

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Office of Remediation & Materials Management, Deputy Commissioner
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February 1, 2017

To the Operators of Retail Pharmacies:

The New York State Department of Environmental Conservation (DEC) is pleased to announce two new initiatives to help retail pharmacies prevent violations and protect public health and the environment. Under the first initiative, DEC is inviting pharmacies to participate in a special Environmental Audit Incentive program to improve hazardous waste handling. Under the second, DEC will work with pharmacies to support the collection of unused and unwanted drugs from consumers.

In recent years, DEC has identified potentially significant compliance issues in the retail pharmacy sector. Issues are primarily associated with the failure to properly make hazardous waste determinations and manage hazardous wastes under the Federal Resource Conservation and Recovery Act (RCRA). Although retail pharmacies have been subject to these requirements for many years, the widespread nature of compliance issues has become apparent.

Over the last year, DEC has worked cooperatively with pharmacy, grocery, and other business associations to develop an approach that will foster industry-wide compliance while avoiding the penalties associated with enforcement actions. We have developed a unique Environmental Audit agreement that gives participating pharmacies time to adopt best practices before auditing their facilities and disclosing any violations to DEC. The agreement also allows participating pharmacies to comply with the streamlined requirements in the U.S. Environmental Protection Agency's new proposed rule, Subpart P, 40 CFR Part 266, in lieu of existing RCRA Subtitle C requirements.

If you would like to participate in the Audit program, please review the enclosed audit agreement, sign and return it to DEC no later than May 1, 2017. By signing the agreement, you commit to proactively adopt best practices, audit your operations, and disclose and correct any violations. In exchange, DEC will allow pharmacies at least 18 months to complete these activities and will defer inspection of any facility covered by the agreement during this time frame. In addition, DEC will waive monetary penalties for violations identified during the audits that fall within the scope of the audit agreement. While audit agreements may be submitted after the May 1 deadline, after that date DEC plans to begin inspecting retail pharmacies. Signed agreements can be mailed to Monica Kreshik, NYSDEC, Office of General Counsel, 625 Broadway, Albany, New York 12233-1500. Guidance information can be found on the DEC website at <http://www.dec.ny.gov/chemical/99555.html>.



As part of the Audit program, pharmacies also commit to make a good faith effort to adopt a system for collecting waste pharmaceuticals from consumers. To support this effort, DEC is pleased to announce a pilot take-back program for interested pharmacies across New York State. DEC will provide participating pharmacies with a medication drop box compliant with U.S. Drug Enforcement Administration (DEA) regulations, and will hire a DEA-registered vendor to pick up, transport, and destroy collected pharmaceuticals for a period of two years. All pharmacies are eligible to participate in the pilot whether or not they sign an audit agreement.

If you are interested in participating in the pilot pharmaceutical take-back program, please visit the DEC website at <http://www.dec.ny.gov/chemical/108213.html> to fill out an on-line application. Applications are due May 1, 2017. DEC is committed to offering pharmacies guidance and technical support. The Product Stewardship Institute recently released a valuable *How-to Guide for Drug Take-Back: Managing a Pharmacy-Based Collection Program for Leftover Household Pharmaceuticals* that includes a step-by-step process for establishing a successful program. It can be found at www.bit.ly/drug-take-back or at the DEC web link above.

Thank you for taking the time to consider these new initiatives. Please remember you have only 90 days to sign up for the Environmental Audit Incentive program before an inspection may be held at your facility. If you have any questions, please feel free to contact your retail pharmacy association or the following DEC staff:

- Monica Kreshik, Associate Attorney, Office of General Counsel (for legal questions regarding the Audit program or audit agreement), Monica.Kreshik@dec.ny.gov, (518) 402-8555.
- Bill Ottaway, Chief, Training and Technical Support Section, Division of Environmental Remediation (for questions regarding RCRA applicability and compliance issues), william.ottaway@dec.ny.gov, (518) 402-9755.
- Thomas Snow, New York City Watershed Coordinator (for questions on pharmaceutical take-back), thomas.snow@dec.ny.gov, (518) 402-9395.

The Food Industry Alliance is also preparing training materials. For more information, please contact Maston Samson, Vice President of Government Relations for the Food Industry Alliance of New York State, maston@fiany.com, (518) 434-1900. We look forward to working with you.

Sincerely,

/Martin Brand/

Martin Brand
Deputy Commissioner

STATE OF NEW YORK
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

ENVIRONMENTAL AUDIT AGREEMENT No. _____

This Environmental Audit Agreement (“Agreement”) is entered into by and between _____ (the “Regulated Entity”), located at _____ and the New York State Department of Environmental Conservation (the "Department").

WHEREAS, the Department is responsible, by and through the Commissioner, to carry out the policy of the state as set forth in the Environmental Conservation Law and regulations promulgated pursuant to the ECL;

WHEREAS, environmental auditing plays a role in protecting human health and the environment by identifying, correcting, and ultimately preventing violations of environmental law and regulations;

WHEREAS, the Department adopted Commissioner Policy # 59, Environmental Audit Incentive Policy (Policy) to encourage regulated entities to perform environmental audits; disclose compliance deficiencies; and adopt effective approaches to prevent future violations, including pollution prevention measures, thereby increasing compliance with environmental laws and regulations statewide and protecting public health and the environment;

WHEREAS, the Department has determined that the above referenced Regulated Entity meets the eligibility criteria in the Policy;

WHEREAS, this Agreement details the manner in which the Regulated Entity will audit the facility or facilities identified in Attachment A of this Agreement (Facility) for environmental regulatory compliance, disclose and correct deficiencies, and prevent future violations; and includes the benefits that inure to the Regulated Entity as a result of this activity;

WHEREAS, this Agreement is governed by the terms of the Policy, except to the extent that those terms are explicitly modified herein;

WHEREAS, the Department has identified potentially significant environmental compliance issues in the retail pharmacy sector. These compliance issues relate to the Federal Resource Conservation and Recovery Act (RCRA) Subtitle C and associated state laws (Environmental Conservation Law Article 27 Title 9) and implementing regulations (6 NYCRR Parts 370-376); and are primarily associated with the failure to make hazardous waste determinations and failure to properly manage hazardous wastes, including universal waste, ignitable liquids, hazardous waste pharmaceuticals, and other hazardous wastes;

WHEREAS, on September 25, 2015, the federal Environmental Protection Agency published the proposed rule, Subpart P, 40 CFR Part 266, Management Standards for Hazardous Waste Pharmaceuticals. The proposed rule is intended to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to hospitals, pharmacies and other healthcare-related facilities; and clarify the regulation of the reverse distribution mechanism used for the management of unused or expired pharmaceuticals;

WHEREAS, the Department recognizes that proper management of hazardous waste pharmaceuticals is critical and a final rule may take time to promulgate;

WHEREAS, the Department staff believe that implementation of the proposed rule would protect the environment, effectively manage hazardous waste pharmaceuticals, and alleviate the difficulties that hospitals, pharmacies and other healthcare-related facilities have faced over the years in trying to comply with the RCRA Subtitle C hazardous waste regulations;

WHEREAS, the Department has legal authority to impose hazardous waste management requirements that are more restrictive than current federal requirements and believes it is in the best interest of New York State and regulated entities to allow pharmacies that enter into an Environmental Audit Agreement to comply with the proposed rule until a final rule is promulgated;

WHEREAS the Department will exercise prosecutorial discretion not to enforce the current requirements of RCRA Subtitle C and related state laws and implementing regulations regarding the management of hazardous waste pharmaceuticals provided that the Regulated Entity complies with the corresponding requirements of the federal Environmental Protection Agency's proposed rule for a new Subpart P of 40 CFR Part 266 (80 FR 58014; September 25, 2015) and any subsequent final rule addressing the management of hazardous waste pharmaceuticals.

NOW, THEREFORE, IN CONSIDERATION OF AND IN EXCHANGE FOR THE MUTUAL COVENANTS AND PROMISES SET FORTH HEREIN, THE PARTIES HERETO AGREE TO THE FOLLOWING:

1. OBLIGATIONS OF THE REGULATED ENTITY

A. IDENTIFY DEFICIENCIES, AND DEVELOP A COMPLIANCE PLAN

- i. Within 180 days (approximately 6 months) of the effective date of this agreement, the Regulated Entity will:
 - (1) identify environmental regulatory compliance requirements at the Facility, consistent with proposed rule, Subpart P, 40 CFR part 266;
 - (2) develop a compliance plan to address deficiencies pertaining to the management of hazardous waste pharmaceuticals. This activity will include a compliance plan, training program and monitoring system to maintain compliance with environmental requirements, as appropriate;
 - (3) identify qualified personnel or consultants to perform an environmental audit (the "Audit") of the Facility for compliance with the above referenced regulatory requirements and communicate this information to the Department in writing. (The Department may reject unqualified personnel or consultants where warranted.); and
 - (4) identify a schedule for completing the Audit within the prescribed time frame and communicate this information to the Department in writing.

B. IMPLEMENT THE COMPLIANCE PLAN AND BEGIN THE AUDIT

Within 365 days (one year) of the effective date of this agreement, the Regulated Entity will implement the compliance plan and audit the Facility for compliance with requirements of proposed rule, Subpart P, 40 CFR part 266.

C. COMPLETE THE AUDIT AND DISCLOSE DEFICIENCIES

- i. Within 425 days (approximately one year and two months) of the effective date of this Agreement, the Regulated Entity will complete the Audit required by this Agreement and disclose to the Department in a written disclosure report or reports any deficiencies identified during the audit that have been corrected and any that require additional corrective action.
- ii. Each disclosure report will include a certification by the Regulated Entity's responsible official that the disclosure report is true, accurate, and complete; and, with reference to identified deficiencies requiring corrective action, contain:
 - (1) A citation to the relevant law or regulatory provision ;
 - (2) The action(s) selected by the Regulated Entity to correct the condition;
 - (3) The status of the corrective action with expected date of completion; and
 - (4) The means taken by the Regulated Entity to prevent recurrence of the violation.
- iii. Each disclosure report is subject to review and comment by the Department. If the Department disagrees with information in a disclosure report, including any of the corrective action identified therein, the Regulated Entity will consult with Department staff, revise the disclosure report accordingly and submit a timely revised disclosure report to the Department. If the Department disapproves the revised disclosure report, the Regulated Entity may invoke dispute resolution pursuant to Section 5 of this Agreement.

D. EFFECT OF AUDIT

The Regulated Entity waives its right to seek judicial or administrative review of any issue of law or fact related to the terms of this Agreement, except as related to corrective action. If a dispute arises concerning any of the corrective action set forth in the revised disclosure report which cannot be resolved by the parties to the Agreement, the Department or the Regulated Entity may invoke the dispute resolution procedures described in Section 5 of the Agreement to resolve the dispute.

E. CORRECTION PERIOD

- i. Within 545 days (approximately one year and six months) of the effective date of this Agreement, the Regulated Entity will implement corrective action and notify the Department in writing. If the Regulated Entity is unable to correct a deficiency within the prescribed time frame, it shall request an extension of time from the Department in writing and provide a schedule, accompanied by a justification of the requested extension. Any extension of the prescribed time frame shall be subject to Department approval which shall not be unreasonably withheld.
- ii. Once a disclosed deficiency is corrected, and a disclosure report is submitted to the Department indicating completion of the corrective action, no further action concerning that condition, or the status of corrective action, is required.

- iii. Pursuant to the Section V.E of the Policy, the Regulated Entity will undertake corrective action consistent with any applicable protocol prescribed by law and regulation, or as may be directed by the Department in writing. Correcting identified deficiencies includes remediating any environmental harm associated with the condition, and where appropriate shall include implementing procedures to prevent future violations.

F. COLLECTION OF UNUSED OR UNWANTED PHARMACEUTICALS

The Regulated Entity, with guidance and technical support from the Department, will make a good faith effort to develop and implement a program to collect and dispose of unused, unwanted or expired pharmaceuticals from consumers. At a minimum, a good faith effort will include a thorough investigation of the costs and benefits of multiple collection and disposal options, including the installation of US Drug Enforcement Administration-compliant drug collection boxes. Any program implemented shall comply with the Federal Disposal of Controlled Substances rule promulgated September 9, 2014.

2. OBLIGATIONS OF THE DEPARTMENT

A. PENALTY WAIVER

- i. The Department will waive the gravity-based penalties for reported deficiencies which are determined to be eligible under section V.B. of the Policy that are voluntarily discovered through the Audit, timely disclosed and corrected, in accordance with the Policy and this Agreement. Disclosed deficiencies that are ineligible for a penalty waiver under Section V.B. of the Policy may be considered for penalty mitigation at the discretion of the Department in accordance with the provisions of DEE-1 Civil Penalty Policy.
- ii. The Department reserves the right to seek penalties based upon potential economic benefits to the Regulated Entity to the extent that the Department can demonstrate that such benefits exceed \$5,000.00.
- iii. Economic benefit penalties that exceed \$5,000.00 will be reduced by an amount not to exceed the amount that the entity commits to invest in pollution prevention not otherwise required by law at the Facility. The pollution prevention investment will be subject to review and approval by the Department.

B. COORDINATION WITH U.S. ENVIRONMENTAL PROTECTION AGENCY

The Department will inform staff at U.S. Environmental Protection Agency, Region 2 (“EPA”) of this Agreement and will provide a copy to EPA. Nothing herein restricts EPA from acting as it deems appropriate.

3. ADDITIONAL BENEFITS AND INCENTIVES

Regulated Entities that perform an environmental audit of all significant aspects of the Facility’s operation and disclose and correct all conditions identified in the environmental audit are entitled to additional benefits and incentives identified in the Policy and by the Department. Regulated Entities that go on to implement environmental management systems covering all significant aspects of the Facility’s operation and those that implement pollution prevention are entitled to further benefits as identified in the Policy.

4. COMMUNICATION

- A. All written communications required by this Agreement may be transmitted by the United States Postal Service, by private courier service, by hand delivery, or by electronic mail.
- B. The Department designates as its contact for all communication related to this Agreement:

Monica Kreshik, Esq.
New York State Department of Environmental Conservation
Office of General Counsel
625 Broadway
Albany, N.Y. 12233-1500
(518) 402-8555
Monica.Kreshik@dec.ny.gov

- C. The Regulated Entity designates as its “responsible official” for communication and submission of disclosure reports related to this Agreement:

- D. The Department and the Regulated Entity reserve the right, upon written notice to the other party, to designate additional or alternative individuals to receive communications related to this Agreement.

5. MISCELLANEOUS

- A. Acknowledgement. The Regulated Entity acknowledges that it has read, understands, and agrees to abide by all the terms of the Policy and this Agreement.
- B. Compliance with Law and Regulation. Neither this Agreement, nor compliance with this Agreement relieves the Regulated Entity of its obligation to comply with the regulations covered by this Agreement, and all other applicable federal, state and local laws and regulations.
- C. Duration. This Agreement shall take effect when it is signed by the Commissioner of Environmental Conservation or his designee, and shall expire when the Regulated Entity has fully complied with the requirements of this Agreement. Either party may terminate this Agreement without cause with 30 days advance written notice to the other party.

- D. Access. For the purpose of monitoring or determining compliance with this Agreement, employees and agents of the Department shall be provided access to any facility, site, or records owned, operated, controlled or maintained by the Regulated Entity relating to the management of hazardous waste, in order to inspect and/or perform such tests as the Department may deem appropriate; to copy such records; or to perform any other lawful duty or responsibility. Any information related to trade secrets or confidential business information shall be kept confidential.
- E. Force Majeure. If the Regulated Entity cannot comply with a deadline or requirement of this Agreement because of an Act of God, war, strike, riot, catastrophe, or other condition that was not caused by the negligence or willful misconduct of the Regulated Entity and that could not have been avoided by the Regulated Entity through the exercise of due care, the Regulated Entity shall apply in writing to the Department within 20 days after obtaining knowledge of such fact and request an extension or modification of the deadline or requirement.
- F. Indemnity. The Regulated Entity shall indemnify and hold the Department, the State of New York, and their representatives and employees harmless for all claims, suits, actions, damages and costs resulting from the acts and/or omissions of the Regulated Entity, intentional, negligent, or otherwise, of every nature and description, arising out of or resulting from the compliance or attempted compliance with the provisions of this Agreement by the Regulated Entity or its employees, servants, agents, successors, or assigns.
- G. Priority/Modifications. In the event of any actual or perceived conflict between this Audit Agreement and Commissioner Policy # 59, Environmental Audit Incentive Policy (Policy), this Audit Agreement shall control. No change in this Agreement shall be made or become effective except as agreed to by the parties to this Agreement and specifically set forth in writing. The Regulated Entity's requests for modification shall not be unreasonably denied.
- H. FOIL. Subject to the provisions of the Freedom of Information Law, the Department will respond to any requests made pursuant to that law regarding this Agreement and documents submitted pursuant to this Agreement.
- I. Other Rights. The Department reserves the right to proceed against the Regulated Entity for any alleged violations outside the scope of the Agreement as defined in Section 1.A above or alleged violations within the scope of the Agreement that are not timely reported or timely corrected. Nothing contained in this Agreement shall be construed as barring, diminishing, adjudicating, or in any way affecting (1) any legal, administrative or equitable rights, claims, actions, suits, or demands that the Department may have against anyone other than the Regulated Entity; (2) any right of the Department to enforce the terms, provisions and conditions of this Agreement; (3) any right of the Department to bring any future action, either administrative or judicial, for any other violations of the ECL, the rules and regulations promulgated thereunder, or conditions contained in orders or permits, if any, issued by the Department to the Regulated Entity; or (4) the summary abatement powers of the Department either at common law or as granted pursuant to statute or regulation.

- J. Dispute Resolution. If disputes concerning any of the corrective action set forth in the revised disclosure report cannot be resolved by the parties to the Agreement, the Department or the Regulated Entity may request dispute resolution services from the Assistant Commissioner of the Office of Hearings and Mediation Services (“OHMS”) at the Department of Environmental Conservation. The requesting party must submit the request to the Assistant Commissioner in writing and copy the other party to the Agreement. The Administrative Law Judge assigned to the matter, with input from the parties, will determine the protocol and schedule for the dispute resolution. The parties agree to exhaust this administrative remedy prior to seeking adjudicatory relief. If dispute resolution services fail to resolve the dispute, the parties reserve their judicial, equitable and administrative rights and defenses relating to resolution of the dispute.

- K. Entire Agreement. This Agreement shall constitute the entire agreement of the Department and the Regulated Entity with respect to violations discovered and disclosed to the Department pursuant to the Audit specifically referenced herein. In the event of a conflict between the terms of this Agreement (including any and all attachments thereto and amendments thereof) and the terms of the Policy, the terms of this Agreement shall control.

- L. Binding Effect. The provisions, terms, and conditions of this Agreement shall bind the Regulated Entity and the Regulated Entity's legal representatives, receivers, trustees in bankruptcy, successors and assigns.

DATED: _____

BASIL SEGGOS
COMMISSIONER
NEW YORK STATE DEPARTMENT OF
ENVIRONMENTAL CONSERVATION

By: _____
Thomas S. Berkman
Deputy Commissioner and General Counsel

Appendix A

List of Facilities to be Audited