New Hazardous Waste Pharmaceuticals Rule: Significant Changes Coming for Health Care Facilities

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Health care facilities that provide a host of health care-related services or distribute, sell, or dispense pharmaceuticals[1] will need to learn a whole new set of regulations thanks to a finalized new rule promulgated by the Environmental Protection Agency (EPA). The new rule revises management standards for hazardous waste pharmaceuticals (HWPs) for health care facilities, including nursing, skilled nursing, and inpatient hospice facilities, more than three years following the close of comments for the EPA's initial proposed rule. The revised regulations will take effect six months following publication in the *Federal Register*.[2]

The Resource Conservation Recovery Act (RCRA) governs the generation, management, storage, treatment, and disposal of hazardous wastes. Before the new rule was promulgated, certain health care facilities, such as hospitals, and reverse distributors, were subject to the same hazardous waste requirements under the RCRA as most industries. The management of HWPs at long-term care facilities, however, was excluded from the RCRA and treated the same as HWPs at residential households. EPA makes clear in this new rule that because nursing, skilled nursing, and inpatient hospice facilities are more akin to hospitals, their management of **any hazardous waste, including HWPs**, will also be subject to RCRA requirements.[3]

The final rule revises some of the regulations and management standards for HWPs under the RCRA and sets them apart in a separate section of the RCRA regulations, to be codified at 40 C.F.R. Part 266, Subpart P ("Subpart P"), that are applicable specifically to health care facilities and reverse distributors. According to the EPA, this is necessary because hazardous waste generation and management practices at health care facilities differ significantly from those encountered in industry generally. As a result, regulating HWPs under the standard provisions of RCRA Subtitle C has been unnecessarily difficult. The EPA maintains that the new management standards are more streamlined and tailored specifically for healthcare HWPs and thus will promote proper management of HWPs by healthcare workers and pharmacy employees.

The final rule does not increase the universe of pharmaceuticals that are considered hazardous waste. However, it does accomplish four significant and practical changes in the management of pharmaceuticals: (1) HWPs that are to be sent off-site for reverse distribution will be regulated as hazardous wastes under the RCRA while still at the health care facility, (2) HWPs are banned from being disposed of down a drain or in a toilet, thereby reducing the amount of pharmaceutical ingredients that contaminate drinking water and endanger the environment, (3) it is easier to make a HWP container legally "empty," and (4) nicotine replacement therapies are no longer considered potential hazardous wastes. Some of the components of the final rule will relieve the existing burdens on generators of HWPs, while other components may make the management of HWPs more onerous, at least initially.

1 While the rule applies to a broad array of health care facilities and also to pharmaceutical reverse distributors, this article will focus on long-term care facilities specifically.

2 Publication was delayed due to the recent government shut down but is anticipated to occur soon.

3 Pre-publication copy of "Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," https://www.epa.gov/hwgenerators/pre-publication-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075 (hereinafter, "Pre-publication Copy"), at 142.

Applicability to Long-Term Care Facilities

As noted above, the final rule applies to health care facilities. The definition of "health care facility" specifically includes long-term care facilities. A "long-term care facility," in turn, is defined as:

> [A] licensed entity that provides assistance with activities of daily living, including **managing and administering pharmaceuticals** to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. **Not included within the scope of this definition are group homes, independent living communities, assisted living facilities and the independent and assisted living portions of continuing care retirement communities**. *(emphasis added)*.[4]

The exclusion of assisted living from the definition of long-term care facility in the rule[5] avoids many of the practical issues with control over medications taken directly by patients and use of multiple pharmacies that flow from the functional differences between nursing homes and assisted living facilities. The distinction constitutes a welcome change from the 2015 proposed rule, which sought to include such facilities in the definition of long-term care facility. The EPA stated unequivocally that HWPs that are in (a) the custody of the long-term care facility on behalf of the resident, or (b) an in-house pharmacy maintained by such facility (if any), must be managed under Subpart P.[6]

Definitions and Analysis

The analysis necessary to determine whether a given substance is considered a HWP involves three questions:[7]

Question 1 – Is it a Pharmaceutical?[8] Under the final rule, a pharmaceutical includes, but is not limited to, the following:

- Dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act;
- Prescription drug, as defined by 21 C.F.R. § 203.3(y);
- Over-the-counter drugs;
- Homeopathic drugs;
- Compounded drugs;
- Investigational new drugs;
- Pharmaceuticals remaining in non-empty containers;
- Personal protective equipment contaminated with pharmaceuticals; and
- Clean-up material from spills of pharmaceuticals.

The definition also includes any electronic nicotine delivery system and liquid nicotine packaged for retail sale. Excluded from the definition are sharps and dental amalgam.

Question 2 – Is it a Solid Waste? A solid waste is any discarded material that is not otherwise excluded under the regulations that implement RCRA. What constitutes a RCRA[9] solid waste, however, is not limited to wastes that are physically solid. Many solid wastes are liquid, semi-solid, or gaseous material. A material is considered "discarded" once the facility has decided to discard it, and must be managed appropriately at that point in time. A material that is legitimately going to be used, reused or reclaimed is not discarded and is not a solid waste. Note, however, that

4 See regulatory language to be codified at 40 C.F.R. § 266.500.

5 States may have their own authorized RCRA regulations that are more stringent than the Federal regulations. Some do not consider assisted living facilities to be exempt from the definition of a long-term care facility. As a result, assisted living providers are urged to consult their state regulation (if any).

6 Pre-publication Copy at 239. The EPA also stated that long-term care facilities covered by the rule will not be required to collect HWPs from residents that have custody of and self-administer their medications. *Id.*

7 Again, state regulatory requirements may be more stringent than those in the federal program. Accordingly, providers should check state regulations when undertaking any hazardous waste or HWP analysis.

8 Pharmaceuticals are not "medical wastes" or "biological wastes," which are regulated separately.

9 See 40 C.F.R. § 261.2 for a complete definition and discussion of exclusions. See also Criteria for the Definition of Solid Waste and Solid and Hazardous Waste Exclusions on the EPA website at: https://www.epa.gov/hw/criteria-definition-solid-waste-and-solid-and-hazardous-waste-exclusions

under the final rule, EPA has pre-determined that a health care facility's decision to reverse distribute a pharmaceutical constitutes a decision to discard the pharmaceutical.

Question 3 – Is it a HWP? Solid wastes that are pharmaceuticals are only considered hazardous waste under RCRA if they are either listed as hazardous wastes or exhibit one of the characteristics of hazardous waste. There are four lists--F[10], K[11], P[12] and U[13]--based on either manufacturing and industrial processes, or chemical designations. The F and K lists are based on manufacturing and industrial processes, none of which apply to pharmaceuticals for humans. The P and U lists are based on chemical products. The EPA notes that there are approximately 30 "Commercial Chemical Products" on the P and U lists that have uses in multiple pharmaceuticals. A Commercial Chemical Product is only a waste if (i) it has not been used or used as intended, and (ii) consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed or the chemical is the sole active ingredient in the formulation.[14] If these criteria are not met, then the pharmaceutical is not a HWP, even if included in the P or U list.

As noted above, even if a pharmaceutical waste is not listed on any of the lists, it may also qualify as a hazardous waste if it exhibits one of the four characteristics of hazardous waste:

- Ignitability[15] (something flammable) – for example, solutions containing more than 24% alcohol,
- Corrosivity[16] (something that can rust or decompose) – for example, certain compounding chemicals,
- Reactivity[17] (something explosive), and
- Toxicity[18] (something poisonous).

The answer to all three of the foregoing questions must be yes for the material to qualify as a HWP, though the final rule does contain certain exceptions that may apply to exclude a pharmaceutical from being considered a HWP for purposes of RCRA Subpart P.[19] A long-term care facility that determines that it does generate HWPs must then conduct further analysis to determine the nature of its obligations under Subpart P.

Scope of Obligations under Subpart P – Amount of Waste Generated

Once the determinations have been made that a long-term care facility is covered by the final rule and has HWPs, the analysis shifts from the type of facility and nature of the waste to the amount of the waste, to determine the scope of the facility's obligations under Subpart P. Specifically, the next inquiry is the amount of HWPs that the facility generates. Under RCRA, a "Generator" is a person whose act or process produces hazardous waste or whose act first causes a hazardous waste to become subject to regulation.[20] Therefore a facility that makes the determination to "discard" a

10 40 C.F.R. § 261.31.
11 40 C.F.R. § 261.32.
12 40 C.F.R. § 261.33.
13 40 C.F.R. § 261.33.
14 40 C.F.R. § 261.33(d).
15 40 C.F.R. § 261.21.
16 40 C.F.R. § 261.22.
17 40 C.F.R. § 261.23.
18 40 C.F.R. § 261.24.
19 See regulatory language to be codified at 40 C.F.R. § 266.501(g)(1)-(7). Of note, there are exceptions for pharmaceuticals and Over the Counter pharmaceuticals, dietary supplements or homeopathic drugs that are legitimately used/reused (lawfully donated or redistributed, as the case may be, for their intended purpose), pharmaceuticals being managed in accordance with a recall strategy approved by the Food and Drug Administration (FDA), pharmaceuticals being managed in accordance with a recall corrective action plan accepted by the Consumer Product Safety Commission, pharmaceuticals stored according to a court order or in connection with litigation, pharmaceuticals listed on a schedule of controlled substances by the Drug Enforcement Administration (DEA) (see section on Conditional Exemption for HWPs that are Controlled Substances *infra*), and household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the DEA). If a material has a pharmaceutical and a non-pharmaceutical use, it is considered a pharmaceutical under RCRA if the FDA requires that "Drug Facts" be included on the label.
20 40 C.F.R. § 260.10.

pharmaceutical becomes a Generator. A facility that generates less than or equal to any of the following per calendar month qualifies as a Very Small Quantity Generator (VSQG)[21]:

- 100 kg (220 pounds) of hazardous waste;[22] or
- 1 kg (2.2 pounds) of acute hazardous waste.[23]

Under the final rule, long-term care facilities with 20 or fewer beds are presumed to be VSQGs, thereby shifting the burden of proof to the EPA Administrator to establish that a facility is not a VSQG. Facilities with more than 20 beds, however, bear the responsibility of demonstrating that they qualify as a VSQG.

If a facility generates total hazardous waste in amounts exceeding the VSQG thresholds, it **must** treat its HWPs in accordance with the management standards of Subpart P.[24] While VSQGs may **opt** to handle their HWPs in accordance with the management standards of Subpart P, they are not required to do so except for the sewering ban and empty container provisions of Subpart P.[25] If a VSQG does not opt to comply with the management standards of Subpart P, its HWPs are subject to the general hazardous waste provisions of 40 C.F.R. § 262.14, which may be less than the requirements of Subpart P. Further, a long-term care facility that is a VSQG may dispose of its HWPs (other than contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector that is registered with the Drug Enforcement Administration (DEA), provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable regulations for controlled substances.[26]

Whether a long-term care facility that qualifies as a VSQG opts to treat its HWPs in accordance with the management standards of Subpart P likely will depend on (1) the willingness of the facility to undertake the monthly calculations, monitoring and recordkeeping required to demonstrate that their hazardous waste is within the limits established for VSQGs, or (2) whether the decision not to comply with Subpart P would render the facility subject to more onerous requirements on other hazardous waste that it generates. If a facility also generates non-pharmaceutical RCRA hazardous waste, such as lab wastes for example, those wastes are not regulated under Subpart P but under the existing RCRA regulations. The standard regulations become more stringent as the amount of applicable waste increases. Facilities could decrease the overall amount of waste and thus lessen the impact of the standard regulations by not including the HWPs that are managed instead under Subpart P.[27]

Scope of Obligations under Subpart P - Prescription HWPs versus Non-Prescription HWPs and Non-Creditable Prescription HWPs versus Potentially Creditable Prescription HWPs

Once the determination has been made that a long-term care facility is subject to the management standards of Subpart P, the requirements vary based on whether or not the pharmaceutical required a prescription. For prescription drugs, a facility must determine if it is managing a potentially creditable HWP or a non-creditable HWP. A "potentially creditable hazardous waste pharmaceutical" is a prescription HWP that has a "reasonable expectation to receive manufacturer credit

21 Generating less than or equal to 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris resulting from the clean-up of a spill into or on any land or water, of any acute hazardous wastes listed in 40 C.F.R. §§ 261.31 or 261.33(e) also qualifies as a VSQG.

22 Hazardous waste is the aggregate of HWPs and non-pharmaceutical hazardous waste generated by the facility.

23 See 40 C.F.R. § 261.11(a)(2). A hazardous waste is specifically designated by EPA as "acute" if found to be particularly toxic or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. All P-listed wastes and certain F-listed wastes--F020, F021, F022, F023, F026, and F027--are "acute."

24 Depending on how much hazardous waste is generated above the VSQG thresholds, a facility will either be a Small Quantity Generator or a Large Quantity Generator under RCRA.

25 See section on Generally Applicable Provisions *infra*.

26 See regulatory language to be codified at 40 C.F.R. § 266.504(c). This provision refers to a regulation promulgated in 2014 that governs the disposal of controlled substances. Specifically, that regulation, at 21 C.F.R. § 1317.80 permits a long-term care facility to dispose of controlled substances on behalf of a resident who resides at or has resided at the facility in a collection receptacle placed and maintained by a DEA registrant, such as a pharmacy. See 79 Fed. Reg. 53520 (Sept. 9, 2014). It should be noted, however, that the regulation did not mandate a DEA registrant to place a collection receptacle in a long-term care facility, so the ability of a VSQG facility to take advantage of the DEA exception for HWPs may not always be available.

27 In other words, some facilities will be able to avoid regulatory burdens on the non-pharmaceutical waste if they choose to comply with Subpart P even though they are not obligated to do so.

through reverse distribution and is (1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall) even if opened; (2) undispensed; and (3) unexpired or less than one year past expiration date."[28]

A non-creditable HWP is a prescription pharmaceutical that does not meet the above three criteria and therefore is not likely to receive credit back through reverse distribution. Non-prescription HWPs that do not have a reasonable expectation to be legitimately used, reused or reclaimed are also considered non-creditable HWPs. On the other hand, non-prescription over the counter pharmaceuticals that go through reverse logistics because they have a reasonable

expectation of being recycled are not "Solid Waste" under RCRA at all, and therefore are not subject to Subpart P either. The management standards for potentially creditable HWPs are not as stringent as those for non-creditable HWPs.[29]

Because of the requirement that the pharmaceutical be undispensed, it is likely that only long-term care facilities that have an in-house long-term care pharmacy will be managing potentially creditable HWPs. Those long-term care facilities that contract for their pharmacy services with a long-term care pharmacy will be managing non-creditable HWPs because pharmaceuticals are considered to be dispensed when the order is filled by the external pharmacy.

Unlike the existing general RCRA standards for the management of hazardous wastes, standards for HWPs under the new Subpart P are the same regardless of the amounts generated or the places where they are accumulated.

Management Standards for Non-Creditable HWPs[30]

- **Notification** – A long-term care facility that is subject to the requirements of Subpart P must notify[31] the EPA Regional Administrator within 60 days of the effective date of Subpart P (or within 60 days of becoming subject to Subpart P) that it is a healthcare facility operating under Subpart P, even if the facility already has an EPA Identification Number.[32] Notification may be filed electronically. The facility must keep a copy of the notification on file for as long as the facility is subject to Subpart P. If the facility subsequently qualifies as a VSQG and elects to withdraw from Subpart P, it must so notify the EPA Regional Administrator[33] and may not begin operating under the conditional exemption applicable to VSQGs generally under RCRA until notification has been made. Withdrawal notifications must be kept on file for a period of three (3) years.

- **Training** – All facility personnel that manage HWPs must be trained and be "thoroughly familiar" with proper waste handling and emergency procedures relative to their responsibilities. EPA has not stated whether the agency will offer compliance assistance or training materials to facilities. As a result, because the final rule will become effective six months following publication in the *Federal Register*, facilities should begin exploring their options for training as early as possible.

- **Hazardous Waste Determination** – The facility must determine whether a non-creditable pharmaceutical is a HWP. In lieu of making such a determination, the facility may choose to manage all waste pharmaceuticals as HWPs under Subpart P.

- **Containers** – Because a facility will likely accumulate HWPs for some period of time before shipping them off-site, the final rule prescribes standards for containers that will be used to store HWPs. Generally, any container used to accumulate HWPs must be structurally sound, compatible with its contents, and lack evidence of leakage,

28 See Regulatory language to be codified at 40 C.F.R. § 266.500.

29 For example, there is no accumulation time limit, container management standards, labeling requirements or manifest requirements for potentially creditable HWPs that are sent to a reverse distributor. For a discussion of the management standards that are applicable to potentially creditable HWPs, see *infra*.

30 See regulatory language to be codified at 40 C.F.R. §§ 266.502, 266.508.

31 Using EPA's Site Identification Form 8700-12. The form can be used both to obtain an EPA identification number and make the required notification that the facility is subject to Subpart P.

32 The one exception is for a facility that is regulated as a Large Quantity Generator because of non-pharmaceutical hazardous wastes, in which event the facility will only need to provide Subpart P notification as part of its RCRA Biennial Report.

33 Also using EPA Form 8700-12.

spillage, or damage that could cause leakage under reasonably foreseeable conditions.[34] Such container must be kept closed and secured so as to prevent unauthorized access to its contents.

- **Labeling Containers** – All containers used to accumulate HWP must be labeled or clearly marked with the phrase "Hazardous Waste Pharmaceuticals."

- **Maximum Accumulation Time** – A facility may accumulate non-creditable HWPs on-site for a period not to exceed one year without a permit.[35] The period begins on the date the pharmaceutical first becomes a waste and the facility is responsible for demonstrating how long HWPs have been accumulating. The final rule allows the facility to make this demonstration by marking/labeling the container, maintaining an inventory system or by placing the HWPs in a specific area and identifying the earliest date that any of the HWPs in that area became a waste. To the extent that any HWPs are able to be commingled safely in a container, the date on which the very first HWP was deposited in the container would start the one year clock running.

- **Land Disposal Restrictions** – A facility must comply with extensive requirements pertaining to land disposal restrictions at 40 C.F.R. Section 268.7(a), but these have been relaxed to the extent that the individual waste codes no longer need to be identified on the land disposal restriction notification.

- **Shipping** – As noted above, a long-term care facility may accumulate non-creditable HWPs on-site only for a limited time before it must ship them off-site to a pre-designated authorized facility for treatment, storage or disposal. The final rule includes specific requirements for such shipments.

    - Pre-Transport
        - Packaging, Labeling and Marking – Generally, all waste must be packaged, labeled and marked in accordance with applicable Department of Transportation (DOT) regulations.[36]
            - Containers of 119 gallons or less must be marked with specific words and information, including "HAZARDOUS WASTE."[37]
            - With limited exceptions specified in the final rule,[38] lab packs that will be incinerated are not required to be marked with EPA Hazardous Waste Numbers.
        - Placarding – A long-term care facility must placard or offer the initial transporter the appropriate placards as specified under DOT regulations.[39]
    - Manifests - A facility must use a uniform manifest[40] and comply with applicable manifest requirements except that instead of listing the individual waste codes, the facility should write "PHARMS" on the form.[41]
    - Facilities may ship HWPs across state lines, but will only be able to use the provisions in Subpart P if both states have adopted the same regulations (see below).[42]

- **Managing Rejected Shipments** – A long-term care facility will need to ship any rejected shipments of non-creditable HWPs to a new designated and authorized facility within 90 days of their return.

- **Reporting** – There is no requirement to report the amounts of HWPs generated at a facility unless specifically requested by the EPA. Other than the initial notification, the only report required under the new rule is when the

34 EPA commentary in the preamble to the rule notes that a plastic bag can be a "container" if it meets all of the standards. The regulatory language to be codified at 40 C.F.R. § 266.502(d)(2) contains specific additional container requirements with respect to HWPs that are incompatible, ignitable or reactive, or subject to particular disposal restrictions.

35 The ability to accumulate for a year is a significant change from the existing general RCRA regulations which only allow accumulation without a permit for 180 or 90 days, depending on the amount of waste.

36 See 49 C.F.R. Parts 173, 178, and 180 (packaging), Part 172, Subpart E (labeling), and Part 172, Subpart D (marking).

37 See 49 C.F.R. § 172.304.

38 See regulatory language to be codified at 40 C.F.R. §266.508(a)(1)(iii)(C).

39 See 49 C.F.R. Part 172, Subpart F.

40 EPA Form 8700-22 available at: https://www.epa.gov/hwgenerators/uniform-hazardous-waste-manifest-instructions-sample-form-and-continuation-sheet. A "Manifest" is a form that must accompany each shipment of hazardous waste from the moment it leaves the generator until it reaches its ultimate destination; it must be signed by the generator, the transporter and the final facility, each of which must keep a copy.

41 See 40 C.F.R. Part 262, Subpart B.

42 Any shipment sent out of the country must meet the export requirements of 40 C.F.R. Part 262 Subpart H.

facility does not receive back a copy of a fully received manifest from the receiving facility in connection with a shipment.

- **Recordkeeping** – A health care facility must keep a copy of each manifest, exception report,[43] and hazardous waste determination test result and analysis for three years. All records must be readily available during an inspection.

- **Response to Spills** – Spills of HWPs must be immediately contained and the cleanup materials managed themselves as HWPs.

- **Accepting Non-Creditable HWPs from an Off-Site Facility that is a VSQG** – A facility may accept non-creditable HWPs from a VSQG, such as when a health care facility returns drugs back to a pharmacy, even though the receiving facility does not have a RCRA permit, if the receiving facility (i) is under the same control as the transferring facility or has a business relationship, (ii) is operating under Subpart P, (iii) manages the new wastes under Subpart P, and (iv) keeps records of the shipment for three years.

Management Standards for Potentially Creditable HWPs[44]

As noted above, because the definition of a potentially creditable HWP requires that a pharmaceutical be undispensed, and the use of a third party long-term care pharmacy results in medication being dispensed to a resident by the pharmacy rather than the facility, most long-term care facilities will not be managing potentially creditable HWPs. However, for those facilities that maintain their own in-house long-term care pharmacy, the requirements of the final rule with respect to potentially creditable HWPs are relevant as the facility is likely to have undispensed prescription medications on hand that can qualify as potentially creditable HWPs that can be sent to a reverse distributor.

- **Accepting Potentially Creditable HWPs from an Off-Site Facility that is a VSQG** – A facility may accept potentially creditable HWPs from a VSQG, such as when a care facility returns drugs back to a pharmacy, even though the receiving facility does not have a RCRA permit, if the receiving facility (i) is under the same control as the transferring facility or has a business relationship, (ii) is operating under Subpart P, (iii) manages the new wastes under Subpart P, and (iv) keeps records of the shipment for three years.

- **Only Potentially Creditable HWPs** – A facility is prohibited from sending hazardous wastes other than potentially creditable HWPs to a reverse distributor.

- **Reporting** – There is no requirement to report the amounts of HWPs generated at a facility unless specifically requested by EPA.

- **Recordkeeping** – A facility that initiates a shipment of potentially creditable HWPs to a reverse distributor must retain for a period of three years paper or electronic records of (i) the confirmation of delivery, and (ii) shipping papers prepared in accordance with DOT regulations.[45] All records must be readily available during an inspection.

- **Response to Spills** - Spills of potentially creditable HWPs must be immediately contained and the cleanup materials managed as <u>non-creditable</u> HWPs.

- **Shipping** – Unlike with respect to a non-creditable HWP, a manifest is <u>not</u> required for shipping potentially creditable HWPs to a reverse distributor. Nevertheless, the facility must comply with all applicable DOT regulations in 49 C.F.R. Parts 171 through 180 for any HWP that meets the definition of “hazardous material” in

43 An exception report is completed by a transferring facility when it does not receive a signed copy of the manifest from the ultimate destination of a shipment.
44 See regulatory language to be codified at 40 C.F.R. §§ 266.503, 266.509.
45 49 C.F.R. Part 172, Subpart C.

49 C.F.R. Section 171.8. Also, the receiving reverse distributor must provide confirmation to the facility that it has received the shipment. If the facility has not received such confirmation within 35 calendar days from the date the potentially creditable HWPs were sent, the facility must contact the carrier and the reverse distributor promptly to report that the confirmation was not received and to determine the status of the potentially creditable HWPs.

Conditional Exemption for HWPs that are Controlled Substances:

The final rule includes a conditional exemption from RCRA requirements[46] for HWPs that are listed on a schedule of controlled substances by the DEA. The conditional exemption will apply if the HWPs are collected, stored, transported, and disposed of in compliance with all applicable DEA regulations for controlled substances,[47] and will be destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of five types of combustion facilities.[48]

Generally Applicable Provisions of Subpart P to all HWPs:

The following provisions apply to all health care facilities, regardless of whether the facilities are managing creditable or non-creditable HWPs or are required to comply with the other provisions of Subpart P.

- **Sewering Ban** - All health care facilities covered by the rule are prohibited from discharging HWPs to a sewer system that passes through to a publicly-owned treatment works.[49]

- **Empty Containers** – Under the new regulations, certain stock, dispensing and unit-dose containers are considered "empty" and therefore not regulated as hazardous waste under RCRA, even if minor pharmaceutical residue remains, if they have been emptied using the practices commonly employed to remove materials from that type of container. This also applies to syringes provided that the contents have been removed by fully depressing the plunger into the patient, another delivery device such as an intravenous bag, or a hazardous waste collection container. Intravenous bags avoid RCRA regulation provided the pharmaceuticals inside have been fully administered to a patient.[50] All other types of containers—whether partially or completely empty—are to be managed as non-creditable HWPs unless they meet the general RCRA empty test for non-acute hazardous wastes.[51]

Over the Counter Nicotine Replacement Therapies:

Nicotine and salts are currently included in the hazardous waste listed code P075.[52] The new rule exempts FDA approved over the counter nicotine replacement therapies, specifically patches, gums, and lozenges, from waste code P075. The rule does not exempt e-cigarettes, nicotine-containing e-liquids or prescription nicotine replacement therapies because they are not regulated in the same way as the exempted methods. Nevertheless, any nicotine replacement therapy that has been used in the manner initially intended is not a "solid waste" under RCRA and therefore is not a "hazardous waste" either.

46 40 C.F.R. Parts 262 through 273
47 See note 23 *supra*.
48 See regulatory language to be codified at 40 C.F.R. § 266.506(b)(3)(i)-(v).
49 See regulatory language to be codified at 40 C.F.R. § 266.505. This new rule supersedes the prior RCRA regulation that exempted sewage to a publicly owned treatment works from the definition of "solid waste." Discharges to septic tanks, privately owned treatment works or federally owned treatment works were already prohibited. Though not required, EPA 'strongly" recommends against sewering non-hazardous waste pharmaceuticals as well.
50 See regulatory language to be codified at 40 C.F.R. § 266.507
51 40 C.F.R. § 261.7.
52 40 C.F.R. § 261.33(e).

Effective Date; Authorized State RCRA Programs:

The final rule will become effective six months following publication in the *Federal Register*, however, many states operate their own hazardous waste program. Once authorized by EPA, state hazardous waste programs operate in lieu of the RCRA regulations, though authorized states are required to adopt new regulations that are more stringent than existing rules. Most provisions of the pharmaceutical waste final rule are more stringent than the current RCRA generator regulations. Accordingly, authorized state programs will be required to adopt those provisions such that the new rule will not take effect in any of those states until it has been adopted and the state regulations updated. In contrast, the ban against HWP disposal in a drain or a toilet will be effective in every state as soon as it is effective under Federal law because the sewering prohibition component of the new rule, also more stringent than existing requirements, was adopted under separate legal authority. States are not required to adopt the part of the rule exempting over-the-counter nicotine replacement therapies are exempted from the hazardous waste requirements because it is less stringent. Also, facilities should be aware that states may include more stringent requirements than those included in the final rule. As a result, facilities will need to monitor adoption and implementation efforts in those states very closely.

Conclusion:

There can be no doubt that EPA's final rule will require health care facilities, particularly long-term care facilities other than assisted living facilities, to navigate the new regulatory framework provided in Subpart P, while still potentially being subject to many other RCRA-related provisions and to regulations from other Federal agencies including the DOT. Additionally, facilities in states that have their own authorized hazardous waste program will need to monitor their state agency to determine exactly which rules apply and when. With an effective date only six months following publication of the final rule in the *Federal Register*, no guarantees of education or compliance assistance from EPA other than three webinars scheduled for February and March, 2019,[53] and steep fines for violations, facilities will be hard-pressed to come up to speed in time. Health care facilities are well advised to begin their efforts now to understand the requirements, draft and implement effective policies and procedures, develop a staff training program, and enter into such contractual relationships as may be necessary to ensure compliance.

53 EPA Live Webinars: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the Hazardous Waste Listing for Nicotine, https://clu-in.org/conf/tio/HazWastePharmaceuticals/

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