Available pharmaceutical collection receptacles and current enrollees are shown in the maps in Appendix F.



ii. DEC Reference Information

Because of DEC's existing efforts, the agency has an extensive amount of information available, including CP-66, to educate and advise the public, pharmacies, and LTCFs on the dangers of excess pharmaceuticals and how to properly dispose of them. Descriptions of the resources available on DEC's website can be found in Appendix B.

III. Existing Laws and Proposed Legislation

A. Existing Laws in Other States

Alameda County, California was the first county in the U.S. to pass a pharmaceutical stewardship ordinance that required manufacturers to facilitate and fund a program to collect prescription and nonprescription drugs, drugs in medical devices and combination products, brand name and generic drugs, and drugs for veterinary use.³⁶ The Pharmaceutical Research and Manufacturers of America (PhRMA) and other industry groups sued the County. The U.S. Court of Appeals for the Ninth Circuit upheld the ordinance.³⁷ PhRMA brought the case to the Supreme Court of the U.S., which declined to hear their appeal.

Since Alameda County's legislation was adopted, eight other counties and four cities in California have passed similar legislation. Seven counties in Washington, one in Illinois, Rockland County in New York, and the states of Vermont, Massachusetts, and Washington have also passed pharmaceutical stewardship laws. MED-Project, an industry-funded product stewardship organization, was established to comply with the expanding number of counties passing pharmaceutical stewardship laws. The organization now services most of the counties and cities in California that have passed pharmaceutical stewardship laws as well as all the counties in Washington where these laws have been implemented. A full list

³⁵ (New York State Department of Environmental Conservation, 2018)

³⁶ (Safe Drug Disposal Ordinance, 2013)

³⁷ (PhRMA v. County of Alameda, 2014)

of all adopted pharmaceutical stewardship laws, as well as pending pharmaceutical stewardship bills, is provided in Appendix C; more information on the details of Vermont's, Massachusetts's, and Washington's laws is below.

Washington's Secure Drug Take-Back Act³⁸ requires pharmaceutical manufacturers who sell covered drugs in Washington State to fully fund a drug take-back program, approved by the Washington Department of Health, without charging any fees to consumers.

Unlike the legislation passed in Washington and the counties and cities mentioned above, the laws that established pharmaceutical take-back programs in both Massachusetts and Vermont were embedded into broader bills to address substance use and abuse in those states. Massachusetts passed the Act Relative to Substance Use, Treatment, Education, and Prevention (H4056)³⁹ in March 2016. The drug stewardship program established by the act applies to brand and generic opioids, as well as benzodiazepines. The program is operated and financed by manufacturers of covered drugs either individually or jointly, or manufacturers can enter into an agreement with a product stewardship organization or the Massachusetts Department of Public Health. Each program operator must submit a plan for public outreach and education and an annual report on the volume and type of drugs collected.

Under the Massachusetts law, each program must provide at least two methods of collection, which may include; prepaid mail-back envelopes distributed at the time of prescription filling, pharmaceutical collection receptacles, drop-off day events, or in-home disposal methods, and shall collect any covered drug and any other prescription drug in pill form. Law enforcement facilities and pharmacies are authorized as collection locations, but neither are required to participate under this law.

Vermont passed the Act Relating to Combating Opioid Abuse in Vermont⁴⁰ in June 2016. The act requires the Vermont Department of Health to establish and maintain a collection program for unused and unwanted prescription drugs. The act states that the "program may include establishing secure collection and disposal sites and providing medication envelopes for sending unused prescription drugs to an authorized collection facility for destruction."

B. Proposed Legislation in Other States

Indiana is currently the only state other than New York that has proposed pharmaceutical stewardship legislation. Senate Bill 338⁴¹, introduced in January 2018, is currently a one-house bill. If passed, it would establish a manufacturer funded pharmaceutical take-back program. For more information on this bill, see Appendix E.

C. Existing Laws in New York

Rockland County is currently the only government in New York that has passed a product stewardship law for pharmaceuticals. The local law⁴², passed February 28, 2017, requires producers (corresponding to manufacturers in other laws) of covered drugs sold within Rockland County to administer and finance a comprehensive collection program. The program includes the costs of collection, transport, and disposal of collected drugs as well as recycling or disposal of any collected packaging. Covered drugs, meaning those defined in 21 U.S.C. §321 (g)(1), including brand name and generic drugs and nonprescription drugs, must be disposed of by incineration at a medical waste or hazardous waste facility.

³⁸ (Secure Drug Take Back Act, 2018)

³⁹ (Act Relative to Substance Use, Treatment, Education and Prevention , 2016)

⁴⁰ (An Act Relating to Combating Opioid Abuse in Vermont, 2016)

⁴¹ (Senate Bill No. 338, 2018)

⁴² (Pharmacy Take-Back Act , 2017)

The law mandates that producers operate the product stewardship program individually or jointly with other producers or enter into an agreement with a product stewardship organization. In cases where producers jointly run a program, costs must be divided according to amount of sales in the County. Producers must also pay all costs incurred by Rockland County for administration and enforcement of the program. Costs may not be passed to consumers as a point of sale fee or to collection locations.

Collection methods must be available at all retailers and providers in Rockland County, where retailer is defined as a business that sells drugs with three or more locations in or outside of the County, and provider is defined as any person or entity that sells or distributes drugs at a medical or veterinary office, clinic, or hospital. Each of these locations must have either a collection receptacle or provide pre-paid mail-back envelopes.

The law also requires that producers create promotional and outreach materials for the program, including signage for collection locations, written materials to be provided at the time of purchase, and appropriate advertising. The producers must also set up a website that lists all collection locations and operate a toll-free phone number for public inquiries.

Producers have until August 31, 2018 to submit product stewardship plans to the County for approval.

D. Proposed Legislation in New York

In recent years, the New York State Legislature has advanced legislation to create a statewide pharmaceutical take-back program. Senate Bill 6750/Assembly Bill 387-B⁴³, sponsored by Senator Kemp Hannon and Assembly Member Aileen Gunther, passed both houses of the legislature, but was ultimately vetoed by the Governor (Appendix A) in December 2017, primarily because it placed the costs of the collection on pharmacies and consumers. The bill allowed consumers to be charged up to \$2 per mail-back envelope.

During the 2017-2018 legislative session, Senate Bill 7354⁴⁴, also sponsored by Senator Hannon, passed the Senate on April 25th, but was subsequently recalled and returned to the Senate for reconsideration. This bill would establish a take-back program run and financed by pharmaceutical manufacturers to collect covered drugs at pharmacies and any other authorized locations that voluntarily participate. Pharmacies would be required to offer collection via a pharmaceutical collection receptacle, pre-paid mail-back envelopes, or another approved method, and to display signage about such pharmaceutical collection.

Manufacturers, individually or jointly, would be responsible for covering the cost of collection, transportation, and disposal of covered drugs as well as administrative and enforcement costs incurred by DOH. Manufacturers would also be responsible for conducting education and outreach, including developing a website and signage to advertise the program, and regularly reporting to DOH. In turn, DOH would annually report on the program to the Governor, speaker of the Assembly, and temporary president of the Senate.

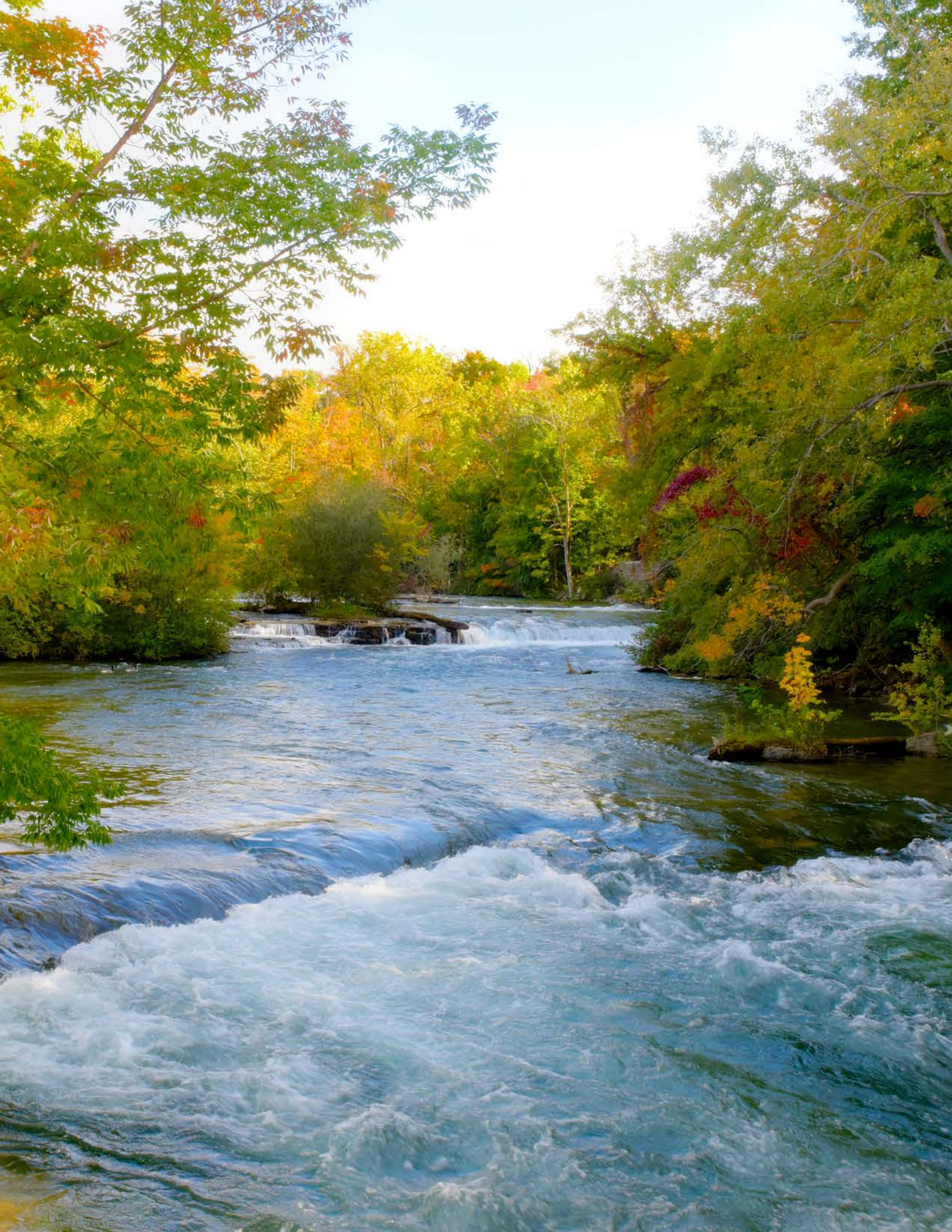
Following Rockland County's example, two other counties in the state—Erie and Westchester—have pharmaceutical product stewardship bills under consideration (see Appendix E). The product stewardship program proposed by the Westchester County's bill⁴⁵ is identical to the program in Rockland County. The program proposed in Erie County's bill⁴⁶ differs in that the program would provide support to participating law enforcement agencies and the program operator would certify that any patient information on pharmaceutical packaging would be promptly destroyed. The bill would also require that Erie County's hospitals, hospice facilities, nursing homes, and LTCFs submit a plan for the safe disposal of unused and expired pharmaceuticals to ensure they do not enter the County's drinking water supply or waterbodies.

⁴³ (S6750, 2017)

⁴⁴ (S7354, 2018)

⁴⁵ (Local Law 10622, 2018)

⁴⁶ (Local Law 1-2, 2017)



Discussion

After reviewing existing pharmaceutical disposal efforts, as well as recent legislative proposals, DEC, and DOH identified several key issues that necessitated additional stakeholder discussion. The following topics were presented for discussion with various stakeholder groups (Appendix D) and are summarized below: (I) product scope, (II) entities that may be required to participate and their respective roles; (III) the entity that will be responsible for implementing the program; (IV) requirements for collection; (V) requirements for disposal; (VI) public education and outreach; (VII) reporting requirements; (VIII) preemption; (IX) compliance, enforcement and, penalties; and (X) implementation schedule. Following the summary of each issue, stakeholder comments that were made in person or received in writing have also been noted.

I. Product Scope

Product scope, which defines the type of products that are included in the pharmaceutical stewardship program, varies amongst the existing and proposed pharmaceutical stewardship programs. Virtually all existing pharmaceutical stewardship programs define “drugs” as a substance intended to diagnose, cure, mitigate, treat, or prevent a disease, in any form (i.e. pill, liquid, etc.). “Covered drugs” are drugs that are purchased by consumers and can include prescription, non-prescription, and veterinary drugs, drugs in medical devices, combination products, medical sharps, vitamins and supplements, homeopathic drugs, herbal remedies, and cosmetics or personal care products.

Prescription drugs require a prescription from a doctor and must be purchased at a pharmacy. Prescription drugs include all controlled substances, as well as other drugs deemed unsafe for nonprescription use because they are habit-forming or toxic, have a high potential for harmful effects, or are for medical conditions that cannot be self-diagnosed. Non-prescription drugs, also called over-the-counter (OTC), do not require a doctor’s prescription and can be purchased off the shelf in stores. They include items such as low-dose ibuprofen and other pain and inflammation reducers, anti-allergy medications, and topical anti-fungal and anti-bacterial lotions. Veterinary drugs are any substances used to diagnose, cure, mitigate, treat, or prevent disease in animals.

Medical devices are items that do not achieve their primary action through pharmacological, immunological, or metabolic means. This includes a range of items, from bandages to implantable pacemakers. Combination products are two or more of the following in a single item: drugs, devices, and biological products, and include items like transdermal patches and inhalers. Medical “sharps” are devices with sharp points or edge that can puncture or cut the skin, such as needles, syringes, and auto injectors, and could have come into contact with blood or other body fluids.⁴⁷

Vitamins and supplements, homeopathic drugs, herbal remedies, and cosmetics or personal care products includes items regulated as both a cosmetic and a nonprescription drug under federal regulations, such as anti-dandruff shampoo, makeup with sun protection, and antiperspirant deodorants.

Input received: Stakeholders from environmental advocacy groups believe that a program should require local sharps disposal options to be posted at all collection receptacle locations, or have sharps collection receptacles directly next to pharmaceutical collection receptacles. They also advocate for covered drugs to include medications in liquid form.

⁴⁷<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm>

II. Stakeholders

This section explores the entities that could be involved in a pharmaceutical stewardship program and their appropriate responsibilities. A successful pharmaceutical stewardship program must clearly delineate responsibilities for each of these entities.

A. Manufacturers

Veto #247 expressly directs DEC to examine the feasibility of requiring manufacturers to provide for collection at no expense to consumers. “Manufacturer” could apply to any entity that manufactures products considered “covered drugs” sold in the state, however defined. As of April 2016, NYSED has licensed 493 manufacturers of pharmaceuticals.

In addition to covering the costs of pharmaceutical collection, transport, and disposal, a program could require manufacturers to design, implement, and operate a full take-back program across the state.

Input received: The consensus amongst stakeholders is that manufacturers should play a key role in a pharmaceutical stewardship program. Representatives from the industry have generally indicated a willingness to participate in such a program. In conversations and meetings with the State, the Pharmaceutical Research and Manufacturers of America (PhRMA) and Pfizer expressed support for a statewide pharmaceutical stewardship program, though both groups have indicated opposition to a program that is fully funded by the manufacturers and believe it should be funded by all participants.

B. Authorized Collectors

Authorized collectors are those businesses and facilities allowed to collect pharmaceuticals pursuant to DEA regulations. A program should define which facilities qualify as collection locations, what types of locations should be prioritized, and which locations, if any, should be required to participate.

Current DEA regulations allow manufacturers, distributors, reverse distributors, narcotics treatment programs, retail pharmacies, and hospitals and clinics with on-site pharmacies to register as authorized collectors. In addition, LTCFs are permitted to dispose of a current or former resident's pharmaceuticals in an on-site collection receptacle.⁴⁸ Any of these authorized collection locations could be included in the definition of authorized collectors.

A distinction could be drawn between independent and chain pharmacies. For instance, a program could define “chain pharmacies” as those with more than a certain number of locations. Chain pharmacies could be subject to different or additional requirements than independent pharmacies. In addition to brick-and-mortar pharmacies, mail-order and online pharmacies also sell pharmaceuticals in New York State. While they cannot host a collection receptacle, they could be required to provide mail-back envelopes or sponsor collection events. According to NYSED, as of April 2016 there are a total of 5,410 licensed pharmacies in the state.

Many law enforcement agencies currently house collection receptacles through DOH's Medication Drop Box Program. Law enforcement agencies may want to continue as a collection location, especially in areas where there are few other collection locations, or they may want to cede responsibilities to other entities.

Input received: All stakeholders emphasized that municipalities should be excluded from the definition of collection locations, as they are not an authorized collector under DEA regulations.

⁴⁸ Title 21 of the Code of Federal Regulations (Drug Enforcement Administration), Volume 9, Chapter 11, April 1, 2015, Part 1317

CCE argued that all chain pharmacies should be required to be collection locations in the established pharmaceutical stewardship program with voluntary participation from other pharmacies. Other stakeholders advocated for the inclusion of narcotic treatment centers and college public safety offices as collection locations. The Pharmacists Society of the State of New York (PSSNY) believes that participation as a collection location should be voluntary for any element that would have a pharmacy assume physical or financial responsibility for pharmaceuticals given to patients by another entity.

Many stakeholders expressed concern over the inclusion of mail-order pharmacies. Representatives from SUNY Buffalo and PSSNY both stated that a large section of pharmaceutical waste collected at collection events and independent pharmacies comes from mail-order pharmacies. Mail-order pharmacies fall under DEA distribution regulations and therefore cannot be authorized collectors, but many stakeholders want to ensure they are held responsible for pharmaceutical stewardship in the same way as brick-and-mortar pharmacies.

C. Consumers

“Consumers” defines who may use pharmaceutical stewardship programs to dispose of unused, expired, or unwanted pharmaceuticals. In other pharmaceutical stewardship laws, any consumer who is a resident of the jurisdiction (i.e. New York State) is typically free to participate in collection. However, most bills expressly forbid commercial generators from being “consumers,” including hospitals, pharmacies, clinics, medical offices, and security or other law enforcement entities (such as airport security).

D. Lead Agency

Among New York State governmental agencies, DEC, DOH, and NYSED each have roles in regulating the distribution and disposal of pharmaceuticals.

DOH generally regulates controlled substances through the BNE and operates the New York State Medication Drop Box Program, which allows law enforcement agencies to voluntarily maintain collection receptacles in eligible offices pursuant to an agreement with DOH.

DEC is currently operating a pilot pharmaceutical take-back program and for more than a decade has been working to assess and limit the presence of pharmaceuticals in New York waterways. DEC also has significant institutional knowledge and experience reviewing and implementing other product stewardship programs. The agency is acutely aware of the challenges of designing and implementing a stewardship program.

NYSED is responsible for licensing pharmacists and registering pharmacies in New York and keeps records of the number of pharmacists, pharmacies, manufacturers, repackagers, and wholesalers selling into New York.

All three agencies could have a responsibility in New York’s pharmaceutical stewardship program, with one of these agencies as the lead agency with the others as support, or it could place the agencies on equal footing. If manufacturers are implementing a pharmaceutical stewardship program, the lead agency could be required to review and approve proposed stewardship plans, review periodic reporting from approved programs, report to the legislature or Governor at regular intervals, and enforce the program. Their responsibilities could also include review and approval of proposed plan changes and some level of public education and outreach.

Alternatively, the lead agency could run the pharmaceutical stewardship program, which would eliminate oversight and review responsibilities. This structure would require the lead agency to design, implement, operate, and enforce the program.

The lead agency could be authorized to conduct audits of programs, which could be scheduled at regular intervals or done as the agency sees fit, to ensure the programs are compliant with the program. The lead agency could also develop regulations to further specify program and implementation requirements.

Input received: PSI advocated for DOH as the lead agency with DEC having, at minimum, an advisory role. DEC has significant experience running a pharmaceutical take-back program. PSI also stated that the lead agency should have authority to adjust the program as needed and to conduct audits.

E. Funeral Homes and Hospice Providers

Funeral homes and hospice providers interact directly with families of the recently deceased, who may have significant quantities of pharmaceuticals. They could have a role in educating the public on take-back options.

Input received: The Office of Mental Health (OMH) believes disposal of the deceased's medications is an important issue and suggested providing a mail-back envelope or educational materials at funeral homes or hospice facilities.

F. Transporters

Depending on the organization of the program, transporters may be common carriers, such as FedEx or UPS, or may be other companies, which would be subject to existing DEA regulation.

G. Final Disposal Facilities

Final disposal facilities are responsible for weighing and safely disposing of collected pharmaceuticals. They could also be required to report the weight and source of disposed pharmaceuticals. Appropriate disposal facilities for pharmaceuticals are municipal solid waste incinerators and hazardous waste incinerators.

III. Pharmaceutical Stewardship Program Operation and Funding

Responsibility for implementing a statewide pharmaceutical stewardship program could be placed on either the manufacturers of covered drugs or on the lead state agency. Either way, a new comprehensive pharmaceutical stewardship program would ultimately be funded by manufacturers and would have to account for the existing collection and take-back infrastructure in place across the state with many law enforcement agencies, pharmacies, and other authorized collectors already participating in DEC's pilot take-back program or other established programs.

A. Manufacturer-Operated Pharmaceutical Stewardship Program

Requiring manufacturers to fund and implement a pharmaceutical stewardship program with state agency oversight allows covered pharmaceutical manufacturers to organize the program in a cost-efficient and effective manner. Manufacturers could operate pharmaceutical stewardship programs, either individually, in one or more groups, or through a separate stewardship organization, as further outlined below and would need to meet all the pharmaceutical program requirements such as product scope, convenience, outreach efforts, and reporting.

Manufacturer-run programs, implemented either individually or in groups, would require the operator of each program to submit for approval to the lead state agency a plan for take-back. Each plan would need to go through an approval process by the lead state agency, and could require multiple rounds of revisions until it is approved.

Typically, a comprehensive stewardship plan is required to include: contact information for all involved and responsible entities; descriptions of the overall proposed collection system including collection, transportation, handling plans and ultimate disposal; descriptions of the costs to be incurred and how the program will be funded; descriptions of the safety and security procedures to be followed; and a description of the education and outreach campaign. In addition, a program can encourage or require stewardship programs to submit program goals in their plans, as well as require details about how the new program will interact with existing pharmaceutical collection programs and require annual reporting to the lead state agency.

Multiple take-back programs could cause confusion for consumers if there are significant differences in collection methods, messaging, or other pharmaceutical take-back program aspects. This issue could be mitigated if all programs are required to coordinate outreach and minimize differences. Alternatively, manufacturers could coordinate their efforts and jointly establish a single, efficient pharmaceutical stewardship program, which would reduce the potential for consumer confusion and oversight, reviews, and enforcement efforts needed by the lead state agency. This approach would require a single uniform pharmaceutical stewardship program plan, which would need to be reviewed and approved by the lead state agency. Allowing multiple manufacturer-run programs adds significant complexity to any proposed statewide program and would place substantial burdens on the lead state agency, regarding program review, oversight and enforcement.

In either manufacturer-implemented approach, all program costs would be paid by covered drug manufacturers. The division of collection, transport, and disposal costs between individual manufacturers can be prescribed or left to their discretion. For example, costs could be required to be apportioned by market share, volume, or weight of pharmaceuticals sold in the state, or evenly, regardless of size. Alternatively, the distribution of costs could be left up to manufacturers entirely, with no state involvement or oversight. While this approach would allow manufacturers more flexibility and reduce state involvement and costs, costs to all manufacturers may not be borne equitably.

Any costs incurred by the lead state agency for administration, oversight, and enforcement can be borne by the state or covered by fees assessed to manufacturers. If fees are chosen, they could be assessed to each manufacturer as either a flat fee or variable fee based on a metric such as market share. Alternatively, a fee could be assessed to each stewardship program. If the objective is to cover costs, the size of this fee would need to be variable. A single larger fee could be assessed at the outset of the program, to fund the start up, and a smaller annual fee to cover long-term oversight.

Regardless of the number of manufacturer-run programs, alterations to approved plans will likely be necessary. A protocol for approving changes should be developed. One option would be to require all changes obtain agency approval. This would allow greater oversight but may also require significant agency resources. Another option would be to delineate between substantive and non-substantive changes. The program developed under Washington's Secure Drug Take-Back Act will operate in this way. Non-substantive changes may require notification 15 days prior to the change, but no approval. Substantive changes may require written approval by the lead state agency before being implemented. A determination would need to be made about what constitutes "a substantive change," but this system would keep the lead state agency apprised of changes without requiring intensive involvement in every detail. A third option would be to tie any changes into a required annual or periodic report.

The program can require audits by either by the lead state agency or by a third party. Audits can be limited in scope, for example, verifying that a program is meeting the law's convenience standard, or can cover the entire scope of the program. Audits can occur at any time, either to determine compliance or to investigate any complaints or at regular intervals.

B. State-operated Pharmaceutical Stewardship Program

The alternative to manufacturer-operated pharmaceutical stewardship programs is for the lead agency (e.g. a state agency) to fully implement a statewide pharmaceutical stewardship program meeting all requirements and charge the manufacturers for the costs of the program. The scope of work would include ensuring sufficient collection across the state, securing vendors for collection receptacles, mail-back envelopes, and disposal; ensuring safe transportation and proper disposal of collection materials; designing and implementing a comprehensive public education campaign; and collecting and analyzing data on the amount of material disposed.

The lead state agency would be responsible for all up-front costs associated with program implementation, but ultimately the covered pharmaceutical manufacturers would be billed and required to reimburse the lead state agency for all program costs. If a market share approach is used to recoup costs from manufacturers, the lead state agency would require all covered pharmaceutical manufacturers to provide sales data to equitably apportion program costs. This structure would help ensure that the program was consistent across the state and met all necessary legislative requirements. However, this approach would require a significant investment by the lead state agency, as several additional staff and associated funding would be required to develop and implement such a large, overarching program. DEC anticipates at least four full-time staff would be required to support such a program effort.

Input received: Environmental advocacy groups prefer a manufacturer-run pharmaceutical stewardship program over a state-run program. Both CCE and PSI stated that manufacturers should be responsible for operating and financing a statewide pharmaceutical stewardship program. PSSNY agrees with this but wants to ensure it is clear that any costs incurred by pharmacies are covered up front. Environmental advocacy groups also believe manufacturers should be required to cover state administrative costs and adopt existing take-back programs (i.e. law enforcement boxes). In terms of the distribution of costs among manufacturers, environmental advocacy group representatives advocated for allowing manufacturers to determine this amongst themselves.

IV. Collection Methods and Convenience Standards

There are several options for physically collecting pharmaceuticals from consumers. One is the use of DEA-compliant collection receptacles, which are locked containers where consumers can deposit their unwanted pharmaceuticals whenever the collection location is open. Another option is mail-back envelopes, which are padded, tear-resistant envelopes that allow consumers to mail their pharmaceuticals to a disposal location. A third option is drug take-back events. Similar to National Prescription Drug Take-Back Days, these are designated events for consumers to dispose of their pharmaceuticals.

Collection receptacles are the most cost-efficient option for pharmaceutical collection. Once the receptacle itself is purchased, the only repeated cost is disposal, and the frequency at which this cost is incurred depends on how quickly the container is filled. Based on the cost of DEC's pilot pharmaceutical take-back program, the one-time cost of a collection receptacle is \$1,250. Each liner is \$46.50 and destruction costs \$49, making the repeated cost \$96.50 each time the receptacle is filled. Based on these costs and assuming containers would be emptied twice a month, on average, the annual costs of liners and disposal would be \$2,300 per collection receptacle. According to New York State Board of Education, there are approximately 4,600 pharmacies, independent and chain, located outside of a healthcare or correctional facility and not already participating or planning to participate in the New York State pilot program. The total cost of collection receptacles for all these locations would be approximately \$5,750,000, plus an annual cost of around \$10,580,000 for liners and disposal.

In addition, collection receptacles are the most convenient and user-friendly option for consumers who have easy access to an authorized collector. The third positive aspect of collection receptacles is that they are a visual reminder to consumers to return their pharmaceuticals instead of flushing. This option is less convenient for the homebound or consumers in rural areas who may not have an authorized collector within a reasonable distance.

Mail-back envelopes are another option for pharmaceutical collection. This option equally serves all populations including rural areas and the homebound, but is not as cost efficient as other options due to the repeated cost of providing mail-back envelopes to consumers. Each envelope costs \$5, making the cost of 250 envelopes equivalent to that of a collection receptacle. Another drawback to mail-back envelopes is that they have limited space, and a consumer may need multiple envelopes depending on the number of medications they are disposing.

Take-back events are the third option for pharmaceutical collection. Take-back events are particularly beneficial for those living in rural areas without authorized collectors within a reasonable distance. In addition, these events facilitate the collection of large amounts of pharmaceuticals that consumers may have in their homes and can raise awareness of the issues surrounding improper disposal of pharmaceuticals. However, take-back events are not accessible to the homebound and are costly to run, as staff and law enforcement must be present throughout the entire event. Take-back events also require approval from the state and must comply with existing federal and state regulations. Finally, take-back events are only periodically available. Events occur infrequently, and if they are the only method available for pharmaceutical disposal, they require consumers to keep their excess, unwanted, and expired pharmaceuticals in their homes until the next event. This increases the chance of those pharmaceuticals being misused.

There are several ways to balance these considerations in a statewide program. The least prescriptive approach would specify that the collection methods must be DEA-compliant collection receptacles, mail-back envelopes, collection events, or another agency-approved method. This allows maximum flexibility for manufacturers, pharmacies, and collection entities. However, this does not ensure convenient collection for all state residents.

The most prescriptive approach would mandate that all authorized collectors offer collection receptacles at each of their locations, provide free mail-back envelopes for those who cannot access collection locations, and host collection events for areas with limited collection locations. This approach would offer the most convenience to consumers, but would place a greater burden on some of the authorized collectors. While many authorized collector locations could easily host a collection receptacle, some may not have the necessary space or staff or may be wary of hosting a collection receptacle due to concerns about the safety of their store and staff.

Intermediate approaches would balance consumer convenience with the concerns of possible collection locations, including requiring collection receptacles only in certain types of locations (i.e. pharmacies) or offering a waiver option for locations that believe they are unable to host a collection receptacle. Rockland County's Pharmacy Take-Back Act limits the requirement for collection receptacles to chain pharmacies (defined as companies with three or more locations in or outside of the county). However, applying this approach statewide could limit access to collection receptacles in many parts of the state. Allowing specific locations to apply for a waiver could help address concerns that some pharmacies may be too small or ill-equipped to house a collection receptacle. However, the lead state agency should be authorized to approve or disapprove the waiver request.

Another option could require manufacturer-run programs to include any authorized collector willing to host a collection receptacle. While this approach eliminates requirements on pharmacies or other authorized collectors, this option alone may not sufficiently ensure convenient accessible collection across the state.

Allowing waivers or relying exclusively on authorized collectors opting in to participation may leave areas of the state underserved (Appendix G). An option to mitigate this concern could include requiring some or all authorized collectors to offer mail-back envelopes, free of cost to consumers, regardless of whether they host a collection receptacle.

Including a convenience standard would ensure that collection is accessible throughout the state without mandating specifics. A convenience standard would place a minimum requirement for consumer access to collection for any approved program. Some convenience standards are determined by geography, mandating a certain number of sites per county or other geographical division. Marin County, California, utilizes a convenience standard and requires a minimum of 25 drop-off locations throughout the county. Others convenience standards are based on population, with a site mandated for a certain number of residents. Santa Clara County, California requires a drop-off site for every 20,000 residents. Others combine the two metrics to create a hybrid convenience standard. King County, Washington requires:

“In every city, town, or unincorporated community service area with a pharmacy or law enforcement facility, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents, geographically distributed...”

Washington's Secure Drug Take-Back Act includes a similar standard, but with the requirement for an additional site set at 20,000 residents.

Some areas of New York may not have sufficient eligible collection locations to meet a convenience standard (Appendix G). To resolve this issue, programs could use mail-back envelopes, or take-back events to fill the gaps and ensure convenient collection across the state.

Input received: In terms of the collection methods required, environmental advocacy groups believe collection receptacles should be required at every collection location with prepaid mail-back envelopes to supplement. They stated that most people only go to one pharmacy, and if collection receptacles are not present at all locations, the program will not reach everyone. They also stated that other programs, such as CCE's collection programs at King Kullen and Stop and Shop, have demonstrated that collection receptacle are the most cost-efficient, effective collection method. Programs conducted with only mail-back envelopes did not collect a significant amount of pharmaceuticals and had less than 1% participation rate.

However, retail and industry representatives have argued for a flexible approach in required collection methods. The NYS Retail Council and some pharmacies oppose any requirement that all retail pharmacies house collection receptacles. This is in part due to the perception that housing a collection receptacle decreases the safety of their store and staff. Retail representatives believe any of DEA approved collection methods should be allowed, without preference on collection receptacles. Environmental advocacy groups responded to the concern of security by stating that a person looking to steal pharmaceuticals would be more likely to take from the pharmacy than the collected drugs in a metal, locked box.

Environmental advocacy groups are in favor of a convenience standard and believe that any collection locations that wish to participate after the program's convenience standard is achieved should still be allowed to enter the program. They also believe that manufacturers should entice locations to participate if the convenience standard is not being met.

V. Disposal Options

Currently, all the pharmaceutical stewardship bills proposed in New York have required disposal by incineration at a permitted hazardous waste facility. All groups of stakeholders, including DEC, expressed concerns that this requirement is too restrictive, will increase the cost of the program, and should be relaxed to allow disposal at municipal waste combustors. This is not only because combustion within a municipal waste combustor should adequately dispose of any collected pharmaceuticals, but also because New York does not currently have an in-state hazardous waste disposal facility. Therefore, all collected pharmaceuticals would need to be shipped out of state, increasing the costs four to five times, as well as incurring the environmental costs associated with transporting such materials a further distance, if the requirement is not changed.

The program could allow the lead agency to evaluate other disposal options. Options could include in-home disposal packets, like those currently being sold and distributed, or other technologies that may exist in the future. Sufficiency could be determined by health impacts, environmental impacts, a combination of the two, or alternative criteria. Such evaluations should be conducted before these other options are allowed.

Input received: In terms of alternative methods of disposal, environmental advocacy groups argue that pouches for in-home pharmaceutical disposal should not be an acceptable disposal option. They stated that pouches are not cost-efficient and have not been proven to be environmentally sound, they are not a DEA approved disposal method, and the research done on their safety has not been peer reviewed. However, a representative of a chain retail pharmacy stated that the company has developed pharmaceutical disposal pouches and is currently distributing them at some locations when prescriptions are filled. Environmental advocacy groups also cautioned that the legislations passed in Vermont and Massachusetts had loopholes that allow pouch disposal, and New York should ensure those loopholes are closed in any pharmaceutical stewardship program proposed.

Evoking a statewide disposal ban for unused, expired, or unwanted pharmaceuticals by prohibiting the disposal outside of a pharmaceutical collection program, or in ways that are not specifically approved, might increase consumer incentive to properly dispose of unused drugs. However, a ban on disposing of pharmaceuticals into municipal solid waste would be difficult to enforce and may ultimately increase flushing of pharmaceuticals. Environmental advocacy groups believe that the lead state agency should discourage in-home disposal of pharmaceuticals, but that it is impractical to impose a ban.

VI. Education and Outreach

Public education and outreach is a crucial component of any successful product stewardship program. Requirements can be broad or detailed. The minimum requirements typically required by existing stewardship programs include a website listing program details and all collection locations, a toll-free phone number to manage inquiries and complaints, and the development and distribution of outreach materials, all paid for and handled by manufacturers.

A more prescriptive approach could include more specific requirements, such as clear information and tools available to consumers for finding the nearest collection location, regular public service announcements, advertising aimed at consumer education and awareness, and written material distributed when prescriptions are picked up or delivered. A program could also require plain-language written materials in several languages and include information that encourages safe storage, promotes pharmaceutical take-back, and discourages flushing and disposal in municipal waste. A program could also require regular updates to educational materials and/or ongoing updates to web materials, such as lists of locations and explanatory images or graphics.

If the option for multiple manufacturer-run programs is included, it could also include a mandate for coordinated education and outreach plans among all approved programs. This would mitigate possible confusion for consumers and eliminate duplication of effort.

The program could also require all pharmacies (even if waivers are obtained for collection receptacles); other retailers (regardless of their status as an authorized collector); and other involved stakeholders, like state agencies, to post and provide information about the program at their locations and/or on their websites. This information could be provided by the manufacturers or by the retailers and other stakeholders.

Input received: Environmental advocacy groups stated that more robust outreach and education requirements should be included in a pharmaceutical stewardship program than what is currently required in Senate Bill 7354. Alternatively, outreach and education requirements could be detailed in regulations. They stated that the outreach and education messaging must be concise, consistent, and comprehensively cover which materials are collected and which are not to avoid consumers returning unaccepted materials. The environmental advocacy groups also argued that if multiple manufacturer-run programs exist, they must all have uniform outreach and education materials.

A representative from the NYS Association of Counties stated that counties would be willing to assist with the dissemination of outreach and education materials. However, counties need more streamlined information from the state and the representative suggested creating an interagency center that houses all information related to a statewide pharmaceutical stewardship program for ease of access.

Environmental advocacy groups also suggested that manufacturers be required to conduct a representative survey of the state before a statewide pharmaceutical stewardship program is implemented to measure baseline awareness and behavior. They also requested that representative surveys be conducted at regular intervals to measure how awareness and behavior change over time, which can be used as a measure of the effectiveness of the outreach and education efforts.

VII. Reporting

Periodic reporting from pharmaceutical stewardship program operators to the lead state agency on program implementation and operations is a common requirement of comprehensive product stewardship laws. Reporting ensures that program goals are being met, identifies shortcomings, and provides accountability to the public. Reporting requirements could include tracking the weight of collected pharmaceuticals, costs, locations of collection and disposal, public education activities, and any significant complaints that were raised and how they were resolved or managed. A program could also include requirements for representative surveys to assess public knowledge about the program and track it over time. This suggestion was supported by many of the environmental representatives. This reporting would help inform the program operators and the lead state agency of program performance and potential program changes that should be considered and implemented to continually improve the overall product stewardship program.

Annual reports are most commonly required in legislation (Appendix E), but reporting could be required more or less frequently.

Other stakeholders could also be required to submit reports to the lead state agency at regular intervals. Collection locations could be required to report how frequently collection receptacles are serviced. Final disposal locations could be required to report the weight of destroyed pharmaceuticals, as well as their sources.

If the state were operating the program and billing manufacturers for the costs, sales data or other determined measure should be reported to assess costs to each manufacturer. This data could come from manufacturers and/or wholesalers and repackagers.

With reporting from other sources, the lead state agency could analyze and verify the collected data and submit a report to the Governor or legislature at regular intervals. This report could include, among other items, state and county collection data, significant changes in the programs since the previous report, and effectiveness of education and promotion campaigns.

Input received: Multiple stakeholders requested that the metric for reporting the amount of pharmaceuticals collected be measured by weight instead of volume since volume can easily be skewed. For example, if a nearly empty prescription bottle is inserted, it would register as a full bottle by volume but as a partial bottle by weight.

Environmental advocacy groups also maintained that a requirement for regular reporting should be included as the best way to ensure compliance. They also stated the information obtained from reports should be used to make amendments to the program where necessary.

VIII. Uniform Statewide Program

To ensure that one easy to understand program is implemented, one statewide approach should be implemented. This is more straightforward for manufacturers, pharmacies, and retailers and more convenient for consumers. This approach is preferable to a patchwork of standards across the state. Accordingly, placing jurisdiction solely with the state is key. As one local pharmaceutical stewardship law already exists in the state (Rockland County) and two others have been introduced, this may mean preempting local laws.

Input received: Stakeholders were largely in favor of preemption, for several reasons. Environmental advocacy groups expressed that a state pharmaceutical stewardship law should only preempt local pharmaceutical stewardship laws if more stringent than the local laws. However, the NYS Association of Counties, as well as retail and industry representatives, were in favor of preemption and support the preemption language in Senate Bill 7354.

IX. Compliance, Enforcement, and Penalties

Enforcement and any ensuing penalties are important tools to ensure compliance. Along with the ability to audit programs for compliance, several enforcement issues should be considered in creating a program. The first is manufacturer compliance. The most critical compliance issues for manufacturers are program participation and reporting. If a manufacturer does not participate in a program, it could be banned from selling its product in the state, although this may be more controversial than in other product stewardship laws as the products are health related and could impact the cost of prescription drugs. Additionally, penalties could be assessed on a per day or per violation basis. Penalties should be high enough to foster compliance.

An additional enforcement issue is collection location participation. Whether the program is limited to all pharmacies or includes all authorized collectors, there should be a small/nominal penalty for noncompliance. Again, the penalty can be assessed on a per day or per violation basis.

A program could also include a system for manufacturers or programs that do not submit approvable plans in the required timeframe. This may include options such as enforcement action and penalties, forcing participation in an existing program, or imposing changes to the proposal.

Input received: Environmental advocacy groups maintain that the consequences for not participating in pharmaceutical stewardship should be strong. They note that noncompliance with a typical product stewardship law would result in the being banned from sale in the state, but other consequences could include fines.

X. Implementation Schedule

A schedule for implementation, starting from the date the law goes into effect, including the development of a stewardship plan, continuing through review, and adoption of a plan to implementation and beyond, should be addressed.

Retailers indicated that they prefer that any schedule developed be marked in the number of days allowed between each event, rather than using specific due dates. At minimum, there should be an effective date and a date (or number of days after the effective date) by which the program must be operational. It could also include the following deadlines for plan approval:

- i. Submission to the lead agency
- ii. Approval or rejection
- iii. Submission of revised proposal
- iv. Approval or rejection of revised proposal

Additional benchmarks could include dates when outreach and educational materials are to be available and distributed, when periodic reporting is due, and when periodic program modifications are to be submitted and approved.

Input received: Estimates from stakeholders for a reasonable timeline for full implementation ranged from 6 to 18 months. Retail stakeholders stated that cost of implementation is an important timeline factor for independent pharmacies as they may need to rearrange or renovate their store to accommodate a collection receptacle. Using the State's Pilot Program as a reference, collection could begin as soon as 15 months after the adoption of a statewide pharmaceutical stewardship program.



Recommendations

DEC and DOH fully support strong pharmaceutical stewardship legislation that creates a comprehensive pharmaceutical stewardship program for all consumers across the state to dispose of their unused and unwanted pharmaceuticals in a safe and convenient manner. Based on the information DEC and DOH have gathered regarding pharmaceutical collection programs, the recent stakeholder meeting discussions, and the review of other state and local legislation, a comprehensive pharmaceutical stewardship program in New York State is feasible and must include the following components.

I. Product Scope

The program should clearly define the scope of covered products to determine what is accepted by the program and which manufacturers must participate. “Covered drugs” should include unused or unwanted prescription drugs, nonprescription drugs, combination products, drugs in medical devices, and veterinary drugs from consumers.

Sharps should not be included as a “covered drug” under the program because there are existing collection requirements already in place for sharps and collection locations available across the state for sharps collection. DEC and DOH believe that existing requirements for sharps, coupled with the risks of handling sharps at covered drug collection locations, warrant the exclusion of collecting sharps as part of this program. Information and instructions about how to properly dispose of sharps should be included in any consumer outreach material.

Along with sharps, vitamins and supplements, homeopathic drugs, herbal remedies, and cosmetics or personal care products (including those regulated as both cosmetics and OTC drugs) should be excluded from the scope of products considered “covered drugs.” These items are not regulated as drugs and their inclusion would expand the group of manufacturers far beyond the intended scope of the program.

II. Pharmaceutical Stewardship Program

DEC and DOH have concluded that a pharmaceutical stewardship program implemented by a single “pharmaceutical stewardship organization” representing all manufacturers that sell covered drugs in New York State would be the best overall approach. Requiring that all manufacturers jointly participate in a single pharmaceutical stewardship program will afford manufacturers the flexibility to divide costs and organize their efforts in a way they deem most suitable for their industry, while also creating a streamlined and convenient experience for consumers that limits the burden of oversight and enforcement on the state. This aligns with how industry is implementing such programs in California and Washington state.

The pharmaceutical stewardship organization should be required to submit a comprehensive pharmaceutical stewardship program plan to DEC, who, after consulting with DOH, must approve the plan based on the requirements laid out below. The plan would outline the free and convenient opportunities for consumers to drop off their unused or unwanted pharmaceutical for proper disposal. Each county should be required to have at least one participating authorized collector, or the stewardship organization must sponsor at least two collection events in the county, per year.

III. Pharmaceutical Stewardship Program Plan

The plan should include information regarding the pharmaceutical stewardship organization, a list of all participating manufacturers along with their contact information, a detailed description of the proposed collection system (including collection locations, collection receptacles, mail-back envelopes, events, transportation and handling plans, and final disposal), a description of how the program will be funded, descriptions of the safety and security procedures, and a description of the education and outreach campaign.

A. Collection

DEC and DOH recommend that all pharmacies be required to house a permanent collection receptacle in accordance with federal requirements as part of a manufacturer-run program, unless they fall into an exception as described below. In addition, any other authorized collector who wishes to participate as a collection location should be allowed to join the manufacturer-run program. Collection at all locations should be fully funded by the manufacturers.

For those counties where there is no pharmacy, or other authorized collector, the pharmaceutical stewardship organization would need to provide a minimum of two authorized collection events per year.

Prepaid, pre-addressed, nondescript mail-back envelopes should be available from all pharmacies and authorized collection locations, provided by the stewardship organization free of charge to the collection locations and to consumers. In addition, consumers should be able to request prepaid, pre-addressed mail-back envelopes directly from the pharmaceutical stewardship organization via the public education website.

The program must include a mechanism to waive the collection receptacle requirement for pharmacies where hosting a collection receptacle would pose an undue hardship. If a waiver is granted, these locations would not be required to host a collection receptacle, but should be required to provide pharmaceutical stewardship program information and offer prepaid, pre-addressed mail-back envelopes.

Mail-order and online pharmacies are also major distributors of pharmaceuticals and should be required to participate in a manufacturer-run stewardship program. We recommend that all mail-order and online pharmacies that fill prescriptions for delivery in New York be required offer a mail-back envelope, at the time of sale, for each sale for delivery in the state.

B. Transportation and Disposal

DEC and DOH recommend that pharmaceuticals collected by the manufacturer supported program or through other collection programs be disposed at a municipal waste combustor, a hazardous waste facility, or by another method approved by the department. Any alternative methods must be at least as protective to humans and the environment as a municipal waste combustor. The plan should contain contact information for all transporters and final disposal facilities.

C. Education and Outreach

The pharmaceutical stewardship organization should be required to develop and maintain, with adequate funding and staffing, an education and outreach program to inform consumers of the opportunity to return unwanted covered drugs at participating collection locations, through mail-back, or at collection events. All aspects of the education and outreach program should be outlined in the plan. Information about collection and disposal should be made available through a dedicated website; a staffed, 24-hour toll free telephone number; and in printed form. All information for consumers should be available in multiple languages that are commonly spoken in New York and be in plain language. The pharmaceutical stewardship program website should, at a minimum, provide a rationale for the collection of unwanted covered drugs, outline what is and is not accepted in the program, include a map tool to provide consumers with their nearest collection locations, and provide mail-back instructions and collection event information. On the website, customers should be able to request mail-back envelopes be sent to them. The website should be written in plain language, readily accessible, and machine readable. A direct link to the centralized web site should be posted on each manufacturer's homepage.

The toll-free phone number should accept inquiries and complaints from customers and provide information about collection locations, how to access mail-back envelopes, accepted products, and any scheduled collection events. A process for dealing with complaints should be outlined in the plan.

Printed material (i.e. posters, flyers, etc.) should be provided by the stewardship organization to all pharmacies and authorized collection locations. Collection locations should be required, in turn, to make them available to consumers. Program information should be provided to consumers at the point of sale, either on patient information sheets, in a separate flyer, or by another method. Collection receptacles should list what items are accepted and which are not accepted. To avoid confusion, guidance regarding sharps disposal should also be displayed on collection receptacles, the pharmaceutical stewardship program website, and on posters and flyers. Information regarding what drugs are accepted by the pharmaceutical stewardship program, and what is not accepted, can be included with the prepaid, pre-addressed mail-back envelopes.

D. Annual Reporting

DEC and DOH recommend that the stewardship organization be required to submit an annual report. The report should include, at a minimum, cost information; the weight of pharmaceuticals collected from each location, as well as from mail-back envelopes and collection events; transportation and final destruction information; number of web site visits and phone calls; and any complaints received and how they were addressed. Annual reports should also address any changes that have been made to the program in the previous year. The results of the representative survey on public understanding should be included with the annual report.

IV. Stakeholder Responsibilities

A. Manufacturers

Manufacturers would be required to join and participate in the pharmaceutical stewardship organization.

B. Pharmaceutical Stewardship Organization

The pharmaceutical stewardship organization would be required to submit a pharmaceutical stewardship program plan to DEC, implement the plan on behalf of all the participating manufacturers, comply with all the plan requirements, and completely fund the program, including allocating the program costs among the participating manufacturers.

C. Authorized Collectors

All authorized collectors, pursuant to DEA regulations, would be allowed to participate in the pharmaceutical stewardship program as collection locations including pharmacies, law enforcement and collection event sponsors.

- **Pharmacies** – Participation in the pharmaceutical stewardship program should be mandatory for all retail pharmacies, hospital pharmacies and pharmacies servicing LTCFs. All pharmacies would be required to host a permanent collection receptacle and all pharmacies should have mail-back envelopes available for consumers, free of charge. A pharmacy may apply for a collection receptacle waiver if they can demonstrate that the placement and maintenance of an on-site collection receptacle creates an undue hardship on the pharmacy. Once granted, these locations would not be required to host a collection receptacle, but would still need to provide information about the pharmaceutical stewardship program and have mail-back envelopes available for consumers.
- **Mail-Order and Online Pharmacies** – Mail-order and online pharmacies that sell into New York would be required to participate in the manufacturer-run program. This would entail including a mail-back envelope in each package and linking to the program website on their website's homepage and on the home screen of their app, if applicable.

- Law Enforcement – Participation would be voluntary for law enforcement locations, such as police stations, sheriff’s office, or State Trooper barracks.
- Collection Events – Collection events would be voluntary, unless there are no participating authorized collectors in the county and therefore required under the pharmaceutical stewardship program plan.
- All written educational and outreach materials developed by the pharmaceutical stewardship organization for consumers should be available for distribution to consumers at all authorized collection locations.

D. State Government

Several state agencies have roles and responsibilities concerning the management of pharmaceuticals, regulating controlled substances, and licensing pharmacies and drug manufacturers.

- DEC – DEC should be the lead oversight agency in consultation with DOH. DEC has both institutional knowledge and practical experience from overseeing multiple product stewardship programs. DEC is also currently implementing an extensive pilot project for pharmaceutical stewardship at over 200 pharmacy locations across the state.
- DOH – DOH should partner with DEC in the development of policies on the proper management and disposal of drugs in particular controlled substances, and provide expertise on controlled substances during the review of the program plan, reports, and audits. DOH should also participate in the review and approval of program plans and education and outreach programs.
- NYSED – NYSED licenses pharmacists and registers pharmacies, wholesalers, repackagers, and pharmaceutical manufacturers that sell into New York. This information is necessary for compliance and enforcement purposes and should be shared with DEC.

V. Disposal Ban

A disposal ban for covered drugs was considered, but is not recommended at this time. A ban on disposal of covered drugs in household waste would be extremely difficult to enforce and could increase consumer flushing, rather than participation in the stewardship program.

VI. Report to the Governor and Legislature

As the lead agency, DEC, in consultation with DOH, would analyze the data from annual reports and develop and prepare a report to the Governor and legislature every three years. This report would address the performance of the pharmaceutical stewardship program, evaluate its effectiveness, and identify areas of potential improvement.

VII. Compliance, Enforcement, & Penalties

The agencies would have the authority to audit the manufacturer-run program, as necessary, to verify compliance and effectively enforce the requirements of the program.

Enforcement provisions should address noncompliance for manufacturers and pharmacies.

Manufacturers should be held accountable for violations of the stewardship organization acting on their behalf. Possible violations for a manufacturer include selling covered drugs in the state without participating in the manufacturer stewardship program, failure to implement the plan and collection program, and failure to submit an annual report to the department. Penalties should be high enough to deter future violations and should be assessed on a per day basis. Pharmacies that do not participate as a collection location should be subject to a nominal fine. The fine should be based on a per violation basis.

VIII. Preemption

We recommend including language that preempts existing and future local laws on pharmaceutical stewardship. Currently, no pharmaceutical stewardship laws have been implemented in New York, though Rockland County has adopted one, so there is no need to alter any existing local regulations. In addition, a single statewide standard is preferable to nearly all stakeholders, including manufacturers, consumers, pharmacies, and municipalities.

IX. Timeline

DEC and DOH recommends that a program be fully operational 18 months from the date the program is created. The stewardship organization should be required to submit a plan nine months after the creation of a program is authorized, and the plan must be implemented within one year of approval.

References

- 6 NYCRR Part 360 Solid Waste Management Facilities. (2017).
- Act Relative to Substance Use, Treatment, Education and Prevention . (2016). *Massachusetts General Laws, Chapter 6, Section 118*.
- An Act Relating to Combating Opioid Abuse in Vermont. (2016). 18 V.S.A. § 4224. Vermont.
- Arnnok, P., Singh, R. R., Burakham, R., Perez-Fuentetaja, A., & Aga, D. S. (2017). Selective Uptake and Bioaccumulation of Antidepressants in Fish from Effluent-Impacted Niagara River. *Environmental Science & Technology*, 10652-10662.
- Blazer, V. S., Iwanowicz, D. D., Walsh, H. L., Sperry, A. J., Iwanowicz, L. R., Alvarez, D. A., . . . Manning, R. (2014). Reproductive health indicators of fishes from Pennsylvania watersheds: association with chemicals of emerging concern. *Environmental Monitoring and Assessment*, 6471-6491.
- Cantwell, M. G., Katz, D. R., Sullivan, J. C., Shapley, D., Lipscomb, J., Epstein, J., . . . O'Mullan, G. D. (2017). Spatial patterns of pharmaceuticals and wastewater tracers in the Hudson River Estuary. *Water Research*.
- DEC Pharmaceuticals Work Group. (n.d.). *Pharmaceuticals as Emerging Contaminants: a Rationale for Reduction in New York State's Waters*. NYS Department of Environmental Conservation.
- Drug Management and Disposal Act. (2009). *Environmental Conservation Law, Article 27, Title 27*.
- Han, B., Compton, W. M., Blanco, C., Crane, E., Lee, J., & Jones, C. M. (2017). Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health . *Annals of Internal Medicine*, 293-301.
- Hedegaard, H., Warner, M., & Minino, A. M. (2017, December 21). *Drug Overdose Deaths in the United States, 1999–2016*. Retrieved from Centers for Disease Control: <https://www.cdc.gov/nchs/products/databriefs/db294.htm>
- Kane, J. M., Colvin, J. D., Bartlett, A. H., & Hall, M. (2018). Opioid-Related Critical Care Resource Use in US Children's Hospitals. *Pediatrics*, 2017-3335.
- Kolpin, D. W., Furlong, E. T., Meyer, M. T., Thurman, E. M., Zaugg, S. D., Barber, L. B., & Buxton, H. T. (2002). Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams 1999-2000: A National Reconnaissance. *Environmental Science & Technology*, 1202-1211.
- Law, A. V., Sakharkar, P., Zargarzadeh, A., Tai, B., Hess, K., Hata, M., . . . Park, T. J. (2015). Taking stock of medication wastage: Unused medications in US households. *Research in Social and Administrative Pharmacy*, 571-578.
- Local Law 10622. (2018). *Establishing a Pharmaceutical Product Stewardship Program*. Westchester County, NY. Retrieved from https://westchestercountyny.iqm2.com/Citizens/Detail_LegiFile.aspx?ID=10622&&_sm_au_=iVVQDPH7rk04n7Ps
- Local Law 1-2. (2017). *Erie County Pharmaceutical Water Pollution Act*. Erie County, NY. Retrieved from http://www2.erie.gov/legislature/sites/www2.erie.gov/legislature/files/uploads/Session_Folders/2017/Session_18/17LLIntro.1-2.PDF
- Malatras, J. (2017). *The Growing Drug Epidemic in New York*. SUNY Rockefeller Institute of Government.
- National Institutes of Health. (2017, September). *Overdose Death Rates*. Retrieved from National Institute on Drug Abuse: <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>
- New York State Department of Environmental Conservation. (2017, May 2). NYSDEC Guidance for Proper Pharmaceutical Disposal: Commissioner's Policy #66. Retrieved from https://www.dec.ny.gov/docs/water_pdf/cp66.pdf

- New York State Department of Environmental Conservation. (2018). *Pilot Pharmaceutical Take-Back Program Open Enrollment*. Retrieved from NYS Dept. of Environmental Conservation: <http://www.dec.ny.gov/chemical/108213.html>
- New York State Department of Health. (2015). *Opioid Poisoning, Overdose, and Prevention: 2015 Report to the Governor and NYS Legislature*.
- Pharmacy Take-Back Act . (2017). *II Code of Ordinances § 317A Article II*. Rockland County, NY.
- PhRMA v. County of Alameda, 13-16833 (9th Cir. September 30, 2014).
- Pratt, L. A., Brody, D. J., & Gu, Q. (2017). *Antidepressant Use Among Persons Aged 12 and Over: United States, 2011-2014*. US Department of Health and Human Services.
- S6750. (2017). *An act to amend the public health law, in relation to disposal sites operated by pharmacies*. 2017-2018 Legislative Session. Retrieved from <https://www.nysenate.gov/legislation/bills/2017/s6750>
- S7354. (2018, January 9). *An act to amend the public health law, in relation to enacting the drug take back act*. 2017-2018 Legislative Session. Retrieved from <https://www.nysenate.gov/legislation/bills/2017/s7354>
- Safe Drug Disposal Ordinance. (2013). *6 Municipal Code §6.53*. Alameda County.
- SAMHSA's Center for the Application of Prevention Technologies. (2016). *Preventing Prescription Drug Misuse: Programs and Strategies*. SAMHSA.
- Secure Drug Take Back Act. (2018). *Revised Code of Washington, Title 69*. Washington.
- Senate Bill No. 338. (2018). Indiana 2018 Legislative Session. Retrieved from <https://iga.in.gov/legislative/2018/bills/senate/338#digest-heading>
- U.S. Poison Control Centers. (2015). *Poison Statistics- National Data 2015*. Retrieved from Poison Control- National Capital Poison Center: <https://www.poison.org/poison-statistics-national-data-from-2015>
- US Drug Enforcement Agency. (2017, October 28). *14th National Take Back Day*. Retrieved from Take Back Day.
- US Drug Enforcement Agency. (2018, April 28). *15th National Take Back Day*. Retrieved from Take Back Day: https://takebackday.dea.gov/sites/default/files/NTBI_XV_Totals.pdf
- US Drug Enforcement Agency. (n.d.). *Take Back Day*. Retrieved from Take Back Day: <https://takebackday.dea.gov/>
- USFDA. (2018, 03 27). *Disposal of Unused Medicines: What You Should Know*. Retrieved from U.S. Food & Drug Administration: <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>
- Volk, K. (2016, 04 19). *Rise in Prescription Drug Misuse and Abuse Impacting Teens*. Retrieved from SAMHSA: <https://www.samhsa.gov/homelessness-programs-resources/hpr-resources/teen-prescription-drug-misuse-abuse>
- Young, S., Juhl, A., & O'Mullan, G. D. (2013). Antibiotic-resistant bacteria in the Hudson River Estuary linked to wet weather sewage contamination. *Journal of Water and Health*, 297-310.

Veto #247

TO THE SENATE:

I am returning herewith, without my approval, the following bill:

Senate Bill Number 6750, entitled:

"AN ACT to amend the public health law, in relation to disposal sites operated by pharmacies"

NOT APPROVED

The bill would amend the Public Health Law (PHL) to require that chain pharmacies, as well as out-of-state pharmacies doing business in New York, provide drug disposal options to their customers for the purposes of collecting unused controlled substances.

I fully support the intent of the bill to create a comprehensive product stewardship program to ensure the proper disposal of unused drugs. However, in its current form, the bill would not achieve its stated objective and could have the unanticipated effect of slowing the adoption of an effective drug "take back" program. As drafted, the bill would require consumers and pharmacies to pay for the return of unused drugs, rather than ensuring the burden is equally shared with the manufacturers of such drugs. It would also preempt local laws that may go further than the scope of this bill in attempting to create a truly comprehensive stewardship approach. For these reasons I am constrained to veto this bill.

I am directing the Department of Environmental Conservation to engage interested stakeholders and local governments on implementing a state-wide pharmaceutical stewardship program. The Department will then prepare a report on the feasibility of creating and implementing such a program, including a requirement that manufacturers provide, at no cost to consumers, collection receptacles or other approved methods for collection and disposal of pharmaceuticals across the state. The Department shall issue its report by May 15, 2018.

The bill is disapproved.

(signed) ANDREW M. CUOMO

Links to DEC

Reference Information

- **Drugs in New York's Waters:** This page details how drugs enter waterways and why this is of concern. It also provides links to DEC's other resources on drug disposal as well as additional background information and published studies of the effects of pharmaceutical contamination on the environment.
- **"Don't Flush" Posting Requirements for Pharmacies, Veterinarians, and Retailers:** This page is targeted to pharmacies, veterinarians, and other retailers that sell drugs, which are all required to post DEC's "Proper Disposal of Pharmaceuticals" notice under New York's Drug Management and Disposal Act of 2008 in a conspicuous location. The page details where and how the poster should be displayed.
- **Safe Medication Disposal for Households:** This page encourages the public to bring unwanted, unused, or expired drugs to one of the existing drop box locations throughout the state. It details other options such as local collection events and the biannual National Prescription Drug Take-Back Day detailed above. This page details how drugs should be disposed with the household's garbage if none of the collection options are reasonably convenient.
- **Household Sharps-Dispose of Them Safely:** DEC has a separate page for the disposal of sharps, as they should not be mixed with unwanted drugs. Sharps should be kept in a puncture-proof container and thoroughly sealed when the container is full. The page details recommendations for sharps disposal including hospitals, nursing homes, clinics, local public works departments, or a licensed medical waste transporter.
- **Safe Medication Disposal for Long-Term Care Facilities, Other Class 3A Facilities, and Veterinarians:** Acceptable methods, including mail-back, collection receptacle, law enforcement collection, and reverse distribution, for pharmaceutical disposal vary based on the type of facility. This page details which methods are available per facility.
- **How to Hold a Pharmaceutical Collection:** This page is targeted to municipalities, pharmacies, law enforcement, and community groups that wish to hold a collection event. Entities must hold the event in partnership with law enforcement, comply with the Controlled Substances Disposal Rule and Public Health Law §3343-b, and dispose of the collected pharmaceuticals at a facility permitted under Part 360, if disposal occurs in the state. Entities must also contact DOH to hold such an event.
- **How to Become an Authorized Collector of Pharmaceuticals:** Retail pharmacies and other entities authorized by DEA may become authorized collectors by modifying their registration with DEA online and complying with all of DEA's requirements in Title 21 of the Code of Federal Rules. Law enforcement may maintain collection receptacles and take-back events without becoming authorized collectors, if they have obtained authorization from BNE.
- **RCRA Compliance Information for Pharmacies and Other Retail Facilities:** DEC has created an Environmental Audit Incentive Program to assist pharmacies and other retail facilities comply with the federal RCRA and improve handling of hazardous waste. This page provides facilities information on the program, how to join, and links to additional compliance information for various types of facilities.
- **Management of Hazardous Waste Pharmaceuticals:** This page explains which pharmaceuticals are considered hazardous waste when disposed of by pharmacies and advises how they should be managed based on DEC's understanding of relevant federal regulations, but encourages facilities to get pharmaceuticals thermally destroyed.

APPENDIX C

Existing Pharmaceutical Stewardship Laws & Proposed Legislation

Existing Pharmaceutical Stewardship Laws

California

- Alameda County passed the Safe Drug Disposal Ordinance (6 Municipal Code Chapter 6.53) in July 2012, which was implemented in 2015 through MED-Project.
- Contra Costa County passed the Safe Drug Disposal Ordinance (4 County Code Chapter 418-16) in December 2016 but has not yet been implemented.
- Marin County passed the Safe Drug Disposal Ordinance (7 Municipal Code Chapter 7.90) in August 2015, which was implemented in 2016 through MED-Project.
- City and County of San Francisco passed the San Francisco Safe Drug Disposal Ordinance (Environment Code Chapter 22) in March 2015, which has been implemented through MED-Project.
- City of Capitola passed the Capitola Safe Drug and Sharps Disposal Ordinance (Ord. 1006 § 1 (part), 2016) in September 2016, which was implemented in April 2016 through MED-Project.
- City of Santa Cruz passed the Santa Cruz Drug & Sharps Disposal Ordinance (6 Municipal Code Chapter 6.93) in August 2016 and has been implemented.
- City of Scotts Valley passed the Scotts Valley Safe Drug Disposal Ordinance (8 Municipal Code Chapter 8.38) December 2016, which has been implemented through MED-Project.
- City of Watsonville passed the Watsonville Safe Drug Disposal Ordinance (Municipal Code Chapter 5-48) in March 2017, which has been implemented through MED-Project.
- San Luis Obispo County Integrated Waste Authority Board of Directors passed and adopted an Ordinance Establishing a Product Stewardship Disposal Program for Home Generate Used Sharps and Unwanted Prescription Medicine in January 2018, but it has not yet been implemented.
- San Mateo County passed the Safe Medicine Disposal Ordinance (4 Code of Ordinances Chapter 4.116) in April 2015 and was implemented in November 2016 through MED-Project.
- Santa Barbara County passed the Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs Ordinance (Code of Ordinances Chapter 18C (II)) in June 2016 and was implemented in January 2018 through MED-Project.
- Santa Clara County passed the Safe Drug Disposal Ordinance (B Ordinance Code § 11(XX)) in June 2015 and has been implemented through MED-Project.
- Santa Cruz County passed the Santa Cruz County Safe Drug and Sharps Disposal Ordinance (7 County Code Chapter 7.95) in January 2016, which has been implemented through MED-Project.

Illinois

- Cook County passed the Cook County Safe Disposal of Pharmaceuticals Ordinance (46 Code of Ordinances II(4)) in October 2016, which is currently in the process of being implemented.

Massachusetts

- The Commonwealth of Massachusetts passed An Act Relative to Substance Use, Treatment, Education, & Prevention (Gen. Laws ch. 94H) in March 2016 and has been implemented.

New York

- Rockland County passed the Pharmacy Take-Back Act (Part II Code of Ordinances § 317A Article II) in February 2017, but it has not yet been implemented.

Vermont

- The State of Vermont passed An Act relating to Combating Opioid Abuse in Vermont (18 V.S.A. § 4224) in June 2016.

Washington

- The State of Washington passed the Secure Drug Take-Back Act (Laws of 2018 Chapter 169) in March 2018. It will become effective in June 2018.
- King County passed the King County Board of Health Secure Medicine Return Regulations (11 BOH Code 11.50) in July 2013, which has been implemented through MED-Project.
- Kitsap County passed the Secure Medicine Return Regulations (Kitsap Public Health Board Ordinance 2016-02) in December 2016, which has been implemented through MED-Project.
- Skagit County passed the Secure Medicine Return Ordinance (12 County Code ch. 12.20) in February 2018, but it has not yet been implemented.
- Snohomish County Board of Health approved the Secure Medicine Return Regulation (Snohomish Health District Sanitary Code Chapter 15) in June 2016, which has been implemented through MED-Project.
- Tacoma-Pierce County passed the Secure Medicine Return Regulation (Environmental Health Code Chapter 7) in December 2016 and has been implemented. The county's collection program will be expanding soon as a result of the county approving MED-Project's stewardship plan.
- Clallam County Board of Health passed the Secure Medicine Return Regulations (Board of Health Ordinance 6) in November 2017, but it has not yet been implemented.
- Whatcom County passed the Secure Medicine Return Ordinance (County Code ch. 24.15) in December 2017, but it has not yet been implemented.

Proposed Pharmaceutical Stewardship Legislation

Location	Bill Number	Status
IN	<u>SB 338</u>	First reading, referred to Committee on Health and Provider Services (1/4/18)
NYS	<u>A 9576</u>	Amended and Recommit to Health (4/24/18)
	<u>S 7354</u>	Passed Senate (4/25/18)
NYS	<u>S 6557</u>	Referred to Health (1/3/18)
Erie County, NY	<u>1-2</u>	Introduced (10/3/17)
Westchester County, NY	<u>10622</u>	Referred to the Committees on Legislation and Public Works (1/22/18); Public Works Committee Meeting (3/6/18)

Pharmaceutical Take-Back Stakeholder Meeting Notes

Notes from Pharmaceutical Take-Back Stakeholder Meeting
Environmental Groups and Experts
2/5/18

Stakeholder Attendees:

Jim Mullooney (Pharma Cycle)
Vivian Fuhrman (Product Stewardship Institute)
Ed Gottlieb (New York Water Association)
Scott Cassel (Product Stewardship Institute)
Daniel Moran (Covanta)
Brian Smith (Citizens Campaign for the Environment)
Andrew Radin (New York Product Stewardship Council)
Paul Galley (Riverkeeper)

DEC Attendees:

David Vitale
Tom Snow
Peter Pettit
Joan Kennedy
Carin Spreitzer
Jen Andaloro
Chris Horan
Valerie Stanson
Peter van Erp
Mark Moroukian
Robert Phaneuf
Rebecca Vaughan
Emily Dominiak
Sarah Covelli
Jeshica Patel
Julie Tighe

Vivian:

- PSI runs a take-back programs and is about to launch in rural NY (already did, include link)
- Interested in discussing how hospitals in their program can eventually shift into the statewide program developed

Dan:

- What kind of facilities have registered for the pilot program?
 - Tom: Independent pharmacies. There is a clear lack of chain pharmacies and grocery store chains.
- What percent of qualifying locations are covered under the pilot program currently?
 - Tom: NYS has 5600 locations that qualify for the pilot. 330 are currently registered for the program, but will probably reach 10% total.
 - Currently working on targeting areas of the state without existing take-back programs.

Pilot:

- Locations of all existing collection sites are on pilot's website. Round 1 locations will be posted in early March
 - Police offices need smaller size collection boxes
 - Ed: Working on making a smaller box available
- Average two-year cost of collection per site is \$6000
 - Box: \$1250
 - Liner: \$46.50 each
 - Destruction: \$49 per
 - The 6-month cost that falls on pharmacies depends on how quickly the bins fill. Will cost \$96.50 per fill
- What would mail-back have added to the cost?
 - The cost of 250 pre-paid mail-back envelopes = the cost of 1 box
- Mark: Is any education and outreach required in the pilot?

CCE:

- Advertise their take-back program through newspaper, online, movie theatre ads to make the public aware of the collection locations.
 - Inexpensive
- Survey area before outreach to measure how awareness and behavior changes over time.

S7354 is limited in that it only required participation of chain pharmacies

CCE:

- Pilot program at King Cullen using collection boxes is successful
- Pilot program with Stop n Shop using only mail-back envelopes was unsuccessful
 - Pre-paid envelopes were free upon request
 - <300 lbs. were collected in 2 years
- Legislation should require drop boxes with mail-back as a supplement
 - PSI agrees
- Convenience standard is a separate, but important, question. Preferably convenience is defined by population size.
- Searching through the contents of a collection box is illegal in the US (DEA regulations).
 - Only exception is for law enforcement.
 - 4% of collected drugs were controlled substances
 - Average person brought 2 lbs. of drugs

Ontario

- Has been running a pharmaceutical take-back program for 15-20 years, most mature program in the world
- Population is 10 million, 300 tons are collected last year
- Canada allows the collected drugs to be sorted; 5% of collected drugs are controlled substances
- Program included location phase in (i.e. 80% of authorized locations must participate by X date)

- Education and outreach efforts are still maturing and the volume collected continues to increase but is starting to plateau
- If boxes are not present at all pharmacies, the program is missing people
 - Most people only go to one pharmacy
 - 100% coverage is the goals

PSI:

- Working to develop education materials for hospitals; they are conducting a survey to see what information is provided now and what is needed.
 - Created toolkit for educating patient (free online).

Sharps:

- The most concerning undesirable material
- Legislation should require that local sharps disposal options to be posted at all collection box locations, or have a sharps collection box directly next to the pharmaceutical collection box

Convenience standard:

- Niagara County is plotting existing take-back locations and what area of the state would be covered if all chain pharmacies were collection locations
 - Shows that a large segment of the state would still not be covered with this requirement
- Scott: Legislation must grant the Department the authority to ask for more (be it locations, education, etc.)
- What happens when more locations per capita want to be in the program than are required by the convenience standard?
 - Scott: The Department must allow them in the program (increase convenience and is fairer to businesses as having a collection box increased foot traffic)- how would this be written into legislation?
 - Manufacturers must notify all potential collection locations of the opportunity to become a collection location.
 - Additional cost to manufacturers of more locations is not very high

Role of mail-order pharmacies:

- Fall under DEA distribution regulations and therefore can't be collectors

Tom:

- Don't flush poster has been updated for pilot program.
- Pharmacies are required to display this sign if they are over a certain square footage.

Pouches for in-home disposal:

- Use a polymer or activated carbon to render drugs non-retrievable
- Not cost effective
- Have not been proven safe for the environment and are not recognized by DEA as an approved disposal method. No peer reviewed research.
 - They should not be considered an acceptable option for disposal.
 - Even when drugs are treated this way they should be taken to a collection box
- Home disposal is exempt from regulation.

- MA and VT may have loopholes in their legislation that allows this form of disposal. Make sure to close those holes in NY's
- WA and RI have not allowed pouches to be distributed to consumers in their states until more research is done
- This method of disposal was formerly not allowed in NYS without the approval of the Bureau of Narcotics Enforcement, but Walmart may have a loophole because they are not considered a pharmacy
- PSI has a ranking of approved disposal methods
- Messaging must be consistent and concise

Who should administer the program?

- Falls between the focus of both DOH and DEC
- DEC needs to be included somehow because the environmental effects of pharmaceuticals are more long-term than the opioid addiction problem, which will hopefully subside
- Other bills around the country that have placed the environmental agency as the lead have failed.
 - All existing laws have health as the lead.
- Which agency has the staffing expertise/ ability?
 - DEC has institutional knowledge
 - Requirement to consult where appropriate
 - Role of the non-lead agency should be clearly stated in legislation
 - Proposed manufacturer plans should be approved by both departments

Destruction

- Covanta: Permitted hazardous waste disposal
 - follow DEA disposal definition in Section 1370
 - “Nonretrievable” is the most important part
- Hannon only allows disposal at hazardous waste facilities
 - Such limits increase the cost 4-5x because of fewer available disposal locations and higher transportation costs
 - Higher carbon footprint associated with disposing of collected pharmaceuticals
 - Recommend expanding destruction locations to solid waste disposal facilities
 - Ultimately, it is up to DEC to look at NYS and determine what combination of destruction facilities works best for the state.

Need to be careful of mercury thermostats (and other hazardous waste) being placed in pharmaceutical collection boxes.

- Should share local disposal methods in outreach materials so people know.

Covanta will share cost differential metrics

Implementation challenges:

- Manufacturers drag their feet
 - Need to include strict deadlines which are overseen and enforced by DEC
- Will industry cover the cost of law enforcement?

- Keeping an eye on requirements outside of DEA
 - DOT rules, special permits for transport
 - Others further limiting what is accepted

Liquid medications should be accepted in the program

Education and Outreach:

- Current Hannon needs to include more specifics on what education and outreach is required, or at least include regulation provision for the lead agency
 - PSI model bill is very thorough on this
- Need a requirement for regular reporting of information chosen by lead to allow lead agency to ensure the program is functioning.
 - Agency should then use this information to suggested legislation changes/ amendments to the legislature.
- Any surveys conducted by manufacturers must be representative surveys, statistically valid
- There must be a method for the public to submit complaints or feedback on the program

Peter: Is Department required or authorized to do regulations?

Preemption:

- Vivian: Statewide program should not preempt local laws, it should be grandfathered in.
 - Ed: Include “If existing local law is at least as protective as this law it is not preempted.”
- Vivian: Talk to counties to see how they would feel about being preempted
- Scott: Want uniformity across the state, but what do you do about local laws that are enacted after the state’s that want to be more stringent? Is that allowed?

PharmaCycle:

- OSHA classification of drugs; 27 highly excreted drugs
- Copenhagen is developing a program to collect the waste of chemo patients to keep the drugs passed through their body out of the water

Notes from Pharmaceutical Take-Back Stakeholder Meeting

Local Governments and Municipalities

2/9/18

Stakeholder Attendees:

Adam Decantur (New York State Office of Mental Health)
Katie Hohman (Association of Counties)
Dawn Timm (Niagara County)
Ed Gottlieb (City of Ithaca)
Gary Carrel (Erie County)
Andrew Radin (Onondaga County Resource Recovery Agency)
Dereth Glance (Onondaga County Resource Recovery Agency)
Debra Hotaling (DOH)

DEC Attendees:

David Vitale
Tom Snow
Peter Pettit
Joan Kennedy
Carin Spreitzer
Jen Andaloro
Chris Horan
Valerie Stanson
Peter van Erp
Mark Moroukian
Robert Phaneuf
Rebecca Vaughan
Emily Dominiak
Sarah Covelli
Jeshica Patel
Julie Tighe

Is there a standard specification for the pilot collection boxes?

- All collection boxes are compliant with DEA regulations; needles are not allowed in the boxes

Ed:

- If more than one brand of collection boxes is used, all brands should be required to have a uniform look and labelling so all collection boxes throughout the state are identifiable, help consumers.

Katie:

- The Association of Counties is okay with the Hannon bill pre-empting existing county efforts
 - Will send information of who they have worked with

Ed:

- Narcotic treatment centers should be included as a collection location, they are authorized collectors by DEA.
- Focus on newer bills as examples, they have learned from older laws
 - Programs in the US are almost all new; look to Canada to see a mature, very effective program
- Don't let industry talk us out of a requirement for education and outreach with the excuse that it doesn't work.

Collection in rural areas:

- Solutions besides mail-back and one-day events
 - Door to door collection (house calls)
 - Mobile collection station
 - Suggestion is to reach out to rural counties to ask what form of collection/ locations would work best for their residents.

Convenience standard:

- Convenience standard necessary; see standards in more recent bills
- The pilot program has coverage gaps in rural areas. Hannon would not solve this problem because it only requires participation of chain pharmacies.
 - Julie: There is a difference, especially in the Adirondacks where the state owns most of the land, between geographic area and where people actually live.
 - Ed: will send the map he mentioned. He thinks the radius around a collection location should be 5-10 miles to display coverage.

PSI EPR recommendations:

- Make collection boxes a requirement
- Convenience standard should be included per population
 - Minimum of 2 locations for county of 50,000 or less
 - Minimum of 3 locations for counties between 50,000 and 100,000
 - One location per 20,000 people for counties more than 100,000
- Collection reports should be by weight, not volume
- Municipalities should not be included as a collection location, this is illegal
- Definition of pharmacy need clarity
- Municipal combustion facilities should be included as authorized disposal locations in addition to hazardous waste facilities. Limiting disposal locations only to hazardous waste would be restrictive and more expensive because there are far less locations
- More detail should be included on the requirements for education and outreach and how those efforts are evaluated.

Voluntary collections locations beyond the minimum convenience standards:

- No turning volunteers away; any authorized collector who volunteers should be required to be included
- If there are not enough volunteers, manufacturers should have to entice locations to participate

Dawn:

- Niagara County created a map showing all existing collection boxes and all chain pharmacy locations. 5-mile radius (can change) around each point to represent 10-minute drive.
 - Some rural communities would be underserved under this model.
 - If drop boxes are mandatory there is always somewhere to go
 - Challenge of collection: what people bring
 - Need comprehensive messaging for what is accepted
 - Packaging fills up the box quickly

Adam:

- Disposal of the elderly's medications are passing is an important issue.
 - Suggested reaching out to family of the deceased; provide mail-back envelope after passing or at hospice
 - Hospice and funeral homes may be good places to disseminate information/ pamphlets about drug disposal
 - Ed stressed that these tasks are the responsibility of the manufacturers

Gary:

- Erie County is using community college public safety offices as collection locations
- The lead agency should discourage home/ trash disposal of drugs as we can't make this illegal
 - Pete: disposal ban is an option but would be a big step.

Katie: Municipalities would be willing to assist with education and outreach.

Ed:

- The best way to ensure compliance is through required annual reporting on collection locations, collected amount, education conducted, calls to the toll-free number and feedback received and how it was addressed.
 - It would then be the responsibility of the lead agency to make sure all manufacturers are participating. Manufacturers may self-police if they are all contributing funds to run a single program.
- Should be strong consequences to not participating. In a typical EPR law, the consequence of not participating is being banned from selling in the state. Consequences could also include a fine.
- More education should be required beyond pamphlets and a toll-free phone number. Possibly require TV ads or one-day events.

Adam:

- Possible complication of requiring costs to be separated based on sales in the state: most of the money OMH spends on drugs goes to pharma, but most of the quantity they buy is from generic drug manufacturers, which often don't have large profit margins like pharma.
 - Ed: Let manufacturers decide amongst themselves how costs are distributed.

Ed:

- If multiple programs exist, they must all have uniform signage, outreach materials, and collection boxes.
 - Pete: Should we allow multiple programs to coexist? More entities makes enforcement more difficult.
 - Ed: There is extreme economic pressure for manufacturers to create a single program. This requirement isn't necessary.
 - Mark: EPR programs with one entity are much easier to manage and preferred by the state. Other industries separate cost burden by volume of sales. Although not in favor, a possible option is a state-run, manufacture-funded program.
 - Andrew and Ed agree, manufacturer-run program is preferred.
- Manufacturers should be required to pay for state administrative costs and adopt existing take-back programs (i.e. law enforcement boxes).

Katie:

- Counties need more streamlined information and it needs to be more clear where various aspects of information are held.
 - Suggests creating an interagency center that houses all of this information (collection locations, amount collected, annual reports, compliance information, etc.)
- How are Narcan kits disposed/ recycled? Handling instructions different for agencies vs households.

Timeline:

- Ed: Law should come into effect immediately. Need time for a baseline knowledge survey before collection begins, then allow a “reasonable amount of time” for implementation
 - See WA bill for good example of this implementation timeline
- Andrew: Implementation within 6 months, timeline in current bill, is reasonable
 - Tom: state could implement pilot in one year (announcement to now)
- Groups tend to take as much time as they can/ do minimum required. Be sure to set strict, detailed deadlines

Plan requirements/ approval:

Ed:

- Gunther bill requirements for plan approval timeline seem reasonable. Requires survey at the beginning, one year in, and then every other year.
- Requirement for collection boxes should not preclude other options. Boxes should be used as a primary tool and other collection methods can fill-in.
 - Mail-back should be a required available option. Anyone can call and get envelopes shipped to them. This is especially important in rural areas and for the homebound.
 - Dawn agrees.

Jen:

- Would municipalities continue their existing programs and takeback day events if this type of bill is passed? Would they be okay partnering with manufacturers?
 - Katie: probably yes, especially because, under this structure, manufacturers would be funding source.
 - Ed and Gary: yes

Notes from Pharmaceutical Take-Back Stakeholder Meeting

Industry and Retail

2/12/18

Stakeholder Attendees:

Tim Sheridan (rep. Consumer Healthcare Products Association)
Anne Fellows (National Association of Chain Drug Stores)
Terry Talbott (CVS Health)
Marcy Savage (rep. Chain Pharmacy Association)
Kyle Christiansen (AstraZeneca)
Maston Sansom (Food Industry Alliance)
Michael Rosen (Food Industry Alliance)
Melissa O'Connor (Retail Council of New York State)
Heather Ferrarese (Bartle's Pharmacy/Pharmacists Society of the State of New York)
Diana Ehrlich (rep. Walmart)
Stacey Stump (DOH)
Scott Cassel (Product Stewardship Institute)
Charley John (Walgreens)
Carlos Gutierrez (Consumer Healthcare Products Association)
Vivian Fuhrman (Product Stewardship Institute)
Karl Fiebelkorn (UBuffalo Pharmacy)
Steve Moore (Condo Pharmacy/Pharmacists Society of the State of New York)
Kristen Murphy (rep. Pharmaceutical Research and Manufacturers of America)
Ashton Matyi (Retail Council of New York State)
Kayla Bogdanowicz (rep. Chain Pharmacy Association)
Stephanie Darwak (rep. AstraZeneca)

DEC Attendees:

David Vitale
Tom Snow
Peter Pettit
Joan Kennedy
Carin Spreitzer
Jen Andaloro
Chris Horan
Valerie Stanson
Peter van Erp
Mark Moroukian
Robert Phaneuf
Rebecca Vaughan
Emily Dominiak
Sarah Covelli
Jeshica Patel
Julie Tighe

Pilot program:

- Who applied to pilot program? No chain applicants
- How big is box?
 - 38-gal liner
 - 52 in. high, 20.5 in deep
- What is the cost for the 6 months after pilot program?
 - \$96.50 per destruction event
 - Box stays at no cost to pharmacy

Maston:

- Preemption is important: statewide standard is easier to comply with and enforce. FIA supports current preemption language in current Hannon
 - Marcy and Melissa also support preemption

Marcy:

- Counties put laws in motion because they wanted action taken, they would likely be okay with preemption.
 - FIA: Rockland County law has not yet been implemented.

Julie:

- Would retailers be okay with having a role in take-back?
 - Melissa: Retail Council supported the vetoed bill
 - Marcy: took a neutral stance on the vetoed bill. Pharmacies want take-back options; don't like the requirement for collection boxes. Hannon is closer to support from Chain Pharmacy Assn; like that LTCF are included, pharmacies should not bear the sole responsibility.

Julie:

- Mail-back doesn't work, has less than 1% participation rate
 - Vivian agrees and offered to send supplement information. Collection boxes are visible at pharmacies, more cost effective, and is the standard for pharmaceutical take-back internationally.
 - Terry: some pharmacies are not physically big enough to house a collection box that is in line with DEA regulations
 - Pete: What percent of pharmacy have this limitation?
 - Vivian: size options are being developed in response to this problem
 - Steve: space is limited at community pharmacies

Diana:

- Walmart has developed in-home destruction packets that are distributed when prescriptions are filled.
 - Vivian: health and environmental safety studies not peer reviewed, lack of information transparency, effects not studied under all conditions. Packets also not cost effective.
 - Walmart will share research

Maston:

- Boxes pose a security risk to pharmacies, other take-back options needed
 - Tom: that has not yet been an issue with any of the pharmacies participating in the pilot, none of expressed concern about security because they already have staff coverage and cameras.

Julie:

- Does pharma currently run any take-back programs? No

Heather:

- How will mail order pharmacy take-back be addressed?
 - Stephanie: This is a big issue. Fluctuations in dosing can lead to a lot of unused drugs.
 - Karl: runs drug disposal program via take-back day events in Western NY. ~30% of drugs collected are from mail order.
 - Peter: If you sell into New York, you must have a program in place. Most EPR laws leave it up to industry but are sure to mandate inclusion of these manufacturers/ distributors.
 - Steve: vast majority of community pharmacy waste comes from mail order pharmaceuticals, don't want to pay for others waste. Provided 170 pages of mail order waste

Marcy:

- Project Orange in Albany County: funded by the county, provided mail-back envelopes

FIA:

- What is the scope of drug take-back?
 - Both prescription and non-prescription drugs
- Issues with taking back medications under someone else's name- getting pulled over
 - Tom: ultimate user as assigned by DEA regulations

Melissa:

- Consistency between federal, state, and local laws is key. Mirror DEA disposal options
 - PSI: goal is to harmonize legislation nationally; wants to work with manufacturers on a model.

Kristen: Pharma opposed Hannon

Anne:

- Support flexibility in take-back options; will increase compliance
 - FIA: Options are important; collection boxes are a security concern
 - Joan and Tom: King Kullen in Suffolk County has had a collection box for years and has never had a security issue
 - Vivian: if someone were going to target pharmacies, it wouldn't be contents of locked box, it would be drugs behind the counter
 - Anne: collection boxes are important, but should not be the only option

Peter: Is there interaction between pharmacies and local doctors?

- Melissa: No
- Marcy: policies are being developed- CME

Maston:

- If collection boxes are the preferred method of collection, an incentive should be provided such as the collection boxes are provided
 - Dave: We want manufacturers to pay. Would that ease concerns?
 - Maston: It would help, but removing flexibility is still not the right thing to do.
 - Mark: Consumers want the convenience of drop boxes, plus it drives foot traffic to the location. Proposition:
 - Mandatory collection box at all pharmacies, but no mandatory box size. Pharmacies may submit a waiver if they cannot host a box for some reason.

- Envelopes available in rural areas for which pharmacies wouldn't meet the convenience requirements
- Collection day events

Karl:

- Police empty collection box daily
- Supports Hannon, support manufacturer funded program with costs incurred by pharmacies reimbursed
 - Tax on manufacturers based on market share in NYS
 - Marcy: Tax is not a good idea because it will be passed on; plus, it is difficult to collect taxes from manufacturers domiciled outside of NYS.

Method of destruction:

- Diana: Bill has narrow options, should be expanded to licensed waste facilities, not only hazardous waste facilities.
 - Scott: some states required hazardous waste facilities, but PSI prefers including both types of facilities

503B facilities are recognized as manufacturers in NYS

Maston:

- What outreach has been done in NYS re: mail-back? Is lack of education why it is underutilized?
 - Tom: mail-back option is included on DEC drug disposal poster, which should be displayed at all pharmacies; people should know about the option.

Timeline:

- Melissa: difficult to say what their timeline preference is without knowing who would be responsible for running the program. However, they do prefer timelines outlined in number of days over dates.
- Steve: cost is an important factor in developing a timeline for community pharmacies. This factor remains even if manufacturers are responsible for the costs because they may still have to rearrange/ renovate their store to accommodate the box.
- Covanta on boxes:
 - Planning: ~6 months
 - Manufacturing: 6-12 months

APPENDIX E

Law and Bill Details

Passed – National				
	Alameda County, CA	MA	VT	WA
Covered Products	Any drug offered for sale in the County including: <ul style="list-style-type: none"> • Prescription and non-prescription drugs. • Brand name and generic. • Veterinary drugs. • Drugs in medical and combination products. 	<ul style="list-style-type: none"> • Brand and generic opioids. • Benzodiazepines. • Any other drug in pill form. 	Prescription drugs.	Prescription and non-prescription drugs, brand name and generic, veterinary drugs, and drugs in medical and combination products.
Collection Locations	Not specified.	Law enforcement and pharmacies are authorized but neither are required to participate.	Not specified.	Any location registered with DEA, including pharmacies, hospitals or clinics with on-site pharmacy, law enforcement agency, LTCFs.
Convenience Standard	Not specified.	Not specified.	Not specified.	<ul style="list-style-type: none"> • 1 location per population center. • 1 additional for every 50,000 residents. • If there are insufficient locations, manufacturers must hold periodic collection events.
Methods of Collection	A pharmaceutical collection receptacle must be provided to any authorized location that requests one.	At least two of the following: <ul style="list-style-type: none"> • Prepaid mail-back envelopes distributed at time of prescription filling. • Pharmaceutical collection receptacles. • Drop-off day events. • In-home disposal. 	Disposal sites. Medication envelopes.	One or more of the following: <ul style="list-style-type: none"> • Pharmaceutical collection receptacles. • Prepaid mail-back envelopes. • Drop off events. • Other approved collection method.
Methods of Disposal	Drugs must be disposed by incineration at a medical waste or hazardous waste facility.	Not specified.	Authorized collection facility.	<ul style="list-style-type: none"> • Hazardous waste disposal facility unless unfeasible, then a large municipal waste combustor is allowed. • Or alternate approved by the department that is more protective of the environment and human health.

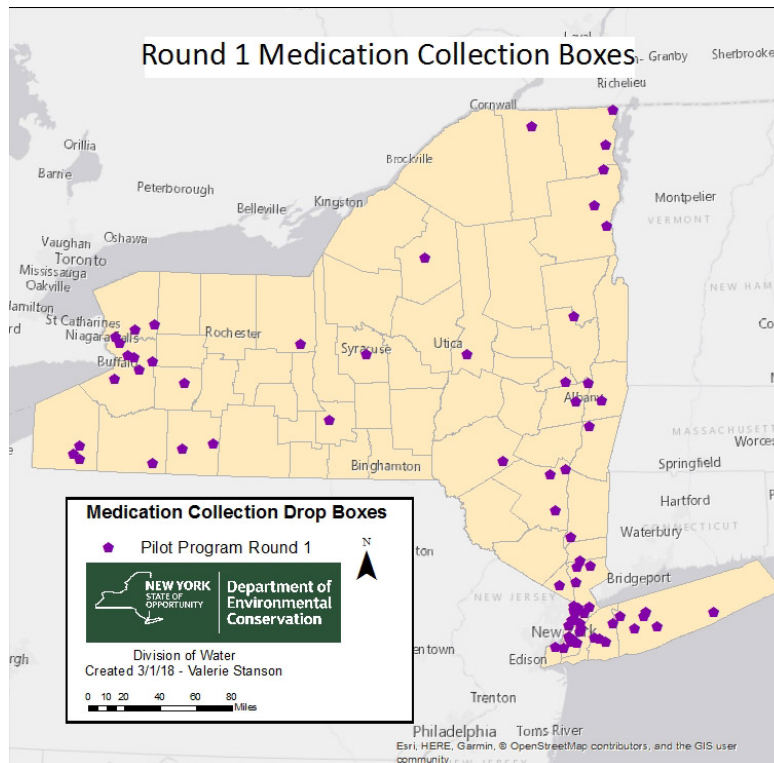
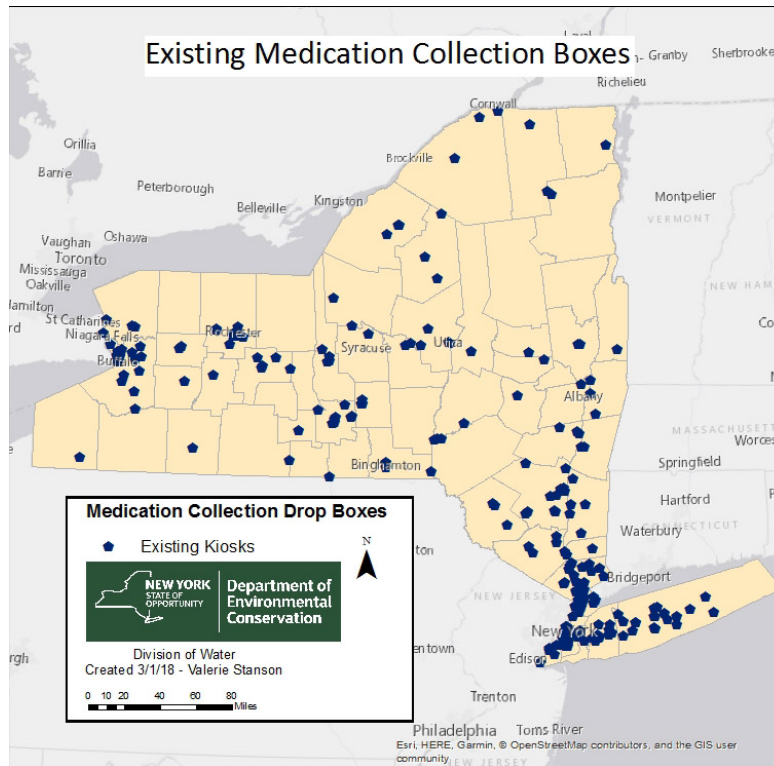
Passed – National				
	Alameda County, CA	MA	VT	WA
Outreach and Education	<ul style="list-style-type: none"> Promotion and outreach, including signage for collection locations, written materials to be provided at the time of purchase, and appropriate advertising. Website and toll-free phone number Must ensure program is widely understood by public and health professionals. 	Must submit a plan to the Department.	Not specified.	<ul style="list-style-type: none"> Must include website, toll-free phone number, and written materials. Must encourage use of take-back and discourage disposal via garbage or sewage system. Must ensure program is widely understood by public and health professionals. Designs must be standardized and consistent across programs. Promotional materials should be provided to pharmacies, and other locations that sell medication, for free and upon request. Pharmacies are required to provide information about any take-back programs to customers upon request
Reporting	Program operators must annually report to the department the weight collected, a description of the program, and a summary of any issues with implementation or security.	Program operators must annually report to the department. Report shall include the volume and type of drugs collected.	Not specified	Program operators must annually report to the department. Report shall include effectiveness of promotion and education programs, quantities collected, expenditures, and progress toward program goals.
Program Administration	Manufacturers can run and finance program individually, as a group, or enter into an agreement with a product stewardship organization.	Manufacturers can run and finance program individually, as a group, or enter into an agreement with a product stewardship organization or MA Department of Public Health.	Vermont Department of Health	Manufacturers can run and finance program individually, as a group, or through a product stewardship organization.
Program Costs	<ul style="list-style-type: none"> Administrative, enforcement, and operational costs covered by the manufacturer. May not be passed to the consumer. 	Covered by manufacturers.	Not specified.	<ul style="list-style-type: none"> Covered by manufacturers. May not be passed to consumers.

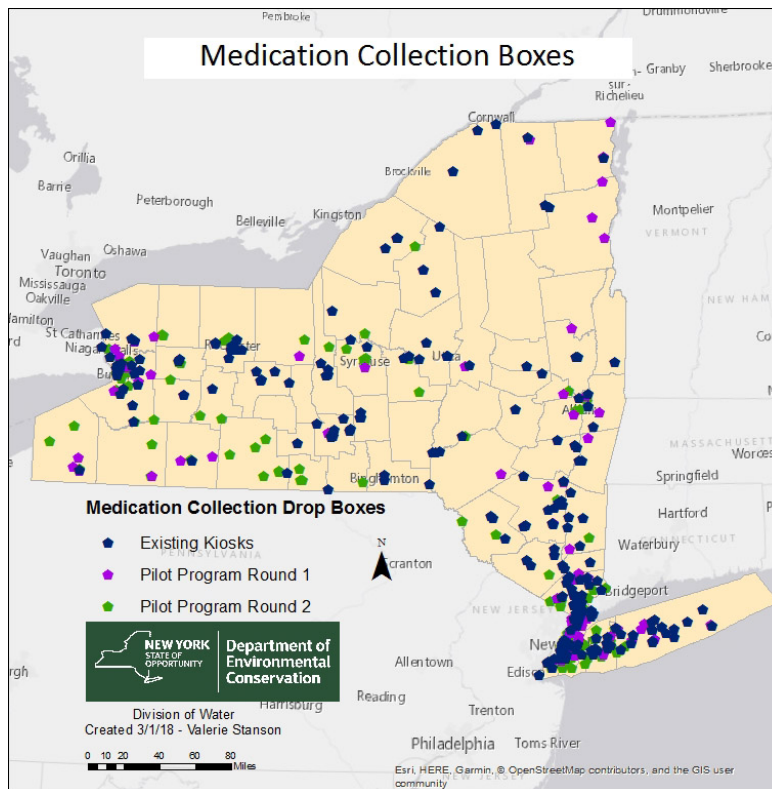
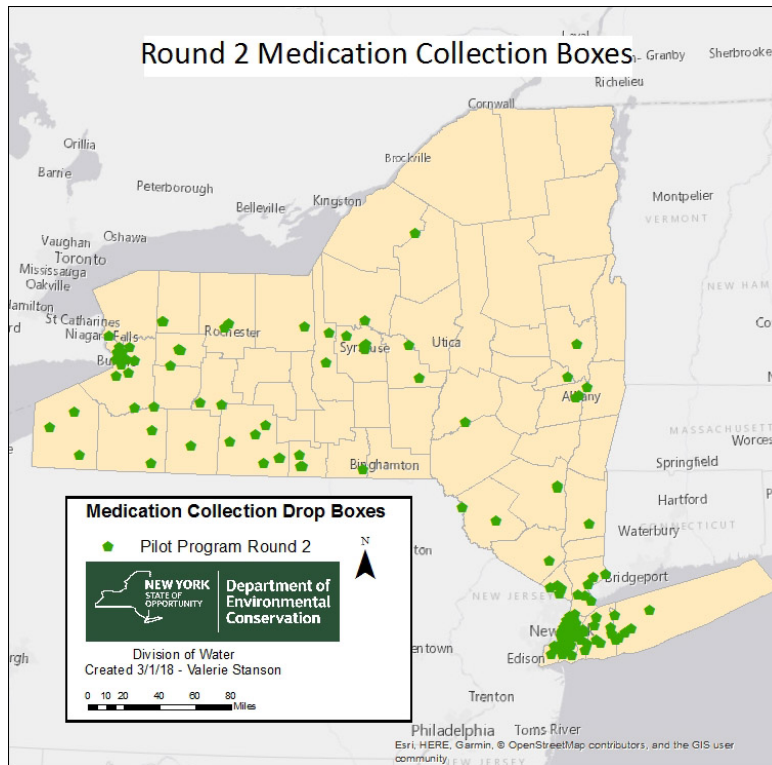
Proposed – National	
	IN
Covered Products	Schedule II or schedule III drugs.
Collection Locations	Not specified.
Convenience Standard	Not specified.
Methods of Collection	<p>At least two of the following:</p> <ul style="list-style-type: none"> • Prepaid, pre-addressed mail-back envelopes to distribute when filling a prescription or by request. • Pharmaceutical collection receptacle. • Drop-off day events. • In-home disposal method. • Any other method approved by state department or recommended by DEA.
Methods of Disposal	Not specified.
Outreach and Education	Must submit a plan of these activities to the state department.
Reporting	Program operators must annually report to the department. Report shall include a description of program activities and the volume and type of drugs collected.
Program Administration	Manufacturers can run and finance program individually, as a group, or enter an agreement with a product stewardship organization or the Indiana State Department of Health.
Program Costs	<p>Administrative and operational costs covered by the manufacturer.</p> <p>May not be passed to the consumer.</p>

Passed and Proposed – NY Counties			
	Rockland County	Westchester County	Erie County
Covered Products	Those defined in 21 U.S.C. §321 (g)(1) including brand name and generic drugs and nonprescription drugs.	Those defined in 21 U.S.C. §321 (g)(1) including brand name and generic drugs and nonprescription drugs.	Those defined in 21 U.S.C. §321 (g)(1) including brand name and generic drugs, nonprescription drugs, medical devices and combination products, and drugs for veterinary use.
Collection Locations	<ul style="list-style-type: none"> Any business that sells drugs with three or more locations. Any medical or veterinary office, hospital, or clinic that sells drugs. 	<ul style="list-style-type: none"> Any business that sells drugs with three or more locations. Any medical or veterinary office, hospital, or clinic that sells drugs. 	Any DEA authorized location can voluntarily participate.
Convenience Standard	Not specified.	Not specified.	Not specified.
Methods of Collection	Pharmaceutical collection receptacle or prepaid mail-back envelopes.	Pharmaceutical collection receptacle or prepaid mail-back envelopes.	Pharmaceutical collection receptacle provided to any authorized location that requests one.
Methods of Disposal	<ul style="list-style-type: none"> Drugs must be disposed by incineration at a medical waste or hazardous waste facility. Any packing collected shall be recycled or disposed. 	<ul style="list-style-type: none"> Drugs must be disposed by incineration at a medical waste or hazardous waste facility. Any packing collected shall be recycled or disposed. 	Drugs must be disposed by incineration at a medical waste or hazardous waste facility.
Outreach and Education	<ul style="list-style-type: none"> Promotion and outreach, including signage for collection locations, written materials to be provided at the time of purchase, and appropriate advertising. Establish website and toll-free phone number. 	<ul style="list-style-type: none"> Promotion and outreach, including signage for collection locations, written materials to be provided at the time of purchase, and appropriate advertising. Establish website and toll-free phone number. 	Promotion and outreach, including signage for collection locations, written materials to be provided at the time of purchase, and appropriate advertising.
Reporting	Not specified.	Not specified.	Program operators must annually report to the department. Report shall include the weight of drugs collected, a description of collection systems, activities of the program, and education and outreach conduct as well as how its effectiveness is being evaluated.
Program Administration	Manufacturers can run and finance program individually, as a group, or through an agreement with a product stewardship organization.	Manufacturers can run and finance program individually, as a group, or through an agreement with a product stewardship organization.	Manufacturers can run and finance program individually, as a group, or through an agreement with a product stewardship organization.
Program Costs	<ul style="list-style-type: none"> Administrative, enforcement, and operational costs covered by the manufacturer. If manufacturers choose to jointly run the program, costs are to be allocated according to the number of covered drugs the manufacturers sell in the County. May not be passed to the consumer. 	<ul style="list-style-type: none"> Administrative, enforcement, and operational costs covered by the manufacturer. If manufacturers choose to jointly run the program, costs are to be allocated according to the number of covered drugs the manufacturers sell in the County. May not be passed to the consumer. 	<ul style="list-style-type: none"> Administrative, enforcement, and operational costs covered by the manufacturer. If manufacturers choose to jointly run the program, costs are to be allocated according to the number of covered drugs the manufacturers sell in the County. May not be passed to the consumer.

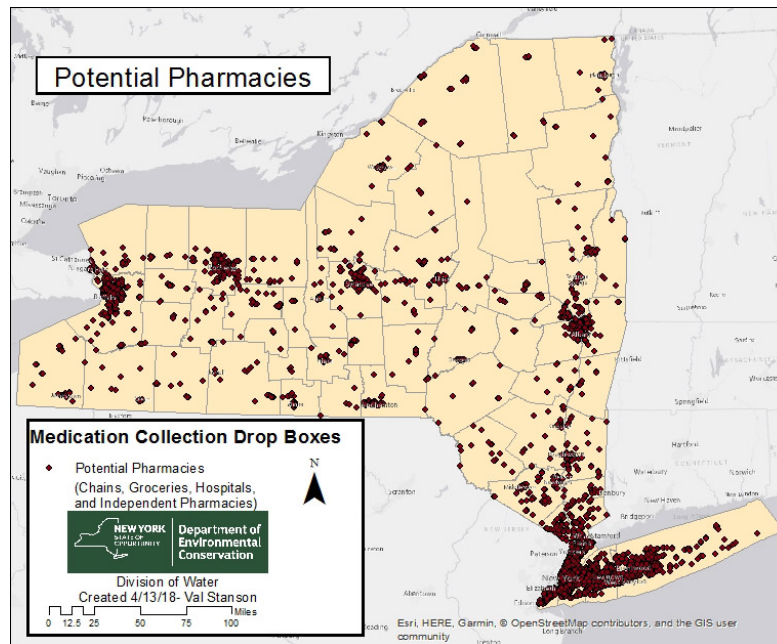
Proposed – NYS			
	<u>A10298</u>	<u>S6750</u>	<u>S7354</u>
Covered Products	Any prescription drug.	Any prescription drug.	Prescription and non-prescription, brand and generic, and veterinary drugs.
Collection Locations	Not specified.	<ul style="list-style-type: none"> Chain pharmacies. Law enforcement, nonchain pharmacies, and other DEA approved locations may participate voluntarily. 	Pharmacies and any other DEA authorized locations that voluntarily participate.
Convenience Standard	Not specified.	Not specified.	Not specified.
Methods of Collection	<ul style="list-style-type: none"> At least two of the following: Prepaid mail-back envelopes. Pharmaceutical collection receptacles. Collection-day events. 	<ul style="list-style-type: none"> Chain pharmacies: pharmaceutical collection receptacles, mail-back envelopes at a cost of no more than \$2, or other approved method. Nonresident pharmacies: mail-back envelopes at a cost of no more than \$2. 	<ul style="list-style-type: none"> Pharmaceutical collection receptacle. Prepaid mail-back envelopes. Other approved method.
Methods of Disposal	Not specified	Not specified	Permitted hazardous waste disposal facility.
Outreach and Education	Must submit a plan of these activities to the department.	Chain pharmacies required to post notice of disposal methods offered at each location.	<ul style="list-style-type: none"> Must post notice of the disposal methods available at each location. Must develop website to advertise the program.
Reporting	Program operators must annually report to the department. Report shall include the program's activities and the volume and type of drugs collected.	Not specified.	Program operators must report to the Department in a manner determined by the Department. The Department would annually report program activities, volume collected, collection locations, and education and outreach efforts to the Governor, speaker of the Assembly and temporary president of the Senate.
Program Administration	Manufacturers can run and finance program. individually, as a group, or through an agreement with a product stewardship organization or the Department.	Pharmacies run and finance their take-back program individually.	Manufacturers can run and finance program individually, as a group, or through an agreement with a product stewardship organization or the Department.
Program Costs	<ul style="list-style-type: none"> Administrative and operational costs covered by the manufacturer. May not be passed to consumer. 	Not specified.	<ul style="list-style-type: none"> Administrative, enforcement, and operational costs covered by the manufacturer. If manufacturers choose to jointly run the program, costs are to be allocated according to the number of covered drugs the manufacturers sell in the State. May not be passed to the consumer.

Pharmaceutical Collection Receptacles in New York State





Pharmacies in New York State





www.dec.ny.gov

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