UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

OCT 17 2019

MEMORANDUM

SUBJECT: EPA's Regulations on Reverse Distribution and Policy on Reverse Logistics

FROM: Barnes Johnson, Director
Office of Resource Conservation and Recovery

TO: LCRD Division Directors
Regions 1 – 10

The purpose of this memorandum is to focus your attention toward EPA's regulations on reverse distribution and policy on reverse logistics. Over the last 10 years, a number of questions have been raised by both retailers and regulators regarding how reverse distribution and reverse logistics are regulated, or should be regulated, under RCRA. The complex systems that the retail industry uses to manage the reverse flow of unsold retail items have created questions about exactly when discard occurs and when RCRA regulations apply to these unsold retail items. EPA recently addressed and answered these questions for prescription pharmaceuticals in reverse distribution, nonprescription pharmaceuticals in reverse logistics, and other retail items in reverse logistics in the final rule, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (Hazardous Waste Pharmaceuticals Final Rule) (84 FR 5816, February 22, 2019). Since the policy on reverse logistics articulated in this rule applies beyond pharmaceuticals and to the entire retail sector, we have excerpted the relevant preamble section and attached it to this memorandum to promote its wide dissemination. We encourage the regions to further disseminate this information with our state and tribal partners as well as the regulated community.

*Background*

EPA's efforts to address the challenges the retail sector faces in complying with RCRA have spanned many years. In 2008, EPA initiated a review of RCRA's applicability to the retail sector, and subsequently published a Notice of Data Availability (Retail NODA) in order to better

understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[1] An analysis of the comments received on the Retail NODA, in addition to EPA's outreach efforts, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of reasons.

In response to the Retail NODA comments, EPA released a plan on September 12, 2016, to address the unique challenges faced by the retail sector called the "Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework" (Retail Strategy).[2] In the Strategy, EPA recognized that the industry-oriented framework of the RCRA regulations may not always be the best fit for some aspects of the retail sector. One such aspect, reverse distribution and reverse logistics, warranted further action from EPA. One of the commitments EPA made in the Retail Strategy was to develop a comprehensive policy regarding the applicability of RCRA to retail items that have become unsalable at stores.

In the 2019 Hazardous Waste Pharmaceuticals Final Rule, EPA fulfilled its commitment made in the Retail Strategy to address unsold retail items and provide clarity on how RCRA regulations apply to reverse distribution and reverse logistics. In this final rule, EPA:

1. Codified regulations for the reverse distribution of prescription hazardous waste pharmaceuticals,
2. Codified EPA's long-standing interpretation for the reverse logistics of nonprescription pharmaceuticals, and
3. Established the Reverse Logistics Policy for the reverse logistics of other unsold retail items (i.e., non-pharmaceuticals).

The attached excerpt from the 2019 Hazardous Waste Pharmaceuticals Final Rule preamble summarizes the regulations on reverse distribution and establishes the reverse logistics policy. In addition to our final determinations, this excerpt includes a background section to provide you with key context and terminology regarding EPA's efforts to address the reverse flow of unsold retail items. We hope that by providing this excerpt that it will assist in outreach and communication while providing clarity on how RCRA applies to the handling of unsold pharmaceuticals and retail items via reverse distribution and reverse logistics. We stand ready to assist you in this effort. If you have any questions, please contact Laura Stanley at (703) 308-7285 in my office.

Attachment:
Excerpt: Reverse Distribution and Reverse Logistics Section, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (84 FR 5827-35)

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[1] February 14, 2014 (79 FR 8926).

[2] EPA's Retail Strategy is available at: *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.*

## VI. Reverse Distribution and Reverse Logistics

### *A. Summary*

Based on information collected from outreach efforts and comments received on the proposed rulemaking, EPA is finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals, codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals,[1] and establishing a policy for the reverse logistics of other unsold retail items.[2] In the case of prescription pharmaceuticals, EPA maintains its position as stated in the proposed rulemaking preamble that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (e.g., retail store).[3] In contrast, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store[4] if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose)[5] or reclaimed.[6] Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of

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[1] Under the final rule, the definition of pharmaceutical includes, but is not limited to, prescription drugs, over-the-counter drugs, dietary supplements, and homeopathic drugs. See the definition of pharmaceutical in § 266.500. For the remainder of this section, EPA refers to over-the-counter drugs, dietary supplements, and homeopathic drugs as nonprescription pharmaceuticals. Prescription pharmaceuticals are defined by 21 CFR 203.3(y).

[2] Under the final rule, other unsold retail items can include any non-pharmaceutical unsold retail item from a retail store that if discarded would otherwise meet the definition of hazardous waste. Examples include but are not limited to aerosol cans, pool chemicals, mercury-containing lightbulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks.

[3] Under the final rule, the definition of healthcare facility includes, but is not limited to, retail facilities such as pharmacies and retailers of over-the-counter medications. See the definition of healthcare facility in §266.500.

[4] Throughout this section, EPA uses the term "retail store" to describe facilities that send nonprescription pharmaceutical and other unsold retail items through reverse logistics. EPA's understanding is that the retail sector is the only industry that sends nonprescription pharmaceuticals and other unsold items through reverse logistics. However, EPA's final policy that nonprescription pharmaceuticals and other unsold retail items, excluding prescription pharmaceuticals, that are sent through reverse logistics are not solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed, is not limited to the retail sector.

[5] Commenters from the retail industry commonly use the terms "liquidation" or "donation" to refer to legitimate methods of redistribution. For example, see comment numbers EPA-HQ-RCRA-2007-0932-0312 and EPA-HQ-RCRA-2007-0932-0340 in the docket. Under RCRA's definition of solid waste regulations in §261.2(e), redistribution would be referred to as use/reuse.

[6] See §261.1(b)(4) for the definition of reclamation and §261.1(b)(5) for the definition of use/reuse.

being legitimately used/reused (e.g. lawfully redistributed for their intended purpose) or reclaimed. The remainder of this section proceeds as follows. First, EPA provides a brief background on the Agency's work to better understand the retail sector and provide guidance on RCRA's applicability to the retail sector. EPA then describes the proposal to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors under the pharmaceuticals proposed rulemaking. Finally, EPA provides the rationale for finalizing distinct regulations and policies for the reverse distribution of prescription hazardous waste pharmaceuticals and the reverse logistics of other unsold retail items and nonprescription pharmaceuticals and describes new information received in comments on the proposed rulemaking.

*B. Background*

In 2008, EPA initiated a review of RCRA's applicability to the retail sector in order to understand the challenges the retail sector faces in complying with RCRA. EPA's review consisted of discussions with various members of the retail community and states through meetings, conferences, and site visits. In 2014, EPA published a NODA for the Retail Sector in order to better understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[7]

Subsequent to issuance of the NODA, EPA continued conducting outreach efforts (e.g., meetings, conferences, site visits) with stakeholders to gather information regarding the management of unsold retail items. EPA's outreach efforts, combined with an analysis of comments received on the NODA, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of

[7] February 14, 2014 (79 FR 8926)

reasons. Unsold retail items include excess inventory, such as expired or outdated items, seasonal items, overstock, recalled items, and returned items that cannot be returned to stock/inventory. In the NODA, EPA used the terms "reverse distribution" and "reverse logistics" to describe the process or system employed by the retail sector to manage these unsold retail items.

Based on information gathered through outreach and comments to the Retail NODA, EPA developed a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations. This plan is called the "Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework" (Retail Strategy) and was made publicly available on September 12, 2016.[8]

Throughout the Retail Strategy, EPA used the term "reverse distribution" to describe the system through which unsold retail items flow and the term "reverse logistic center" to describe the facilities managing the reverse flow of these items. In crafting the Retail Strategy, EPA recognized that the reverse distribution process that retail stores employ to send unsold retail items to reverse logistics centers is a well-established business practice in the retail sector and retail stores sometimes rely upon arrangements with manufacturers[9] to determine the ultimate disposition of these goods. EPA also noted that a number of questions have been raised by both retailers and regulators regarding how the reverse distribution process is regulated, or should be regulated, under RCRA. In addition, this issue becomes more complicated for national retailers with store locations in multiple states, as states have taken various positions on how RCRA regulations apply. The Agency's understanding when crafting the Retail Strategy was that

[8] EPA's Retail Strategy is available at https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.

[9] EPA has not distinguished among the terms "supplier" and "vendor" (the latter more commonly used in the retail industry) versus "manufacturer" and these terms are used interchangeably in this preamble, although the Agency realizes that the flow of goods/products more commonly occurs between retailers and suppliers/vendors (or agents thereof) and that suppliers themselves may also be manufacturers or product formulators.

"reverse distribution" is the term most commonly used for the return of all pharmaceuticals (both prescription and nonprescription) that have the potential to receive manufacturer credit, whereas "reverse logistics" is the term used for the reverse flow of retail items other than pharmaceuticals.[10]

Because of the challenges facing the retail sector in complying with RCRA, EPA stated in the Retail Strategy its intent to develop a policy addressing the reverse distribution process for the retail sector as a whole. In the Retail Strategy, EPA agreed to develop a comprehensive policy that applied to all unsold retail items, not just pharmaceuticals. In order to fulfill EPA's intent to address the reverse distribution process for the retail sector as a whole, EPA is establishing a policy for the reverse logistics of other unsold retail items in addition to finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals.

*C. EPA's Proposed Regulations for Reverse Distribution of Pharmaceuticals*

In the proposed Management Standards for Hazardous Waste Pharmaceuticals, EPA proposed to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturer credit. EPA's original position was outlined in two RCRA policy memos released in 1981 and 1991.[11] In the first memo, EPA agreed that pharmaceuticals did not become wastes until the decision to discard was made at a manufacturing plant. EPA's interpretation was based on the understanding that the decision to either return goods for reclamation or dispose of them took place only at the manufacturing plant. In the second memo, EPA agreed that pharmaceuticals returned to a manufacturer,

[10] As discussed subsequently in this preamble, the distinction between "reverse distribution" and "reverse logistics" has become important in light of the Agency's response to comments received on the proposed rule.
[11] Refer to the preamble of the proposed rule (pages 58042 and 58043), which includes discussion of the two EPA policy memos, dated May 13, 1981 (RCRA Online #11012) and May 16, 1991 (RCRA Online #11606).

wholesaler, or third-party service company would not be considered wastes until a decision to discard has been made. In this 1991 memo, EPA specifically noted that, "to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered waste until a determination to discard them is made." Although EPA made a statement in the preamble to the 2008 Pharmaceutical Universal Waste proposal that linked the value of these pharmaceuticals, in the form of manufacturers credit, to the idea that these pharmaceuticals would not be considered waste, EPA never finalized this universal waste rule or that interpretation. Thus, the 1991 memo describes EPA's interpretation regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors prior to this final rulemaking.

In the preamble to the proposed rulemaking, EPA indicated the Agency's intent to modify its position regarding the point of generation in circumstances where a pharmaceutical is sent to a reverse distributor. EPA proposed that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. That is, EPA proposed that, once the decision is made to send a potentially creditable hazardous waste pharmaceutical[12] from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid waste. This proposed change of policy was based on the EPA's understanding that in almost all cases, pharmaceuticals returned to a reverse distributor for manufacturer credit are ultimately discarded.[13] Under the proposed rulemaking, the definition of "pharmaceutical reverse distributor" included any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose

[12] Potentially creditable hazardous waste pharmaceutical in the proposal was generally defined as a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. See 80 FR 58014.
[13] See further discussion in the proposed rule preamble at 80 FR 58043.

of facilitating or verifying manufacturer credit. Additionally, under the proposed rulemaking, the definition of "pharmaceutical" included not just prescription pharmaceuticals but also nonprescription pharmaceuticals. Therefore, under the proposal, potentially creditable prescription pharmaceuticals and nonprescription pharmaceuticals transported to a facility that facilitates or verifies manufacturer credit, even in cases where a credit determination is yet to be made, would be considered discarded and, therefore, solid wastes at the healthcare facility.

In proposing this shift, EPA specifically stated that, although a pharmaceutical may retain monetary value within the reverse distribution system (i.e., potential exists for a manufacturer to issue credit), the pharmaceutical would still be considered a solid waste. The "decision point" on whether a pharmaceutical is a solid waste is when it has been discarded or when the decision has been made to discard the material. That is, when a pharmaceutical is discarded determines whether it is a solid waste, not whether the pharmaceutical has value. This interpretation is consistent with EPA's approach under RCRA that materials that are discarded are solid wastes, regardless of their monetary value or the economics of the system in which those discarded materials are handled. EPA has long maintained, and continues to maintain, the interpretation that value is not determinative of solid waste status.

In 1986, EPA released a memo on the regulation of hazardous wastes that are recycled, and wrote that "persons transporting and storing hazardous wastes before recycling are similar to persons transporting and storing hazardous waste before disposal: there is nothing about the waste that makes it so valuable that safe handling is assured absent regulation."[14] EPA reaffirmed this interpretation in a 1989 memo on the regulatory status of solder skimmings

[14] See RCRA Online #12762 for the October 8, 1986 letter from EPA to Senator John Glenn titled "Hazardous Wastes that are Recycled, Handling."

(tin/lead alloy) purchased for reclamation, writing that even though the skimmings have value, they are still considered a solid waste.[15]

In a more recent application of this interpretation, EPA outlined its position on chlorofluorocarbons (CFCs) that are processed back into the refrigerant market or sent for destruction, but receive carbon offset credits and thus have value, in two memos signed in 2017.[16] Irrespective of whether facilities pay for hazardous CFCs or receive carbon offsets for the destruction of CFCs, the material is considered a solid waste. As another example of a material that is discarded as solid waste but has monetary value, EPA maintains that spent lead acid batteries being reclaimed are regulated as hazardous waste under part 266 subpart G or under universal waste irrespective of the fact that the batteries may have value and that reclamation facilities sometimes buy batteries due to the monetary value of the lead.[17] This finding was upheld in *United States v. Ilco Inc*., 996 F. 2d 1126, where the court found that the fact that the batteries were discarded "does not change just because a reclaimer has purchased or finds value in the components." EPA also maintains that recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, and other various previous metals are still regulated as hazardous waste under part 266 subpart F despite the fact that the precious metals have monetary value. Additionally, the holdings of multiple court decisions is that simply because a hazardous waste has, or may have, monetary value does not mean the material loses its status as a solid waste. See *American Petroleum Institute* v. *EPA*, 906 F.2d 741 n.16 (DC Cir.

[15] See RCRA Online #11446 for the July 20, 1989 memo from EPA to Electrum Recovery Works, Inc.
[16] See docket number EPA-HQ-RCRA-2007-0932 for the January 30, 2017 letter from EPA Region 5 to Tradewater, LLC and the July 14, 2017 letter from EPA to A-Gas U.S. Holdings, Inc.
[17] See docket number EPA-HQ-RCRA-2007-0932 for notes from a November 19, 2013 site visit to a lead acid battery recycler.

1990); *United States v. ILCO Inc.*, 996 F.2d 1126 1131-32 (11th Cir. 1993); *Owen Steel v. Browner*, 37 F.3d 146, 150 (4th Cir. 1994).

*D. EPA's Final Reverse Distribution Regulation and Reverse Logistics Policy*

1. Introduction

In light of comments received on the proposed rulemaking, along with EPA's understanding of current business practices, the Agency is making a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals. In addition to receiving information from comments on the proposed rulemaking, EPA gathered information from site visits and by participating as an observer in the Retail Waste Working Group.[18] In the case of prescription pharmaceuticals, EPA is finalizing, as proposed, that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility. However, EPA notes that these tailored RCRA regulations for prescription pharmaceuticals going through reverse distribution are designed with existing business practices in mind. For more explanation, see section 4 below and section XVII of this preamble. EPA is also codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals. EPA makes it clear in § 266.501(g)(2) that nonprescription pharmaceuticals are not solid wastes [if] they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed (also see section IX of this preamble). Also in this preamble, EPA is establishing a policy that other unsold retail items that are sent through reverse logistics

[18] See the report prepared by the Retail Waste Working Group, "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

are not solid wastes at the retail store [if] they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.[19]

2. Comments on EPA's Proposed Reverse Distribution Regulation

EPA received numerous comments on the proposed position that the decision to send potentially creditable pharmaceuticals through reverse distribution is a decision to discard. States were generally supportive of the proposed change in position, while many comments from the retail industry objected to the Agency's proposed change in position.

EPA received many broad comments on EPAs proposed position regarding the waste status of pharmaceuticals going through reverse distribution and reverse logistics, which are discussed in further detail in section XVII. EPA also received many comments describing the potential burden that the revised interpretation would place on the retail industry, which are also discussed in further detail in section XVII. The remainder of this section focuses on comments received on the distinction between the reverse distribution of prescription pharmaceuticals and the reverse logistics of nonprescription pharmaceuticals and other unsold retail items.

EPA received numerous comments that described the key distinctions between reverse distribution and reverse logistics as they pertain to the waste status of pharmaceuticals and other unsold retail items going through these two processes. Multiple commenters argued that EPA mistakenly concluded that pharmaceuticals, including nonprescription pharmaceuticals, transported to facilities that facilitate or verify manufacturer credit are in most, if not all cases,

[19] The brackets indicate that we have amended the language from how it appeared in the preamble to the Hazardous Waste Pharmaceuticals Final Rule. We made these two amendments to be consistent with the meaning of regulatory language and the rest of the preamble.

discarded.[20] Commenters argued that the Agency failed to take into account the ability to donate, liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in most, if not all cases, discarded. Commenters argued that this fact contradicts EPA's rationale in proposing that all pharmaceuticals, including nonprescription pharmaceuticals, going through reverse distribution and reverse logistics are wastes at the healthcare facility.

Overall, commenters encouraged EPA to adopt the terminology used by industry where "reverse distribution" only refers to the process by which prescription pharmaceuticals are sent to a reverse distributor for the evaluation of manufacturers credit and "reverse logistics" refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Commenters requested that if EPA intends to finalize that a decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical, that EPA also adopt separate and distinct policies regarding how RCRA applies to prescription pharmaceuticals going through "reverse distribution" and to nonprescription pharmaceuticals and other unsold retail items going through "reverse logistics."[21] One commenter noted that reverse logistics is an integral component of inventory management, product recall confirmation, sale through liquidation, donation for use, and reclamation of commercial products—contributing billions of dollars to the retail industry annually.[22] Moreover, this commenter noted that the reverse logistics operations help maximize the amount of OTC pharmaceuticals and dietary

[20] See the preamble to the proposed rule for a discussion of the comments received on the 2008 Pharmaceutical Universal Waste proposal and the 2014 Retail Notice of Data Availability that argued that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused (80 FR 58043).
[21] For example, see comment number EPA-HQ-RCRA-2007-0932-0377.
[22] See comment number EPA-HQ-RCRA-2007-0932-0295 in the docket.

supplements that can be reused or reclaimed. Another commenter made a similar argument, writing that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.[23]

One commenter honed in on the argument that EPA failed to take into account the ability to legitimately use/reuse or reclaim nonprescription pharmaceuticals that are sent through reverse logistics.[24] This commenter pointed out that stringent chain-of-custody documentation and disposal requirements under DEA regulations and state Board of Pharmacy Requirements only apply to prescription pharmaceuticals. In contrast, most nonprescription pharmaceuticals are not susceptible to the same diversion risks as prescription pharmaceuticals and do not face the same documentation and disposal requirements. This makes it possible to use/reuse or reclaim nonprescription pharmaceuticals.

Walmart Stores Inc. commented that pharmaceuticals going through reverse distribution that are ultimately discarded are likely prescription pharmaceuticals.[25] Walmart wrote that only a small percentage of the consumer goods[26] managed at Walmart's six Return Centers, which will be considered reverse logistics centers under EPA's final policy, are discarded. According to Walmart's data, only 2% of the consumer goods managed at Walmart's Return Centers are discarded by Walmart, while 28% are donated, recycled, or liquidated and 70% are returned to

[23] See comment number EPA-HQ-RCRA-2007-0932-0312 in the docket.
[24] Ibid.
[25] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.
[26] EPA uses the term "unsold retail items" to refer to excess inventory, such as expired or outdated items, seasonal items, overstock, recalled products, and returned items that cannot be return to stock/inventory. Walmart and other commenters from the retail industry use the term "consumer goods" to refer to similar items.

the vendor.[27] Further, for the consumer products that are considered RCRA hazardous waste when discarded, only 1% are discarded, 33% are liquidated or donated, and 66% are returned to the vendor.[28] Inmar, Inc. also argued that only a small percentage of the OTC pharmaceuticals returned to a reverse logistics center are disposed rather than liquidated, donated, or returned to the vendor.[29] Inmar does not maintain specific data on this issue, but wrote that it would not be unusual for one of their subsidiary reverse logistics centers handling nonprescription pharmaceuticals and other consumer goods to send as little as 5% of the products for destruction.

Retail Industry Leaders Association (RILA) et al. pointed out that nonprescription pharmaceuticals do not face the same restrictions that preclude the redistribution or donation of prescription pharmaceuticals.[30] RILA et al. added that nonprescription pharmaceuticals are regularly donated and liquidated and cited data from two retailers.

Inmar Inc. also noted that when an item is returned because an expiration date has been exceeded, disposal is more often the required disposition, but the products may be returned to the manufacturer for further evaluation for potential liquidation.[31] Inmar also wrote that nonprescription pharmaceuticals with "best by" dates (as opposed to expiration dates) can still be donated or liquidated after the date has passed.

Overall, these comments help to underscore the differences between how prescription pharmaceuticals and other unsold retail items, including nonprescription pharmaceuticals, are

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[27] EPA has not distinguished among the terms "supplier" and "vendor" verses "manufacturer" and the terms are used interchangeably throughout the preamble. The Agency more frequently used the term "manufacturer" while retail industry commenters more frequently used the term "vendor."

[28] EPA did not receive data on the ultimate disposition of consumer products returned to the vendor. EPA further discusses our policy on unsold retail items that are returned to the vendor in section "e.) Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes."

[29] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

[30] See comment number EPA-HQ-RCRA-2007-0932-0295 in the docket.

[31] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

managed within the reverse supply chain. These comments led EPA to make a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of all other unsold retail items, including nonprescription pharmaceuticals.

3. Distinction Between Reverse Distribution and Reverse Logistics

EPA acknowledges that reverse distribution and reverse logistics processes share common elements in terms of the role each plays in the management of pharmaceuticals. However, based on the comments received on the proposal, especially those summarized above, the Agency recognizes that there is a key distinction between how prescription pharmaceuticals and nonprescription pharmaceuticals (see definition of pharmaceutical in § 266.500) are managed in the reverse supply chain. The key distinction is that there is not a reasonable expectation of legitimate use/reuse (e.g., lawful redistribution for its intended purpose) or reclamation for prescription pharmaceuticals, except in very limited circumstances, but there is for other retail items, including nonprescription pharmaceuticals.

Prescription pharmaceuticals shipped from healthcare facilities to reverse distributors for the evaluation of manufacturer credit are almost always discarded. EPA is aware that prescription pharmaceuticals are sometimes lawfully donated, in which case the pharmaceuticals would not be a solid waste.[32] In the case of nonprescription pharmaceuticals and other unsold retail items that are sent to a reverse logistics center, there is often a reasonable expectation that they will be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

[32] EPA is aware of one non-profit organization that facilitates donations of prescription pharmaceuticals. See comment from SIRUM in the docket (EPA-HQ-RCRA-2007-0932-0353). EPA is also aware of multiple states, including Iowa, Wyoming, and Oklahoma, that run prescription pharmaceutical return and reuse programs. For more information, see "State Prescription Drug Return, Reuse and Recycling Laws" at http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.

EPA recognizes that the awarding of credit for unsold pharmaceuticals is a critical element of both the reverse distribution and reverse logistics processes as it provides a healthcare facility financial incentive to not only stock a particular pharmaceutical but also to defray costs associated with transporting a pharmaceutical to a reverse distributor or reverse logistics center. However, it is EPA's position that the inherent monetary "value" conferred on any pharmaceutical due to the potential to receive manufacturer credit is not a proper indicator of waste status. Rather, the decision to discard is determinative of when an unsold product becomes a solid waste. Under EPA's final rule and preamble, if a nonprescription pharmaceutical or other retail item becomes unsalable at a retail store it can continue to be considered a product until a reverse logistics center or other subsequent entity makes the decision to discard it, as long as there is a reasonable expectation of it being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

4. Prescription Pharmaceuticals going through Reverse Distribution Are Wastes at the Healthcare Facility

In the case of prescription pharmaceuticals, EPA maintains its position, as stated in the proposed rulemaking preamble and reflected in the regulatory text, that prescription pharmaceuticals moving through reverse distribution are solid wastes starting at the healthcare facility. This includes prescription pharmaceuticals that, as potentially creditable hazardous waste pharmaceuticals, are sent from a retail facility or healthcare facility to a reverse distributor for manufacturer credit evaluation (see definition of potentially creditable hazardous waste pharmaceutical in § 266.500). Although the potential exists for a manufacturer to issue credit for a prescription pharmaceutical, the "decision point" on when a pharmaceutical is a solid waste is when the decision has been made to discard the item. That is, a pharmaceutical is a solid waste

when the decision has been made to discard regardless of whether the pharmaceutical has value. Although prescription pharmaceuticals are evaluated for, and in many cases ultimately receive, manufacturer credit, it remains apparent to EPA that these pharmaceuticals will seldom, if ever, be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed after they are sent to a reverse distributor. Thus, a decision to send prescription pharmaceuticals to a reverse distributor is a decision to discard the material. None of the comments on the proposed rule alter EPA's position regarding the likelihood of redistribution or reclamation of prescription pharmaceuticals being managed through reverse distribution. Rather, EPA received many comments that agreed with EPA's proposed interpretation that the decision to send a pharmaceutical to a reverse distributor is a decision to discard as it pertains to prescription pharmaceuticals because there are limited opportunities to legitimately use/reuse or reclaim prescription pharmaceuticals. In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste and we have specifically noted this in the regulations (see § 266.501(g)(1) and the definition of hazardous waste pharmaceutical in § 266.500).

Many of the broad comments in support of the proposed reinterpretation provided examples but did not distinguish between prescription pharmaceuticals and nonprescription pharmaceuticals. For example, multiple commenters argued that pharmaceuticals transported to a reverse distributor are rarely redistributed or reclaimed, and are usually destroyed, but did not explain if this applied only to prescription pharmaceuticals. One commenter observed that many manufacturers contract with reverse distributors to dispose of unsold pharmaceuticals after review for credit eligibility is complete, suggesting that use/reuse or reclamation does not generally occur. This commenter was only aware of one instance of potential reuse of a

pharmaceutical after being sent through reverse distribution.[33] That being said, based on what EPA has learned from retail industry commenters, site visits, and discussions with retailers about prescription pharmaceuticals verses nonprescription pharmaceuticals, EPA can infer that these comments likely refer to the reverse distribution of prescription pharmaceuticals .[34] EPA's inference is supported by other comments received on the proposal. For example, Walmart argued that the comments EPA received on the 2008 Pharmaceutical Universal Waste proposal (where pharmaceuticals were defined only as prescription pharmaceuticals) and the 2014 Retail Notice of Data Availability that pharmaceuticals going through reverse distribution are ultimately discarded were likely talking about prescription pharmaceuticals.[35]

In conclusion, a material is considered a solid waste if it is accumulated or stored before or in lieu of being disposed of, burned, or incinerated (§261.2(b)(3)). Even if the healthcare facility intends to receive credit for the prescription pharmaceutical and the reverse distributor intends to evaluate the prescription pharmaceutical for credit, the pharmaceutical is still considered a discarded material (§261.2(a)(2)(i)) because it is being accumulated and stored prior to being sent for treatment (rather than being accumulated or stored prior to being used/reused or reclaimed). Although the healthcare facility or reverse distributor intends to elicit credit from the prescription pharmaceutical in the interim period before it is sent for treatment, the pharmaceutical is still considered a discarded material. An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive.

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[33] The example cited was an unconfirmed claim that a rodent poison manufacturer could use discarded pharmaceutical warfarin tablets as feedstock in its process. See comment number EPA-HQ-RCRA-2007-0932-0358 in the docket.

[34] See docket number EPA-HQ-RCRA-2007-0932 for reverse distributor responses to EPA's questions about reverse distribution of pharmaceuticals, notes from Agency meetings with retail industry representatives, and notes from site visits to reverse distribution facilities.

[35] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.

Although EPA maintains its position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility, this final rule establishes streamlined, practical standards for managing potentially creditable hazardous waste pharmaceuticals that will reduce regulatory burden on retailers and align with the existing practices of the retail sector. Thus, EPA's position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility only subjects these hazardous waste pharmaceuticals to the streamlined part 266 subpart P standards versus the full RCRA Subtitle C regulations. For example, EPA does not require healthcare facilities to use a hazardous waste manifest or a hazardous waste transporter when shipping potentially creditable hazardous waste pharmaceutical to a reverse distributor. See section XVI.D for a discussion of the shipping standards for potentially creditable hazardous waste pharmaceuticals.

Because the point of generation of potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, EPA can impose the RCRA Subtitle C cradle-to-grave management of hazardous wastes. Specifically, it allows us to impose consistent and enforceable tracking of hazardous waste pharmaceuticals from healthcare facilities en route to reverse distributors. Lack of tracking was identified as a regulatory gap by many commenters on our 2008 proposal to add pharmaceuticals to the Universal Waste program. The tracking provides the benefit of reducing the risk of diversion of these unused hazardous waste pharmaceuticals onto the black market, thus fulfilling our statutory mandate of protecting human health.

5. Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes If They Have a Reasonable Expectation of Being Legitimately Used/Reused or Reclaimed

Although EPA includes nonprescription pharmaceuticals in the definition of "pharmaceutical" under the final rule, the Agency makes it clear in the definition of "hazardous waste pharmaceutical" that nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals, if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. The applicability of the final rule also has a new provision in § 266.501(g)(2) making it clear that a nonprescription pharmaceutical that is not a solid waste because it has a reasonable expectation of being legitimately used/reused or reclaimed is not subject to parts 260–273. Additionally, the final definition of reverse distributor has been revised so that it applies only to the reverse distribution of prescription pharmaceuticals.

In the final rule, EPA is reaffirming the Agency's previous policies on redistribution expressed in memos in 1981 and 1991 with respect to nonprescription pharmaceuticals and other retail items that have become unsalable at the retail store and are being managed by a reverse logistics center through the reverse logistics process. That is, EPA is maintaining a policy that nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. EPA recognizes that reverse logistics centers are designed to evaluate unsold retail items, analyze secondary markets, and assess the suitability of the unsold retail items for reuse in those secondary markets. These services promote the donation, liquidation, and reuse of unsold retail items and reduce overall waste. Importantly, these activities are distinct from the activities of reverse distributors of prescription pharmaceuticals. Reverse distributors of prescription pharmaceuticals are not designed to evaluate unsold prescription pharmaceuticals and assess the suitability of the

prescription pharmaceuticals for reuse in secondary markets. As mentioned previously, commenters pointed out that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.

Although EPA is reaffirming this policy, EPA remains concerned about the potential for overuse of reverse logistics centers, a concern we originally raised in a 1991 memo related to reverse distribution: "a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place…to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them."[36] To reiterate, in order to avoid being considered solid waste, items, including nonprescription pharmaceuticals, sent through reverse logistics, must have some reasonable expectation of being legitimately used/reused or reclaimed. The 199l guidance allowing pharmaceuticals to go through reverse distribution without being considered solid waste was based on the notion that they had the potential for recycling by use/reuse. Over the years, however, many have come to disregard the intent behind this guidance and erroneously believed that it was a blanket statement that pharmaceuticals going through reverse distribution were not solid wastes, even if they did not have a reasonable expectation of being redistributed or recycled. We strongly encourage the use of reverse logistics centers to facilitate redistribution and legitimate recycling to the fullest extent possible, and thus, reduce the amount of waste being generated. But we also caution

[36] See memo dated May 16, 1991, From Lowrance to Schulz, RCRA Online #11606.

reverse logistic centers not to become *de facto* waste management facilities for their customers. If this were to occur, it could be the case that the decision to discard for nonprescription pharmaceuticals and other retail items would have occurred at the retail store or healthcare facility.

Of course, once a reverse logistics center makes a decision to discard an item, it becomes a solid waste and, if it is listed or exhibits a characteristic, a hazardous waste. The reverse logistics center is subject to the applicable RCRA regulations, such as part 262, for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals, but not part 266 subpart P.

EPA notes that although nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed, the items must be shipped in accordance will all applicable Department of Transportation (DOT) regulations. For example, DOT promulgated a final rule in March 2016 on the reverse logistics of hazardous materials. This rule includes provisions to help ensure that items, including consumer grade fireworks, are in original packaging when shipped from a retail store to a manufacturer, supplier, or distribution facility.[37]

There are six issues that came to EPA's attention when shaping this final reverse logistics policy. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. The second issue regards unsold retail items that have expired. The third issue involves instances when retail items cannot be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition."

[37] See 81 FR 18527; March 31, 2016.

The fourth issue regards the crediting process for unsold retail items. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. The final issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking.

a. *Unsold retail items returned to the manufacturer or vendor.*

The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. As noted previously, data from commenters suggests a majority of unsold retail items moving through reverse logistics are returned to the manufacturer or vendor.[38] EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer or vendor from a reverse logistics center. For this final action, EPA assumes the items are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. However, if nonprescription pharmaceuticals or other retail items do not have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed after they are returned to a manufacturer or vendor, then the nonprescription pharmaceutical or other unsold retail item would be a solid and potentially hazardous waste at the reverse logistics center.

b. *Unsold retail items that have expired.*

The second issue regards unsold retail items that have expired.[39] As mentioned previously, commenters noted that when an item is sent to a reverse logistics center because an expiration date has been exceeded, disposal is most often the required disposition, however the

[38] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.
[39] EPA uses the term "expired" consistent with Food and Drug Administration regulations. See 21 CFR part 201.66, part 201.17, and 211.137.

items may be returned to the manufacturer for further evaluation for potential liquidation.[40] Furthermore, nonprescription pharmaceuticals with "best by" dates (as opposed to expiration dates) often can still be donated or liquidated after the date has passed. In addition to information received from commenters suggesting that expired products might be considered eligible for redistribution, FDA occasionally allows the donation of drugs that are past the expiration date shown on the label when provided sufficient information to show the expired pharmaceuticals are safe and effective and other specific criteria have been met.[41] Thus, for this final action, EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. These items are in their original, intact packaging and do not pose a high risk of release to the environment. Further, this position is consistent with the goal of the RCRA statute to reduce waste, as EPA is concerned that considering unsold retail items that have expired to be wastes at the retail store could introduce an unintended incentive for retailers to remove those items from shelves in advance of expiration dates, resulting in an unnecessary increase in overall waste generation.

c. *Unsold retail items subject to a destroy disposition*.

The third issue involves instances when retail items cannot be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition." A destroy disposition is when a manufacturer has established "business rules" that prohibit unsold retail items from being redistributed for their intended purpose (i.e., liquidated or donated). The term "business rules" (i.e., manufacturer return policies) refers to the

[40] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.
[41] See U.S. Food and Drug Administration "Question and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts" available at: https://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf.

rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[42] The Agency's understanding is that manufacturers adopt destroy dispositions over concerns related to liability and brand protection and that assigning a destroy disposition is not a common practice because it precludes income from potential redistribution and results in disposal costs.[43] For this final action, if a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition," and that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility. However, if a manufacturer has established business rules that do not imply that disposal is the ultimate disposition for unsold retail items, and there is a reasonable expectation the items will be reclaimed, these items would not be solid wastes at the retail store when they are sent through reverse logistics. Thus, a manufacturer can adopt business rules that prohibit the lawful redistribution of retail items for their intended purpose (i.e., liquidation or donation), but allow for the items to be sent through reverse logistics for reclamation. These items would not be wastes at the retail store if there is a reasonable expectation the items will be reclaimed.

d. *Crediting process for unsold retail items*.

The fourth issue regards the crediting process for unsold retail items. It is the Agency's understanding that there are two primary credit models. The first is the "traditional approach" whereby credit is awarded after unsold retail items are returned to a reverse logistics center for

[42] This definition is derived from the definition of "business rules" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

[43] See discussion of "destroy dispositions" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

processing. The second is the adjustable rate policy, which is also commonly referred to as a "swell allowance," whereby credit is awarded up-front based on an assumption that a certain percentage of items will become unsalable for various reasons at the primary retailer.[44] EPA's understanding is that one of the goals of the adjustable rate policy is to reduce the amount of unsold items sent through to reverse logistics centers and to encourage sale at the primary retailer – even if this means discounting those items. EPA's understanding is that under such an approach, retailers are responsible for managing unsold retail items and determining the ultimate disposition since the manufacturer is not involved in the disposition decision. That being said, retailers can utilize reverse logistics to assist in the management and disposition of unsold retail items sold under an adjustable rate policy. More importantly, under EPA's final policy, although the potential exists for a manufacturer to issue credit for an unsold retail item, the "decision point" on whether a retail item is a solid waste is when the decision has been made to discard the material. In other words, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Thus, for this final action, the credit model is not relevant to the waste status of unsold retail items. EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

e. *Unsold retail items subject to a recall.*

[44] Additional information on the Adjustable Rate Policy and other reimbursement policies for unsalable items can be found in the publication entitled, 2008 Joint Industry Unsaleables Management Study: The Real Causes and Actionable Solutions. This publication is available at http://www.gmaonline.org/downloads/research-and-reports/UnsaleablesFINAL091108.pdf.

The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. Almost all pharmaceutical recalls are overseen by FDA. However, under the Poison Prevention Packaging Act, the U.S. Consumer Product Safety Commission (CPSC) has authority regarding special packaging (sometimes called child resistant packaging) of certain household products, including drugs (as that term is defined in the Federal Food, Drug, and Cosmetic Act).[45] Similarly, under the child Nicotine Poisoning Prevention Act of 2015, CPSC has authority for administering special packaging requirements for liquid nicotine containers.[46] Thus, CPSC oversees a recall if there is a problem with a pharmaceutical's special packaging or containers for liquid nicotine. Additionally, CPSC has jurisdiction over recalls of many other consumer products sold at retail stores.[47] EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. This is true whether they become subject to a recall at a reverse logistics center, healthcare facility, or retail store. It is possible that recalled nonprescription pharmaceuticals and other unsold retail items are not a solid waste if they are legitimately used/reused or reclaimed. For example, if CPSC oversees a recall if there is a problem with a pharmaceutical's packaging (e.g., an item's packaging poses a threat because it is not sufficiently child resistant), it is possible the pharmaceutical could still be sent for reclamation. Although it is difficult for EPA to make a blanket determination on whether all recalled nonprescription pharmaceuticals and other unsold retail items are or are not solid wastes, EPA is choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and

[45] See 15 U.S.C. 1471-1477 for the Poison Prevention Packaging Act.
[46] Public Law No. 114-116 (January 28, 2016).
[47] The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools. See https://www.recalls.gov/cpsc.html for more information.

other unsold retail items provided the recall is overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items, the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

Although FDA and CPSC are the federal agencies that primarily regulate recalled nonprescription pharmaceuticals and other unsold retail items, other federal agencies regulate some recalled retail items. For example, the National Highway Traffic Safety Administration oversees motor vehicle defects and safety recalls. Although other federal agencies may occasionally regulate recalled retail items, EPA is only choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. CPSC requires manufacturers to develop a recall strategy that outlines all of the actions to be taken on behalf of the manufacturer from start to finish. FDA requires firms that initiate a recall to develop a recall strategy and recommends that firms that initiate a FDA-requested recall develop a recall strategy.[48] Included as a required component of a comprehensive recall strategy is a requirement that FDA or CPSC approves a manufacturer's decision to take the action to discard some or all of the recalled items. Thus, EPA believes it is reasonable not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. However, the Agency will continue to evaluate recalled nonprescription pharmaceuticals and other unsold retail items managed by other federal agencies on a case-by-case basis. As an example, see the memo that EPA released in 2017 that describes how RCRA regulations apply to recalled Takata airbag

[48] See 21 CFR 7.46(a)(8) and 21 CFR 7.45(b), respectively.

inflators while they are being held under the 2015 DOT preservation order.[49] EPA's policy does not apply to unused pesticides that are suspended or canceled under the Federal Insecticide, Fungicide, and Rodenticide Act and recalled, as these can be managed as universal waste under 40 CFR part 273. Finally, while EPA is not applying RCRA regulations in these situations, we note that if recalled nonprescription pharmaceuticals and other unsold retail items are not managed and stored in a manner that prevents release to the environment, they may be considered a solid waste and a hazardous waste under sections 3007, 3013, and 7003 of RCRA.

f. *Unsold retail items that are broken, damaged, or leaking.*

The sixth issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking. In recent years, EPA took multiple enforcement actions against national retailers for sending hazardous waste, in the form of broken and/or leaking items with hazardous contents, to unpermitted TSDFs (in the form of reverse distributors and reverse logistics centers), among other RCRA violations.[50] The resulting settlements specify that unsold retail items with broken and/or leaking packaging are waste at the retailer and, if they are hazardous, cannot be sent to a reverse distributor or reverse logistics center. CVS commented on the proposed rulemaking and asked that EPA clarify that when pharmaceutical packaging is in sufficiently poor condition that it is broken, leaking, or otherwise unable to be used for its intended purpose, that those pharmaceuticals become solid waste at the healthcare facility.[51] CVS noted that this is consistent with their current practice, whereby broken and leaking items are managed as waste at their facilities and are not sent through reverse distribution or reverse logistics.

[49] See RCRA Online #14893 for the June 23, 2017 memo titled "Recalled Takata Airbag Inflators."
[50] Walmart Consent Agreement and Final Order, Docket Nos. RCRA-HQ-2013-4001 and FIFRA-HQ-2013-5056.
[51] See comment number EPA-HQ-RCRA-2007-0932-0312 in the docket.

Although EPA affirms the resulting settlements and agrees that nonprescription pharmaceuticals and other retail items cannot be sent through reverse logistics when they are broken, damaged, or leaking, the Agency is aware that there is inherent uncertainty surrounding when these items are considered broken, damaged, or leaking. For example, a nonprescription pharmaceutical could experience damage to the outer packaging while the inner container remains intact. For this final action, unsold retail items, including nonprescription pharmaceuticals, are not considered waste at the retail store if their packaging is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the materials to the environment,[52] and they are contained to prevent releases to the environment,[53] and they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. Thus, the Agency intends that nonprescription pharmaceuticals and other unsold retail items can be sent to a reverse logistics center and are not considered wastes at the retail store if they meet this standard. For example, if an outer cardboard box containing vials of nonprescription pharmaceuticals is damaged, but the vials are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.

In order to prevent exposures to personnel, the public, and the environment, if items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the stores in accordance with the applicable hazardous waste regulations. Specifically, if the broken, damaged, or leaking item is a hazardous waste pharmaceutical, the retail store must manage it under the streamlined standards of part 266 subpart P (unless it is a

[52] As defined in §260.10, unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures.
[53] These conditions are derived from the definition of contained as defined in §260.10.

VSQG for all its hazardous waste). Otherwise, the retail store would manage hazardous wastes under the applicable RCRA regulations, including part 262 generator regulations.