**Section 726.602 Standards for Non-Creditable Hazardous Waste Pharmaceuticals**

a) Notification and Withdrawal from Subpart P for Healthcare Facilities Managing Hazardous Waste Pharmaceuticals

1) Notification. A healthcare facility must notify the Agency, using Notification of RCRA Subtitle C Activities (Site Identification Form) (USEPA Form 8700-12), that it is a healthcare facility operating under Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using the Site Identification Form) for each site or USEPA identification number.

A) A healthcare facility that already has a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or, if not required to submit an annual report, within 60 days after becoming subject to Subpart P.

B) A healthcare facility that does not have a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or if not required to submit an annual report, within 60 days after becoming subject to Subpart P.

C) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to Subpart P.

BOARD NOTE: Corresponding 40 CFR 266.602(a)(1) requires biennial reporting. The Board has required annual reporting, since Section 20.1 of the Act requires the Agency to assemble annual reports, and only annual facility activity reports will enable the Agency to meet this mandate.

2) Withdrawal. A healthcare facility that operated under Subpart P but is no longer subject to Subpart P, because it is a VSQG under 35 Ill. Adm. Code 722.114, and that elects to withdraw from Subpart P, must notify the appropriate agency using USEPA Form 8700-12 that it is no longer operating under Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of USEPA Form 8700-12 with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using USEPA Form 8700-12) for each USEPA identification number.

A) A healthcare facility must submit USEPA Form 8700-12 notifying that it is withdrawing from Subpart P before it begins operating under the conditional exemption of 35 Ill. Adm. Code 722.114.

B) A healthcare facility must keep a copy of its withdrawal on file for three years after the date of signature on the notification of its withdrawal.

b) Training of Personnel Managing Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must ensure that all personnel managing non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

c) Hazardous Waste Determination for Non-Creditable Pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in Subpart D of 35 Ill. Adm. Code 721 or is listed in Subpart D of 35 Ill. Adm. Code 721) to determine if the waste is subject to Subpart P. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under Subpart P.

d) Standards for Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals, must manage the container so that it does not have the potential to do any of the following:

A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

D) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

E) Through other like means threaten human health or the environment.

3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to their contents.

4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and nonhazardous non-creditable waste pharmaceuticals in the same container, except that the non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) (i.e., metal-bearing waste codes listed in 35 Ill. Adm. Code 728.Appendix K, unless one or more of the criteria in 35 Ill. Adm. code 728.103(c)(1) through (c)(6) are met), or because it is prohibited from being lab packed due to 35 Ill. Adm. Code 728.Table C) must be accumulated in separate containers, and labeled with all applicable USEPA hazardous waste numbers.

e) Labeling Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals".

f) Maximum Accumulation Time for Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the facility has accumulated the non-creditable hazardous waste pharmaceuticals, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

A) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date when the non-creditable hazardous waste pharmaceuticals became a waste;

B) Maintaining an inventory system that identifies the date when the accumulated non-creditable hazardous waste pharmaceuticals first became a waste;

C) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date when any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

g) Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in 35 Ill. Adm. Code 728.107(a), except that it is not required to identify the USEPA hazardous waste numbers on the land disposal restrictions notification.

h) Procedures for Healthcare Facilities for Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in compliance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the rejected non-creditable hazardous waste pharmaceuticals on-site for up to an additional 90 days if the rejected or returned shipment is managed in compliance with subsections (d) and (e). Upon receipt of the returned shipment, the healthcare facility must:

1) Sign the applicable of the following:

A) Item 18c (Signature of Alternate Facility (or Generator)) of the original manifest, if the original manifest was used for the returned shipment; or

B) Item 20 (Designated Facility Owner or Operator. Certification of hazardous materials covered by the manifest except as noted in Item 18a) of the new manifest, if a new manifest was used for the returned shipment;

2) Provide the transporter a copy of the manifest;

3) Within 30 days after receiving the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

4) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment in compliance with the shipping standards of Section 726.608(a).

i) Reporting by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) Biennial Reporting by Healthcare Facilities. Healthcare facilities are not subject to annual reporting requirements under 35 Ill. Adm. Code 722.141, with respect to non-creditable hazardous waste pharmaceuticals managed under Subpart P.

2) Exception Reporting by Healthcare Facilities for a Missing Copy of the Manifest

A) For Shipments from a Healthcare Facility to a Designated Facility. If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days after the date when the initial transporter accepted the non-creditable hazardous waste pharmaceuticals, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) 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 hazardous waste pharmaceuticals and the results of those efforts.

B) For Shipments Rejected by the Designated Facility and Shipped to an Alternate Facility. If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days after the date when the initial transporter forwarded the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility accepted the non-creditable hazardous waste, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) 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 hazardous waste pharmaceuticals and the results of those efforts.

3) Additional Reports. The Agency may, in writing, require a healthcare facility to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

j) Recordkeeping by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) A healthcare facility must keep a copy of each manifest signed in compliance with 35 Ill. Adm. Code 722.123(a) for three years or until it receives a signed copy from the designated facility that received the non-creditable hazardous waste pharmaceuticals. The healthcare facility must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the waste.

2) A healthcare facility must keep a copy of each exception report for a period of at least three years after the date of the report.

3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determinations consistent with 35 Ill. Adm. Code 722.111(f), for at least three years after the date the waste was last sent to onsite or off-site treatment, storage, or disposal. A healthcare facility that manages all of its non-creditable nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of its hazardous waste determinations.

4) The periods of retention referred to in this Section are extended automatically during any unresolved enforcement action regarding the regulated activity or as requested in writing by the Agency.

5) A healthcare facility must make all records readily available upon request by a USEPA or Agency inspector.

k) Response to Spills of Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in compliance with the requirements of Subpart P.

l) Accepting Non-Creditable Hazardous Waste Pharmaceuticals from an Off-Site Healthcare Facility That Is a VSQG. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under 35 Ill. Adm. Code 722.114, without a permit or without having interim status, if the receiving healthcare facility meets the following conditions:

1) The receiving healthcare facility is under the control of the same person (as defined in 35 Ill. Adm. Code 720.110) as the VSQG healthcare facility sending the non-creditable hazardous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility. ("Control", for this subsection (l)(1), means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise. A contractor that operates a healthcare facility on behalf of a different person, as defined in 35 Ill. Adm. Code 720.110, does not "control" a healthcare facility);

2) The receiving healthcare facility is operating under Subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

3) The receiving healthcare facility manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with Subpart P; and

4) The receiving healthcare facility keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years after the date when it received the shipment.

(Source: Amended at 48 Ill. Reg. 17108, effective November 7, 2024)