**Section 726.601 Applicability**

a) A healthcare facility that is a VSQG when counting all hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 35 Ill. Adm. Code 722.114 and is not subject to Subpart P, except for Sections 726.605 and 726.607 and the optional provisions of Section 726.604.

b) A healthcare facility that is a VSQG when counting all hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with Section 726.601(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with 35 Ill. Adm. Code 722.114 and the optional provisions of Section 726.604.

c) A healthcare facility or reverse distributor remains subject to all applicable requirements in 35 Ill. Adm. Code 722 through 725 with respect to the management of its non-pharmaceutical hazardous waste.

d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to the following instead of 35 Ill. Adm. Code 722 through 725:

1) Sections 726.602 and 726.605 through 726.608 with respect to the management of the following:

A) Non-creditable hazardous waste pharmaceuticals; and

B) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

2) Sections 726.602(a), 726.603, 726.605 through 726.607, and 726.609 for the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and that are destined for a reverse distributor.

e) A reverse distributor is subject to Sections 726.605 through 726.610, instead of 35 Ill. Adm. Code 722 through 725, for the management of hazardous waste pharmaceuticals.

f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to Subpart P. Other generators are subject to 35 Ill. Adm. Code 722 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

g) The following are not subject to 35 Ill. Adm. Code 720 through 733, except as otherwise specified:

1) Pharmaceuticals that are not solid waste, as defined by 35 Ill. Adm. Code 721.102, because they are legitimately used or reused (e.g., lawfully donated for their intended purpose) or reclaimed.

2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by 35 Ill. Adm. Code 721.102, because there is a reasonable expectation of their being legitimately used or reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

3) Pharmaceuticals being managed according to a recall strategy that has been approved by the Food and Drug Administration in under subpart C of 21 CFR 7. Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

4) Pharmaceuticals being managed according to a recall corrective action plan that has been accepted by the Consumer Product Safety Commission under 16 CFR 1115. Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

5) Pharmaceuticals stored according to a preservation order or during an investigation or judicial proceeding, until after the preservation order, investigation, or judicial proceeding has concluded or a decision is made to discard the pharmaceuticals.

6) Investigational new drugs for which an investigational new drug application is in effect under the Food and Drug Administration's regulations in 21 CFR 312. Subpart P applies to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

7) Household waste pharmaceuticals, including those that have been collected by a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, provided the authorized collector complies with the conditional exemption in Section 726.606(a)(2) and (b).

BOARD NOTE: The Drug Enforcement Administration regulations define "collector" in the second segment of the definition of "collection" in 21 CFR 1300.01. The authorized status of the collector is part of the definition.

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