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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Underground Storage Tanks and Solid Waste Disposal Control Board
Division:	Solid Waste Management
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0400-12-01	Hazardous Waste Management
Rule Number	Rule Title
0400-12-01-.01	Hazardous Waste Management System: General
0400-12-01-.02	Identification and Listing of Hazardous Waste
0400-12-01-.03	Notification Requirements and Standards Applicable to Generators of Hazardous Waste
0400-12-01-.05	Interim Status Standards for Owners and Operators of Existing Hazardous Waste Treatment, Storage, and Disposal Facilities
0400-12-01-.06	Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
0400-12-01-.07	Permitting of Hazardous Waste Treatment, Storage, and Disposal Facilities
0400-12-01-.08	Fee System for Transporters, Storers, Treaters, Disposers, and Certain Generators of Hazardous Waste and for Certain Used Oil Facilities or Transporters
0400-12-01-.09	Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities
0400-12-01-.10	Land Disposal Restrictions
0400-12-01-.12	Standards for Universal Waste Management

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to <https://sos.tn.gov/products/division-publications/rulemaking-guidelines>.

Chapter 0400-12-01
Hazardous Waste Management

Amendments

Subparagraph (a) of paragraph (2) of Rule 0400-12-01-.01 Hazardous Waste Management System: General is amended by modifying the definitions of “battery,” “destination facility,” “FIFRA,” “lamp,” “large quantity handler of universal waste,” “mercury-containing equipment,” “pesticide,” “small quantity handler of universal waste,” “universal waste transfer facility,” and “universal waste transporter” to read as follows while remaining in alphabetical order.

~~“Battery” means a device consisting of one or more electrically connected electrochemical cells which is designed to receive, store, and deliver electric energy. An electrochemical cell is a system consisting of an anode, cathode, and an electrolyte, plus such connections (electrical and mechanical) as may be needed to allow the cell to deliver or receive electrical energy. The term battery also includes an intact, unbroken battery from which the electrolyte has been removed battery as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Destination facility” means a facility that treats, disposes of, or recycles a particular category of universal waste, except those management activities described in parts (2)(d)1 and 3 and (3)(d)1 and 3 of Rule 0400-12-01-.12. A facility at which a particular category of universal waste is only accumulated, is not a destination facility for purposes of managing that category of universal waste destination facility as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“FIFRA” means the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136y) FIFRA as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Lamp,” also referred to as “universal waste lamp,” is defined as the bulb or tube portion of an electric lighting device. A lamp is specifically designed to produce radiant energy, most often in the ultraviolet, visible, and infra-red regions of the electromagnetic spectrum. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high pressure sodium, and metal halide lamps means lamp as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Large Quantity Handler of Universal Waste quantity handler of universal waste” means a universal waste handler (as defined in this subparagraph) who accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, or lamps calculated collectively) at any time. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which 5,000 kilograms or more total of universal waste is accumulated large quantity handler of universal waste as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Mercury-containing equipment” means a device or part of a device (including thermostats, but excluding batteries and lamps) that contains elemental mercury integral to its function mercury-containing equipment as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Pesticide” means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that: pesticide as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~1. — is a new animal drug under FFDCA section 201(w), or~~

~~2. — is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or~~

~~3. Is an animal feed under FFDC section 201(x) that bears or contains any substances described by parts 1 or 2 of this definition.~~

~~“Small Quantity Handler of Universal Waste quantity handler of universal waste” means a universal waste handler (as defined in this subparagraph) who does not accumulate more than 5,000 kilograms total of universal waste (batteries, pesticides, thermostats, or lamps calculated collectively) at any time small quantity handler of universal waste as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Universal Waste Transfer Facility waste transfer facility” means any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of universal waste are held during the normal course of transportation for ten days or less universal waste transfer facility as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

~~“Universal Waste Transporter waste transporter” means a person engaged in the off-site transportation of universal waste by air, rail, highway, or water universal waste transporter as defined in subparagraph (1)(i) of Rule 0400-12-01-.12.~~

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Subpart (i) of part 1 of subparagraph (d) of paragraph (1) of Rule 0400-12-01-.02 Identification and Listing of Hazardous Waste is amended by deleting it in its entirety and substituting instead the following:

- (i) (I) Domestic sewage; and
- (II) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works (POTW) for treatment, except as prohibited by subparagraph (16)(f) of Rule 0400-12-01-.09 and Clean Water Act requirements at 40 CFR 403.5(b). “Domestic sewage” means untreated sanitary wastes that pass through a sewer system.

(Comment: This exclusion does not exclude waste/wastewaters while they are being generated, collected, stored, or treated before entering the sewer system. This exclusion applies when the material enters the sewer system where it will mix with sanitary wastes at any point before reaching the POTW whereupon this material is regulated under water pollution statutes and regulations. This material is subject to all applicable reporting, monitoring, and permitting requirements of the T.C.A. §§ 68-221-101, ~~69-3-101, et seq. 69-3-101 to -148~~ and the associated regulations. Management of this material must be in compliance with all applicable authorization (permits, etc.) associated with disposal into a POTW for subsequent treatment.)

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Subparagraph (g) of paragraph (1) of Rule 0400-12-01-.02 Identification and Listing of Hazardous Waste is amended by adding part 3 following part 2 to read as follows:

3. Containers of hazardous waste pharmaceuticals are subject to subparagraph (16)(h) of Rule 0400-12-01-.09 for determining when they are considered empty, in lieu of this subparagraph, except as provided by parts (16)(h)3 and 4 of Rule 0400-12-01-.09.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 3 of subparagraph (d) of paragraph (4) of Rule 0400-12-01-.02 Identification and Listing of Hazardous Waste is amended by deleting it in its entirety and substituting instead the following:

- 3. 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 part 5 or 6 of this subparagraph, unless the container is

empty as defined in [part \(1\)\(g\)2 of Rule 0400-12-01-.02\(1\)\(g\)2 or subparagraph \(16\)\(h\) of Rule 0400-12-01-.09.](#)

(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.)

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 5 of subparagraph (d) of paragraph (4) of Rule 0400-12-01-.02 Identification and Listing of Hazardous Waste is amended by deleting it in its entirety and substituting instead the following:

5. The commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates referred to in parts 1 through 4 of this subparagraph, are identified as acute hazardous wastes (H) and are subject to the small quantity exclusion defined in part (1)(e)5 and 6 of this rule.

(Comment: For the convenience of the regulated community the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), and R (Reactivity). Absence of a letter indicates that the compound only is listed for acute toxicity.)

These wastes and their corresponding Hazardous Waste Codes are:

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 H ₃ AsO ₄

P012	1327-53-3	Arsenic oxide As ₂ O ₃
P011	1303-28-2	Arsenic oxide As ₂ O ₅
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	181-81-2	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-hexachloro-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-hexachloro-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	172-20-8	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	1534-52-1	4,6-Dinitro-o-cresol, & salts
P048	51-28-5	2,4-Dinitrophenol
P020	88-85-7	Dinoseb
P085	152-16-9	Diphosphoramidate, 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-Methylactonitrile
P071	298-00-0	Methyl parathion
P190	1129-41-5	Metolcarb.
P128	315-18-4	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	154-11-5	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 NO ₂
P081	55-63-0	Nitroglycerine (R)
P082	62-75-9	N-Nitrosodimethylamine
P084	4549-40-0	N-Nitrosomethylvinylamine
P085	152-16-9	Octamethylpyrophosphoramidate
P087	20816-12-0	Osmium oxide OsO ₄ , (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-
P128	315-18-4	Phenol, 4-(dimethylamino)-3,5-dimethyl-, methylcarbamate (ester).
P199	2032-65-7	Phenol, (3,5-dimethyl-4-(methylthio)-, methylcarbamate
P048	51-28-5	Phenol, 2,4-dinitro-
P047	1534-52-1	Phenol, 2-methyl-4,6-dinitro-, & salts
P202	64-00-6	Phenol, 3-(1-methylethyl)-, methyl carbamate.

P201	2631-37-0	Phenol, 3-methyl-5-(1-methylethyl)-, methyl carbamate.
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)
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
P203	1646-88-4	Propanal, 2-methyl-2-(methylsulfonyl)-, O-[(methylamino)carbonyl] oxime.
P070	116-06-3	Propanal, 2-methyl-2-(methylthio)-, 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	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts <u>(this listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).</u>
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	157-24-9	Strychnidin-10-one, & salts
P018	357-57-3	Strychnidin-10-one, 2,3-dimethoxy-
P108	157-24-9	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 Tl_2O_3
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 $[(H_2N)C(S)]_2NH$
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 V_2O_5
P120	1314-62-1	Vanadium pentoxide

P084	4549-40-0	Vinylamine, N-methyl-N-nitroso-
P001	181-81-2	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 Zn ₃ P ₂ , when present at concentrations greater than 10% (R,T)
P205	137-30-4	Ziram.

FOOTNOTE: ¹CAS Number given for parent compound only.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 2 of subparagraph (a) of paragraph (1) of Rule 0400-12-01-.03 Notification Requirements and Standards Applicable to Generators of Hazardous Waste is amended by adding subparts (xii) and (xiii) following subpart (xi) to read as follows:

(xii) All reverse distributors (as defined in subparagraph (16)(a) of Rule 0400-12-01-.09) are subject to paragraph (16) of Rule 0400-12-01-.09 for the management of hazardous waste pharmaceuticals in lieu of this rule.

(xiii) (I) Each healthcare facility (as defined in subparagraph (16)(a) of Rule 0400-12-01-.09) must determine whether it is subject to paragraph (16) of Rule 0400-12-01-.09 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).

(II) 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 clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in subparagraph (4)(b) of Rule 0400-12-01-.02 or part (4)(d)5 of Rule 0400-12-01-.02, is subject to paragraph (16) of Rule 0400-12-01-.09 for the management of hazardous waste pharmaceuticals in lieu of this rule.

(III) 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 subparagraph (e) of this paragraph and is not subject to paragraph (16) of Rule 0400-12-01-.09, except for subparagraphs (16)(f) and (h) of Rule 0400-12-01-.09 and the optional provisions of subparagraph (16)(e) of Rule 0400-12-01-.09.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 3 of subparagraph (d) of paragraph (1) of Rule 0400-12-01-.03 Notification Requirements and Standards Applicable to Generators of Hazardous Waste is amended by adding subpart (x) following subpart (ix) to read as follows:

(x) Is a hazardous waste pharmaceutical, as defined in subparagraph (16)(a) of Rule 0400-12-01-.09, that is subject to or managed in accordance with paragraph (16) of Rule 0400-12-01-.09 or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under subparagraph (16)(g) of Rule 0400-12-01-.09.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Items (IX) and (X) of subpart (v) of part 1 of subparagraph (e) of paragraph (1) of Rule 0400-12-01-.03 Notification Requirements and Standards Applicable to Generators of Hazardous Waste is amended by deleting them in their entirety and substituting instead the following:

- (IX) Reserved A reverse distributor (as defined in subparagraph (16)(a) of Rule 0400-12-01-.09), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in subparagraph (16)(a) of Rule 0400-12-01-.09);
- (X) Reserved A healthcare facility (as defined in subparagraph (16)(a) of Rule 0400-12-01-.09) that meets the conditions in parts (16)(c)12 and (16)(d)2 of Rule 0400-12-01-.09, 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; or

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 2 of subparagraph (b) of paragraph (1) of Rule 0400-12-01-.05 Interim Status Standards for Owners and Operators of Existing Hazardous Waste Treatment, Storage, and Disposal Facilities is amended by adding subpart (xiii) following subpart (xii) and before the comment to read as follows:

- (xiii) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in subparagraph (16)(a) of Rule 0400-12-01-.09. Reverse distributors are subject to regulation under paragraph (16) of Rule 0400-12-01-.09 in lieu of this rule for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 2 of subparagraph (b) of paragraph (1) of Rule 0400-12-01-.06 Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities is amended by adding subpart (xi) following subpart (x) to read as follows:

- (xi) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in subparagraph (16)(a) of Rule 0400-12-01-.09. Reverse distributors are subject to regulation under paragraph (16) of Rule 0400-12-01-.09 in lieu of this rule for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 4 of subparagraph (b) of paragraph (1) of Rule 0400-12-01-.07 Permitting of Hazardous Waste Treatment, Storage, and Disposal Facilities is amended by adding subpart (x) immediately following subpart (ix) to read as follows:

- (x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in subparagraph (16)(a) of Rule 0400-12-01-.09. Reverse distributors are subject to regulation under paragraph (16) of Rule 0400-12-01-.09 for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 3 of subparagraph (a) of paragraph (4) of Rule 0400-12-01-.08 Fee System for Transporters, Stors, SS-7039 (March 2020)

Treaters, Disposers, and Certain Generators of Hazardous Waste and for Certain Used Oil Facilities or Transporters is amended by deleting it in its entirety and substituting instead the following:

3. Each person transporting used oil and that is required to submit an annual report under Rule 0400-12-01-.11 shall submit to the Commissioner an annual maintenance fee of 200 dollars by March 1 of each year.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 2 of subparagraph (a) of paragraph (5) of Rule 0400-12-01-.08 Fee System for Transporters, Storers, Treaters, Disposers, and Certain Generators of Hazardous Waste and for Certain Used Oil Facilities or Transporters is amended by deleting it in its entirety and substituting instead the following:

2. A generator shall determine the quantity it generated each calendar month in the same manner as a generator determines it under subparagraph (1)(d) of Rule 0400-12-01-.03, except the quantities ~~generated during episodic event(s) and managed in accordance with paragraph (11) of Rule 0400-12-01-.03 of hazardous wastes identified in subparts (i) and (ii) of this part~~ are included in the calendar month generation rate calculations for the purposes of paying the annual generator base fee required by this subparagraph:
 - (i) Hazardous waste generated during episodic event(s) and managed in accordance with paragraph (11) of Rule 0400-12-01-.03; and
 - (ii) Hazardous waste pharmaceuticals, as defined in subparagraph (16)(a) of Rule 0400-12-01-.09, that are subject to or managed in accordance with paragraph (16) of Rule 0400-12-01-.09, however, a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under subparagraph (16)(g) of Rule 0400-12-01-.09 is not counted.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Paragraphs (15) through (26) of Rule 0400-12-01-.09 Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities are amended by deleting them in their entirety and substituting instead the following:

~~(15) through (26) (RESERVED) [40 CFR 266 Subpart O-Z]~~

(15) Reserved.

(16) Hazardous Waste Pharmaceuticals

(a) Definitions for this paragraph.

The following definitions apply to this paragraph:

“Evaluated hazardous waste pharmaceutical” means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with subpart (k)1(iii) of this paragraph 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 subparagraph (1)(b) of Rule 0400-12-01-.02 and exhibits one or more characteristics identified in paragraph (3) of Rule 0400-12-01-.02 or is listed in paragraph (4) of Rule 0400-12-01-.02. A pharmaceutical is not a solid waste, as defined in subparagraph (1)(b) of Rule 0400-12-01-.02, 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 subparagraph (1)(b) of Rule 0400-12-01-.02, 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:

- (i) 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
- (ii) 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 subparagraph (1)(b) of Rule 0400-12-01-.02 but is excluded from being a hazardous waste under subpart (1)(d)2(i) of Rule 0400-12-01-.02.

“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 subparagraph (1)(b) of Rule 0400-12-01-.02, and is not listed in paragraph (4) of Rule 0400-12-01-.02, and does not exhibit a characteristic identified in paragraph (3) of Rule 0400-12-01-.02.

“Non-pharmaceutical hazardous waste” means a solid waste, as defined in subparagraph (1)(b) of Rule 0400-12-01-.02, that is listed in paragraph (4) of Rule 0400-12-01-.02, or exhibits one or more characteristics identified in paragraph (3) of Rule 0400-12-01-.02, but is not a pharmaceutical, as defined in this subparagraph.

“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:

- (i) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- (ii) Undispensed; and
- (iii) 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.

(b) Applicability

1. 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 subparagraph (1)(e) of Rule 0400-12-01-.03 and is not subject to this paragraph, except for subparagraphs (f) and (h) of this paragraph and the optional provisions of subparagraph (e) of this paragraph.
2. 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 part 4 of this subparagraph for the management of its hazardous waste pharmaceuticals as an alternative to complying with subparagraph (1)(e) of Rule 0400-12-01-.03 and the optional provisions of subparagraph (e) of this paragraph.
3. 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.
4. With the exception of healthcare facilities identified in part 1 of this subparagraph, a healthcare facility is subject to the following in lieu of Rules 0400-12-01-.03 through 0400-12-01-.06:
 - (i) Subparagraphs (c) and (f) through (i) of this paragraph 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.
 - (ii) Part (c)1 of this paragraph, and subparagraphs (d), (f), (g), (h), and (i) of this paragraph with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.
5. A reverse distributor is subject to subparagraphs (f) through (k) of this paragraph in lieu of

Rules 0400-12-01-.03 through 0400-12-01-.06 with respect to the management of hazardous waste pharmaceuticals.

6. 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 paragraph. Other generators are subject to Rule 0400-12-01-.03 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

7. The following are not subject to this chapter, except as specified:

(i) Pharmaceuticals that are not solid waste, as defined by subparagraph (1)(b) of Rule 0400-12-01-.02, because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed.

(ii) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by subparagraph (1)(b) of Rule 0400-12-01-.02, because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

(iii) 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 paragraph does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(iv) 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 paragraph does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(v) 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.

(vi) 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 paragraph 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.

(vii) 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 subpart (g)1(ii) of this paragraph and part (g)2 of this paragraph.

(c) Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

1. Notification and withdrawal from this paragraph for healthcare facilities managing hazardous waste pharmaceuticals.

(i) Notification.

A healthcare facility must notify the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a healthcare facility operating under this paragraph. A healthcare facility is not required to identify the hazardous waste

codes on the notification form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification form for each site or EPA identification number.

(I) A healthcare facility that already has an EPA identification number must notify the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or if not required to submit an annual report, within 60 days of the effective date of this paragraph, or within 60 days of becoming subject to this paragraph.

(II) A healthcare facility that does not have an EPA identification number must obtain one by notifying the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or if not required to submit an annual report, within 60 days of the effective date of this paragraph, or within 60 days of becoming subject to this paragraph.

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

(ii) Withdrawal.

A healthcare facility that operated under this paragraph but is no longer subject to this paragraph, because it is a very small quantity generator under subparagraph (1)(e) of Rule 0400-12-01-.03, and elects to withdraw from this paragraph, must notify the Commissioner using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form that it is no longer operating under this paragraph. A healthcare facility is not required to identify the hazardous waste codes on the notification form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification form for each site or EPA identification number.

(I) A healthcare facility must submit a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form that it is withdrawing from this paragraph before it begins operating under the conditional exemption of subparagraph (1)(e) of Rule 0400-12-01-.03.

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

2. 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.

3. 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 paragraph (3) of Rule 0400-12-01-.02 or is listed in paragraph (4) of Rule 0400-12-01-.02) in order to determine whether the waste is subject to this paragraph. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this paragraph.

4. Standards for containers used to accumulate non-creditable hazardous waste

pharmaceuticals at healthcare facilities.

- (i) 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.
- (ii) 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.
- (iii) 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.
- (iv) 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 part (1)(c)3 of Rule 0400-12-01-.10 must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (i.e., hazardous waste codes).

5. 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."

6. Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.

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

7. 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 Rule 0400-12-01-.10. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with part (1)(g)1 of Rule 0400-12-01-.10 requirements, except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the land disposal restrictions notification.

8. 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 subparagraph (5)(c) of Rule 0400-12-01-.05 or subparagraph (5)(c) of Rule 0400-12-01-.06 may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with parts 4 and 5 of this subparagraph. Upon receipt of the returned shipment, the healthcare facility must:

(i) 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;

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

(iii) Within 30 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

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of part (i)1 of this paragraph.

9. Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

(i) Annual reporting by healthcare facilities. Healthcare facilities are not subject to annual reporting requirements under subparagraph (5)(b) of Rule 0400-12-01-.03, with respect to non-creditable hazardous waste pharmaceuticals managed under this paragraph.

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

(I) For shipments from a healthcare facility to a designated facility.

I. 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 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

A. A legible copy of the original manifest, indicating that the

healthcare facility has not received confirmation of delivery, to the Commissioner; and

B. 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.

II. [Reserved]

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

I. 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 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:

A. A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Commissioner; and

B. 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.

II. [Reserved]

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

10. Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

(i) A healthcare facility must keep a copy of each manifest signed in accordance with part (3)(d)1 of Rule 0400-12-01-.03 for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

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

(iii) 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 part (1)(b)6 of Rule 0400-12-01-.03, for at least three 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.

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

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

11. 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 paragraph.

12. 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 subparagraph (1)(e) of Rule 0400-12-01-.03, without a permit or without having interim status, provided the receiving healthcare facility:

(i) Is under the control of the same person, as defined in subparagraph (2)(a) of Rule 0400-12-01-.01, 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 subpart, 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 subparagraph (2)(a) of Rule 0400-12-01-.01 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;

(ii) Is operating under this paragraph for the management of its non-creditable hazardous waste pharmaceuticals;

(iii) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this paragraph; and

(iv) 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.

(d) Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

1. 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 paragraph (4) of Rule 0400-12-01-.02 or exhibits a characteristic identified in paragraph (3) of Rule 0400-12-01-.02). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this paragraph.

2. 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 subparagraph (1)(e) of Rule 0400-12-01-.03, without a permit or without having interim status, provided the receiving healthcare facility:

(i) Is under the control of the same person, as defined in subparagraph (2)(a) of

Rule 0400-12-01-.01, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site ("control," for the purposes of this subpart, 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 subparagraph (2)(a) of Rule 0400-12-01-.01 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;

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

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

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

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

4. Annual reporting by healthcare facilities. Healthcare facilities are not subject to annual reporting requirements under subparagraph (5)(b) of Rule 0400-12-01-.03 with respect to potentially creditable hazardous waste pharmaceuticals managed under this paragraph.

5. Recordkeeping by healthcare facilities.

(i) 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 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.

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

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

6. 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 paragraph.

(e) Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

1. 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.

2. 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:

- (i) The receiving healthcare facility meets the conditions in parts (c)12 of this paragraph and part (d)2 of this paragraph, as applicable; or
- (ii) The very small quantity generator healthcare facility meets the conditions in item (1)(e)1(v)(VIII) of Rule 0400-12-01-.03 and the receiving large quantity generator meets the conditions in part (1)(h)6 of Rule 0400-12-01-.03.

3. 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.

4. Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to subparagraph (1)(e) of Rule 0400-12-01-.03 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this paragraph, except for subparagraphs (f) and (h) of the paragraph and the other optional provisions of this subparagraph. The Commissioner has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in subparagraph (2)(a) of Rule 0400-12-01-.01. A long-term care facility with more than 20 beds that operates as a very small quantity generator under subparagraph (1)(e) of Rule 0400-12-01-.03 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by subparagraph (2)(a) of Rule 0400-12-01-.01.

(f) Prohibition of sewerage hazardous waste pharmaceuticals.

All healthcare facilities, including very small quantity generators operating under subparagraph (1)(e) of Rule 0400-12-01-.03 in lieu of this paragraph, 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 40 CFR 403.5(b)(1).

(g) Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

1. Conditional exemptions. Provided the conditions of part 2 of this subparagraph are met, the following are exempt from Rules 0400-12-01-.03 through 0400-12-01-.07, 0400-12-01-.09 through 0400-12-01-.12:

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

2. Conditions for exemption. The hazardous waste pharmaceuticals must be:

- (i) Managed in compliance with the sewer prohibition of subparagraph (f) of this

paragraph; and

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

(iii) Destroyed by a method that 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 Subparts Eb for new large municipal waste combustors;

(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 Subparts AAAA for new small municipal waste combustors;

(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; or

(V) A permitted hazardous waste combustor subject to 40 CFR Part 63 Subpart EEE.

(h) Residues of hazardous waste pharmaceuticals in empty containers.

1. 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.

2. Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this paragraph 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 paragraph and any applicable federal, state, and local requirements for sharps containers and medical waste.

3. Intravenous (IV) bags. An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the 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 paragraph, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in subpart (1)(g)2(i) of Rule 0400-12-01-.02.

4. 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 paragraph, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in subpart (1)(g)2(i) or (ii) of Rule 0400-12-01-.02. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(i) Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

1. 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:

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

(I) Packaging. Package the waste in accordance with the applicable 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 Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(III) Marking.

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

II. 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 _____

III. Lab packs that will be incinerated in compliance with part (3)(c)3 of Rule 0400-12-01-.10 are not required to be marked with hazardous waste code(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 hazardous waste code(s).

(IV) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR Part 172 Subpart F.

(ii) The manifest requirements of paragraph (3) of Rule 0400-12-01-.03 [40 CFR 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" or "PHRM" in Item 13 of EPA Form 8700-22.
- 2. 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 paragraph (9) of Rule 0400-12-01-.03.
- 3. 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 paragraph (9) of Rule 0400-12-01-.03. 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.
- (j) Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.
 - 1. 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 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 Department of Transportation regulations.
 - 2. 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.
 - 3. Procedures for when delivery confirmation is not received within 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 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.
 - 4. 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 portions of paragraph (9) of Rule 0400-12-01-.03 except the manifesting requirement of part (9)(d)3 of Rule 0400-12-01-.03, in addition to parts 1 through 3 of this subparagraph.
 - 5. Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to parts 1 through 3 of this subparagraph in lieu of paragraph (9) of Rule 0400-12-

01-.03. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this paragraph.

- (k) 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:

1. Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(i) Notification. A reverse distributor must notify the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a reverse distributor operating under this paragraph.

(I) A reverse distributor that already has an EPA identification number must notify the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a reverse distributor, as defined in subparagraph (a) of this paragraph, within 60 days of the effective date of this paragraph, or within 60 days of becoming subject to this paragraph.

(II) A reverse distributor that does not have an EPA identification number must obtain one by notifying the Commissioner, using a notification form provided by the Commissioner and completed in accordance with the instructions accompanying the form, that it is a reverse distributor, as defined in subparagraph (a) of this paragraph, within 60 days of the effective date of this paragraph, or within 60 days of becoming subject to this paragraph.

(ii) 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 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 subpart 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 item.

(iii) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days 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 part 2 of this subparagraph.

(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 part 3 of this subparagraph.

(iv) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with part 3 of this subparagraph.

(v) 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 180 calendar days or less. The 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 this part and the container labeling and management standards in items 3(iv)(I) through (VI) of this subparagraph.

(vi) 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:

I. A 24-hour continuous monitoring surveillance system;

II. An artificial barrier such as a fence; or

III. A means to control entry, such as keycard access.

(II) If the reverse distributor already meets the security requirements of this subpart 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 item.

(vii) 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 paragraph (12) of Rule 0400-12-01-.03.

(viii) 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 items (1)(h)1(viii)(II) and (III) of Rule 0400-12-01-.03.

(ix) 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 Commissioner within 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:

I. The EPA identification number, name and address of the reverse distributor;

II. The date the reverse distributor received the unauthorized waste;

III. The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

IV. A description and the quantity of each unauthorized waste the reverse distributor received;

V. The method of treatment, storage, or disposal for each unauthorized waste; and

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

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

(x) 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 subpart are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Commissioner.

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

(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 years from the date the shipment arrives at the reverse distributor; and

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

2. 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 part 1 of this subparagraph, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(i) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow part 3 of this subparagraph for evaluated hazardous waste pharmaceuticals.

(ii) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow part 3 of this subparagraph for evaluated hazardous waste pharmaceuticals.

(iii) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with subparagraph (j) of this paragraph.

(iv) 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 years from the date of shipment. The periods of retention referred to in this subpart are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Commissioner.

(I) The confirmation of delivery; and

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

3. 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 part 1 of this subparagraph, for the management of evaluated hazardous waste pharmaceuticals:

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

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

(iii) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of subpart (1)(h)1(vii) of Rule 0400-12-01-.03.

(iv) 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 which 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:
 - I. Generate extreme heat or pressure, fire or explosion, or violent reaction;
 - II. Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;
 - III. Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;
 - IV. Damage the structural integrity of the container of hazardous waste pharmaceuticals; or
 - V. Through other like means threaten human health or the environment; and
- (VI) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of part (1)(c)3 of Rule 0400-12-01-.10 (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.
- (v) 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).
- (vi) 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 part (i)1 or 2 of this paragraph.
- (vii) 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 subparagraph (5)(c) of Rule 0400-12-01-.05 or subparagraph (5)(c) of Rule 0400-12-01-.06, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site

accumulation area provided the rejected or returned shipment is managed in accordance with part 1 of this subparagraph and with this part. Upon receipt of the returned shipment, the reverse distributor must:

(I) 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;

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

(III) Within 30 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 90 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 part (i)1 or 2 of this paragraph.

(viii) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of Rule 0400-12-01-.10. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with part (1)(g)1 of Rule 0400-12-01-.10 requirements.

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

(I) Annual reporting by a reverse distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of an annual report to the Commissioner by March 1 of each year in accordance with subparagraph (5)(b) of Rule 0400-12-01-.03.

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

I. For shipments from a reverse distributor to a designated facility.

A. 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 35 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.

B. A reverse distributor must submit an exception report to the Commissioner if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

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

(B) 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.

II. For shipments rejected by the designated facility and shipped to an alternate facility.

A. 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 35 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 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.

B. A reverse distributor must submit an Exception Report to the Commissioner if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 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:

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

(B) 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.

(x) 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 subpart (ii) of this part. This log must be retained as a record for at least three years from the date of the inspection.

(II) A reverse distributor must keep a copy of each manifest signed in accordance with part (3)(d)1 of Rule 0400-12-01-.03 for three 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 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 annual report for at least three years from the due date of the report.

(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 item (1)(h)1(vii)(IV) of Rule 0400-12-01-.03.

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

4. 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 Rule 0400-12-01-.05 and 0400-12-01-.06 and the permit requirements of Rule 0400-12-01-.07, if the reverse distributor:

(i) Does not meet the conditions of this subparagraph;

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

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

(17) through (26) (RESERVED)

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Subparagraph (g) of paragraph (1) of Rule 0400-12-01-.10 Land Disposal Restrictions is amended without amending its parts by deleting its title and substituting a new title to read as follows:

(g) Testing, Tracking, and Recordkeeping Requirements for Generators, Reverse Distributors, Treaters, and Disposal Facilities [40 CFR 268.7]

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 1 of subparagraph (g) of paragraph (1) of Rule 0400-12-01-.10 Land Disposal Restrictions is amended without amending its subparts by deleting the colon and adding "and reverse distributors." so that as amended the introductory text of part 1 before subpart (i) shall read as follows:

1. Requirements for generators: and reverse distributors.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 1 of subparagraph (a) of paragraph (4) of Rule 0400-12-01-.10 Land Disposal Restrictions is amended by adding subparts (iv) and (v) following subpart (iii) to read as follows:

(iv) 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 subparagraphs (16)(c) and (d) of Rule 0400-12-01-.09.

(v) 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 subparagraph (16)(k) of Rule 0400-12-01-.09.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Part 1 of subparagraph (a) of paragraph (7) of Rule 0400-12-01-.12 Standards for Universal Waste Management is amended by deleting it in its entirety and substituting instead the following:

1. Any Except as provided in part 4 of this subparagraph, any person seeking to add a hazardous waste or a category of hazardous waste to this rule may petition for a regulatory amendment under this paragraph and Rules 0400-12-01-.01(3)(a)1 and 4.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

Subparagraph (a) of paragraph (7) of Rule 0400-12-01-.12 Standards for Universal Waste Management is amended by adding part 4 following part 3 to read as follows:

4. Hazardous waste pharmaceuticals are regulated by paragraph (16) of Rule 0400-12-01-.09 and may not be added as a category of hazardous waste for management under this rule.

Authority: T.C.A. §§ 68-212-101 et seq. and 4-5-201 et seq.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Stacey Cothran (Solid/Hazardous Waste Management Industry)					
Pat Flood, P.E. (Commissioner's Designee, Dept. of Environment and Conservation)					
Dr. George Hyfantis, Jr. (Institution of Higher Learning)					
Alan M. Leiserson (Environmental Interests)					
Jared L. Lynn (Manufacturing experienced with Solid/Hazardous Waste)					
David Martin (Working in a field related to Agriculture)					
Jeff McCormick (Municipal Government)					
Richard "Ric" Morris (Single Facility with less than 5 Underground Storage Tanks)					
William "Will" Ownby (Manufacturing experienced with Underground Storage Tanks/Hazardous Waste)					
Brian Parnell (Petroleum Business with at least 15 Underground Storage Tanks)					
DeAnne Redman (Petroleum Management Business)					
The Honorable Bob Rial (County Government)					
Jimmy West (Commissioner's Designee, Dept. of Economic and Community Development)					
Mark Williams (Small Generator of Solid/Hazardous Materials representing Automotive Interests)					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Underground Storage Tanks and Solid Waste Disposal Control Board on 08/04/2021, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 05/12/2021

Rulemaking Hearing(s) Conducted on: (add more dates). 07/06/2021

Date: _____

Signature: _____

Name of Officer: _____

Title of Officer: _____

Agency/Board/Commission: Underground Storage Tanks and Solid Waste Disposal Control Board

Rule Chapter Number(s): 0400-12-01

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

1. Comment: A commenter suggested that the definition language of the terms “battery,” “FIFRA,” and “pesticide” remain in Rule 0400-12-01-.01 and not referenced to Rule 0400-12-01-.12 to determine the meaning of each term.

Response: It is the intent of the Underground Storage Tanks and Solid Waste Disposal Control Board (Board) to not have a term’s definition duplicated in Chapter 0400-12-01 in different rules. Although, the terms “battery” and “pesticide” are used in rules outside of Rule 0400-12-01-.12 it is used more extensively in Rule 0400-12-01-.12 Standards for Universal Waste Management. Therefore, the Board is amending the definitions of these terms in Rule 0400-12-01-.01 so they will have the meanings as given in Rule 0400-12-01-.12 as proposed.

2. Comment: A commenter suggested that the terms “hazardous waste pharmaceuticals,” “healthcare facilities,” and “reverse distributors” be defined in Rule 0400-12-01-.01 instead of subparagraph (16)(a) of Rule 0400-12-01-.09 and that such a change be accompanied by the removal of the parenthetical phrase “as defined in subparagraph (16)(a) of Rule 0400-12-01-.09.”

Response: The Board intended to amend Chapter 0400-12-01 to incorporate the federal amendments for the management of hazardous waste pharmaceuticals strictly equivalent to EPA. The only exception is requiring reverse distributors to make annual reports instead of biennial reports, which is consistent with Tennessee Code Annotated § 68-212-118. Therefore, these rules are being adopted as proposed.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

- (1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from, the proposed rule.

The Department has received notification information from the following healthcare facilities: 144 pharmacies and drug stores; 10 drug manufacturers, 9 drug wholesalers; 21 supermarkets and other grocery stores (except convenience stores); 24 warehouse clubs and Supercenters; 1 veterinary service; 1 physicians' office; 1 ambulatory health care service; 20 dental offices; 1 outpatient care center; 2 psychiatric and substance abuse centers; 50 hospitals; and 1 nursing facility. There are approximately 13,000 healthcare facilities of various sizes in Tennessee. The vast majority of the approximately 13,000 healthcare facilities are small businesses and very small quantity generators, and, therefore, will not be required to notify the Department or pay annual maintenance fees. There are five potentially creditable hazardous waste pharmaceutical reverse distributors in the Tennessee. All healthcare facilities and reverse distributors will benefit from having rules specifically tailored to their needs. Overall costs to comply is expected to be reduced.

- (2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The reporting, recordkeeping, and other administrative requirements in this rulemaking for healthcare facilities and reverse distributors are the same as those required by federal law, except reverse distributors are required to submit annual reports instead of biennial reports. Reverse distributors of potentially creditable hazardous waste pharmaceuticals are knowledgeable about pharmaceuticals and about hazardous waste characterization and will have no difficulty recording the appropriate hazardous waste codes, the quantities shipped, the identity of the hazardous waste transporter, and the hazardous waste treatment, storage, or disposal facility that received the hazardous waste pharmaceuticals. The cost of the additional report is estimated to be less than \$2,000 of added cost per reporting year.

- (3) A statement of the probable effect on impacted small businesses and consumers.

Healthcare facilities that are also small businesses will be affected the same way as larger healthcare facilities since both will be required to comply with requirements that are written specifically for healthcare facilities generating hazardous waste pharmaceuticals. The prohibition from using the sewer as a method of disposal will require healthcare facilities to bear additional cost to collect and ship hazardous waste pharmaceuticals to hazardous waste management facilities. There is no impact on consumers.

- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business.

The rules must meet the federal requirements of being substantially equivalent to the federal regulations, however, the Department is developing an outreach program with the aim of educating healthcare facilities of their regulatory responsibilities. The Department believes that compliance rates are directly tied to increasing the regulated community's awareness.

- (5) A comparison of the proposed rule with any federal or state counterparts.

These rule amendments are comparable to those in surrounding states. Like Tennessee, surrounding states have hazardous waste programs that are also authorized by EPA.

- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

If small businesses were exempted from these amendments, then small business healthcare facilities would remain subject to the existing regulatory requirements and be denied the benefit of complying with a new set of sector-specific rules tailored for healthcare facilities.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://publications.tnsosfiles.com/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly.)

The Board anticipates that these amended rules will not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Some pharmaceuticals are regulated as hazardous waste under Chapter 0400-12-01 Hazardous Waste Management when discarded. These proposed rules provide requirements for the management of hazardous waste pharmaceuticals that are specifically tailored for healthcare facilities and reverse distributors of creditable pharmaceuticals. When these amendments become effective, healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under a new set of sector-specific standards in lieu of the existing hazardous waste generator rules. Among other things, these amendments will:

- Prohibit the disposal of hazardous waste pharmaceuticals down the drain;
- Eliminate the dual regulation of hazardous waste pharmaceuticals that are also Drug Enforcement Administration controlled substances;
- Preserve the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while providing for their proper disposal;
- Codify the Environmental Protection Agency's prior policy on the status of nonprescription pharmaceuticals going through reverse logistics;
(Note: The term "reverse distributors" is used to describe persons who receive prescription pharmaceuticals that are hazardous wastes from generators in order for these generators to receive any monetary credit offered by the manufacturers of these prescription pharmaceuticals before the pharmaceuticals are destroyed. In contrast, the term "reverse logistics" is used to describe non-prescription pharmaceuticals that are unsold and returned for redistribution or reclamation. These non-prescription pharmaceuticals that are sent through reverse logistics are not wastes at the retail store if they have a reasonable expectation of being legitimately used (i.e., lawfully redistributed for their intended purpose) or reclaimed.)
- Define when containers that held hazardous waste pharmaceuticals are considered "empty;"
- Amend the listing description of the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration-approved over-the-counter nicotine replacement therapies are not included in the listing;
- Count hazardous waste pharmaceuticals in the calendar month generation rate for the purpose of paying the generator annual maintenance fee, except a hazardous waste pharmaceutical that is also Drug Enforcement Administration controlled substance and is conditionally exempt under subparagraph (16)(g) of Rule 0400-12-01-.09; and
- Remove any potential discrepancies with the universal waste terms defined in Rule 0400-12-01-.01 and Rule 0400-12-01-.12.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

There is no federal law or regulation or any state law or regulation that mandates the promulgation of these amendments. These amendments are authorized by Tennessee Code Annotated Title 68, Chapter 212, Part 1.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Healthcare facilities are most directly affected by the rule. Health Care facilities 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 distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This rule also affects hazardous waste pharmaceutical reverse distributors.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Board is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

Amending the hazardous waste listing description of P075 nicotine and salts, an acute hazardous waste, to not include discarded U.S. Food and Drug Administration-approved over-the-counter nicotine replacement therapies is anticipated to reduce hazardous waste generator annual maintenance fees collected by the Department by \$120,000 to \$300,000.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Wayne Gregory
Office of General Counsel
Tennessee Department of Environment and Conservation
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(615) 253-5420
Wayne.Gregory@tn.gov

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Horace Tipton
Legislative Liaison
Office of General Counsel

- (H)** Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel
Tennessee Department of Environment and Conservation
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(615) 253-5339
Horace.Tipton@tn.gov

- (I)** Any additional information relevant to the rule proposed for continuation that the committee requests.

- (1) A description of the action proposed, the purpose of the action, the legal authority for the action and the plan for implementing the action.

This rulemaking will prohibit the disposal of hazardous waste pharmaceuticals down the drain; eliminate the dual regulation of hazardous waste pharmaceuticals that are also Drug Enforcement Administration controlled substances; preserve the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while providing for their proper disposal; codify the Environmental Protection Agency's prior policy on the status of nonprescription pharmaceuticals going through reverse logistics; define when containers that held hazardous waste pharmaceuticals are considered "empty;" amend the listing description of the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration-approved over-the-counter nicotine replacement therapies are not included in the listing; count hazardous waste pharmaceuticals in the calendar month generation rate for the purpose of paying the hazardous waste generator annual maintenance fee, except a hazardous waste pharmaceutical that is also Drug Enforcement Administration controlled substance and is conditionally exempt; and remove any potential discrepancies with the universal waste terms defined in Rule 0400-12-01-.01 and Rule 0400-12-01-.12.

The purpose of this rulemaking is to add requirements for the management of hazardous waste pharmaceuticals that are specifically tailored for healthcare facilities and reverse distributors of creditable pharmaceuticals.

These amendments are authorized by Tennessee Code Annotated Title 68, Chapter 212, Part 1.

- (2) A determination that the action is the least-cost method for achieving the stated purpose.

Hazardous waste pharmaceuticals are required by the current rules to be managed by the same rules which govern industries and manufacturers that generate hazardous waste. By providing rules specifically tailored for healthcare facilities is the least-cost method for achieving the stated purpose.

- (3) A comparison of the cost-benefit relation of the action to nonaction.

Hazardous waste pharmaceuticals are currently regulated under Chapter 0400-12-01 Hazardous Waste Management. These proposed rules provide requirements for the management of hazardous waste pharmaceuticals that are specifically tailored for healthcare facilities and reverse distributors of creditable pharmaceuticals. The cost-benefit of these amendments when they become effective, healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under a new set of sector-specific standards in lieu of the existing hazardous waste generator rules which will be less expensive. Failure to amend these rules as proposed would result in regulating many over-the-counter nicotine smoking cessation products in a broader manner than EPA and could result in Tennessee losing program authorization.

- (4) A determination that the action represents the most efficient allocation of public and private resources.

This action represents the most efficient allocation of public and private resources because providing rules tailored to healthcare facilities will result in most cost-effective management of these types of wastes. These tailored rules are expected to improve compliance rates and the greater the compliance, the greater the protection of public health and the environment.

- (5) A determination of the effect of the action on competition.

There should not be a noticeable effect on competition in the marketplace. Hazardous waste pharmaceuticals are currently subject to hazardous waste regulation, and the infrastructure for managing hazardous waste already exists. These rule amendments provide healthcare facilities with requirements that are tailored to them to help make managing hazardous waste pharmaceuticals easier to achieve.

- (6) A determination of the effect of the action on the cost of living in the geographical area in which the action would occur.

These rule amendments will not have any noticeable impact on the cost of living in any geographical area in the state.

- (7) A determination of the effect of the action on employment in the geographical area in which the action would occur.

These rule amendments will not have any noticeable impact on employment in any geographical area in the state.

- (8) The source of revenue to be used for the action.

This action will be accomplished with existing resources.

- (9) A conclusion as to the economic impact upon all persons substantially affected by the action, including an analysis containing a description as to which persons will bear the costs of the action and which persons will benefit directly and indirectly from the action.

When these amendments become effective, some healthcare facilities will be required to notify the Department and adjust to the new tailored requirements, but after this initial period it is expected to lower a healthcare facility's overall compliance costs.