Step-by-Step Guide to Notifying under Subpart P

The Q&As and recommendations included below are intended for use by healthcare facilities whose primary function is patient care, including hospitals and urgent care facilities. Other types of RCRA hazardous waste generators (e.g., pharmaceutical manufacturers, oil refineries) that have on-site facilities that meet the definition of healthcare facility are also subject to Subpart P for the management of their hazardous waste pharmaceuticals, but there may be some notable differences in how the 8700-12 Site Identification Form should be completed.

Be aware that some states require the use of their own notification form which should be used in lieu of the 8700–12 Site Identification Form. Although state-specific forms are equivalent to the federal form, the instructions below may not be applicable. The instructions below are for notification using the federal 8700–12 Site Identification Form.

1. Why do some healthcare facilities need to notify to report their hazardous waste pharmaceutical activities?

The notification requirement for healthcare facilities was finalized by the 2019 final rule, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine."

2. Who must notify under Subpart P?

Any healthcare facility operating under Subpart P must notify, even if it previously received a RCRA ID number.

Healthcare facilities that are very small quantity generators (VSQGs) of hazardous waste are not federally required to operate under Subpart P but may opt in, in which case, they must notify. All other healthcare facilities that generate hazardous waste pharmaceuticals (i.e., SQGs and LQGs) must operate under Subpart P and notify their state or EPA Region.

3. Whom do I notify?

If the healthcare facility is in Iowa, Alaska, Indian country, or U.S. territories (other than Guam), then it must notify the EPA Regional Office. In all other cases, the healthcare facility must notify the <u>state environ-mental agency</u>.

4. When do I have to notify under subpart P?

If the healthcare facility is required to submit a Biennial Report (or state annual report), it can notify as part of that report. Otherwise, the healthcare facility must notify within 60 days of Subpart P becoming effective in that state, or within 60 days of becoming subject to subpart P (e.g., moving up in generator category from VSQG to SQG).

5. How do I notify under subpart P?

A healthcare facility can notify by submitting the EPA Site Identification Form (Form 8700–12) or equivalent state notification form to your authorized state or EPA Region.

Some states also allow users to notify electronically via the myRCRAid online tool of U.S. EPA's RCRAInfo hazardous waste data system. To notify using myRCRAid, you must first register as an industry user with RCRAInfo. After you have access, you must complete and submit the required information and indicate that you are operating under Subpart P. EPA encourages healthcare facilities to notify electronically wherever possible. Please check with your state environmental agency to see if the electronic myRCRAid tool is available to you. If you are located in Iowa, Alaska, Indian country, or a U.S. Territory, EPA encourages you to use myRCRAid. The instructions for this form are available at: <u>https://www.</u> epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage-and.

6. How do I determine if my healthcare facility has an EPA Identification Number?

If your healthcare facility has an existing EPA Identification Number you will be able to look it up on RCRAInfo Web's Search by Site page: <u>https://rcrapublic.epa.gov/rcrainfoweb/action/modules/hd/</u> <u>handlerindex</u>. One simple way to find your facility is to enter your zip code and browse the results. If your facility has an EPA Identification Number, it will be listed. If you do not see your healthcare facility, it is likely you do not have an EPA Identification Number and you will be assigned one as part of the notification process. This will inform how you complete Items No. 1 and 2 of Form 8700–12.

This document was developed as an Appendix to the 2022 Edition of A 10-Step Blueprint for Managing Hazardous Waste Pharmaceuticals in US Healthcare Facilities. It has also been published as a separate document for your convenience.

Note that none of the fields on the Search by Site page are required, so you can enter as much or as little information as you like. Keep in mind, however, that the more information you enter, the more you risk not retrieving the correct results (e.g., typos or information that does not match what is in RCRAInfo will not return results.)

7. How do I complete Form 8700-12?

If you are not familiar with the Form 8700-12, it may be helpful to complete the Form 8700-12 offline first, even if you plan to enter your information into myRCRAid.

Item No. 1. Reason for Submittal: If notifying independent of a biennial report, check "Obtaining or updating an EPA ID Number of an on-going regulated activity that will continue for a period of time." If notifying as part of your biennial report, check, "Submitting as a component of the Hazardous Waste Report for ______ (Reporting Year)." Select only one.

Item No. 2. Site EPA ID Number: Enter the number if you already have one (see Question 6 above for information on how to find it) or leave blank if you do not yet have an EPA ID Number.

Item No. 3. Site Name: The common name used to identify the site, e.g., Anytown Medical Center. If your facility is part of a chain, group, etc. with the same or similar names, try to use the convention already in the system (e.g., Anytown Medical vs. Any Town Medical).

Item No. 4. Site Location Address: Enter a physical address, not a Post Office box number. EPA ID Numbers are issued to a specific piece of land and stay with the land regardless of ownership changes. You can ignore the latitude and longitude coordinates.

Item No. 5. Site Mailing Address: If this is the same as the physical address, check the "Same as Location Address" box. If different than the physical address, enter the mailing address. This entry may include a Post Office box number, if appropriate.

Item No. 6. Site Land Type: This will usually be "private" for a healthcare facility, but could be County, Federal, Tribal, etc. Select only one type: Private, County, District, Federal, Tribal, Municipal, State, or Other. If your site's Land Type could be described as Municipal and another Land Type, such as County, District, or Tribal, do not place an "X" in Municipal. Instead, choose the other appropriate Land Type. (For example, if your site's Land Type is both Municipal and County, you would place an "X" in the box for County.)

Item No. 7. North American Industry Classification System (NAICS) Codes: Provide the code that best fits your primary function in Box A. A six-digit code is preferable, although a five-digit code is allowed. A four-digit code is not acceptable. This code should be available from your accounting department, or you may search on <u>https://www.census.gov/naics/</u>. NAICS Codes are very specific, so be sure to review all relevant options. For example, general hospitals are listed as: 622110 (General Medical and Surgical Hospitals), whereas emergency centers are listed as 621493 (Freestanding Ambulatory Surgical and Emergency Centers). Including more than one NAICS code is optional.

Item No. 8. Site Contact Information: Enter the information for the primary RCRA hazardous waste contact responsible for your submission. This will allow the state agency to follow up if they need any clarification or additional information. If there are additional people who may be contacted about your submission, enter their information in Item 18: Comments.

Item No. 9. Legal Owner of the Site and Operator of the Site: Since many hospitals operate under names different from the name of the legal owner, check with your business office to determine the legal owner of the site for this entry. List all owners of the site. The Date Became an Owner entry is optional and usually difficult to determine, so it may be left blank. Also indicate the owner type, which may be different than the Site Land Type indicated in No. 6. Pick only one owner type, choosing the most descriptive, e.g., County rather than Municipal.

Also provide the name of the Operator. Be aware that the Operator is responsible for the overall operation of a RCRA site. This is the legal entity which controls the RCRA site operation rather than the plant or site manager. This is usually a company or business name, most likely to be the name under which the healthcare facility is commonly known in the community. The date they became an Operator is also optional.

Item No. 10. Type of Regulated Waste Activity: This section has multiple parts, with suggested responses noted below.

A. *Hazardous Waste Activities: 1. Generator of Hazardous Waste.* Indicate if your facility is an LQG, SQG, or VSQG. If you are operating under Subpart P, when you determine your generator category (See <u>Appendix G</u>) you do not need to count your hazardous waste pharmaceuticals. Most healthcare facilities will respond "No" to the remainder of the guestions in section A.

- B. Waste Codes for Federally Regulated Hazardous Wastes. List all NON-PHARMACEUTI-CAL hazardous waste codes. When notifying under Subpart P, you are not required to list the waste codes for hazardous waste pharmaceuticals. You are, however, required to list the other non-pharmaceutical hazardous waste codes you generate. Your hazardous waste vendor can provide you a list of waste codes from either the profile they have created or a year-to-date list of hazardous wastes transported, which will include the waste codes. Typical waste codes will include D001, for ignitable lab waste, and F003, for spent non-halogenated solvents, again from the lab. All other relevant waste codes (excluding hazardous waste pharmaceuticals) should be included and added to this section.
- C. Waste Codes for State-Regulated (non-Federal) Hazardous Wastes. A number of states list additional wastes as state-only hazardous wastes, including for pharmaceuticals. Check with your state to determine if this is the case and if these must be included on this form.

Item No. 11. Additional Regulated Waste Activities:

- A. Other Waste Activities. Suggested answer: "No." Most healthcare facilities will not be involved in the activities in this section.
- B. Universal Waste Activities. Suggested answer: "No." While it is likely healthcare facilities will generate batteries, lamps, etc. as universal waste, it is unlikely they will qualify as a Large Quantity Handler of Universal Waste (accumulation of 5,000 kg or more).
- C. Used Oil Activities. Suggested answer: "No." It is also unlikely for most healthcare facilities to be involved in used oil activities.
- D. Pharmaceutical Activities. Required answer: "Yes." 1. Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals. Mark only a. Healthcare Facility. Do not mark b. Reverse Distributor. 2. Withdrawing from operating under 40 CFR Part 266 Subpart P for the management of hazardous waste pharmaceuticals. Required answer for initial notification: "No."

Item No. 12. Eligible Academic Entities with Laboratories: Suggested answer: "No." Most healthcare facilities will not be operating under the Academic Labs Rule (also known as Subpart K). If the hospital is a teaching hospital that has opted into using Subpart K for its laboratory hazardous waste, answer "Yes."

Item No. 13. Episodic Generation: Suggested answer: "No." It is unlikely that a healthcare facility would need to submit an episodic notification in conjunction with their initial Subpart P notification. However, VSQG or SQG healthcare facilities operating under Subpart P may use the episodic generation provisions in 40 CFR part 262 Subpart L as necessary with respect to their non-pharmaceutical hazardous waste. They would also have to fill out the Addendum to the Site Identification Form: Episodic Generator.

Item No. 14. LQG Consolidation of VSQG Hazardous Waste: Suggested answer: "No." This item on the notification is not required for off-site consolidation that is done under Subpart P. Under Subpart P, a VSQG healthcare facility is allowed to send its hazardous waste pharmaceuticals to another healthcare facility that is operating under Subpart P, provided the receiving healthcare facility meets certain conditions, but notification of the consolidation activity is not required by either healthcare facility.

A healthcare facility that is an LQG with respect to its non-pharmaceutical hazardous waste may receive hazardous waste (both pharmaceutical and non-pharmaceutical) from an off-site VSGQ under the consolidation provisions in 40 CFR 262.17(f), and accordingly, would answer "yes" to this question and fill out the required Addendum to the Site Identification Form: LQG Consolidation of VSQG Hazardous Waste.

Item No. 15. Notification of LQG Site Closure for a Central Accumulation Area (CAA) OR Entire Facility: Suggested answer: "No." This is not a Subpart P provision and likely not applicable to healthcare facilities upon initial notification, unless the facility is closing the CAA or the entire facility in conjunction with initial notification.

Item No. 16. Notification of Hazardous Secondary Material Activity: Suggested answer: "No." not relevant to a healthcare facility.

Item No. 17. Electronic Manifest Broker: Required answer: "No." Not applicable for healthcare facilities.

Item No. 18. Comments: This section is available for any additional information generated above that

requires more space. Include the item number and box letter, if applicable. Add your EPA Identification number to any additional sheets.

Item No. 19. Certification: Upon submission of the form either via mailed hard copy or scanned and emailed copy, this certification must be signed and dated by the generator's owner, operator, or authorized representative of the site. Only one signature is required, but multiple people may sign. An authorized representative is a person responsible for the overall operation of the site or a hazardous waste accumulation area (i.e., a plant manager or superintendent, or a person of equivalent responsibility). Authorized representatives must be authorized by one of the officers of the organization by submitting their name in writing to the state Director in an authorized state or the EPA Regional Director in non-authorized states (e.g., IA, AK), Indian country, and U.S. territories. This certification is a serious responsibility and should not be taken lightly. Misinformation could lead to enforcement actions and significant civil and even criminal penalties.

Submitting Form 8700–12. If submitting the hard copy of the form to the state, some states require what is still referred to as a "wet ink" copy to be sent to the person indicated on the <u>State Contacts web-</u> <u>page</u>. In other words, print out the completed form, have the appropriate site representative physically sign the document, and deliver it to the appropriate state contact. Other states accept a scanned copy sent via email. Check with your state to determine their preferred method. If submitting the information via myRCRAid, see the suggested websites below for additional guidance or contact your EPA Regional Office or your state environmental agency directly.

Federal Resources for myRCRAid:

- <u>RCRAInfo State Contacts</u>
- <u>RCRAInfo Registration or Sign In</u>
- <u>RCRAInfo FAQs</u>

Examples of Helpful State Resources for myRCRAid

- <u>California</u>
- Delaware
- <u>Ohio</u>

Pharmaceuticals Rule Notification Flowchart

