Rulemaking Notice Form

Notice Number: ________________  Rule Number: Env-Hw 1300

1. Agency Name & Address:

Department of Environmental Services
29 Hazen Drive
P.O. Box 95
Concord, NH 03302-0095

2. RSA Authority:

RSA 147-A:3, I-VI;
RSA 147-B:7, I

3. Federal Authority:

42 U.S.C. §§6921 - 6939e;
40 CFR Parts 260 - 279

4. Type of Action:

Adoption  X  Repeal  Readoption  Readoption w/amendment

5. Short Title: Hazardous Waste Pharmaceuticals

6. (a) Summary of what the rule says and of any proposed amendments:

The Resource Conservation and Recovery Act (RCRA), Subtitle C, establishes federal requirements for the management of hazardous waste (HW) and provides for federal authorization of state programs that are at least as stringent as the federal program. Once authorized, the state program is enforceable in lieu of the federal program. Federal requirements for the management of HW pharmaceuticals have been adopted as 40 CFR 266 Subpart P and are considered more stringent than current federal standards that apply to this type of HW. Therefore, authorized states are required to adopt rules to implement 40 CFR 266 Subpart P.

The proposed rules, Env-Hw 1300, incorporate by reference the federal requirements for the management of HW pharmaceuticals. The Department proposes to incorporate most of 40 CFR 266 Subpart P requirements with some modifications to conform with state-specific terminology, cross-references, and existing requirements in subtitle Env-Hw.

The proposed rules, once adopted, require healthcare facilities to determine the applicability of Env-Hw 1300 to their facilities by counting all the HW (pharmaceuticals and other HW) they generate per month. Healthcare facilities that, when counting all their HW, are federal small quantity generators or large quantity generators (collectively called full quantity generators in New Hampshire), as well as reverse distributors, shall manage their HW pharmaceuticals under these new sector-specific rules in lieu of the existing HW generator rules. The sector-specific rules incorporate cost-saving, streamlined standards for handling HW pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment. Federal very small quantity generators (known in New Hampshire as small quantity generators) when counting all their HW will have the option to manage their HW pharmaceuticals under Env-Hw 1300 or under the existing HW generator rules in subtitle Env-Hw.

In addition, the proposed rules incorporate the federal prohibition on disposal of HW pharmaceuticals to a sewer system that connects to a publicly owned treatment works (POTW) and eliminate the dual regulation of HW pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances.
6. (b) Brief description of the groups affected:

The rules affect any healthcare facility or reverse distributors that generate or manage hazardous waste pharmaceuticals.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<table>
<thead>
<tr>
<th>Rule Section(s)</th>
<th>State Statute Implemented</th>
<th>Federal Statute/Regulation Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Env-Hw 1300</td>
<td>RSA 147-A:3, I-VI; RSA 147-B:7; RSA 147-B:8; RSA 147-B:9; RSA 147-B:11</td>
<td>40 CFR 266 Subpart P</td>
</tr>
</tbody>
</table>

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: Wendy Bonner  
Title: Regulatory Manager  
Address: Department of Environmental Services  
29 Hazen Drive  
P.O. Box 95  
Concord, NH 03302-0095  
Phone #: (603) 271-2937  
Fax#: (603) 271-2456  
E-mail: Wendy.S.Bonner@des.nh.gov  
TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The rules also can be viewed in PDF in the Public Comment Opportunities section of the NHDES website at https://www.des.nh.gov/public-comment-opportunities and selecting “Rulemaking”

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **4:00 p.m. on Friday, April 15, 2022**

- [ ] Fax  
- [x] E-mail  
- [ ] Other format (specify):
9. Public hearing scheduled for:

   Date and Time:    Friday, April 8, 2022 at 11:00 a.m.
   Place:            Room 208C, DES Offices, 29 Hazen Drive, Concord NH

   NOTE: NHDES security procedures require all visitors to sign in and present photo identification (such as a driver’s license). If you plan to attend the public hearing in person, please bring photo identification with you.

   You also may attend the hearing via GoToWebinar, which can be accessed through the following link:

   https://attendee.gotowebinar.com/register/8580869539956104462

   After registering using this link, interested participants will be provided a confirmation email with information about joining the hearing remotely.

   You also may join the meeting by phone:

   Call in Number:  1 (562) 247-8422
   Access Code:     872-463-431
   Webinar ID:      853-426-339

   If you have any questions or technical issues connecting to the hearing, contact Tara Albert at Tara.M.Albert@des.nh.gov or (603) 271-3713.

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant):

   FIS #22:032 dated: 03/07/22

   1. Comparison of the costs of the proposed rule(s) to the existing rule(s):
      
      Not applicable these are new rules.

   2. Cite the Federal mandate. Identify the impact on state funds:
      
      Resource Conservation and Recovery Act (RCRA), Subtitle C, establishes federal requirements for the management of hazardous waste and provides for federal authorization of state programs that are at least as stringent as the federal program. Regulation 40 CFR 271 specifies the requirements that must be met by a state’s hazardous waste program (including adoption of requirements promulgated by Environmental Protection Agency (EPA) under the authority of RCRA, the Hazardous and Solid Waste Amendments of 1984, or the Hazardous Waste Electronic Manifest Establishment Act) to receive and maintain final authorization from EPA. Once authorized, the state program is enforceable in lieu of the federal program. The Department has been authorized by EPA to implement the RCRA Subtitle C program in New Hampshire and currently receives approximately $522,000 annually to implement the program. The Department states if rules are not updated and if issues identified during New Hampshire’s RCRA authorization application process are not addressed, EPA may initiate proceedings to revoke the authorization, and the Department will lose the federal funds and the ability to enforce the state program.

   3. Cost and benefits of the proposed rule(s):
      
      The proposed rules, Env-Hw 1300, incorporate by reference the federal requirements for the management of hazardous waste pharmaceuticals. Once a healthcare facility has determined the applicability of Env-Hw 1300 and manages hazardous waste pharmaceuticals under those provisions, those HW pharmaceuticals will no longer be counted toward the healthcare facility’s hazardous waste
generator classification, thereby potentially lowering the classification and, as a result, their operating costs. These potential savings are attributable to federal requirements and not to the rules.

The proposed rule includes two modifications to 40 CFR 266 Subpart P that are not existing requirements in the HW rules as described above and are more stringent than the federal requirements. The costs of these provisions are attributable to the state rules. First, at Env-Hw 1302.02(c)(1), the Department is proposing to require all healthcare facilities to notify the Department of pharmaceutical activities within 60 days, instead of allowing those healthcare facilities subject to federal biennial reporting to notify the Department as part of their biennial report, which could be up to two years in the future. Second, at Env-Hw 1302.02(e)(2), the Department is proposing to require long-term care facilities (LTCFs) with 20 beds or fewer to determine the applicability of Env-Hw 1300, instead of presuming that such LTCFs are federal very small quantity generators (i.e., New Hampshire small quantity generators) and therefore not subject to most provisions of Env-Hw 1300. These changes may increase costs to healthcare facilities and LTCFs with 20 or fewer beds by an indeterminable, but likely small, amount.

A. To State general or State special funds:

The proposed incorporation by reference of 40 CFR 266 Subpart P will likely reduce revenues to the Hazardous Waste Cleanup Fund by an indeterminate amount. Once a healthcare facility has determined the applicability of Env-Hw 1300 and manages hazardous waste pharmaceuticals under those provisions, those hazardous waste pharmaceuticals will no longer be counted toward the healthcare facility’s generator classification, thereby potentially lowering the classification. As a result, the Certified Hazardous Waste Coordinator Program and the Small Quantity Hazardous Waste Generator Self-Certification Program are expected to see a decrease in participation, and therefore revenue. Due to the number and variability of factors involved, an estimate of the costs cannot be made.

No impact on state general fund.

B. To State citizens and political subdivisions:

There may be an impact to costs to a political subdivision, to the extent it operates a health care facility (see 3 above). No impact on state citizens.

C. To independently owned businesses:

There may be an impact to costs to a privately owned business, to the extent it operates a health care facility (see 3 above).

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules incorporate federal requirements that are required to be adopted in accordance with the State’s federal RCRA authorization. In the absence of a State authorized program, the federal rules would apply to regulated entities. The proposed rules do include two modifications to the federal rules that are not existing requirements in the State’s rules. The costs of these modifications are attributable to the rules. There are no healthcare facilities currently operated by political subdivisions that are subject to the proposed modifications. Accordingly, the proposed rules do not violate Part I, Article 28-a of the New Hampshire Constitution, because the rules do not assign any new, modified, or expanded programs or responsibilities to any political subdivision of the state in such a way as to increase local expenditures.