



# Recommendations to New York Department of Environmental Conservation

For Inclusion in its Report to Governor Andrew Cuomo

Creating and Implementing a Manufacturer-Funded Drug Take-Back Program for New York State

February 28, 2018

The New York Product Stewardship Council (NYPSC) and the Product Stewardship Institute (PSI) appreciate the opportunity to provide the following recommendations to NY DEC for its report to the Governor regarding an effective drug take-back program for the State.

## **Producer Responsibility**

Drug manufacturers should be responsible for funding, designing, and running take-back programs. These programs save government and taxpayers money, fairly incorporate the true cost of managing these products in the purchase price, and provide a direct financial incentive for pharmaceutical companies to reduce unnecessary prescriptions.

## **State Government Oversight**

State government should provide oversight to drug manufacturers as they implement the take-back program. NY Department of Health is the most logical oversight agency due to its familiarity with the stakeholders involved, and similar bills passed around the country have health as the lead agency. However, NY Department of Environmental Conservation (DEC)has significant experience running its own government-funded drug take-back program, and should have, at minimum, an advisory/consulting role in the program approval and implementation process. The oversight department should be given authority to adjust program requirements as needed, including the convenience standard, education and outreach, and reporting. It should also be given the right to audit or inspect the program, including program records and an authorized collector's facilities, vehicles, and equipment used in carrying out the program.

#### **Collection Convenience**

The DEC drug take-back pilot currently includes 10 percent of pharmacies operating in the state. While this is a strong start, more collection locations are needed to achieve convenience for all NY residents. We recommend DEC ensure that a manufacturer-funded program incorporates existing locations from the current DEC pilot without interruption of service to the public. We also recommend all federal Drug Enforcement Administration (DEA) authorized locations wanting to participate (e.g., pharmacies, narcotic treatment centers, long-term care facilities, or law enforcement agency sites) be allowed to serve as collection locations within 90 days of making a formal request to the manufacturer stewardship organization running the program. This provision will add convenience and ensure no entities are left out of the program if they want to participate.

A convenience standard is one of the most important aspects of high-performing producer responsibility laws in operation in the U.S. Adding chain pharmacies that would be required to participate under the Hannon/Gunther bill (S.7354 same as A.9576), currently under consideration by the Legislature, still would not provide adequate service to rural residents, as demonstrated by the coverage gaps in this GIS map of chain pharmacies (10 or more locations) and existing drug take-back locations, which was developed by the Niagara County Department of Public

Works. To ensure all residents are served, particularly those in rural areas, we recommend requiring a minimum number of collection locations per area and/or per number of residents (equitably distributed geographically). Depending on preferences of DEC and the Legislative Committee, there are two alternatives that would both achieve adequate convenience. These would require the following number of collection locations at a minimum:

## Approach #1

- 2 for counties of 50,000 population or fewer;
- 3 for counties of 50,000 to 100,000; and
- 1 for each additional 20,000 population over 100,000.

## Approach #2

- 1 in each population center (defined as a city or town and the unincorporated area within a 10-mile radius);
- 1 additional for every 20,000 residents of the city or town in the population center; and
- on islands and in areas outside population centers, 1 additional at every potential authorized collector (e.g., retail pharmacy, hospital/clinic, police station) that is regularly open to the public, unless that site is unwilling or unqualified.

#### **Drop-Boxes and Other Collection Methods**

At every collection location, we recommend DEC require drop-boxes (i.e., on-site collection receptacle "kiosks") as the primary method of collection in the program. They are convenient, visible, and secure. PSI's 2016 drug take-back pilot program in rural New York clearly showed that, compared to drop-boxes, mail-back envelopes collect unwanted drugs at lower rates and are more expensive per unit of drug destroyed (see <a href="attached">attached</a> report). Another pilot project by Citizens Campaign for the Environment supports these findings. Drop-boxes of various sizes and shapes are available to fit limited store space. We recommend DEC provide limited exemptions to pharmacies that prove they cannot accommodate a drug take-back drop-box. Consistent branding should be required for all drop-boxes.

In cases where the oversight department is confident that manufacturers cannot otherwise meet convenience standards, we recommend the oversight department require collection events and/or mail-back envelopes as alternative collection methods. Mail-back envelopes accommodate a limited amount of material and are more expensive, but can meet the needs of home-bound or differently-abled residents. These options should be made available to NY residents upon request via the program's website and toll-free phone number.

#### **Collection Locations**

"A Municipality" should <u>not</u> be included in the definition of "Authorized Collector" in legislation, as this is not permissible under DEA rules.

## **Destruction Facility Requirement**

We recommend DEC <u>not</u> require that collected medications be destroyed in a "permitted hazardous waste disposal facility." <u>Municipal</u> waste combustion facilities can meet DEA standards for rendering collected material "non-retrievable," and would lower the program's carbon footprint by reducing the distance to transport waste medications for disposal. We recommend that both methods of destruction of collected material be allowed. We support the following language to incorporate this recommendation into legislation:

"Explains how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction, policies to ensure security and compliance with all applicable laws and regulations including disposal and destruction at a licensed waste disposal facility that renders drugs non-retrievable as required by 21 CFR §1317.90 DEA regulations;"

## **Alternate Drug Disposal Method**

We recommend that any drug disposal method included in the program must be pre-approved by the oversight department prior to being used. Approved methods should be at least as stringent as disposal at a licensed waste combustion facility in protecting public health and the environment. Drop-boxes should be the first choice when available, and mail-back envelopes the second choice. At present, any form of drug disposal in the household trash should be considered a <u>last resort</u>. When in-home disposal products or "pouches" are used, messaging should direct consumers to use a take-back solution. The oversight department should be wary of approving activated carbon or other material claiming to render pharmaceuticals safe to dispose of in the household trash for the following reasons:

- These products have not been approved by the DEA or U.S. Environmental Protection Agency (EPA), and there is not enough scientific evidence that the products are safe or effective, as summarized in this <u>PSI</u> overview document.
- A <u>report</u> commissioned by the San Francisco Department of the Environment points out the many questions still left about the effectiveness and mode of action of the products.

## **Reporting Requirements**

Clarifying which manufacturers are required to report is critical to developing a successful program plan to be approved by the oversight department. This information can be self-reported, with a requirement for periodic independent audits paid for by the manufacturers. We recommend specifying reporting requirements including the following at minimum: public education strategy, awareness survey results, a description of safety/security problems, program feedback received, and the amount (in weight) collected by each location and by each method. We recommend that "weight collected" be required in the reporting requirements. It should replace "volume collected" in the Hannon/Gunther bill (S.7354 same as A.9576) under consideration by the Legislature. Weight is more accurate and appropriate as volume does not account for large/empty pill packaging or dense liquids.

#### **Public Education Requirements**

We recommend DEC consider requiring manufacturers to include (at a minimum) the following in their public education strategy: signage for drop-boxes, posters for participating and non-participating pharmacies, and pamphlets for providers. Program signage should clearly state what material is and is not accepted for collection by the program. DEA rules include minimum signage requirements. To reduce undesirable material (e.g., medical sharps, mercury thermostats, etc.), signs should clearly state where/how to safely dispose of material not accepted. We also recommend that manufacturers be required to develop a program information website that identifies all drop off locations, as well as a toll-free number, and that outreach materials be available in all languages commonly spoken in NY. To evaluate education efforts, representative public and provider awareness surveys should be required of manufacturers before the program launches, 12-15 months after the program launches, and every other year thereafter.

#### Preemption

We recommend that preemption of local drug take-back laws be included in legislation only if the state law is more stringent than the local laws they would replace. Local laws that are more stringent than the state law should not be preempted. Sample language to that effect can be found in the <u>WA State bill</u>, pg. 19.

For more information, contact:

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