**Section 726.610 Standards for Reverse Distributors**

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that the reverse distributor complies with the following conditions:

a) Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals

1) Notification. A reverse distributor must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor operating under this Subpart P.

A) A reverse distributor that already has a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, before September 3, 2020, or within 60 days after becoming subject to this Subpart P.

B) A reverse distributor that does not have a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, within 60 days after becoming subject to this Subpart P.

2) Inventory by the Reverse Distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the reverse distributor has accumulated on site.

A) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days after each waste arrived at the reverse distributor.

B) The inventory must include the identity (e.g., name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

BOARD NOTE: The National Drug Code (NDC) is a three-segment number (including labeler code, product code, and package code) uniquely identifying drugs. The Food and Drug Administration (FDA) assigns the labeler code, and the labeler assigns the product and package codes. 21 CFR 207.33. The NDC is required in applications for registration. 21 CFR 1.74(a) and 1.75(a). The FDA maintains an Internet database for NDC look-up (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory). The FDA requests but does not require use of the NDC on the product label. 21 CFR 201.2. However, if required on drug packaging, the bar code includes the NDC. 21 CFR 201.25(c).

C) If the reverse distributor already meets the inventory requirements of this subsection (a)(2) through compliance with other regulatory requirements, such as 68 Ill. Adm. Code 1330 under the Pharmacy Practice Act [225 ILCS 85] or 68 Ill. Adm. Code 1510 under the Wholesale Drug Distribution Licensing Act [225 ILCS 120], the facility is not required to provide a separate inventory under this Section.

3) Evaluation by a Reverse Distributor That Is Not a Manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days after the waste arrived at the reverse distributor to establish whether the waste is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

A) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (b).

B) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (c).

4) Evaluation by a Reverse Distributor That Is a Manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days after the waste arrived at the facility, and the reverse distributor must manage the evaluated hazardous waste pharmaceuticals in accordance with subsection (c) following the evaluation.

5) Maximum Accumulation Time for Hazardous Waste Pharmaceuticals at a Reverse Distributor

A) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 or fewer calendar days. The 180 days start after the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether the pharmaceuticals are destined for another reverse distributor (i.e., the pharmaceuticals are potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., the pharmaceuticals are evaluated hazardous waste pharmaceuticals).

B) Aging Pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the reverse distributor manages the unexpired pharmaceuticals in accordance with subsection (a) and the container labeling and management standards in subsection (c)(4).

6) Security at the Reverse Distributor Facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility if the reverse distributor keeps potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

A) Examples of methods that a reverse distributor may use to prevent unknowing entry and minimize the possibility for unauthorized entry include the following:

i) A 24-hour continuous monitoring surveillance system;

ii) An artificial barrier such as a fence; or

iii) A means to control entry, such as keycard access.

B) If the reverse distributor already meets the security requirements of this subsection (a)(6) through compliance with other regulatory requirements, such as federal DEA or Department of Financial and Professional Regulation rules, the facility is not required to provide separate security measures under this Section.

7) Contingency Plan and Emergency Procedures at a Reverse Distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of Subpart M of 35 Ill. Adm. Code 722.

8) Closure of a Reverse Distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with 35 Ill. Adm. Code 722.117(a)(8)(B) and (a)(8)(C).

9) Reporting by a Reverse Distributor

A) Unauthorized Waste Report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste, etc.). The reverse distributor must prepare and submit an unauthorized waste report to the Agency within 45 calendar days after the unauthorized waste arrives at the reverse distributor, and the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor or its authorized representative. The report must contain the following information:

i) The USEPA identification number, name, and address of the reverse distributor;

ii) The date the reverse distributor received the unauthorized waste;

iii) The USEPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

iv) A description and the quantity of each unauthorized waste the reverse distributor received;

v) The method of treatment, storage, or disposal for each unauthorized waste; and

vi) A brief explanation of why the waste was unauthorized, if known.

B) Additional Reports. The Agency may require a reverse distributor to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the Agency determines in writing are necessary to demonstrate compliance with this Subpart P.

10) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) A copy of its notification under Section 726.602 on file for as long as the facility is subject to this Subpart P;

B) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years after the date when the shipment arrives at the reverse distributor;

C) A copy of its current inventory for as long as the facility is subject to this Subpart P.

b) Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in subsection (a), for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section 726.609.

4) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years after the date of shipment. The retention periods referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) The confirmation of delivery; and

B) The USDOT shipping papers prepared in accordance with subpart C of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111, if applicable.

c) Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (a), for the management of evaluated hazardous waste pharmaceuticals:

1) Accumulation Area at the Reverse Distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

2) Inspections of On-Site Accumulation Area. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

3) Personnel Training at a Reverse Distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 35 Ill. Adm. Code 722.117(a)(7).

4) Labeling and Management of Containers at On-Site Accumulation Areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must do the following:

A) Label the containers with the words "hazardous waste pharmaceuticals";

B) Ensure the containers are in good condition and managed to prevent leaks;

C) Use containers made of or lined with materials that will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

D) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, and sealed packaging or in repackaged, intact, and sealed packaging, they meet the closed-container standard;

E) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to do any of the following:

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

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

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

iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

v) Through other like means threaten human health or the environment; and

F) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

5) Hazardous Waste Numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the USEPA hazardous waste numbers.

6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage, or disposal facility in accordance with the applicable shipping standards in Section 726.608(a) or (b).

7) Procedures for a Reverse Distributor for Managing Rejected Shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and that later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area, provided the rejected or returned shipment is managed in accordance with subsections (a) and (c). Upon receipt of the returned shipment, the reverse distributor must do the following:

A) Sign the appropriate of the following:

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

ii) 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;

B) Provide the transporter a copy of the manifest;

C) Within 30 days after receipt of the rejected shipment of evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

D) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Section 726.608(a) or (b).

8) Land Disposal Restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 35 Ill. Adm. Code 728.107(a) requirements.

9) Reporting by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) Biennial Reporting by a Reverse Distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of an annual report to the Agency by March 1 of each year in accordance with 35 Ill. Adm. Code 722.141.

B) Exception Reporting by a Reverse Distributor for a Missing Copy of the Manifest

i) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 35 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals, the reverse distributor must contact the transporter or the owner or operator of the designated or alternate facility, as applicable, to determine the status of the evaluated hazardous waste pharmaceuticals. For a shipment from the designated facility to an alternate facility, the 35-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them.

ii) A reverse distributor must submit an exception report to the Agency if it has not received a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 45 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals. In the case of a shipment from the designated facility to an alternate facility, the 45-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

BOARD NOTE: The Board combined 40 CFR 266.510(c)(9)(ii)(A)(1) and (c)(9)(ii)(B)(1) as subsection (c)(9)(B)(i) and 40 CFR 266.510(c)(9)(ii)(A)(2), (c)(9)(ii)(A)(2)(i), (c)(9)(ii)(A)(2)(ii), (c)(9)(ii)(B)(2), (c)(9)(ii)(B)(2)(i), and (c)(9)(ii)(B)(2)(ii) as subsection (c)(9)(B)(ii) to comport with codification requirements.

10) Recordkeeping by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) A reverse distributor must keep a log (written or electronic) of the inspections of its onsite accumulation area required by subsection (c)(2). The reverse distributor must retain this log as a record for at least three years after the date of the inspection.

B) A reverse distributor must keep a copy of each manifest signed in accordance 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 evaluated hazardous waste pharmaceutical. The reverse distributor must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the evaluated hazardous waste pharmaceutical.

C) A reverse distributor must keep a copy of each biennial report for at least three years after the due date of the report.

D) A reverse distributor must keep a copy of each exception report for at least three years after submitting the report.

E) A reverse distributor must keep records to document personnel training, in accordance with 35 Ill. Adm. Code 722.117(a)(7)(D).

F) All records must be readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this subsection (c)(10) are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

d) When a Reverse Distributor Must Have a Permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 35 Ill. Adm. Code 724, 725, and 727 and the permit requirements of 35 Ill. Adm. Code 703, if the reverse distributor does any of the following:

1) The reverse distributor fails to meet the conditions of this Section;

2) The reverse distributor accepts manifested hazardous waste from off site; or

3) The reverse distributor treats or disposes of hazardous waste pharmaceuticals on site.

(Source: Added at 44 Ill. Reg. 15427, effective September 3, 2020)