Checklist for Registering a Healthcare Organization on EPA Form 8700-12 in Compliance with 40 CFR 266 Subpart P

INTRODUCTION:

On August 21, 2019, EPA's Final Rule, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, became operative in certain states and territories. In addition, several states that are authorized to manage their own hazardous waste programs adopted the final rule on or about that date. Other states have until July 1, 2021 or July 1, 2022 to adopt the more stringent aspects of the rule. For a complete discussion of the Final Rule and for FAQs, refer to https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075.

Healthcare facilities that are either Small or Large Quantity Generators of total hazardous waste, including hazardous waste pharmaceuticals, are required to register with EPA or their state as participants in Subpart P after the rule becomes effective in their state. This checklist is designed to facilitate that process.

PREPARATION INSTRUCTIONS:

1. Determine if your facility is either a Small Quantity Generator or Large Quantity Generator of total hazardous waste. If you are not sure of the quantity limits, please refer to EPA's Summary Table at https://www.epa.gov/hwgenerators/hazardous-waste-generator-regulatory-summary. You must count hazardous waste generated anywhere in the facility, including pharmacy, nursing, environmental services, lab, grounds and maintenance, etc.
2. If you determine you are a Very Small Quantity Generator of hazardous waste, including hazardous waste pharmaceuticals, you may still register under Subpart P to receive the benefits but you are not required to do so. If you do not, your state's current hazardous waste generator rules for VSQGs will apply and you must still document your hazardous waste pharmaceutical generation monthly going forward, including P-listed waste, such as warfarin.
3. Determine if your state requires you to use their state-specific version or the federal Form 8700-12 Site Identification Form by checking this website and following your state's instructions. https://rcrainfo.epa.gov/rcrainfoprod/action/public/public-site/state-contacts. You can also check this site to determine if your state offers an electronic submission process through RCRAInfo Industry Application using myRCRAid.
4. The remaining instructions will address only the federal form 8700-12 but should provide enough information to assist with state forms also. A general review of the process can be accessed at https://www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage-and.
5. Access the actual 8700-12 form at the following website. https://www.epa.gov/sites/production/files/2019-09/documents/excerpt_site_id_instructions_andforms_september_2019.pdf It is extracted from a larger form that contains two other forms, the Biennial Report Form and the Part A Permit Application which are not relevant to Subpart P and this process.

6. Carefully read the instructions on pages 1 through 4. The information through page 10 is background information you may find interesting but since you have already decided to file Form 8700-12, it is not necessary.
7. Obtain or update an EPA ID number. If you already have an EPA ID number, you will be updating it to indicate you are managing hazardous waste pharmaceuticals under Subpart P. If you have never registered with EPA, you will also be obtaining an EPA ID number in addition to registering under Subpart P. See pages 11 through 13 of Form 8700-12 instructions. Registration under Subpart P is not specifically called out in this discussion. If you do not know if you have an EPA ID number or are not sure what it is, you can search for it at https://rcrapublic.epa.gov/rcrainfoweb/action/modules/hd/handlerindex.
8. Specific requirements for completing the form are listed on page 14 of the Form 8700-12 instructions. Use black ink, indicate choices with an X as instructed, submit the final form with an original signature, not a photocopy. Enter your EPA ID number in the top left-hand corner of each page if you have one. If you are submitting for the first, leave it blank.

COMPLETING FORM 8700-12

No. 1: Reason for Submittal: Check "Obtaining or updating an EPA ID number for an on-going regulated activity that will continue for a period of time."

No. 2: Site EPA ID Number. The first two characters of the EPA identification number must be a valid State postal code. If this is your initial notification for this site, leave the EPA identification number blank.

No. 3: Site Name

No. 4: Site Location Address. Do NOT use a PO number. This must be a physical address.

No. 5: Site Mailing Address: If it is the same as your physical address, you can check the "Same as Location Address" box. This entry may include a PO number.

No. 6: Site Land Type. Usually this will be private for a healthcare facility, but could be County, Federal, Tribal, etc. Pick the most descriptive e.g. County rather than Municipal.

No. 7: North American Industry Classification System (NAICS) Codes. Provide the code that best fits your primary function in box A. Use the six-digit code if available. You may use a five-digit code if necessary, but not a four-digit code. Your accounting or business staff should have this information. If you need to search for your code, go to https://www.census.gov/eos/www/naics/. See pages 523 to 541 for healthcare-related codes. These are very specific so be sure to review all relevant options. For example, general hospitals are listed and described as follows: **622110 General Medical and Surgical Hospitals**
This industry comprises establishments known and licensed as general medical and surgical hospitals primarily engaged in providing diagnostic and medical treatment (both surgical and nonsurgical) to inpatients with any of a wide variety of medical conditions. These establishments maintain inpatient beds and provide patients with food services that meet their nutritional requirements. These hospitals have an

organized staff of physicians and other medical staff to provide patient care services. These establishments usually provide other services, such as outpatient services, anatomical pathology services, diagnostic X-ray services, clinical laboratory services, operating room services for a variety of procedures, and pharmacy services.

No. 8: Site Contact Information: Enter the primary site RCRA hazardous waste contact here. If there are other contact people involved, enter their information in Item 18: Comments, including the person completing the form, if they are not the primary site contact.

No. 9: Legal Owner and Operator of the Site: Indicate all owners and operators of this site. For example, if a realty company owns the land but a healthcare facility is operating a hospital, both entities should be listed with the appropriate contact information. The owner and operator information is broken out accordingly. The Date Became an Owner, month, date, and year is OPTIONAL INFORMATION based on the guidance document noted above. There may be multiple owners, e.g. of the land and of the building. All must be listed. The Comments section may be used for this information and additional pages may be added, but the EPA ID number, if known, must be in the upper left-hand corner of each page. The operator is the person responsible for the overall operation of a RCRA site. Additional operators can be added to the Comments page or additional pages attached with the EPA number in the upper left-hand corner.

NOTE: Change in operator or move of business to a new location: A subsequent notification is recommended when the owner or operator of a site changes. Because an EPA Identification Number is site-specific, the new owner will keep the existing EPA Identification Number for that location. If your business moves to another location, the owner or operator must notify the State or EPA Regional Office of this change. Since your business has changed locations, a new EPA Identification Number will be assigned.

No. 10. Type of Regulated Waste Activity (at your site): This section has multiple parts, as follows:

A. Hazardous Waste Activities: 1. Generator of Hazardous Waste. Indicate if LQG, SQG, or VSQG. Most healthcare facilities will respond “No” to the remainder of questions in this section.
B. Waste Codes for Federally Regulated Hazardous Wastes: List all non-pharmaceutical hazardous waste codes. A healthcare facility operating under Part 266 Subpart P is not required to list the waste codes for its hazardous waste pharmaceuticals. All other nationally defined waste codes are listed here: https://www.epa.gov/sites/production/files/2019-09/documents/excerpt_site_id_instructions_andforms_september_2019.pdf List them in the order given at this site.
C. State-Regulated (Non-Federal) Hazardous Wastes: A number of states list additional pharmaceuticals as state-only hazardous wastes. Check with your state to determine if this is the case and if these must be listed on this form.

No. 11. Additional Regulated Waste Activities:

A. Other Waste Activities: "No," most healthcare facilities will not be involved in these activities.
B. Universal Waste Activities: "No," while it is likely healthcare facilities will recycle batteries, lamps, etc., 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: "No," also unlikely for healthcare facilities to be involved.
D. Pharmaceutical Activities: "Yes," 1. Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals. Mark only a. Healthcare Facility, not b. Reverse Distributor.

No. 12. Eligible Academic Entities with Laboratories: "No," not applicable.

No. 13. Episodic Generation: "No," not usually applicable to healthcare facilities.

No. 14. LQG Consolidation of VSQG Hazardous Waste: If operating under Subpart P, this option already exists for the management of hazardous waste pharmaceuticals. If other hazardous wastes are being consolidated under this provision of the Generator Improvements Rule, respond "Yes" and fill out the required Addendum.

No. 15. Notification of LQG Site Closure for a Central Accumulation Area OR Entire Facility: "No," not applicable unless the facility is closing.

No. 16. Notification of Hazardous Secondary Material Activity: "No," not relevant to healthcare facilities.

No. 17. Electronic Manifest Broker: "No," not applicable for healthcare facilities.

No. 18. Comments section for any additional information generated above requiring more space. Include the item and box letter, if applicable. Add your ID number to additional sheets.

No. 19. Certification: This certification must be signed and dated by the generator(s), owner(s), operator(s), or authorized representative(s) of the site. Anyone other than a recognized authority within an organization 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. This certification is a serious responsibility and should not be taken lightly.

This information is solely for educational purposes and provides only a general description of various regulatory requirements. For a complete description, please consult the relevant federal and state regulatory statutes. Nothing in this presentation constitutes legal advice and you should not legally rely on any information provided in this presentation. We make no warranty, express or implied, with respect to such information and disclaim all liability resulting from any use or reliance of this information.