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Statutory Authority: 44-56-10 et seq.

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 Law, exempt GA review

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Document No. 4976

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑56‑10 et seq.

61‑79. Hazardous Waste Management Regulations.

**Synopsis:**

The Department of Health and Environmental Control (“Department”) amends R.61‑79, Hazardous Waste Management Regulations, to adopt the Environmental Protection Agency (“EPA”) final rule “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine,” published on February 22, 2019, at 84 FR 5816‑5950. The rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over‑the‑counter Food and Drug Administration (“FDA”)‑approved nicotine replacement therapies.

The Department had a Notice of Drafting published in the April 24, 2020, *South Carolina State Register*.

**Instructions:**

Amend R.61-79 pursuant to each individual instruction provided with the text of the amendments below.

**Text:**

61‑79. Hazardous Waste Management Regulations.

(Statutory Authority: 1976 Code Ann. Section 44‑56‑30)

**Revise 261.4(a)(1)(ii) to read:**

 (ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly owned treatment works for treatment, except as prohibited by Section 266.505 and Clean Water Act requirements at R.61‑9.403.5(b)(1). “Domestic sewage” means untreated sanitary wastes that pass through a sewer system.

**Add** **261.7(c) to read:**

 (c) Containers of hazardous waste pharmaceuticals are subject to section 266.507 for determining when they are considered empty, in lieu of this section, except as provided by sections 266.507(c) and (d).

**Revise 261.33(c) and comment to read:**

 (c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in Section 261.7(b) or 266.507 of this chapter.

[Comment: Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re‑use, recycling or reclamation, the Department considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re‑use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

**Revise the entries in 261.33(e) Table to read:**

| **Section 261.33(e) Lists of Acute Hazardous Wastes**  |
| --- |
| Hazardous waste No. | Chemical abstracts No. | Substance |
| P023 | 107‑20‑0 | Acetaldehyde, chloro‑ |
| P002 | 591‑08‑2 | Acetamide, N‑(aminothioxomethyl)‑ |
| P057 | 640‑19‑7 | Acetamide, 2‑fluoro‑ |
| P058 | 62‑74‑8 | Acetic acid, fluoro‑, sodium salt |
| P002 | 591‑08‑2 | 1‑Acetyl‑2‑thiourea |
| P003 | 107‑02‑8 | Acrolein |
| P070 | 116‑06‑3 | Aldicarb |
| P203 | 1646‑88‑4 | Aldicarb sulfone |
| P004 | 309‑00‑2 | Aldrin |
| P005 | 107‑18‑6 | Allyl alcohol |
| P006 | 20859‑73‑8 | Aluminum phosphide (R,T) |
| P007 | 2763‑96‑4 | 5‑(Aminomethyl)‑3‑isoxazolol |
| P008 | 504‑24‑5 | 4‑Aminopyridine |
| P009 | 131‑74‑8 | Ammonium picrate (R) |
| P119 | 7803‑55‑6 | Ammonium vanadate |
| P099 | 506‑61‑6 | Argentate(1‑), bis(cyano‑C)‑, potassium |
| P010 | 7778‑39‑4 | Arsenic acid H3 AsO4 |
| P012 | 1327‑53‑3 | Arsenic oxide As2 O3 |
| P011 | 1303‑28‑2 | Arsenic oxide As2 O5 |
| P011 | 1303‑28‑2 | Arsenic pentoxide |
| P012 | 1327‑53‑3 | Arsenic trioxide |
| P038 | 692‑42‑2 | Arsine, diethyl‑ |
| P036 | 696‑28‑6 | Arsonous dichloride, phenyl‑ |
| P054 | 151‑56‑4 | Aziridine |
| P067 | 75‑55‑8 | Aziridine, 2‑methyl‑ |
| P013 | 542‑62‑1 | Barium cyanide |
| P024 | 106‑47‑8 | Benzenamine, 4‑chloro‑ |
| P077 | 100‑01‑6 | Benzenamine, 4‑nitro‑ |
| P028 | 100‑44‑7 | Benzene, (chloromethyl)‑ |
| P042 | 51‑43‑4 | 1,2‑Benzenediol, 4‑[1‑hydroxy‑2‑(methylamino)ethyl]‑, (R)‑ |
| P046 | 122‑09‑8 | Benzeneethanamine, alpha,alpha‑dimethyl‑ |
| P014 | 108‑98‑5 | Benzenethiol |
| P127 | 1563‑66‑2 | 7‑Benzofuranol, 2,3‑dihydro‑2,2‑dimethyl‑, methylcarbamate |
| P188 | 57‑64‑7 | Benzoic acid, 2‑hydroxy‑, compd. with (3aS‑cis)‑1,2,3,3a,8,8a‑hexahydro‑1,3a,8‑trimethylpyrrolo[2,3‑b]indol‑5‑yl methylcarbamate ester (1:1) |
| P001 | 1 81‑81‑2 | 2H‑1‑Benzopyran‑2‑one, 4‑hydroxy‑3‑(3‑oxo‑1‑phenylbutyl)‑, & salts, when present at concentrations greater than 0.3% |
| P028 | 100‑44‑7 | Benzyl chloride |
| P015 | 7440‑41‑7 | Beryllium powder |
| P017 | 598‑31‑2 | Bromoacetone |
| P018 | 357‑57‑3 | Brucine |
| P045 | 39196‑18‑4 | 2‑Butanone, 3,3‑dimethyl‑1‑(methylthio)‑, O‑[(methylamino)carbonyl] oxime |
| P021 | 592‑01‑8 | Calcium cyanide |
| P021 | 592‑01‑8 | Calcium cyanide Ca(CN)2 |
| P189 | 55285‑14‑8 | Carbamic acid, [(dibutylamino)‑ thio]methyl‑, 2,3‑dihydro‑2,2‑dimethyl‑ 7‑benzofuranyl ester. |
| P191 | 644‑64‑4 | Carbamic acid, dimethyl‑, 1‑[(dimethyl‑amino) carbonyl]‑ 5‑methyl‑1H‑ pyrazol‑3‑yl ester |
| P192 | 119‑38‑0 | Carbamic acid, dimethyl‑, 3‑methyl‑1‑ (1‑methylethyl)‑1H‑ pyrazol‑5‑yl ester. |
| P190 | 1129‑41‑5 | Carbamic acid, methyl‑, 3‑methylphenyl ester |
| P127 | 1563‑66‑2 | Carbofuran |
| P022 | 75‑15‑0 | Carbon disulfide |
| P095 | 75‑44‑5 | Carbonic dichloride |
| P189 | 55285‑14‑8 | Carbosulfan |
| P023 | 107‑20‑0 | Chloroacetaldehyde |
| P024 | 106‑47‑8 | p‑Chloroaniline |
| P026 | 5344‑82‑1 | 1‑(o‑Chlorophenyl)thiourea |
| P027 | 542‑76‑7 | 3‑Chloropropionitrile |
| P029 | 544‑92‑3 | Copper cyanide |
| P029 | 544‑92‑3 | Copper cyanide Cu(CN) |
| P202 | 64‑00‑6 | m‑Cumenyl methylcarbamate. |
| P030 |  | Cyanides (soluble cyanide salts), not otherwise specified |
| P031 | 460‑19‑5 | Cyanogen |
| P033 | 506‑77‑4 | Cyanogen chloride |
| P033 | 506‑77‑4 | Cyanogen chloride (CN)Cl |
| P034 | 131‑89‑5 | 2‑Cyclohexyl‑4,6‑dinitrophenol |
| P016 | 542‑88‑1 | Dichloromethyl ether |
| P036 | 696‑28‑6 | Dichlorophenylarsine |
| P037 | 60‑57‑1 | Dieldrin |
| P038 | 692‑42‑2 | Diethylarsine |
| P041 | 311‑45‑5 | Diethyl‑p‑nitrophenyl phosphate |
| P040 | 297‑97‑2 | O,O‑Diethyl O‑pyrazinyl phosphorothioate |
| P043 | 55‑91‑4 | Diisopropylfluorophosphate (DFP) |
| P004 | 309‑00‑2 | 1,4,5,8‑Dimethanonaphthalene, 1,2,3,4,10,10‑hexa‑ chloro‑1,4,4a,5,8,8a,‑hexahydro‑, (1alpha,4alpha,4abeta,5alpha,8alpha,8abeta)‑ |
| P060 | 465‑73‑6 | 1,4,5,8‑Dimethanonaphthalene, 1,2,3,4,10,10‑hexa‑ chloro‑1,4,4a,5,8,8a‑hexahydro‑, (1alpha,4alpha,4abeta,5beta,8beta,8abeta)‑ |
| P037 | 60‑57‑1 | 2,7:3,6‑Dimethanonaphth[2,3‑b]oxirene, 3,4,5,6,9,9‑hexachloro‑1a,2,2a,3,6,6a,7,7a‑octahydro‑, (1aalpha,2beta,2aalpha,3beta,6beta,6aalpha,7beta, 7aalpha)‑ |
| P051 | 1 72‑20‑8 | 2,7:3,6‑Dimethanonaphth [2,3‑b]oxirene, 3,4,5,6,9,9‑hexachloro‑1a,2,2a,3,6,6a,7,7a‑octahydro‑, (1aalpha,2beta,2abeta,3alpha,6alpha,6abeta,7beta, 7aalpha)‑, & metabolites |
| P044 | 60‑51‑5 | Dimethoate |
| P046 | 122‑09‑8 | alpha,alpha‑Dimethylphenethylamine |
| P191 | 644‑64‑4 | Dimetilan |
| P047 | 1 534‑52‑1 | 4,6‑Dinitro‑o‑cresol, & salts |
| P048 | 51‑28‑5 | 2,4‑Dinitrophenol |
| P020 | 88‑85‑7 | Dinoseb |
| P085 | 152‑16‑9 | Diphosphoramide, octamethyl‑ |
| P111 | 107‑49‑3 | Diphosphoric acid, tetraethyl ester |
| P039 | 298‑04‑4 | Disulfoton |
| P049 | 541‑53‑7 | Dithiobiuret |
| P185 | 26419‑73‑8 | 1,3‑Dithiolane‑2‑carboxaldehyde, 2,4‑dimethyl‑, O‑ [(methylamino)‑ carbonyl]oxime. |
| P050 | 115‑29‑7 | Endosulfan |
| P088 | 145‑73‑3 | Endothall |
| P051 | 72‑20‑8 | Endrin |
| P051 | 72‑20‑8 | Endrin, & metabolites |
| P042 | 51‑43‑4 | Epinephrine |
| P031 | 460‑19‑5 | Ethanedinitrile |
| P194 | 23135‑22‑0 | Ethanimidothioic acid, 2‑(dimethylamino)‑N‑[[(methylamino) carbonyl]oxy]‑2‑oxo‑, methyl ester. |
| P066 | 16752‑77‑5 | Ethanimidothioic acid, N‑[[(methylamino)carbonyl]oxy]‑, methyl ester |
| P101 | 107‑12‑0 | Ethyl cyanide |
| P054 | 151‑56‑4 | Ethyleneimine |
| P097 | 52‑85‑7 | Famphur |
| P056 | 7782‑41‑4 | Fluorine |
| P057 | 640‑19‑7 | Fluoroacetamide |
| P058 | 62‑74‑8 | Fluoroacetic acid, sodium salt |
| P198 | 23422‑53‑9 | Formetanate hydrochloride |
| P197 | 17702‑57‑7 | Formparanate. |
| P065 | 628‑86‑4 | Fulminic acid, mercury(2 ) salt (R,T) |
| P059 | 76‑44‑8 | Heptachlor |
| P062 | 757‑58‑4 | Hexaethyl tetraphosphate |
| P116 | 79‑19‑6 | Hydrazinecarbothioamide |
| P068 | 60‑34‑4 | Hydrazine, methyl‑ |
| P063 | 74‑90‑8 | Hydrocyanic acid |
| P063 | 74‑90‑8 | Hydrogen cyanide |
| P096 | 7803‑51‑2 | Hydrogen phosphide |
| P060 | 465‑73‑6 | Isodrin |
| P192 | 119‑38‑0 | Isolan |
| P202 | 64‑00‑6 | 3‑Isopropylphenyl N‑methylcarbamate. |
| P007 | 2763‑96‑4 | 3(2H)‑Isoxazolone, 5‑(aminomethyl)‑ |
| P196 | 15339‑36‑3 | Manganese, bis(dimethylcarbamodithioato‑S,S′)‑, |
| P196 | 15339‑36‑3 | Manganese dimethyldithiocarbamate |
| P092 | 62‑38‑4 | Mercury, (acetato‑O)phenyl‑ |
| P065 | 628‑86‑4 | Mercury fulminate (R,T) |
| P082 | 62‑75‑9 | Methanamine, N‑methyl‑N‑nitroso‑ |
| P064 | 624‑83‑9 | Methane, isocyanato‑ |
| P016 | 542‑88‑1 | Methane, oxybis[chloro‑ |
| P112 | 509‑14‑8 | Methane, tetranitro‑ (R) |
| P118 | 75‑70‑7 | Methanethiol, trichloro‑ |
| P198 | 23422‑53‑9 | Methanimidamide, N,N‑dimethyl‑N′‑[3‑[[(methylamino)‑carbonyl]oxy]phenyl]‑, monohydrochloride |
| P197 | 17702‑57‑7 | Methanimidamide, N,N‑dimethyl‑N′‑[2‑methyl‑4‑[[(methylamino)carbonyl]oxy]phenyl]‑ |
| P050 | 115‑29‑7 | 6,9‑Methano‑2,4,3‑benzodioxathiepin, 6,7,8,9,10,10‑ hexachloro‑1,5,5a,6,9,9a‑hexahydro‑, 3‑oxide |
| P059 | 76‑44‑8 | 4,7‑Methano‑1H‑indene, 1,4,5,6,7,8,8‑heptachloro‑ 3a,4,7,7a‑tetrahydro‑ |
| P199 | 2032‑65‑7 | Methiocarb |
| P066 | 16752‑77‑5 | Methomyl |
| P068 | 60‑34‑4 | Methyl hydrazine |
| P064 | 624‑83‑9 | Methyl isocyanate |
| P069 | 75‑86‑5 | 2‑Methyllactonitrile |
| P071 | 298‑00‑0 | Methyl parathion |
| P190 | 1129‑41‑5 | Metolcarb. |
| P128 | 315‑8‑4 | Mexacarbate |
| P072 | 86‑88‑4 | alpha‑Naphthylthiourea |
| P073 | 13463‑39‑3 | Nickel carbonyl |
| P073 | 13463‑39‑3 | Nickel carbonyl Ni(CO)4, (T‑4)‑ |
| P074 | 557‑19‑7 | Nickel cyanide |
| P074 | 557‑19‑7 | Nickel cyanide Ni(CN)2 |
| P075 | 1 54‑11‑5 | Nicotine & salts (this listing does not include patches, gums, and lozenges that are FDA‑approved over‑the‑counter nicotine replacement therapies) |
| P076 | 10102‑43‑9 | Nitric oxide |
| P077 | 100‑01‑6 | p‑Nitroaniline |
| P078 | 10102‑44‑0 | Nitrogen dioxide |
| P076 | 10102‑43‑9 | Nitrogen oxide NO |
| P078 | 10102‑44‑0 | Nitrogen oxide NO2 |
| P081 | 55‑63‑0 | Nitroglycerine (R) |
| P082 | 62‑75‑9 | N‑Nitrosodimethylamine |
| P084 | 4549‑40‑0 | N‑Nitrosomethylvinylamine |
| P085 | 152‑16‑9 | Octamethylpyrophosphoramide |
| P087 | 20816‑12‑0 | Osmium oxide OsO4, (T‑4)‑ |
| P087 | 20816‑12‑0 | Osmium tetroxide |
| P088 | 145‑73‑3 | 7‑Oxabicyclo[2.2.1]heptane‑2,3‑dicarboxylic acid |
| P194 | 23135‑22‑0 | Oxamyl |
| P089 | 56‑38‑2 | Parathion |
| P034 | 131‑89‑5 | Phenol, 2‑cyclohexyl‑4,6‑dinitro‑ |
| P048 | 51‑28‑5 | Phenol, 2,4‑dinitro‑ |
| P047 | 1 534‑52‑1 | Phenol, 2‑methyl‑4,6‑dinitro‑, & salts |
| P020 | 88‑85‑7 | Phenol, 2‑(1‑methylpropyl)‑4,6‑dinitro‑ |
| P009 | 131‑74‑8 | Phenol, 2,4,6‑trinitro‑, ammonium salt (R) |
| P128 | 315‑18‑4 | Phenol, 4‑(dimethylamino)‑3,5‑dimethyl‑, methylcarbamate (ester) |
| P199 | 2032‑65‑7 | Phenol, (3,5‑dimethyl‑4‑(methylthio)‑, methylcarbamate |
| P202 | 64‑00‑6 | Phenol, 3‑(1‑methylethyl)‑, methyl carbamate. |
| P201 | 2631‑37‑0 | Phenol, 3‑methyl‑5‑(1‑methylethyl)‑, methyl carbamate |
| P092 | 62‑38‑4 | Phenylmercury acetate |
| P093 | 103‑85‑5 | Phenylthiourea |
| P094 | 298‑02‑2 | Phorate |
| P095 | 75‑44‑5 | Phosgene |
| P096 | 7803‑51‑2 | Phosphine |
| P041 | 311‑45‑5 | Phosphoric acid, diethyl 4‑nitrophenyl ester |
| P039 | 298‑04‑4 | Phosphorodithioic acid, O,O‑diethyl S‑[2‑(ethylthio)ethyl] ester |
| P094 | 298‑02‑2 | Phosphorodithioic acid, O,O‑diethyl S‑[(ethylthio)methyl] ester |
| P044 | 60‑51‑5 | Phosphorodithioic acid, O,O‑dimethyl S‑[2‑(methylamino)‑2‑oxoethyl] ester |
| P043 | 55‑91‑4 | Phosphorofluoridic acid, bis(1‑methylethyl) ester |
| P089 | 56‑38‑2 | Phosphorothioic acid, O,O‑diethyl O‑(4‑nitrophenyl) ester |
| P040 | 297‑97‑2 | Phosphorothioic acid, O,O‑diethyl O‑pyrazinyl ester |
| P097 | 52‑85‑7 | Phosphorothioic acid, O‑[4‑[(dimethylamino)sulfonyl]phenyl] O,O‑dimethyl ester |
| P071 | 298‑00‑0 | Phosphorothioic acid, O,O,‑dimethyl O‑(4‑nitrophenyl) ester |
| P204 | 57‑47‑6 | Physostigmine |
| P188 | 57‑64‑7 | Physostigmine salicylate |
| P110 | 78‑00‑2 | Plumbane, tetraethyl‑ |
| P098 | 151‑50‑8 | Potassium cyanide |
| P098 | 151‑50‑8 | Potassium cyanide K(CN) |
| P099 | 506‑61‑6 | Potassium silver cyanide |
| P201 | 2631‑37‑0 | Promecarb |
| P070 | 116‑06‑3 | Propanal, 2‑methyl‑2‑(methylthio)‑, O‑[(methylamino)carbonyl]oxime |
| P203 | 1646‑88‑4 | Propanal, 2‑methyl‑2‑(methyl‑sulfonyl)‑, O‑[(methylamino)carbonyl] oxime |
| P101 | 107‑12‑0 | Propanenitrile |
| P027 | 542‑76‑7 | Propanenitrile, 3‑chloro‑ |
| P069 | 75‑86‑5 | Propanenitrile, 2‑hydroxy‑2‑methyl‑ |
| P081 | 55‑63‑0 | 1,2,3‑Propanetriol, trinitrate (R) |
| P017 | 598‑31‑2 | 2‑Propanone, 1‑bromo‑ |
| P102 | 107‑19‑7 | Propargyl alcohol |
| P003 | 107‑02‑8 | 2‑Propenal |
| P005 | 107‑18‑6 | 2‑Propen‑1‑ol |
| P067 | 75‑55‑8 | 1,2‑Propylenimine |
| P102 | 107‑19‑7 | 2‑Propyn‑1‑ol |
| P008 | 504‑24‑5 | 4‑Pyridinamine |
| P075 | 1 54‑11‑5 | Pyridine, 3‑(1‑methyl‑2‑ pyrrolidinyl),‑ (S)‑, & salts (this listing does not include patches, gums, and lozenges that are FDA‑approved over‑the‑counter nicotine replacement therapies) |
| P204 | 57‑47‑6 | Pyrrolo[2,3‑b]indol‑5‑ol, 1,2,3,3a,8,8a‑hexahydro‑1,3a,8‑trimethyl‑, methylcarbamate (ester), (3aS‑cis)‑ |
| P114 | 12039‑52‑0 | Selenious acid, dithallium(1 ) salt |
| P103 | 630‑10‑4 | Selenourea |
| P104 | 506‑64‑9 | Silver cyanide |
| P104 | 506‑64‑9 | Silver cyanide Ag(CN) |
| P105 | 26628‑22‑8 | Sodium azide |
| P106 | 143‑33‑9 | Sodium cyanide |
| P106 | 143‑33‑9 | Sodium cyanide Na(CN) |
| P108 | 1 57‑24‑9 | Strychnidin‑10‑one, & salts |
| P018 | 357‑57‑3 | Strychnidin‑10‑one, 2,3‑dimethoxy‑ |
| P108 | 1 57‑24‑9 | Strychnine, & salts |
| P115 | 7446‑18‑6 | Sulfuric acid, dithallium(1 ) salt |
| P109 | 3689‑24‑5 | Tetraethyldithiopyrophosphate |
| P110 | 78‑00‑2 | Tetraethyl lead |
| P111 | 107‑49‑3 | Tetraethyl pyrophosphate |
| P112 | 509‑14‑8 | Tetranitromethane (R) |
| P062 | 757‑58‑4 | Tetraphosphoric acid, hexaethyl ester |
| P113 | 1314‑32‑5 | Thallic oxide |
| P113 | 1314‑32‑5 | Thallium oxide Tl2 O3 |
| P114 | 12039‑52‑0 | Thallium(I) selenite |
| P115 | 7446‑18‑6 | Thallium(I) sulfate |
| P109 | 3689‑24‑5 | Thiodiphosphoric acid, tetraethyl ester |
| P045 | 39196‑18‑4 | Thiofanox |
| P049 | 541‑53‑7 | Thioimidodicarbonic diamide [(H2 N)C(S)]2 NH |
| P014 | 108‑98‑5 | Thiophenol |
| P116 | 79‑19‑6 | Thiosemicarbazide |
| P026 | 5344‑82‑1 | Thiourea, (2‑chlorophenyl)‑ |
| P072 | 86‑88‑4 | Thiourea, 1‑naphthalenyl‑ |
| P093 | 103‑85‑5 | Thiourea, phenyl‑ |
| P185 | 26419‑73‑8 | Tirpate |
| P123 | 8001‑35‑2 | Toxaphene |
| P118 | 75‑70‑7 | Trichloromethanethiol |
| P119 | 7803‑55‑6 | Vanadic acid, ammonium salt |
| P120 | 1314‑62‑1 | Vanadium oxide V2 O5 |
| P120 | 1314‑62‑1 | Vanadium pentoxide |
| P084 | 4549‑40‑0 | Vinylamine, N‑methyl‑N‑nitroso‑ |
| P001 | 1 81‑81‑2 | Warfarin, & salts, when present at concentrations greater than 0.3% |
| P205 | 137‑30‑4 | Zinc, bis(dimethylcarbamodithioato‑S,S′)‑, |
| P121 | 557‑21‑1 | Zinc cyanide |
| P121 | 557‑21‑1 | Zinc cyanide Zn(CN)2 |
| P122 | 1314‑84‑7 | Zinc phosphide Zn3 P2, when present at concentrations greater than 10% (R,T) |
| P205 | 137‑30‑4 | Ziram |
|  |  |  |
| P001 | 1 81‑81‑2 | 2H‑1‑Benzopyran‑2‑one, 4‑hydroxy‑3‑(3‑oxo‑1‑phenylbutyl)‑, & salts, when present at concentrations greater than 0.3% |
| P001 | 1 81‑81‑2 | Warfarin, & salts, when present at concentrations greater than 0.3% |
| P002 | 591‑08‑2 | Acetamide, ‑(aminothioxomethyl)‑ |
| P002 | 591‑08‑2 | 1‑Acetyl‑2‑thiourea |
| P003 | 107‑02‑8 | Acrolein |
| P003 | 107‑02‑8 | 2‑Propenal |
| P004 | 309‑00‑2 | Aldrin |
| P004 | 309‑00‑2 | 1,4,5,8‑Dimethanonaphthalene, 1,2,3,4,10,10‑hexa‑chloro‑1,4,4a,5,8,8a,‑hexahydro‑, (1alpha,4alpha,4abeta,5alpha,8alpha,8abeta)‑ |
| P005 | 107‑18‑6 | Allyl alcohol |
| P005 | 107‑18‑6 | 2‑Propen‑1‑ol |
| P006 | 20859‑73‑8 | Aluminum phosphide (R,T) |
| P007 | 2763‑96‑4 | 5‑(Aminomethyl)‑3‑isoxazolol |
| P007 | 2763‑96‑4 | 3(2H)‑Isoxazolone, 5‑(aminomethyl)‑ |
| P008 | 504‑24‑5 | 4‑Aminopyridine |
| P008 | 504‑24‑5 | 4‑Pyridinamine |
| P009 | 131‑74‑8 | Ammonium picrate (R) |
| P009 | 131‑74‑8 | Phenol, 2,4,6‑trinitro‑, ammonium salt (R) |
| P010 | 7778‑39‑4 | Arsenic acid H3 AsO4 |
| P011 | 1303‑28‑2 | Arsenic oxide As2 O5 |
| P011 | 1303‑28‑2 | Arsenic pentoxide |
| P012 | 1327‑53‑3 | Arsenic oxide As2 O3 |
| P012 | 1327‑53‑3 | Arsenic trioxide |
| P013 | 542‑62‑1 | Barium cyanide |
| P014 | 108‑98‑5 | Benzenethiol |
| P014 | 108‑98‑5 | Thiophenol |
| P015 | 7440‑41‑7 | Beryllium powder |
| P016 | 542‑88‑1 | Dichloromethyl ether |
| P016 | 542‑88‑1 | Methane, oxybis[chloro‑ |
| P017 | 598‑31‑2 | Bromoacetone |
| P017 | 598‑31‑2 | 2‑Propanone, 1‑bromo‑ |
| P018 | 357‑57‑3 | Brucine |
| P018 | 357‑57‑3 | Strychnidin‑10‑one, 2,3‑dimethoxy‑ |
| P020 | 88‑85‑7 | Dinoseb |
| P020 | 88‑85‑7 | Phenol, 2‑(1‑methylpropyl)‑4,6‑dinitro‑ |
| P021 | 592‑01‑8 | Calcium cyanide |
| P021 | 592‑01‑8 | Calcium cyanide Ca(CN)2 |
| P022 | 75‑15‑0 | Carbon disulfide |
| P023 | 107‑20‑0 | Acetaldehyde, chloro‑ |
| P023 | 107‑20‑0 | Chloroacetaldehyde |
| P024 | 106‑47‑8 | Benzenamine, 4‑chloro‑ |
| P024 | 106‑47‑8 | p‑Chloroaniline |
| P026 | 5344‑82‑1 | 1‑(o‑Chlorophenyl)thiourea |
| P026 | 5344‑82‑1 | Thiourea, (2‑chlorophenyl)‑ |
| P027 | 542‑76‑7 | 3‑Chloropropionitrile |
| P027 | 542‑76‑7 | Propanenitrile, 3‑chloro‑ |
| P028 | 100‑44‑7 | Benzene, (chloromethyl)‑ |
| P028 | 100‑44‑7 | Benzyl chloride |
| P029 | 544‑92‑3 | Copper cyanide |
| P029 | 544‑92‑3 | Copper cyanide Cu(CN) |
| P030 |  | Cyanides (soluble cyanide salts), not otherwise specified |
| P031 | 460‑19‑5 | Cyanogen |
| P031 | 460‑19‑5 | Ethanedinitrile |
| P033 | 506‑77‑4 | Cyanogen chloride |
| P033 | 506‑77‑4 | Cyanogen chloride (CN)Cl |
| P034 | 131‑89‑5 | 2‑Cyclohexyl‑4,6‑dinitrophenol |
| P034 | 131‑89‑5 | Phenol, 2‑cyclohexyl‑4,6‑dinitro‑ |
| P036 | 696‑28‑6 | Arsonous dichloride, phenyl‑ |
| P036 | 696‑28‑6 | Dichlorophenylarsine |
| P037 | 60‑57‑1 | Dieldrin |
| P037 | 60‑57‑1 | 2,7:3,6‑Dimethanonaphth[2,3‑b]oxirene, 3,4,5,6,9,9‑hexachloro‑1a,2,2a,3,6,6a,7,7a‑octahydro‑, (1aalpha,2beta,2aalpha,3beta,6beta,6aalpha,7beta, 7aalpha)‑ |
| P038 | 692‑42‑2 | Arsine, diethyl‑ |
| P038 | 692‑42‑2 | Diethylarsine |
| P039 | 298‑04‑4 | Disulfoton |
| P039 | 298‑04‑4 | Phosphorodithioic acid, O,O‑diethyl S‑[2‑(ethylthio)ethyl] ester |
| P040 | 297‑97‑2 | O,O‑Diethyl O‑pyrazinyl phosphorothioate |
| P040 | 297‑97‑2 | Phosphorothioic acid, O,O‑diethyl O‑pyrazinyl ester |
| P041 | 311‑45‑5 | Diethyl‑p‑nitrophenyl phosphate |
| P041 | 311‑45‑5 | Phosphoric acid, diethyl 4‑nitrophenyl ester |
| P042 | 51‑43‑4 | 1,2‑Benzenediol, 4‑[1‑hydroxy‑2‑(methylamino)ethyl]‑, (R)‑ |
| P042 | 51‑43‑4 | Epinephrine |
| P043 | 55‑91‑4 | Diisopropylfluorophosphate (DFP) |
| P043 | 55‑91‑4 | Phosphorofluoridic acid, bis(1‑methylethyl) ester |
| P044 | 60‑51‑5 | Dimethoate |
| P044 | 60‑51‑5 | Phosphorodithioic acid, O,O‑dimethyl S‑[2‑(methyl amino)‑2‑oxoethyl] ester |
| P045 | 39196‑18‑4 | 2‑Butanone, 3,3‑dimethyl‑1‑(methylthio)‑, O‑[(methylamino)carbonyl] oxime |
| P045 | 39196‑18‑4 | Thiofanox |
| P046 | 122‑09‑8 | Benzeneethanamine, alpha,alpha‑dimethyl‑ |
| P046 | 122‑09‑8 | alpha,alpha‑Dimethylphenethylamine |
| P047 | 1 534‑52‑1 | 4,6‑Dinitro‑o‑cresol, & salts |
| P047 | 1 534‑52‑1 | Phenol, 2‑methyl‑4,6‑dinitro‑, & salts |
| P048 | 51‑28‑5 | 2,4‑Dinitrophenol |
| P048 | 51‑28‑5 | Phenol, 2,4‑dinitro‑ |
| P049 | 541‑53‑7 | Dithiobiuret |
| P049 | 541‑53‑7 | Thioimidodicarbonic diamide [(H2 N)C(S)]2 NH |
| P050 | 115‑29‑7 | Endosulfan |
| P050 | 115‑29‑7 | 6,9‑Methano‑2,4,3‑benzodioxathiepin, 6,7,8,9,10,10‑hexachloro‑1,5,5a,6,9,9a‑hexahydro‑, 3‑oxide |
| P051 | 1 72‑20‑8 | 2,7:3,6‑Dimethanonaphth [2,3‑b]oxirene, 3,4,5,6,9,9‑hexachloro‑1a,2,2a,3,6,6a,7,7a‑octahydro‑, (1aalpha,2beta,2abeta,3alpha,6alpha,6abeta,7beta, 7aalpha)‑, & metabolites |
| P051 | 72‑20‑8 | Endrin |
| P051 | 72‑20‑8 | Endrin, & metabolites |
| P054 | 151‑56‑4 | Aziridine |
| P054 | 151‑56‑4 | Ethyleneimine |
| P056 | 7782‑41‑4 | Fluorine |
| P057 | 640‑19‑7 | Acetamide, 2‑fluoro‑ |
| P057 | 640‑19‑7 | Fluoroacetamide |
| P058 | 62‑74‑8 | Acetic acid, fluoro‑, sodium salt |
| P058 | 62‑74‑8 | Fluoroacetic acid, sodium salt |
| P059 | 76‑44‑8 | Heptachlor |
| P059 | 76‑44‑8 | 4,7‑Methano‑1H‑indene, 1,4,5,6,7,8,8‑heptachloro‑3a,4,7,7a‑tetrahydro‑ |
| P060 | 465‑73‑6 | 1,4,5,8‑Dimethanonaphthalene, 1,2,3,4,10,10‑hexa‑chloro‑1,4,4a,5,8,8a‑hexahydro‑, (1alpha,4alpha,4abeta,5beta,8beta,8abeta)‑ |
| P060 | 465‑73‑6 | Isodrin |
| P062 | 757‑58‑4 | Hexaethyl tetraphosphate |
| P062 | 757‑58‑4 | Tetraphosphoric acid, hexaethyl ester |
| P063 | 74‑90‑8 | Hydrocyanic acid |
| P063 | 74‑90‑8 | Hydrogen cyanide |
| P064 | 624‑83‑9 | Methane, isocyanato‑ |
| P064 | 624‑83‑9 | Methyl isocyanate |
| P065 | 628‑86‑4 | Fulminic acid, mercury(2 ) salt (R,T) |
| P065 | 628‑86‑4 | Mercury fulminate (R,T) |
| P066 | 16752‑77‑5 | Ethanimidothioic acid, N‑[[(methylamino)carbonyl]oxy]‑, methyl ester |
| P066 | 16752‑77‑5 | Methomyl |
| P067 | 75‑55‑8 | Aziridine, 2‑methyl‑ |
| P067 | 75‑55‑8 | 1,2‑Propylenimine |
| P068 | 60‑34‑4 | Hydrazine, methyl‑ |
| P068 | 60‑34‑4 | Methyl hydrazine |
| P069 | 75‑86‑5 | 2‑Methyllactonitrile |
| P069 | 75‑86‑5 | Propanenitrile, 2‑hydroxy‑2‑methyl‑ |
| P070 | 116‑06‑3 | Aldicarb |
| P070 | 116‑06‑3 | Propanal, 2‑methyl‑2‑(methylthio)‑, O‑[(methylamino)carbonyl]oxime |
| P071 | 298‑00‑0 | Methyl parathion |
| P071 | 298‑00‑0 | Phosphorothioic acid, O,O,‑dimethyl O‑(4‑nitrophenyl) ester |
| P072 | 86‑88‑4 | alpha‑Naphthylthiourea |
| P072 | 86‑88‑4 | Thiourea, 1‑naphthalenyl‑ |
| P073 | 13463‑39‑3 | Nickel carbonyl |
| P073 | 13463‑39‑3 | Nickel carbonyl Ni(CO)4, (T‑4)‑ |
| P074 | 557‑19‑7 | Nickel cyanide |
| P074 | 557‑19‑7 | Nickel cyanide Ni(CN)2 |
| P075 | 1 54‑11‑5 | Nicotine & salts (this listing does not include patches, gums, and lozenges that are FDA‑approved over‑the‑counter nicotine replacement therapies) |
| P075 | 1 54‑11‑5 | Pyridine, 3‑(1‑methyl‑2‑pyrrolidinyl),‑ (S)‑, & salts (this listing does not include patches, gums, and lozenges that are FDA‑approved over‑the‑counter nicotine replacement therapies) |
| P076 | 10102‑43‑9 | Nitric oxide |
| P076 | 10102‑43‑9 | Nitrogen oxide NO |
| P077 | 100‑01‑6 | Benzenamine, 4‑nitro‑ |
| P077 | 100‑01‑6 | p‑Nitroaniline |
| P078 | 10102‑44‑0 | Nitrogen dioxide |
| P078 | 10102‑44‑0 | Nitrogen oxide NO2 |
| P081 | 55‑63‑0 | Nitroglycerine (R) |
| P081 | 55‑63‑0 | 1,2,3‑Propanetriol, trinitrate (R) |
| P082 | 62‑75‑9 | Methanamine, ‑methyl‑N‑nitroso‑ |
| P082 | 62‑75‑9 | N‑Nitrosodimethylamine |
| P084 | 4549‑40‑0 | N‑Nitrosomethylvinylamine |
| P084 | 4549‑40‑0 | Vinylamine, ‑methyl‑N‑nitroso‑ |
| P085 | 152‑16‑9 | Diphosphoramide, octamethyl‑ |
| P085 | 152‑16‑9 | Octamethylpyrophosphoramide |
| P087 | 20816‑12‑0 | Osmium oxide OsO4, (T‑4)‑ |
| P087 | 20816‑12‑0 | Osmium tetroxide |
| P088 | 145‑73‑3 | Endothall |
| P088 | 145‑73‑3 | 7‑Oxabicyclo[2.2.1]heptane‑2,3‑dicarboxylic acid |
| P089 | 56‑38‑2 | Parathion |
| P089 | 56‑38‑2 | Phosphorothioic acid, O,O‑diethyl O‑(4‑nitrophenyl) ester |
| P092 | 62‑38‑4 | Mercury, (acetato‑O)phenyl‑ |
| P092 | 62‑38‑4 | Phenylmercury acetate |
| P093 | 103‑85‑5 | Phenylthiourea |
| P093 | 103‑85‑5 | Thiourea, phenyl‑ |
| P094 | 298‑02‑2 | Phorate |
| P094 | 298‑02‑2 | Phosphorodithioic acid, O,O‑diethyl S‑[(ethylthio)methyl] ester |
| P095 | 75‑44‑5 | Carbonic dichloride |
| P095 | 75‑44‑5 | Phosgene |
| P096 | 7803‑51‑2 | Hydrogen phosphide |
| P096 | 7803‑51‑2 | Phosphine |
| P097 | 52‑85‑7 | Famphur |
| P097 | 52‑85‑7 | Phosphorothioic acid, O‑[4‑[(dimethylamino)sulfonyl]phenyl] O,O‑dimethyl ester |
| P098 | 151‑50‑8 | Potassium cyanide |
| P098 | 151‑50‑8 | Potassium cyanide K(CN) |
| P099 | 506‑61‑6 | Argentate(1‑), bis(cyano‑C)‑, potassium |
| P099 | 506‑61‑6 | Potassium silver cyanide |
| P101 | 107‑12‑0 | Ethyl cyanide |
| P101 | 107‑12‑0 | Propanenitrile |
| P102 | 107‑19‑7 | Propargyl alcohol |
| P102 | 107‑19‑7 | 2‑Propyn‑1‑ol |
| P103 | 630‑10‑4 | Selenourea |
| P104 | 506‑64‑9 | Silver cyanide |
| P104 | 506‑64‑9 | Silver cyanide Ag(CN) |
| P105 | 26628‑22‑8 | Sodium azide |
| P106 | 143‑33‑9 | Sodium cyanide |
| P106 | 143‑33‑9 | Sodium cyanide Na(CN) |
| P108 | 1 157‑24‑9 | Strychnidin‑10‑one, & salts |
| P108 | 1 157‑24‑9 | Strychnine, & salts |
| P109 | 3689‑24‑5 | Tetraethyldithiopyrophosphate |
| P109 | 3689‑24‑5 | Thiodiphosphoric acid, tetraethyl ester |
| P110 | 78‑00‑2 | Plumbane, tetraethyl‑ |
| P110 | 78‑00‑2 | Tetraethyl lead |
| P111 | 107‑49‑3 | Diphosphoric acid, tetraethyl ester |
| P111 | 107‑49‑3 | Tetraethyl pyrophosphate |
| P112 | 509‑14‑8 | Methane, tetranitro‑(R) |
| P112 | 509‑14‑8 | Tetranitromethane (R) |
| P113 | 1314‑32‑5 | Thallic oxide |
| P113 | 1314‑32‑5 | Thallium oxide Tl2 O3 |
| P114 | 12039‑52‑0 | Selenious acid, dithallium(1 ) salt |
| P114 | 12039‑52‑0 | Tetraethyldithiopyrophosphate |
| P115 | 7446‑18‑6 | Thiodiphosphoric acid, tetraethyl ester |
| P115 | 7446‑18‑6 | Plumbane, tetraethyl‑ |
| P116 | 79‑19‑6 | Tetraethyl lead |
| P116 | 79‑19‑6 | Thiosemicarbazide |
| P118 | 75‑70‑7 | Methanethiol, trichloro‑ |
| P118 | 75‑70‑7 | Trichloromethanethiol |
| P119 | 7803‑55‑6 | Ammonium vanadate |
| P119 | 7803‑55‑6 | Vanadic acid, ammonium salt |
| P120 | 1314‑62‑1 | Vanadium oxide V2O5 |
| P120 | 1314‑62‑1 | Vanadium pentoxide |
| P121 | 557‑21‑1 | Zinc cyanide |
| P121 | 557‑21‑1 | Zinc cyanide Zn(CN)2 |
| P122 | 1314‑84‑7 | Zinc phosphide Zn3 P2, when present at concentrations greater than 10% (R,T) |
| P123 | 8001‑35‑2 | Toxaphene |
| P127 | 1563‑66‑2 | 7‑Benzofuranol, 2,3‑dihydro‑2,2‑dimethyl‑, methylcarbamate |
| P127 | 1563‑66‑2 | Carbofuran |
| P128 | 315‑8‑4 | Mexacarbate |
| P128 | 315‑18‑4 | Phenol, 4‑(dimethylamino)‑3,5‑dimethyl‑, methylcarbamate (ester) |
| P185 | 26419‑73‑8 | 1,3‑Dithiolane‑2‑carboxaldehyde, 2,4‑dimethyl‑, O‑[(methylamino)‑carbonyl]oxime |
| P185 | 26419‑73‑8 | Tirpate |
| P188 | 57‑64‑7 | Benzoic acid, 2‑hydroxy‑, compd. with (3aS‑cis)‑1,2,3,3a,8,8a‑hexahydro‑1,3a,8‑trimethylpyrrolo[2,3‑b]indol‑5‑yl methylcarbamate ester (1:1) |
| P188 | 57‑64‑7 | Physostigmine salicylate |
| P189 | 55285‑14‑8 | Carbamic acid, [(dibutylamino)‑thio]methyl‑, 2,3‑dihydro‑2,2‑dimethyl‑7‑benzofuranyl ester |
| P189 | 55285‑14‑8 | Carbosulfan |
| P190 | 1129‑41‑5 | Carbamic acid, methyl‑, 3‑methylphenyl ester |
| P190 | 1129‑41‑5 | Metolcarb |
| P191 | 644‑64‑4 | Carbamic acid, dimethyl‑, 1‑[(dimethyl‑amino)carbonyl]‑5‑methyl‑1H‑pyrazol‑3‑yl ester |
| P191 | 644‑64‑4 | Dimetilan |
| P192 | 119‑38‑0 | Carbamic acid, dimethyl‑, 3‑methyl‑1‑(1‑methylethyl)‑1H‑pyrazol‑5‑yl ester |
| P192 | 119‑38‑0 | Isolan |
| P194 | 23135‑22‑0 | Ethanimidthioic acid, 2‑(dimethylamino)‑N‑[[(methylamino) carbonyl]oxy]‑2‑oxo‑, methyl ester |
| P194 | 23135‑22‑0 | Oxamyl |
| P196 | 15339‑36‑3 | Manganese, bis(dimethylcarbamodithioato‑S,S′)‑, |
| P196 | 15339‑36‑3 | Manganese dimethyldithiocarbamate |
| P197 | 17702‑57‑7 | Formparanate |
| P197 | 17702‑57‑7 | Methanimidamide, N,N‑dimethyl‑N′‑[2‑methyl‑4‑[[(methylamino)carbonyl]oxy]phenyl]‑ |
| P198 | 23422‑53‑9 | Formetanate hydrochloride |
| P198 | 23422‑53‑9 | Methanimidamide, N,N‑dimethyl‑N′‑[3‑[[(methylamino)‑carbonyl]oxy]phenyl]‑monohydrochloride |
| P199 | 2032‑65‑7 | Methiocarb |
| P199 | 2032‑65‑7 | Phenol, (3,5‑dimethyl‑4‑(methylthio)‑, methylcarbamate |
| P201 | 2631‑37‑0 | Phenol, 3‑methyl‑5‑(1‑methylethyl)‑, methyl carbamate |
| P201 | 2631‑37‑0 | Promecarb |
| P202 | 64‑00‑6 | m‑Cumenyl methylcarbamate |
| P202 | 64‑00‑6 | 3‑Isopropylphenyl N‑methylcarbamate |
| P202 | 64‑00‑6 | Phenol, 3‑(1‑methylethyl)‑, methyl carbamate |
| P203 | 1646‑88‑4 | Aldicarb sulfone |
| P203 | 1646‑88‑4 | Propanal, 2‑methyl‑2‑(methyl‑sulfonyl)‑, O‑[(methylamino)carbonyl] oxime |
| P204 | 57‑47‑6 | Physostigmine |
| P204 | 57‑47‑6 | Pyrrolo[2,3‑b]indol‑5‑ol, 1,2,3,3a,8,8a‑hexahydro‑1,3a,8‑trimethyl‑, methylcarbamate (ester), (3aS‑cis)‑ |
| P205 | 137‑30‑4 | Zinc, bis(dimethylcarbamodithioato‑S,S′)‑, |
| P205 | 137‑30‑4 | Ziram |

**Add 262.10(m) to read:**

 (m) All reverse distributors (as defined in Section 266.500) are subject to part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

**Add 262.10(n) to read:**

 (n) Each healthcare facility (as defined in Section 266.500) must determine whether it is subject to part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in Section 261.31 or Section 261.33(e), is subject to part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non‑pharmaceutical hazardous waste, remains subject to Section 262.14 and is not subject to part 266, subpart P, except for Sections 266.505 and 266.507 and the optional provisions of Section 266.504.

**Add 262.13 (c)(9) to read:**

 (9) Is a hazardous waste pharmaceutical, as defined in Section 266.500, that is subject to or managed in accordance with part 266, subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under Section 266.506.

**Add 262.14(a)(5)(ix) to read:**

 (ix) A reverse distributor (as defined in Section 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in Section 266.500).

**Add 262.14(a)(5)(x) to read:**

 (x) A healthcare facility (as defined in Section 266.500) that meets the conditions in Sections 266.502(l) and 266.503(b), as applicable, to accept non‑creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off‑site healthcare facility that is a very small quantity generator.

**Add and reserve 264.1(g)(12) to read:**

 (12) [Reserved]

**Add 264.1(g)(13) to read:**

 (13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

**Add and reserve 265.1(c)(15) to read:**

 (15) [Reserved]

**Add 265.1(c)(16) to read:**

 (16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

**Revise the 266. Table of Contents to read:**

**SUBPART O: [RESERVED]**

**SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS**

266.500. Definitions for this subpart.

266.501. Applicability.

266.502. Standards for healthcare facilities managing non‑creditable hazardous waste pharmaceuticals.

266.503. Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

266.504. Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste.

266.505. Prohibition of sewering hazardous waste pharmaceuticals.

266.506. Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take‑back event or program.

266.507. Residues of hazardous waste pharmaceuticals in empty containers.

266.508. Shipping non‑creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

266.509. Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

266.510. Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

**Add 266.500 to read:**

**266.500. Definitions for this subpart.**

The following definitions apply to this subpart:

“Evaluated hazardous waste pharmaceutical” means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with Section 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

“Hazardous waste pharmaceutical” means a pharmaceutical that is a solid waste, as defined in Section 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261, subpart D. A pharmaceutical is not a solid waste, as defined in Section 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over‑the‑counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in Section 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

“Healthcare facility” means any person that is lawfully authorized to –

(1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) distribute, sell, or dispense pharmaceuticals, including over‑the‑counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third‑party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long‑term care facilities, ambulance services, pharmacies, long‑term care pharmacies, mail‑order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

“Household waste pharmaceutical” means a pharmaceutical that is a solid waste, as defined in Section 261.2, but is excluded from being a hazardous waste under Section 261.4(b)(1).

“Long‑term care facility” means 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.

“Non‑creditable hazardous waste pharmaceutical” means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean‑up material from the spills of pharmaceuticals.

“Non‑hazardous waste pharmaceutical” means a pharmaceutical that is a solid waste, as defined in Section 261.2, and is not listed in part 261, subpart D, and does not exhibit a characteristic identified in part 261, subpart C.

“Non‑pharmaceutical hazardous waste” means a solid waste, as defined in Section 261.2, that is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C, but is not a pharmaceutical, as defined in this Section.

“Pharmaceutical” means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e‑liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre‑filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 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. This definition does not include dental amalgam or sharps.

“Potentially creditable hazardous waste pharmaceutical” means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is‑

(1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(2) undispensed; and

(3) unexpired or less than one year past expiration date.

The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over‑the‑counter drugs, homeopathic drugs, and dietary supplements.

“Reverse distributor” means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third‑party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

**Add 266.501 to read:**

**266.501. Applicability.**

 (a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non‑pharmaceutical hazardous waste, remains subject to Section 262.14 and is not subject to this subpart, except for Sections 266.505 and 266.507 and the optional provisions of Section 266.504.

 (b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non‑pharmaceutical hazardous waste, has the option of complying with Section 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with Section 262.14 and the optional provisions of Section 266.504.

 (c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non‑pharmaceutical hazardous waste.

 (d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to the following in lieu of parts 262–265:

 (1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

 (i) Non‑creditable hazardous waste pharmaceuticals, and

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

 (2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

 (e) A reverse distributor is subject to Sections 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

 (f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

 (g) The following are not subject to parts 260 through 273, except as specified:

 (1) Pharmaceuticals that are not solid waste, as defined by Section 261.2, because they are legitimately used/re‑used (e.g., lawfully donated for their intended purpose) or reclaimed.

 (2) Over‑the‑counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by Section 261.2, because they have a reasonable expectation of being legitimately used/re‑used (e.g., lawfully redistributed for their intended purpose) or reclaimed.

 (3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7, subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

 (4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

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

 (6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration’s regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

 (7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in Sections 266.506(a)(2) and 266.506(b).

**Add 266.502 to read:**

**266.502. Standards for healthcare facilities managing non‑creditable hazardous waste pharmaceuticals.**

 (a) Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals—

(1) Notification. A healthcare facility must notify the Department, using the Site Identification Form (EPA Form 8700‑12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

 (i) A healthcare facility that already has an EPA identification number must notify the Department using the Site Identification Form (EPA Form 8700‑12) that it is a healthcare facility. A large quantity generator must notify the Department in its next quarterly report per Section 262.41. A small quantity generator must notify the Department in its annual declaration per Section 262.44.

 (ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the Department using the Site Identification Form (EPA Form 8700‑12) that it is a healthcare facility within thirty (30) calendar days of the effective date of this subpart or within thirty (30) calendar days of becoming subject to this subpart.

 (iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

 (2) Withdrawal*.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under Section 262.14, and elects to withdraw from this subpart, must notify the Department using the Site Identification Form (EPA Form 8700‑12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

 (i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of Section 262.14.

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

 (b) Training of personnel managing non‑creditable hazardous waste pharmaceuticals at healthcare facilities*.* A healthcare facility must ensure that all personnel that manage non‑creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

 (c) Hazardous waste determination for non‑creditable pharmaceuticals*.* A healthcare facility that generates a solid waste that is a non‑creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in part 261, subpart C or is listed in part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non‑hazardous waste pharmaceuticals as non‑creditable hazardous waste pharmaceuticals under this subpart.

 (d) Standards for containers used to accumulate non‑creditable hazardous waste pharmaceuticals at healthcare facilities.

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

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

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

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

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

 (iv) Damage the structural integrity of the container of non‑creditable hazardous waste pharmaceuticals; or

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

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

 (4) A healthcare facility may accumulate non‑creditable hazardous waste pharmaceuticals and non‑hazardous non‑creditable waste pharmaceuticals in the same container, except that non‑creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of Section 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (i.e., hazardous waste codes).

 (e) Labeling containers used to accumulate non‑creditable hazardous waste pharmaceuticals at healthcare facilities.A healthcare facility must label or clearly mark each container of non‑creditable hazardous waste pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals.”

 (f) Maximum accumulation time for non‑creditable hazardous waste pharmaceuticals at healthcare facilities.

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

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

 (i) Marking or labeling the container of non‑creditable hazardous waste pharmaceuticals with the date that the non‑creditable hazardous waste pharmaceuticals became a waste;

 (ii) Maintaining an inventory system that identifies the date the non‑creditable hazardous waste pharmaceuticals being accumulated first became a waste; or

 (iii) Placing the non‑creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non‑creditable hazardous waste pharmaceuticals in the area became a waste.

 (g) Land disposal restrictions for non‑creditable hazardous waste pharmaceuticals. The non‑creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of part 268. A healthcare facility that generates non‑creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with Section 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the land disposal restrictions notification.

 (h) Procedures for healthcare facilities for managing rejected shipments of non‑creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non‑creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section 264.72 or Section 265.72 of this chapter may accumulate the returned non‑creditable hazardous waste pharmaceuticals on‑site for up to an additional ninety (90) calendar days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

 (1) Sign either:

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

 (ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

 (2) Provide the transporter a copy of the manifest;

 (3) Within thirty (30) calendar days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

 (4) Within ninety (90) calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of Section 266.508(a).

 (i) Reporting by healthcare facilities for non‑creditable hazardous waste pharmaceuticals.

 (1) Reporting by healthcare facilities.Healthcare facilities are not subject to reporting requirements under Section 262.41 or Section 262.44 with respect to non‑creditable hazardous waste pharmaceuticals managed under this subpart.

 (2) Exception reporting by healthcare facilities for a missing copy of the manifest.

 (i) For shipments from a healthcare facility to a designated facility:

 (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within sixty (60) days of the date the non‑creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

 (*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department for the Region in which the healthcare facility is located, and

 (*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non‑creditable hazardous waste pharmaceuticals and the results of those efforts.

 (B) [Reserved]

 (ii) For shipments rejected by the designated facility and shipped to an alternate facility.

 (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non‑creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within sixty (60) days of the date the non‑creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non‑creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

 (*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department for the state in which the healthcare facility is located; and

 (*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non‑creditable hazardous waste pharmaceuticals and the results of those efforts.

 (B) [Reserved]

 (3) Additional reports.The Department may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non‑creditable hazardous waste pharmaceuticals.

 (j) Recordkeeping by healthcare facilities for non‑creditable hazardous waste pharmaceuticals*.*

 (1) A healthcare facility must keep a copy of each manifest signed in accordance with Section 262.23(a) for three (3) years or until it receives a signed copy from the designated facility that received the non‑creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three (3) years from the date the waste was accepted by the initial transporter.

 (2) A healthcare facility must keep a copy of each exception report for a period of at least three (3) years from the date of the report.

 (3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with Section 262.11(f), for at least three (3) years from the date the waste was last sent to on‑site or off‑site treatment, storage, or disposal. A healthcare facility that manages all of its non‑creditable non‑hazardous waste pharmaceuticals as non‑creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

 (4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

 (5) All records must be readily available upon request by an inspector.

 (k) Response to spills of non‑creditable hazardous waste pharmaceuticals at healthcare facilities*.* A healthcare facility must immediately contain all spills of non‑creditable hazardous waste pharmaceuticals and manage the spill clean‑up materials as non‑creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

 (l) Accepting non‑creditable hazardous waste pharmaceuticals from an off‑site healthcare facility that is a very small quantity generator.A healthcare facility may accept non‑creditable hazardous waste pharmaceuticals from an off‑site healthcare facility that is a very small quantity generator under Section 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

 (1) Is under the control of the same person (as defined in Section 260.10) as the very small quantity generator healthcare facility that is sending the non‑creditable hazardous waste pharmaceuticals off‑site (“control,” for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in Section 260.10 of this chapter shall not be deemed to “control” such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

 (2) Is operating under this subpart for the management of its non‑creditable hazardous waste pharmaceuticals;

 (3) Manages the non‑creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

 (4) Keeps records of the non‑creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

**Add 266.503 to read:**

**266.503. Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.**

 (a) Hazardous waste determination for potentially creditable pharmaceuticals.A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is listed in part 261, subpart D or exhibits a characteristic identified in part 261, subpart C). A healthcare facility may choose to manage its potentially creditable non‑hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

 (b) Accepting potentially creditable hazardous waste pharmaceuticals from an off‑site healthcare facility that is a very small quantity generator.A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off‑site healthcare facility that is a very small quantity generator under Section 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

 (1) Is under the control of the same person, as defined in Section 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

 (2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

 (3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

 (4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three (3) years from the date that the shipment is received.

 (c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

 (d) Reporting by healthcare facilities.Healthcare facilities are not subject to reporting requirements under Section 262.41 or Section 262.44 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

 (e) Recordkeeping by healthcare facilities.

 (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three (3) years from the date of shipment:

 (i) The confirmation of delivery; and

 (ii) The shipping papers prepared in accordance with 49 CFR part 172, subpart C, if applicable.

 (2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

 (3) All records must be readily available upon request by an inspector.

 (f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean‑up materials as non‑creditable hazardous waste pharmaceuticals in accordance with this subpart.

**Add 266.504 to read:**

**266.504. Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste.**

 (a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

 (b) Off‑site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off‑site to another healthcare facility, provided:

 (1) The receiving healthcare facility meets the conditions in Section 266.502(l) of this subpart and Section 266.503(b), as applicable; or

 (2) The very small quantity generator healthcare facility meets the conditions in section 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in Section 262.17(f).

 (c) Long‑term care facilities that are very small quantity generators. A long‑term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean‑up materials) in an on‑site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

 (d) Long‑term care facilities with twenty (20) beds or fewer.A long‑term care facility with twenty (20) beds or fewer is presumed to be a very small quantity generator subject to Section 262.14 for both hazardous waste pharmaceuticals and non‑pharmaceutical hazardous waste and not subject to this subpart, except for Sections 266.505 and 266.507 and the other optional provisions of this section. The Department has the responsibility to demonstrate that a long‑term care facility with twenty (20) beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in Section 260.10. A long‑term care facility with more than twenty (20) beds that operates as a very small quantity generator under Section 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by Section 260.10.

**Add 266.505 to read:**

**266.505. Prohibition of sewering hazardous waste pharmaceuticals.**

All healthcare facilities—including very small quantity generators operating under section 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in R.61‑9.403.5(b)(1).

**Add 266.506 to read:**

**266.506. Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take‑back event or program.**

 (a) Conditional exemptions*.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from parts 262 through 273:

 (1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

 (2) Household waste pharmaceuticals that are collected in a take‑back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

 (b) Conditions for exemption.The hazardous waste pharmaceuticals must be:

 (1) Managed in compliance with the sewer prohibition of Section 266.505;

 (2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

 (3) Destroyed by a method that the Drug Enforcement Administration has publicly deemed in writing to meet their non‑retrievable standard of destruction or combusted at one of the following:

 (i) A permitted large municipal waste combustor, subject to 40 CFR part 62, subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60, subpart Eb for new large municipal waste combustors; or

 (ii) A permitted small municipal waste combustor, subject to 40 CFR part 62, subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60, subpart AAAA for new small municipal waste combustors; or

 (iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62, subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60, subpart Ec for new hospital, medical and infectious waste incinerators.

 (iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62, subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60, subpart CCCC for new commercial and industrial solid waste incinerators.

 (v) A permitted hazardous waste combustor subject to 40 CFR part 63, subpart EEE.

**Add 266.507 to read:**

**266.507. Residues of hazardous waste pharmaceuticals in empty containers.**

 (a) Stock, dispensing, and unit‑dose containers.A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit‑dose container (e.g., a unit‑dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit‑dose container using the practices commonly employed to remove materials from that type of container.

 (b) Syringes*.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non‑creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

 (c) Intravenous (IV) bags.An intravenous (IV) bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the intravenous (IV) bag have been fully administered to a patient. If an intravenous (IV) bag is not empty, the intravenous (IV) bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non‑creditable hazardous waste pharmaceutical under this subpart, unless the intravenous (IV) bag held non‑acute hazardous waste pharmaceuticals and is empty as defined in Section 261.7(b)(1).

 (d) Other containers, including delivery devices.Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non‑creditable hazardous waste pharmaceuticals under this subpart, unless the container held non‑acute hazardous waste pharmaceuticals and is empty as defined in Section 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

**Add 266.508 to read:**

**266.508. Shipping non‑creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.**

 (a) Shipping non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility must ship non‑creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off‑site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

 (1) The following pre‑transport requirements, before transporting or offering for transport off‑site:

 (i) Packaging.Package the waste in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

 (ii) Labeling.Label each package in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

 (iii) Marking.

(A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D;

 (B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

“HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility’s or Reverse distributor’s Name and Address \_\_\_\_\_.

Healthcare Facility’s or Reverse distributor’s EPA Identification Number\_\_\_\_\_.

Manifest Tracking Number \_\_\_\_\_.”

 (C) Lab packs that will be incinerated in compliance with Section 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

 (iv) Placarding.Placard or offer the initial transporter the appropriate placards according to U.S. Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

 (2) The manifest requirements of part 262, subpart B, except that:

 (i) A healthcare facility shipping non‑creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700‑22.

 (ii) A healthcare facility shipping non‑creditable hazardous waste pharmaceuticals must write the word “PHARMS” in Item 13 of EPA Form 8700‑22.

 (b) Exporting non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.A healthcare facility or reverse distributor that exports non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262, subpart H.

 (c) Importing non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals*.* Any person that imports non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262, subpart H. A healthcare facility or reverse distributor may not accept imported non‑creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

**Add 266.509 to read:**

**266.509. Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.**

 (a) Shipping potentially creditable hazardous waste pharmaceuticals*.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off‑site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the U.S. Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the U.S. Department of Transportation regulations.

 (b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

 (c) Procedures for when delivery confirmation is not received within thirty‑five (35) calendar days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within thirty‑five (35) calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

 (d) Exporting potentially creditable hazardous waste pharmaceuticals*.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of part 262, subpart H, except the manifesting requirement of Section 262.83(c), in addition to paragraphs (a) through (c) of this section.

 (e) Importing potentially creditable hazardous waste pharmaceuticals.Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of part 262, subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

**Add 266.510 to read:**

**266.510. Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.**

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

 (a) Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals—

 (1) Notification*.* A reverse distributor must notify the Department, using the Site Identification Form (EPA Form 8700‑12), that it is a reverse distributor operating under this subpart.

 (i) A reverse distributor that already has an EPA identification number must notify the Department, using the Site Identification Form (EPA Form 8700‑12), that it is a reverse distributor, as defined in section 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

 (ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the Department, using the Site Identification Form (EPA Form 8700‑12), that it is a reverse distributor, as defined in Section 266.500, within sixty (60) calendar days of the effective date of this subpart, or within sixty (60) calendar days of becoming subject to this subpart.

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

 (i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within thirty (30) calendar days of each waste arriving at the reverse distributor.

 (ii) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

 (iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

 (3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within thirty (30) calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

 (i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a “potentially creditable hazardous waste pharmaceutical” and must be managed in accordance with paragraph (b) of this section.

 (ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage, or disposal facility is considered an “evaluated hazardous waste pharmaceutical” and must be managed in accordance with paragraph (c) of this section.

 (4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within thirty (30) calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

 (5) Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.

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

 (ii) Aging pharmaceuticals.Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in Section 266.510(c)(4)(i)‑(vi).

 (6) Security at the reverse distributor facility*.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

 (i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

 (A) A 24‑hour continuous monitoring surveillance system;

 (B) An artificial barrier such as a fence; or

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

 (ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

 (7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off‑site must prepare a contingency plan and comply with the other requirements of part 262, subpart M.

 (8) Closure of a reverse distributor*.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with Section 262.17(a)(8)(ii) and (iii).

 (9) Reporting by a reverse distributor.

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

 (A) The EPA identification number, name and address of the reverse distributor;

 (B) The date the reverse distributor received the unauthorized waste;

 (C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

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

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

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

 (ii) Additional reports*.* The Department may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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

 (i) A copy of its notification on file for as long as the facility is subject to this subpart;

 (ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three (3) years from the date the shipment arrives at the reverse distributor;

 (iii) A copy of its current inventory for as long as the facility is subject to this subpart.

 (b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor*.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

 (1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within one hundred eighty (180) calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

 (2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within one hundred eighty (180) calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

 (3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section 266.509.

 (4) Recordkeeping by reverse distributors*.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three (3) years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

 (i) The confirmation of delivery; and

 (ii) The DOT shipping papers prepared in accordance with 49 CFR part 172, subpart C, if applicable.

 (c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

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

 (2) Inspections of on‑site accumulation area*.* A reverse distributor must inspect its on‑site accumulation area at least once every seven (7) calendar days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

 (3) Personnel training at a reverse distributor*.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of Section 262.17(a)(7).

 (4) Labeling and management of containers at on‑site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on‑site accumulation area must:

 (i) Label the containers with the words, “hazardous waste pharmaceuticals”;

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

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

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

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

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

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

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

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

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

 (vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of Section 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

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

 (6) Shipments*.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage, or disposal facility in accordance with the applicable shipping standards in Section 266.508(a) or (b).

 (7) Procedures for a reverse distributor for managing rejected shipments*.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section 264.72 or Section 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on‑site for up to an additional ninety (90) calendar days in the on‑site accumulation area provided the rejected or returned shipment is managed in accordance withSections 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

 (i) Sign either:

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

 (B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

 (ii) Provide the transporter a copy of the manifest;

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

 (iv) Within ninety (90) calendar days of receipt of the rejected shipment, transport, or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Section 266.508(a) or (b).

 (8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off‑site must comply with the land disposal restrictions in accordance with Section 268.7(a) requirements.

 (9) Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals.

 (i) Reporting by a reverse distributor. A reverse distributor that ships more than 1,000 kg per month of evaluated hazardous waste pharmaceuticals off‑site must report to the Department in its quarterly report per Section 262.41. A reverse distributor that ships less than 1,000 kg per month of evaluated hazardous waste pharmaceuticals off‑site must report to the Department in its annual declaration per Section 262.44.

 (ii) Exception reporting by a reverse distributor for a missing copy of the manifest.

 (A) For shipments from a reverse distributor to a designated facility.

 (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within thirty‑five (35) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

 (*2*) A reverse distributor must submit an exception report to the Department for the state in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within forty‑five (45) calendar days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

 (*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

 (*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

 (B) For shipments rejected by the designated facility and shipped to an alternate facility.

 (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within thirty‑five (35) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The thirty‑five (35)‑day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

 (*2*) A reverse distributor must submit an exception report to the Department for the state in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within forty‑five (45) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The forty‑five (45)‑day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The exception report must include:

 (*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

 (*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

 (10) Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.

 (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on‑site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three (3) years from the date of the inspection.

 (ii) A reverse distributor must keep a copy of each manifest signed in accordance with Section 262.23(a) for three (3) years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three (3) years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

 (iii) A reverse distributor must keep a copy of each quarterly report or annual declaration for at least three (3) years from the due date of the report or declaration.

 (iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

 (v) A reverse distributor must keep records to document personnel training, in accordance with Section 262.17(a)(7)(iv).

 (vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

 (d) When a reverse distributor must have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of parts 264, 265, and the permit requirements of part 270, if the reverse distributor:

 (1) Does not meet the conditions of this section;

 (2) Accepts manifested hazardous waste from off site; or

 (3) Treats or disposes of hazardous waste pharmaceuticals on‑site.

**Revise 268.7 title and item (a) to read:**

268.7. Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

 (a) Requirements for generators and reverse distributors:

**Add 268.50(a)(4) and (5) to read:**

 (4) A healthcare facility accumulates such wastes in containers on‑site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in Sections 266.502 and 266.503 of this chapter.

 (5) A reverse distributor accumulates such wastes in containers on‑site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with Section 266.510 of this chapter.

**Revise 270.1(c)(2)(x) to read:**

 (x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

**Add 270.1(c)(2)(xi) to read:**

 (xi) Any transporter who moves hazardous waste only on the site of a hazardous waste generator or a permitted hazardous waste treatment, storage or disposal facility.

**Revise 273.80(a) to read:**

 (a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or a category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 260.20 and 260.23.

**Add 273.80(d) to read:**

 (d) Hazardous waste pharmaceuticals are regulated by part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

**Statement of Need and Reasonableness:**

The following presents an analysis of the factors listed in 1976 Code Sections 1‑23‑115(C)(1)‑(3) and (9)‑(11):

DESCRIPTION OF REGULATION: 61‑79, Hazardous Waste Management Regulations.

Purpose: The purpose of these amendments is to maintain state consistency with the following EPA regulation published in the Federal Register: “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine” rule, published on February 22, 2019, at 84 FR 5816‑5950.

Legal Authority: 1976 Code Sections 44‑56‑10 et seq.

Plan for Implementation: The Department’s Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to this amendment. Additionally, printed copies are available for a fee from the Department’s Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendment and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department adopts the “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine” rule, published on February 22, 2019, at 84 FR 5816‑5950. This rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over‑the‑counter FDA‑approved nicotine replacement therapies. Adoption of this rule is required to comply with federal law and brings R.61‑79 into conformity with the federal regulations.

DETERMINATION OF COSTS AND BENEFITS:

The EPA estimates that the annualized cost to industry to comply with the requirements will be off‑set by the cost‑savings resulting from streamlined management standards for healthcare facilities and regulatory relief with regards to FDA‑approved over‑the‑counter nicotine replacement therapy products (Federal Register, Vol. 84, No. 36, page 5818). The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the state or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The revisions to R.61‑79 provide continued protection of the environment and human health in accordance with updates to federal law.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

If the Department does not adopt these amendments, the EPA’s delegation of authority to the state to implement environmental protection programs would be compromised. As a delegated state program, the EPA requires South Carolina’s regulations be at least as stringent as the federal regulations. Adoption of these revisions ensure equivalency with federal requirements.