



FLORIDA DEPARTMENT OF Environmental Protection

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HEALTHCARE FACILITIES

40 CFR 266 Subpart P – Hazardous Waste Pharmaceuticals

Facility Name: _____ Date: _____
Facility Representative: _____ Facility ID #: _____
Email Address: _____ Inspector: _____

NOTIFICATION REQUIREMENTS

- Has the healthcare facility notified that it is operating under Part 266 Subpart P as required by 40 CFR 266.502(a)(1) using form 8700-12FL? Y___ N___ N/A___
Note: Until DEP updates the 8700-12FL Form, the Federal 8700-12 Form will be required.
- If the healthcare facility already had an EPA ID number on 8/xx/2019 and was required to file a biennial report, was the 8700-12FL submitted by March 1, 2020? [266.502(a)(1)(i)] Y___ N___ N/A___
- If the healthcare facility already had an EPA ID number on 8/xx/2019 and was not required to file a biennial report, was the 8700-12FL submitted by October xx, 2019, or within 60 days of the facility becoming subject to Subpart P? [266.502(a)(1)(i)] Y___ N___ N/A___
- If the healthcare facility did not have an EPA ID number on 8/xx/2019, was the 8700-12FL submitted by October xx, 2019, or within 60 days of the facility becoming subject to Subpart P? [266.502(a)(1)(ii)] Y___ N___ N/A___
- Is a copy of the 8700-12FL maintained in the facility's files for as long as the healthcare facility is subject to Subpart P? [266.502(a)(1)(iii)] Y___ N___ N/A___
- If the healthcare facility's generator status becomes VSQG and the facility elects to withdraw from Subpart P, did the facility submit an 8700-12FL before it began operating as a VSQG under 40 CFR 262.14? [266.502(a)(2)(i)] Y___ N___ N/A___
- Is a copy of the 8700-12FL maintained in the facility's files for 3 years from the date of the signature on the notification of its withdrawal from Subpart P? [266.502(a)(2)(ii)] Y___ N___ N/A___

GENERAL STANDARDS – NON-CREDITABLE HW PHARMACEUTICALS

- Has the healthcare facility correctly determined whether the non-creditable pharmaceuticals generated are hazardous waste pharmaceuticals? [266.502(c)] Y___ N___ N/A___
NOTE: A healthcare facility that manages all of its non-creditable non-HW pharmaceuticals as non-creditable HW pharmaceuticals is not required to keep documentation of hazardous waste determinations
- If the healthcare facility had a spill of non-creditable HW pharmaceuticals was the spill cleaned up immediately and the cleanup material managed as non-creditable pharmaceuticals? [266.502(k)] Y___ N___ N/A___
- Does the healthcare facility comply with the land disposal restrictions in accordance with the requirements of 40 CFR 268.7(a), except that EPA waste codes are not required on the LDR notification? [266.502(g)] Y___ N___ N/A___

11. Are all employees managing non-creditable HW pharmaceuticals thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies? [266.502(b)] Y___ N___ N/A___
12. Does the healthcare facility ensure hazardous waste pharmaceuticals are not discharged to a sewer system that passes through to a publicly owned treatment works (POTW)? [266.505] Y___ N___ N/A___

RECORDKEEPING – NON-CREDITABLE HW PHARMACEUTICALS

13. Does the healthcare facility keep a copy of each manifest signed in accordance with 40 CFR 262.23(a) for 3 years or until it receives a signed copy from the designated facility which received the non-creditable HW pharmaceuticals? This signed copy must be retained as a record for at least 3 years from the date the waste was accepted by the initial transporter. [266.502(j)(1)] Y___ N___ N/A___
14. Does the healthcare facility keep a copy of each exception report for a period of at least 3 years from the date of the report? [266.502(j)(2)] Y___ N___ N/A___
15. Does the healthcare facility keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with 40 CFR 262.11(f), for at least 3 years from the date the waste was last sent to onsite or off-site treatment, storage or disposal? [266.502(j)(3)] Y___ N___ N/A___
16. Are all records readily available upon request by the inspector? [266.502(j)(5)] Y___ N___ N/A___

NON-CREDITABLE HW PHARMACEUTICALS – STORAGE REQUIREMENTS

17. Are non-creditable HW pharmaceuticals only stored in containers that are structurally sound, compatible with the contents, and that lack evidence of leakage, spillage, or damage that could cause leakage? [266.502(d)(1)] Y___ N___ N/A___
18. Are containers of ignitable, reactive, or co-mingled incompatible non-creditable HW pharmaceuticals managed to prevent the potential to generate extreme heat or pressure, fire or explosion, or violent reaction? [266.502(d)(2)(i)] Y___ N___ N/A___
19. Are containers of ignitable, reactive, or co-mingled incompatible non-creditable HW pharmaceuticals managed to prevent the potential to produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health? [266.502(d)(2)(ii)] Y___ N___ N/A___
20. Are containers of ignitable, reactive, or co-mingled with incompatible non-creditable HW pharmaceuticals managed to prevent the potential to produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosion? [266.502(d)(2)(iii)] Y___ N___ N/A___
21. Are containers of ignitable, reactive, or co-mingled incompatible non-creditable HW pharmaceuticals managed to prevent the potential to damage the structural integrity of the container? [266.502(d)(2)(iv)] Y___ N___ N/A___
22. Are containers of ignitable, reactive, or co-mingled incompatible non-creditable HW pharmaceuticals managed to prevent the potential to threaten human health or the environment? [266.502(d)(2)(v)] Y___ N___ N/A___
23. Are containers of non-creditable HW pharmaceuticals kept closed and secured in a manner that prevents unauthorized access to the contents? [266.502(d)(3)] Y___ N___ N/A___

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24. Does the healthcare facility accumulate non-creditable HW pharmaceuticals prohibited from being combusted because of the dilution prohibition of 268.3(c) in separate containers that are labeled with all applicable EPA waste codes? [266.502(d)(4)] Y___ N___ N/A___
- [NOTE: The hazardous waste pharmaceuticals not suitable for incineration include characteristic metal wastes (i.e., D004–D043) as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon.]
25. Are containers of non-creditable HW pharmaceuticals clearly marked or labeled “Hazardous Waste Pharmaceuticals”? [266.502(e)] Y___ N___ N/A___
26. Are containers of non-creditable HW pharmaceuticals stored on-site for one year or less? [266.502(f)(1)] Y___ N___ N/A___
27. How does the healthcare facility demonstrate non-creditable HW pharmaceuticals were stored on-site for one year or less?
- Marking or labeling the container of non-creditable HW pharmaceuticals with the date the non-creditable pharmaceuticals became a waste? [266.502(f)(2)(i)] Y___ N___ N/A___
- Maintaining an inventory system that identifies the date the non-creditable HW pharmaceuticals first became a waste? [266.502(f)(2)(ii)] Y___ N___ N/A___
- Placing the non-creditable HW pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable HW pharmaceuticals in the area became a waste? [266.502(f)(2)(iii)]

ACCEPTING NON-CREDITABLE HW PHARMACEUTICALS FROM OFF-SITE ___N/A
VSQG HEALTHCARE FACILITY

28. If the healthcare facility is receiving non-creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility under the control of the same person (as defined in § 260.10) as the VSQG healthcare facility that is sending the non-creditable HW pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility? [266.502(l)(1)] Y___ N___ N/A___
29. If the healthcare facility is receiving non-creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility operating under 40 CFR Part 266 Subpart P for its non-creditable HW pharmaceuticals? [266.502(l)(2)] Y___ N___ N/A___
30. If the healthcare facility is receiving non-creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility managing the non-creditable HW pharmaceuticals it receives from off-site in compliance with 40 CFR Part 266 Subpart P? [266.502(l)(3)] Y___ N___ N/A___
31. If the healthcare facility is receiving non-creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility keeping records of the non-creditable HW pharmaceutical shipments it receives for 3 years from the date the shipment is received? [266.502(l)(4)] Y___ N___ N/A___

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PRE-TRANSPORT REQUIREMENTS ____N/A

If the transporter is not on-site during the inspection, then this section is usually "N/A."

If waste has been improperly transported off-site the requirements in this section apply.

- 32. Has the healthcare facility packaged the non-creditable hazardous waste pharmaceuticals for shipment in accordance with the applicable DOT regulations under 49 CFR parts 173, 178, and 180? [266.508(a)(1)(i)] Y___ N___ N/A___

49 CFR 173 – Shippers – General Requirements for Shipments and Packagings
49 CFR 178 – Specifications for Packagings
49 CFR 180 – Continuing Qualification and Maintenance of Packagings

- 33. Has the healthcare facility labeled each package for shipment in accordance with the applicable DOT regulations under 49 CFR Part 172 Subpart E – diamond-shaped DOT hazard class container label? [266.508(a)(1)(ii)] Y___ N___ N/A___

- 34. Has the healthcare facility marked each package for shipment in accordance with the applicable DOT regulations under 49 CFR Part 172 Subpart D – correct DOT shipping name and UN, NA, or ID number? [266.508(a)(1)(iii)(A)] Y___ N___ N/A___

- 35. Has the healthcare facility marked each container of 119 gallons or less used in transportation with the following words and information in accordance with 49 CFR 172.304? [266.508(a)(1)(iii)(B)] Y___ N___ N/A___

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's
Name and Address _____
Healthcare Facility's or Reverse distributor's
EPA Identification Number _____
Manifest Tracking Number _____

- 36. Has the healthcare facility marked each lab pack containing non-creditable hazardous waste pharmaceuticals that will be incinerated in compliance with 40 CFR 268.42(c) with the EPA waste codes D004, D005, D006, D007, D008, D010, and D011, where applicable? [266.508(a)(1)(iii)(B)] Y___ N___ N/A___

NOTE: A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

- 37. Has the healthcare facility placarded or offered the initial transporter the appropriate placards according to DOT regulations for hazardous materials under 49 CFR Part 172 Subpart F? [266.508(a)(1)(iv)] Y___ N___ N/A___

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SHIPPING NON-CREDITABLE HW PHARMACEUTICALS THE MANIFEST

- 38. Does the healthcare facility use a paper manifest (EPA Form 8700-22; OMB #2050-0039) for off-site shipment(s) of hazardous wastes pharmaceuticals? [262.20(a)(1)] Y___ N___ N/A___
- 39. Does the healthcare facility use an electronic manifest for off-site shipment(s) of hazardous wastes pharmaceuticals that complies with the e-manifest requirements of 40 CFR 262.24 [262.20(a)(3)] Y___ N___ N/A___
- 40. Does the manifest contain the word "PHARMS" in Item 13? [266.508(a)(2)(ii)] Y___ N___ N/A___
- 41. Are all manifest fields on the paper manifest, other than Item 13 "Waste Codes," filled out correctly? [262.20(a)(1)] Y___ N___ N/A___
- 42. Are all manifest fields on the electronic manifest, other than Item 13 "Waste Codes," filled out correctly? [262.20(a)(3)] Y___ N___ N/A___
- 43. Does the facility ship by water or rail? [If so, check 262.23(c) and (d)] Y___ N___ N/A___

NOTE: If any manifest discrepancies are noted, please describe in narrative.

Identify manifest document numbers and dates of manifests with errors below:

Manifest #	Date	Destination	Error(s)

REJECTED LOADS NON-CREDITABLE HW PHARMACEUTICALS ___ N/A

- 44. If the healthcare facility received a rejected shipment of non-creditable HW pharmaceuticals back in accordance with the manifest discrepancy provisions of 40 CFR 264.72 or 265.72 was the returned shipment managed in accordance with the requirements of 40 CFR 266(502(d) and (e)? [266.502(h)] Y___ N___ N/A___
- 45. Upon receipt of the rejected shipment of non-creditable HW pharmaceuticals did the facility sign either; (i) Item 18c of the original manifest, if the original was used for the returned shipment; or (ii) Item 20 of the new manifest, is a new manifest was used for the returned shipment? [266.502(h)(1)] Y___ N___ N/A___
- 46. Upon receipt of the rejected shipment of non-creditable HW pharmaceuticals did the facility provide the transporter a copy of the manifest? [266.502(h)(2)] Y___ N___ N/A___
- 47. Within 30 days of receipt of the rejected shipment, did the facility send a copy of the manifest to the designated facility that returned the shipment? [266.502(h)(3)] Y___ N___ N/A___
- 48. Within 90 days of receipt of the rejected shipment, did the facility transport, or offer for transport the returned shipment in accordance with the shipping standards of 40 CFR 266.508(a)? [266.502(h)(4)] Y___ N___ N/A___
- 49. If the healthcare facility did not receive a copy of the manifest signed by the designated facility within 60 days of the date the non-creditable HW pharmaceuticals were accepted by the initial transporter, did the healthcare facility submit a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to DEP? [266.502(i)(2)(i)(A)(1)] Y___ N___ N/A___

Facility: _____
Date: _____

50. If the healthcare facility did not receive a copy of the manifest signed by the designated facility within 60 days of the date the non-creditable HW pharmaceuticals were accepted by the initial transporter, did the facility submit to DEP a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable HW pharmaceuticals and the results of those efforts? [266.502(i)(2)(i)(A)(2)] Y ___ N ___ N/A ___
51. For a shipment rejected by the designated facility and shipped to an alternate facility, if the healthcare facility did not receive a copy of the manifest signed by the alternate designated facility within 60 days of the date the non-creditable HW pharmaceuticals were accepted by the initial transporter forwarding the shipment from the designated facility to the alternate facility, did the healthcare facility submit a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to DEP? [266.502(i)(2)(ii)(A)(1)] Y ___ N ___ N/A ___
52. For a shipment rejected by the designated facility and shipped to an alternate facility, if the healthcare facility did not receive a copy of the manifest signed by the alternate designated facility within 60 days of the date the non-creditable HW pharmaceuticals were accepted by the initial transporter forwarding the shipment from the designated facility to the alternate facility, did the healthcare facility submit to DEP a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable HW pharmaceuticals and the results of those efforts? [266.502(i)(2)(i)(A)(2)] Y ___ N ___ N/A ___

GENERAL STANDARDS – POTENTIALLY CREDITABLE PHARMACEUTICALS ___ N/A

53. Has the healthcare facility correctly determined whether the potentially creditable pharmaceuticals generated are potentially creditable HW pharmaceuticals? [266.503(a)] Y ___ N ___ N/A ___
54. If the healthcare facility had a spill of potentially creditable HW pharmaceuticals was the spill cleaned up immediately and the cleanup material managed as non-creditable HW pharmaceuticals? [266.503(f)] Y ___ N ___ N/A ___

Note: "Potentially creditable" HW pharmaceuticals apply only to prescription pharmaceuticals with a reasonable expectation of credit and are: (1) undispensed, (2) in the manufacturer's original container, and (3) are less than one-year past expiration

Facility: _____
Date: _____

**ACCEPTING POTENTIALLY CREDITABLE HW PHARMACEUTICALS
FROM OFF-SITE VSQG HEALTHCARE FACILITY ___ N/A**

55. If the healthcare facility is receiving potentially creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility under the control of the same person (as defined in § 260.10) as the VSQG healthcare facility that is sending the potentially creditable HW pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility? [266.503(b)(1)] Y ___ N ___ N/A ___
56. If the healthcare facility is receiving potentially creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility operating under 40 CFR Part 266 Subpart P for its potentially creditable HW pharmaceuticals? [266.503(b)(2)] Y ___ N ___ N/A ___
57. If the healthcare facility is receiving potentially creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility managing the potentially creditable HW pharmaceuticals it receives from off-site in compliance with 40 CFR Part 266 Subpart P? [266.503(b)(3)] Y ___ N ___ N/A ___
58. If the healthcare facility is receiving potentially creditable HW pharmaceuticals from an off-site VSQG healthcare facility, is the receiving facility keeping records of the potentially creditable HW pharmaceutical shipments it receives for 3 years from the date the shipment is received? [266.503(b)(4)] Y ___ N ___ N/A ___

SHIPPING – CREDITABLE HW PHARMACEUTICALS ___ N/A

59. Does the healthcare facility send hazardous waste other than potentially creditable HW pharmaceuticals to a reverse distributor? [266.503(c)] Y ___ N ___ N/A ___
60. For off-site shipments of potentially creditable HW pharmaceuticals to a reverse distributor, does the healthcare facility keep copies of the confirmation of delivery for 3 years from the date of the shipment? [266.503(e)(1)(i)] Y ___ N ___ N/A ___
61. For off-site shipments of potentially creditable HW pharmaceuticals to a reverse distributor, does the healthcare facility keep copies of the shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable? [266.503(e)(1)(ii)] Y ___ N ___ N/A ___
62. Are all records readily available upon request by the inspector? [266.503(e)(3)] Y ___ N ___ N/A ___
63. For shipment(s) of potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor, did the healthcare facility comply with all applicable DOT regulations in 49 CFR Parts 171 through 180 for any potentially creditable HW pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8? [266.509(a)] Y ___ N ___ N/A ___

NOTE: For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

64. Did the healthcare facility receive confirmation (paper or electronic) within 35 days from the date a shipment of potentially creditable HW pharmaceuticals was sent, that the shipment was received and is under the control of the reverse distributor? [266.509(b)] Y ___ N ___ N/A ___
65. If the healthcare facility did not receive delivery confirmation (paper or electronic) within 35 days from the date a shipment of potentially creditable HW pharmaceuticals was sent to a reverse distributor, did the healthcare facility contact the carrier and the reverse distributor promptly to report the delivery confirmation was not received and determine the status of the shipment? [266.509(c)] Y ___ N ___ N/A ___

Facility: _____

Date: _____

DEA CONTROLLED SUBSTANCES – CONDITIONAL EXEMPTION ___ N/A

66. If the healthcare facility manages any HW pharmaceuticals that are also listed on a schedule of controlled substances by the DEP in 21 CFR Part 1308 using the conditional exemption identified in 40 CFR 266.506(a), were the HW pharmaceuticals managed in compliance with the sewer prohibition of 266.506? [266.506(a)] Y___ N___ N/A___
67. If the healthcare facility manages any HW pharmaceuticals that are also listed on a schedule of controlled substances by the DEP in 21 CFR Part 1308 using the conditional exemption identified in 40 CFR 266.506(a), were the HW pharmaceuticals collected, stored, transported, and disposed of in compliance with all applicable DEA regulations for controlled substances? [266.506(a)] Y___ N___ N/A___
68. If the healthcare facility manages any HW pharmaceuticals that are also listed on a schedule of controlled substances by the DEP in 21 CFR Part 1308 using the conditional exemption identified in 40 CFR 266.506(a), were the HW pharmaceuticals destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at a municipal waste combustor or incinerator identified in 40 CFR 266.506(b)(3)? [266.506(a)] Y___ N___ N/A___