

November 26, 2019

Mr. Joshua S. Vinciguerra
Director
Bureau of Narcotic Enforcement
New York State Department of Health
150 Broadway
Albany, NY 12204

RE: Joint Comments on the Proposed Drug Take Back Act Regulations

Dear Mr. Vinciguerra:

We, the undersigned coalition of environmental, product stewardship, public health, law enforcement, wastewater treatment, solid waste management, local government, and fishing organizations, thank you for the opportunity to provide comments on the New York State Department of Health's ("the Department") proposed regulations for implementing the requirements of Article 2-B of the Public Health Law regarding the creation of a statewide drug take back program for the safe disposal of drugs. Collectively, we offer the recommendations (summarized below, and described in detail on the following pages) to help ensure that these regulations fulfill the intent of the New York State Drug Take Back Act to provide free, convenient access to safe drug disposal for all New Yorkers:

- **Expedite the timeline for program implementation**
- **Allow all authorized collectors to participate in the program at the manufacturer's expense.**
- **Pharmacies enrolled in the DEC Pilot Project should be rolled into the new program, unless they decline the opportunity**
- **Include a statewide convenience standard**
- **Require collection receptacles (aka "kiosks" or "drop boxes") at pharmacies and other authorized collectors participating in the program**
- **Maximize the effectiveness of mail back (as a supplement to collection receptacles)**
- **Make manufacturers pay the full cost of the program**
- **Ensure transparency in the rulemaking process**

- **Expedite the timeline for program implementation**

The prescription drug epidemic continues to plague New York State, with more than 2,000 New Yorkers dying annually from prescription drug abuse. Water bodies from the Great Lakes to the Hudson River to Long Island Sound are polluted with trace amounts of pharmaceutical drugs, adversely impacting fish and the health of our ecosystem, and potentially impacting drinking water quality. Rolling out a robust, statewide drug take back program to provide all New Yorkers with safe, convenient drug disposal options as soon as possible will help to protect our treasured waters and protect public health. *This take back program will save lives, and we cannot afford to delay.*

New York is already behind schedule. A number of deadlines, laid out in Chapter 120 laws for 2018, have been missed. These include a July 5, 2019 deadline for manufacturers, and/or organizations, to submit a proposal to operate a drug take back program and the deadline for the Department to then approve or deny proposals within 60 days.

We urge you to move as expeditiously as possible to reach full implementation of the drug take back program. When regulations are finalized, we urge you to set a firm deadline for manufacturers/organizations to submit proposals for approval or denial by the Department in consultation with the DEC.

- **Allow all authorized collectors to participate in the program at the manufacturer's expense**

In defining the Drug Take Back Program, the statute (§ 291 (4)) states that, “A manufacturer, individually or jointly, must pay all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting and disposing of covered drugs from pharmacies **and other authorized collectors** and the recycling or disposal, or both, of packing collected with the covered drug.”

Regrettably, the Department's proposed regulations imply that only chain pharmacies will have their costs covered by the manufacturers. The Rural Area Flexibility Analysis in the proposed regulations states, “*While not mandated under these regulations, pharmacies in rural areas that are not part of a chain may choose to operate a drug take back program and **would incur any associated costs with that program.***” This undermines the intent of the law and will have severe consequences on the effectiveness of the statewide take back program:

- If non-chain, authorized collectors have to pay the costs of participating in the take back program, it will be a strong disincentive to their participation.
- Non-chain pharmacies, often “Mom & Pop” operations, will be at an additional competitive disadvantage when chain pharmacies get to add this valuable public service at no cost to themselves.

- Many communities, particularly those in rural areas hard hit by the opioid crisis, will be left without convenient access to safe drug disposal options.
- Law enforcement agencies—an important partner in safe drug disposal—will have to pay program costs. Agencies with an existing program will be more likely to discontinue service if a chain pharmacy in the area offers the service (at no cost to themselves). Law enforcement agencies who want to participate will be less likely to do so if they have to pay all the costs.

We recommend that the regulations be revised to explicitly state that authorized collectors that volunteer to participate in the drug take back program will have take back costs covered by the manufacturers. Costs include the collecting, transporting and disposing of covered drugs, as well as the recycling or disposal of packing left when the covered drugs were dropped off.

Furthermore, the statute (§ 292 (2)) states, “All drug take back program operators shall notify other potential authorized collectors of the opportunity to serve as an authorized collector for the drug take back program.” Notifying potential authorized collectors about the opportunity to participate is paramount to ensure broad program participation from authorized collectors. They can’t participate in a program if they don’t know it exists. Regrettably, this required notification of potential authorized collectors is not explicitly required in the proposed regulations.

We recommend that the regulations explicitly state that operator(s) are required to notify potential authorized collectors of the opportunity to participate, at no cost, as an authorized collector in the drug take back program. Notification efforts should be documented in the operator(s) annual report.

- **Pharmacies enrolled in the DEC Pilot Project should be rolled into the new program, unless they decline the opportunity**

While the regulations reference the DEC Pilot Pharmaceutical Take back Program in the section on costs (referencing potential costs to pharmacies not covered by manufacturers, such as loss of retail space or obtaining a DEA registration), it is not clear if the regulations ensure that pharmacies enrolled in the DEC pilot will be eligible to participate in the operator(s) new take back program, once they are no longer participating in the DEC pilot, with costs (collecting, transporting, disposing of collected drugs) covered by the manufacturers. This must be clarified.

There are currently hundreds of independent pharmacies, geographically distributed across the state, participating in the DEC program and providing convenient access to safe drug disposal for many New Yorkers. A critical incentive for pharmacies to participate was DEC’s offer to cover the full cost of the first two years of the program. If the pharmacies currently enrolled in the DEC pilot do not have the full cost of participating in the new operator(s) take back program (save for limited exceptions, such as loss of retail space) we could potentially lose hundreds of

safe disposal sites across the state. This would be a major step backwards for safe disposal of drugs in New York State.

We recommend that the regulations explicitly state that all pharmacies enrolled in the DEC's Pilot Pharmaceutical Take Back Program are eligible to participate in the operator(s) drug back program.

- **Include a statewide convenience standard**

While the proposed regulations require authorized drug take back programs to offer a minimum number of collection receptacles in cities and certain counties with a population of 125,000 or more, the convenience standard should also cover areas outside the nine cities and counties identified in the proposed regulations.

In defining the Drug Take Back Program, the statute (§ 291 2(C)) requires that a drug take back program, “Details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs pursuant to section two hundred ninety-two of this article that is geographically distributed in a way to ensure access in rural and underserved areas.”

The law makes clear that collection services must be geographically distributed and made available to rural and underserved areas. Without a required convenience standard, we are very concerned that rural and underserved communities will not be adequately served by the take back program. Based on the experience of pharmaceutical EPR programs around the nation and the globe, it is clear that a convenience standard is necessary to provide equitable access to safe drug disposal options.

We recommend that DOH include a statewide convenience standard that must be met by program operator(s) requiring, at a minimum, the following:

- A collection receptacle in all “pharmacies” (i.e., chain pharmacies as defined in the Act)
 - At least one collection receptacle in every village, town, city (regardless of population size), island, and unincorporated community, in every county.
 - At least one additional collection receptacle for every additional ten thousand residents in a village, town, city, island, and unincorporated community.
 - In locations where DOH determines that this convenience standard could not be met, for reasons beyond the control of the program operator(s), require program operator(s) to hold at least two collection events per year and distribute mail back envelopes from at least one, regularly open, public building such as a town hall.
- **Require collection receptacles (aka “kiosks” or “drop boxes”) at pharmacies and other authorized collectors participating in the program**

Existing take back programs have demonstrated that collection receptacles are effective at collecting large amounts of drugs at a low per pound cost. Programs with *only* mail back envelopes have collected only small amounts of drugs and at a higher per pound cost. While mail back is not an effective standalone option, it is a helpful supplement, providing customers who would have difficulty coming back to the pharmacy a practical disposal option.

Some signatories of this letter have direct experience with take back programs on Long Island (and elsewhere), which demonstrated the overwhelming success of collection receptacles at retail pharmacies, and the ineffectiveness of a program that provided *only* mail back envelopes at pharmacies. A pilot project that provided only mail back envelopes at Stop and Shop pharmacies on Long Island for a two-year period—from December of 2013 to December of 2015—yielded disappointing results. That program collected less than 300 pounds and approximately 70% of distributed envelopes were never sent back with unwanted drugs. Contrarily, an ongoing project to provide collection receptacles at several King Kullen pharmacies on Long Island has demonstrated overwhelming success. As of August 2019, the nearly five-year old program has collected over 13,800 pounds of unwanted drugs.

We support the requirement for collection receptacles to be used in pharmacies subject to the convenience standard the Department specified for certain counties and cities. We are concerned that, for a significant portion of New York State, the rules do not require, or even encourage, the use of collection receptacles. The overreliance on voucher mail back system will seriously reduce the effectiveness of the Act.

Pilot projects conducted by the Product Stewardship Institute demonstrate the success of collection receptacle programs in rural communities in New York State. From 2016-2018, several independent and hospital pharmacies in rural NY participated in pilots that included on-site kiosks, mail back envelopes, and outreach. Based on surveys and collection data, the pilots increased residents' knowledge about the risks associated with improper drug storage and disposal, increased their understanding of ideal safe disposal options, and increased the quantity of unwanted and expired medications collected from households in the target areas. Each kiosk collected up to 500 pounds of medication per month, and the amount collected through kiosks far outweighed that collected via mail back envelopes.

We recommend that the final regulations require collection receptacles at pharmacies and other authorized collectors participating in the statewide take back program.

- **Maximize the effectiveness of mail back (as a supplement to collection receptacles)**

Pre-paid mail back envelopes for safe drug disposal are an important supplement to collection receptacles, especially for customers that have difficulty getting to a collection receptacle. To ensure the availability of mail back to members of the public who need it, ***we recommend that the regulations:***

- *Require operator(s) to establish and maintain a website and a toll-free phone number to provide customer service. This would allow members of the public to conveniently request a pre-paid mail back envelope. The website URL and toll-free phone number should be prominently included in the operator(s) public outreach materials.*
- *State that the availability of pre-paid mail back envelopes should not be limited to authorized collectors. Again, this disproportionately impacts rural areas that do not have a nearby authorized collector. Places without a convenient authorized collector nearby should have the opportunity to distribute mail back supplies through locations such as a Town Clerk's office.*
- *Provide vouchers for pre-paid mail back envelopes with the distribution of every covered drug. The regulations should specify a simple, convenient process, for customers to exchange vouchers for pre-paid mail back envelopes (e.g. directly at the pharmacy from which the covered drug was purchased, along with covered drugs send via the mail system, at the town clerk's office, at a local law enforcement agency, through a website/toll free number, etc.).*

- **Make manufacturers pay the full cost of the program**

The regulations should be clear regarding manufacturers' responsibility for paying for *all* costs. According to the Act, manufacturers must pay all administration costs. The State should not incur any costs to administer the program, including initial costs and the additional 5-10 FTE's the Department of Health anticipates needing to hire for implementation and enforcement.

That said, there may be reasonable exceptions for some costs to not be covered by the manufacturers, such as the loss of retail space at pharmacies or the cost of DEA registration.

- **Ensure transparency in the rulemaking process**

To ensure a transparent rulemaking process, *we recommend that the DOH publish all comments, received on the proposed regulations, on its website.*

Thank you for your consideration of our comments.

Sincerely,

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