

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 261**

[SW-FRL-7112-4]

**Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Amendment****AGENCY:** Environmental Protection Agency.**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA, also the Agency or we in this preamble) today is granting a petition to modify an exclusion (or delisting) from the lists of hazardous waste previously granted to Geological Reclamation Operations and Waste Systems, Inc. (GROWS). This action responds to a petition for amendment submitted by GROWS to increase the maximum annual volume of waste covered by its current exclusion.

After careful analysis, we have concluded the petitioned waste does not present an unacceptable risk when disposed of in a Subtitle D (nonhazardous waste) landfill. This exclusion applies to wastewater treatment sludge filter cake generated by GROWS at its facility in Morrisville, Pennsylvania. Accordingly, this final amendment conditionally excludes a specific yearly volume of the petitioned waste from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) when the petitioned waste is disposed of in a Subtitle D landfill which is permitted, licensed, or registered by a State to manage municipal or industrial solid waste.

**EFFECTIVE DATE:** December 4, 2001.

**ADDRESSES:** The RCRA regulatory docket for this final amendment is located at the offices of U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103-2029, and is available for you to view from 8:30 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays. Please call David M. Friedman at (215) 814-3395 for appointments. The public may copy material from the regulatory docket at \$0.15 per page.

**FOR FURTHER INFORMATION CONTACT:** For information concerning this document, please contact David M. Friedman at the address above or at (215) 814-3395.

**SUPPLEMENTARY INFORMATION:** The information in this section is organized as follows:

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**I. Overview Information****A. What Action Is EPA Finalizing?**

After evaluating GROWS' petition, we proposed to amend the current GROWS' delisting to increase the maximum annual waste volume covered by its exclusion from 1000 cubic yards to 2000 cubic yards. See 66 FR 38969, July 26, 2001. EPA is finalizing:

(1) The decision to grant GROWS' petition to increase the maximum annual waste volume covered by its exclusion from 1000 cubic yards to 2000 cubic yards, subject to certain conditions; and

(2) The decision to use the Delisting Risk Assessment Software, which includes the EPACMPT fate and transport model, to evaluate the potential impact of the petitioned waste on human health and the environment. We used this model to predict the concentration of hazardous constituents released from the petitioned waste, once it is disposed of in a Subtitle D landfill.

**B. Why Is EPA Approving This Petition for Amendment?**

GROWS petitioned EPA to exclude the increased volume of its wastewater treatment sludge filter cake because it does not believe, even at the increased volume, that the petitioned waste meets the criteria for which it was listed.

GROWS also believes that the waste does not contain any other constituents that would render it hazardous. Review of this petition included consideration of the original listing criteria, as well as factors (including additional constituents) other than those for which the waste was listed, as required by the Hazardous and Solid Waste Amendments (HSWA) of 1984. See, section 222 of HSWA, 42 U.S.C. 6921(f), and 40 CFR 260.22(a)(1) and (2).

For reasons stated in both the proposed amendment and this

document, we believe that GROWS' wastewater treatment sludge filter cake should continue to be excluded from hazardous waste control at the increased volume. Therefore, we are granting the final amendment to GROWS, located in Morrisville, Pennsylvania, for its wastewater treatment sludge filter cake, generated at a maximum annual volume of 2000 cubic yards.

**C. What Are the Limits of This Exclusion?**

This amended exclusion applies to the waste described in the petition only if the requirements described in Table 1 of Appendix IX to part 261 of Title 40 of the Code of Federal Regulations are satisfied. The maximum annual volume of the wastewater treatment sludge filter cake is 2000 cubic yards.

**D. How Will GROWS Manage the Waste Under This Exclusion?**

The wastewater treatment sludge filter cake is currently being disposed of in a Subtitle D landfill under the provisions of the existing exclusion. This final amendment will allow GROWS to dispose of the specified increased volume of waste in a similar manner.

**E. When Is the Final Amendment Effective?**

This rule is effective December 4, 2001. HSWA amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here because this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. For these same reasons, this rule can become effective immediately (that is, upon publication in the **Federal Register**) under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

**F. How Does This Action Affect States?**

Because EPA is issuing today's exclusion under the Federal RCRA delisting program, only States subject to Federal RCRA delisting provisions would be directly affected. This would exclude two categories of States: States having a dual system that includes Federal RCRA requirements and their own requirements, and States who have received EPA's authorization to make their own delisting decisions. We describe these two situations below.

We allow states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under Section 3009 of RCRA. These more stringent requirements may include a

provision that prohibits a Federally issued exclusion from taking effect in the State, or that prohibits a Federally issued exclusion from taking effect in the State until the State approves the exclusion through a separate State administrative action. Because a dual system (that is, both Federal and State programs) may regulate a petitioner's waste, we urge petitioners to contact the applicable State regulatory authorities or agencies to establish the status of their waste under that State's program.

We have also authorized some States (for example, Delaware and Pennsylvania) to administer a delisting program in place of the Federal program; that is, to make State delisting decisions. Therefore, this exclusion does not necessarily apply within those authorized States. If GROWS transports the petitioned waste to, or manages the waste in, any State with delisting authorization, GROWS must obtain delisting approval from that State before it can manage the waste as nonhazardous in that State.

Today, we are finalizing GROWS' petition for amendment, even though the GROWS' facility is located in a State which has recently been granted authorization for the delisting program, and with the knowledge that the amended exclusion is not automatically effective in a State authorized by EPA to make delisting decisions. Nevertheless, we take this action for the following reasons.

GROWS was granted its current Federal delisting exclusion on August 20, 1991 (56 FR 41286). For reasons described elsewhere in this preamble, on June 12, 2000, GROWS petitioned EPA for an amendment to this exclusion. This petition was received prior to November 27, 2000, the effective date of Pennsylvania's delisting authorization. Upon receiving the GROWS' petition, we began our evaluation of it in consultation with the Pennsylvania Department of Environmental Protection.

The evaluation of this petition was performed using a significant improvement to the methodology previously used by EPA to evaluate risk, as described in detail in the July 26, 2001 proposed amendment (66 FR 38969). The process of amendment also provides an opportunity to update other conditions of the current exclusion.

In order for this amendment to be effective in an authorized State, that State must adopt this amendment through its State administrative process.

## II. Background

### A. What Is a Delisting Petition?

A delisting petition is a formal request from a generator to EPA or another agency with jurisdiction to exclude from the lists of hazardous waste regulated by RCRA, a waste that the generator believes should not be considered hazardous.

### B. What Regulations Allow Hazardous Waste Generators to Delist Waste?

Under 40 CFR 260.20 and 260.22, a generator may petition EPA to remove its waste from hazardous waste control by excluding it from the lists of hazardous wastes contained in 40 CFR 261.31, 261.32 and 261.33. Specifically, 40 CFR 260.20 allows any person to petition the Administrator to modify or revoke any provision of parts 260 through 266, 268 and 273 of Title 40 of the Code of Federal Regulations. 40 CFR 260.22 provides generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific" basis from the hazardous waste lists. A generator can petition EPA for an amendment to an existing exclusion under these same provisions of the Code of Federal Regulations.

### C. What Information Must the Generator Supply?

A petitioner must provide sufficient information to allow EPA to determine that the waste to be excluded does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the Administrator must determine that the waste is not hazardous for any other reason.

## III. EPA's Evaluation of the Waste Data

### A. What Waste Is the Subject of This Amendment?

GROWS operates a commercial landfill and wastewater treatment plant in Morrisville, Pennsylvania. On November 13, 1986, GROWS petitioned EPA under the provisions in 40 CFR 260.20 and 260.22 to exclude from hazardous waste regulation a wastewater treatment sludge filter cake derived from the treatment of landfill leachate. This leachate originates, in part, from its closed landfill containing a mixture of solid wastes and hazardous wastes. The wastewater treatment plant also treats non-hazardous leachate from non-hazardous waste landfills.

A full description of these wastes and the Agency's evaluation of the 1986 GROWS' petition are contained in the "Proposed Rule and Request for Comments" published in the **Federal**

**Register** on September 17, 1990 (55 FR 38090).

After evaluating public comment on the proposed rule, we published a final decision in the **Federal Register** on August 20, 1991 (56 FR 41286), to exclude GROWS' wastewater treatment sludge filter cake derived from the treatment of EPA Hazardous Waste No. F039 (multi-source leachate) from the list of hazardous wastes found in 40 CFR 261.31.

EPA's final decision in 1991 was conditioned on the volume of waste identified in the 1986 GROWS' petition. Specifically, the exclusion granted by EPA is limited to a maximum annual volume of 1000 cubic yards. Any additional waste volume in excess of this limit generated by GROWS in a calendar year had to be managed as hazardous waste.

### B. How Much Waste Did GROWS Propose To Delist?

As a result of an increase in wastewater treatment sludge filter cake production associated with an increase in the efficiency of the wastewater treatment operation, GROWS petitioned EPA on June 12, 2000, for an amendment to its August 20, 1991 final exclusion. In its petition, GROWS requested an increase in the maximum annual waste volume that is covered by its exclusion from 1000 cubic yards to 2000 cubic yards.

### C. How Did GROWS Sample and Analyze the Waste in Its Petition?

The exclusion which we granted to GROWS on August 20, 1991, is a conditional exclusion. In order for its exclusion to remain effective, GROWS must verify that its waste meets prescribed delisting levels.

To support its petition for amendment, GROWS submitted its verification testing results from the past two years to EPA. This submission consisted of the results of twenty-seven (27) analyses conducted on samples collected for the time period from December 15, 1997, until December 10, 1999.

The verification testing program prescribed by EPA in the August 20, 1991 exclusion requires GROWS to analyze metal constituents using the Toxicity Characteristic Leaching Procedure (TCLP), cyanide using a distilled water leaching procedure, and organics using total constituent analysis.

In addition to the two most recent years of verification testing results mentioned above, we also requested that GROWS submit the results of total constituent analyses for a minimum of four samples for the inorganic

constituents. This was necessary because both total constituent analysis data and leachate data are now used in assessing the potential risk from disposal of a petitioned waste, and there is no reliable way to estimate actual total constituent concentrations of the inorganic constituents from leachate data.

Because the verification testing program specified by the current exclusion for GROWS does not require TCLP testing for organic constituents, we evaluated this request for an amendment by calculating theoretical maximum leachate concentrations for the organic constituents by applying the most conservative assumption. The procedure for determining the theoretical maximum leachate concentrations from total constituent analysis concentrations is described in the proposed amendment. *See* 66 FR 38969, July 26, 2001.

#### **IV. Public Comments on the Proposed Amendment**

We received no public comments on the GROWS' proposed amendment.

#### **V. Administrative Assessments**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a rule of general applicability and therefore is not a "regulatory action" subject to review by the Office of Management and Budget. Because this action is a rule of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or

to sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Because the rule will affect only one facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA, or communities of Indian tribal governments, as specified in Executive Order 13175 (65 FR 67249, November 6, 2000). For the same reason, this rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This rule does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following

types of rules (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties (5 U.S.C. 804(3)). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability.

#### **List of Subjects in 40 CFR Part 261**

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

**Authority:** Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: November 26, 2001.

**Donald S. Welsh,**

*Regional Administrator, Region III.*

For the reasons set forth in the preamble, 40 CFR Part 261 is amended as follows:

#### **PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE**

1. The authority citation for Part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

#### **Appendix IX of Part 261—[Amended]**

2. In Table 1 of Appendix IX of Part 261, the entry for "Geological Reclamation Operations and Waste Systems, Inc., Morrisville, PA" is revised to read as follows:

**Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22**

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
Geological Reclamation Operations and Waste Systems, Inc.	Morrisville, Pennsylvania.	<p>Wastewater treatment sludge filter cake from the treatment of EPA Hazardous Waste No. F039, generated at a maximum annual rate of 2000 cubic yards, after December 4, 2001, and disposed of in a Subtitle D landfill. The exclusion covers the filter cake resulting from the treatment of hazardous waste leachate derived from only "old" GROWS and non-hazardous leachate derived from only non-hazardous waste sources. The exclusion does not address the waste disposed of in the "old" GROWS' Landfill or the grit generated during the removal of heavy solids from the landfill leachate. To ensure that hazardous constituents are not present in the filter cake at levels of regulatory concern, GROWS must implement a testing program for the petitioned waste. This testing program must meet the conditions listed below in order for the exclusion to be valid:</p> <p>(1) <i>Testing</i>: Sample collection and analyses, including quality control (QC) procedures, must be performed according to SW-846 methodologies.</p> <p>(A) <i>Sample Collection</i>: Each batch of waste generated over a four-week period must be collected in containers with a maximum capacity of 20-cubic yards. At the end of the four-week period, each container must be divided into four quadrants and a single, full-depth core sample shall be collected from each quadrant. All of the full-depth core samples then must be composited under laboratory conditions to produce one representative composite sample for the four-week period.</p> <p>(B) <i>Sample Analysis</i>: Each four-week composite sample must be analyzed for all of the constituents listed in Condition (3). The analytical data, including quality control information, must be submitted to The Waste and Chemicals Management Division, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, and the Pennsylvania Department of Environmental Protection, Bureau of Land Recycling and Waste Management, Rachel Carson State Office Building, 400 Market Street, 14th Floor, Harrisburg, PA 17105. Data from the annual verification testing must be compiled and submitted to EPA and the Pennsylvania Department of Environmental Protection within sixty (60) days from the end of the calendar year. All data must be accompanied by a signed copy of the statement set forth in 40 CFR 260.22(i)(12) to certify to the truth and accuracy of the data submitted. Records of operating conditions and analytical data must be compiled, summarized, and maintained on-site for a minimum of three years and must be furnished upon request by any employee or representative of EPA or the Pennsylvania Department of Environmental Protection, and made available for inspection.</p> <p>(2) <i>Waste Holding</i>: The dewatered filter cake must be stored as hazardous until the verification analyses are completed. If the four-week composite sample does not exceed any of the delisting levels set forth in Condition (3), the filter cake waste corresponding to this sample may be managed and disposed of in accordance with all applicable solid waste regulations. If the four-week composite sample exceeds any of the delisting levels set forth in Condition (3), the filter cake waste generated during the time period corresponding to the four-week composite sample must be retreated until it meets these levels (analyses must be repeated) or managed and disposed of in accordance with Subtitle C of RCRA. Filter cake which is generated but for which analyses are not complete or valid must be managed and disposed of in accordance with Subtitle C of RCRA, until valid analyses demonstrate that the waste meets the delisting levels.</p> <p>(3) <i>Delisting Levels</i>: If the concentrations in the four-week composite sample of the filter cake waste for any of the hazardous constituents listed below exceed their respective maximum allowable concentrations (mg/l or mg/kg) also listed below, the four-week batch of failing filter cake waste must either be retreated until it meets these levels or managed and disposed of in accordance with Subtitle C of RCRA. GROWS has the option of determining whether the filter cake waste exceeds the maximum allowable concentrations for the organic constituents by either performing the analysis on a TCLP leachate of the waste or performing total constituent analysis on the waste, and then comparing the results to the corresponding maximum allowable concentration level.</p>

(A) Inorganics		Maximum Allow- able Leachate Conc. (mg/l)
Constituent:		
Arsenic .....	3.00e-01	
Barium .....	2.34e+01	
Cadmium .....	1.80e-01	
Chromium .....	5.00e+00	
Lead .....	5.00e+00	
Mercury .....	7.70e-02	
Nickel .....	9.05e+00	
Selenium .....	6.97e-01	
Silver .....	1.23e+00	
Cyanide .....	4.33e+00	
Cyanide extractions must be conducted using distilled water in place of the leaching media specified in the TCLP procedure.		
(B) Organics	Maximum allow- able leachate conc. (mg/l)	Maximum allow- able total conc. (mg/kg)
Constituent:		
Acetone .....	2.28e+01	4.56e+02
Acetonitrile .....	3.92e+00	7.84e+01
Acetophenone .....	2.28e+01	4.56e+02
Acrolein .....	1.53e+03	3.06e+04
Acrylonitrile .....	7.80e-03	1.56e-01
Aldrin .....	5.81e-06	1.16e-04
Aniline .....	7.39e-01	1.48e+01
Anthracene .....	8.00e+00	1.60e+02
Benz(a)anthracene .....	1.93e-04	3.86e-03
Benzene .....	1.45e-01	2.90e+00
Benzo(a)pyrene .....	1.18e-05	2.36e-04
Benzo(b)fluoranthene .....	1.07e-04	2.14e-03
Benzo(k)fluoranthene .....	1.49e-03	2.98e-02
Bis(2-chloroethyl)ether .....	3.19e-02	6.38e-01
Bis(2-ethylhexyl)phthalate .....	8.96e-02	1.79e+00
Bromodichloromethane .....	6.80e-02	1.36e+00
Bromoform (Tribromomethane) .....	5.33e-01	1.07e+01
Butyl-4,6-dinitrophenol, 2-sec-(Dinoseb) .....	2.28e-01	4.56e+00
Butylbenzylphthalate .....	9.29e+00	1.86e+02
Carbon disulfide .....	2.28e+01	4.56e+02
Carbon tetrachloride .....	4.50e-02	9.00e-01
Chlordane .....	5.11e-04	1.02e-02
Chloro-3-methylphenol 4- .....	2.97e+02	5.94e+03
Chloroaniline, p- .....	9.14e-01	1.83e+01
Chlorobenzene .....	6.08e+00	1.22e+02
Chlorobenzilate .....	4.85e-02	9.70e-01
Chlorodibromomethane .....	5.02e-02	1.00e+00
Chloroform .....	7.79e-02	1.56e+00
Chlorophenol, 2- .....	1.14e+00	2.28e+01
Chrysene .....	2.04e-02	4.08e-01
Cresol .....	1.14e+00	2.28e+01
DDD .....	5.83e-04	1.17e-02
DDE .....	1.37e-04	2.74e-03
DDT .....	2.57e-04	5.14e-03
Dibenz(a,h)anthracene .....	5.59e-06	1.12e-04
Dibromo-3-chloropropane, 1,2- .....	3.51e-03	7.02e-02
Dichlorobenzene 1,3- .....	9.35e+00	1.87e+02
Dichlorobenzene, 1,2- .....	1.25e+01	2.50e+02
Dichlorobenzene, 1,4- .....	1.39e-01	2.78e+00
Dichlorobenzidine, 3,3'- .....	9.36e-03	1.87e-01
Dichlorodifluoromethane .....	4.57e+01	9.14e+02
Dichloroethane, 1,1- .....	1.20e+00	2.40e+01
Dichloroethane, 1,2- .....	2.57e-03	5.14e-02
Dichloroethylene, 1,1- .....	7.02e-03	1.40e-01
Dichloroethylene, trans-1,2- .....	4.57e+00	9.14e+01
Dichlorophenol, 2,4- .....	6.85e-01	1.37e+01
Dichlorophenoxyacetic acid, 2,4-(2,4-D) .....	2.28e+00	4.56e+01
Dichloropropane, 1,2- .....	1.14e-01	2.28e+00
Dichloropropene, 1,3- .....	2.34e-02	4.68e-01
Dieldrin .....	6.23e+01	1.25e+03
Diethyl phthalate .....	2.21e+02	4.42e+03
Dimethoate .....	6.01e+01	1.20e+03

(B) Organics	Maximum allow- able leachate conc. (mg/l)	Maximum allow- able total conc. (mg/kg)
Dimethyl phthalate .....	1.20e+02	2.40e+03
Dimethylbenz(a)anthracene, 7,12- .....	1.55e-06	3.10e-05
Dimethylphenol, 2,4- .....	4.57e+00	9.14e+01
Di-n-butyl phthalate .....	5.29e+00	1.06e+02
Dinitrobenzene, 1,3- .....	2.28e-02	4.56e-01
Dinitromethylphenol, 4,6-,2- .....	2.16e-02	4.32e-01
Dinitrophenol, 2,4- .....	4.57e-01	9.14e+00
Dinitrotoluene, 2,6- .....	6.54e-03	1.31e-01
Di-n-octyl phthalate .....	1.12e-02	2.24e-01
Dioxane, 1,4- .....	3.83e-01	7.66e+00
Diphenylamine .....	3.76e+00	7.52e+01
Disulfoton .....	3.80e+02	7.60e+03
Endosulfan .....	1.37e+00	2.74e+01
Endrin .....	2.00e-02	4.00e-01
Ethylbenzene .....	1.66e+01	3.32e+02
Ethylene Dibromide .....	4.13e-03	8.26e-02
Fluoranthene .....	5.16e-01	1.03e+01
Fluorene .....	1.78e+00	3.56e+01
Heptachlor .....	8.00e-03	1.60e-01
Heptachlor epoxide .....	8.00e-03	1.60e-01
Hexachloro-1,3-butadiene .....	9.61e-03	1.92e-01
Hexachlorobenzene .....	9.67e-05	1.93e-03
Hexachlorocyclohexane, gamma-(Lindane) .....	4.00e-01	8.00e+00
Hexachlorocyclopentadiene .....	1.66e+04	3.32e+05
Hexachloroethane .....	1.76e-01	3.52e+00
Hexachlorophene .....	3.13e-04	6.26e-03
Indeno(1,2,3-cd) pyrene .....	6.04e-05	1.21e-03
Isobutyl alcohol .....	6.85e+01	1.37e+03
Isophorone .....	4.44e+00	8.88e+01
Methacrylonitrile .....	2.28e-02	4.56e-01
Methoxychlor .....	1.00e+01	2.00e+02
Methyl bromide (Bromomethane) .....	1.28e+02	2.56e+03
Methyl chloride (Chloromethane) .....	1.80e-01	3.60e+00
Methyl ethyl ketone .....	1.37e+02	2.74e+03
Methyl isobutyl ketone .....	1.83e+01	3.66e+02
Methyl methacrylate .....	1.03e+03	2.06e+04
Methyl parathion .....	1.27e+02	2.54e+03
Methylene chloride .....	2.88e-01	5.76e+00
Naphthalene .....	1.50e+00	3.00e+01
Nitrobenzene .....	1.14e-01	2.28e+00
Nitrosodiethylamine .....	2.81e-05	5.62e-04
Nitrosodimethylamine .....	8.26e-05	1.65e-03
Nitrosodi-n-butylamine .....	7.80e-04	1.56e-02
N-Nitrosodi-n-propylamine .....	6.02e-04	1.20e-02
N-Nitrosodiphenylamine .....	8.60e-01	1.72e+01
N-Nitrosopyrrolidine .....	2.01e-03	4.02e-02
Pentachlorobenzene .....	1.15e-02	2.30e-01
Pentachloronitrobenzene (PCNB) .....	5.00e-03	1.00e-01
Pentachlorophenol .....	4.10e-03	8.20e-02
Phenanthrene .....	2.09e-01	4.18e+00
Phenol .....	1.37e+02	2.74e+03
Polychlorinated biphenyls .....	3.00e-05	6.00e-04
Pronamide .....	1.71e+01	3.42e+02
Pyrene .....	3.96e-01	7.92e+00
Pyridine .....	2.28e-01	4.56e+00
Styrene .....	6.08e+00	1.22e+02
Tetrachlorobenzene, 1,2,4,5- .....	9.43e-03	1.89e-01
Tetrachloroethane, 1,1,2,2- .....	4.39e-01	8.78e+00
Tetrachloroethylene .....	8.55e-02	1.71e+00
Tetrachlorophenol, 2,3,4,6- .....	1.81e+00	3.62e+01
Tetraethyl dithiopyrophosphate (Sulfotep) .....	3.01e+05	6.02e+06
Toluene .....	4.57e+01	9.14e+02
Toxaphene .....	5.00e-01	1.00e+01
Trichlorobenzene, 1,2,4- .....	7.24e-01	1.45e+01
Trichloroethane, 1,1,1- .....	7.60e+00	1.52e+02
Trichloroethane, 1,1,2- .....	7.80e-02	1.56e+00
Trichloroethylene .....	3.04e-01	6.08e+00
Trichlorofluoromethane .....	6.85e+01	1.37e+03
Trichlorophenol, 2,4,5- .....	9.16e+00	1.83e+02
Trichlorophenol, 2,4,6- .....	2.76e-01	5.52e+00
Trichlorophenoxyacetic acid, 2,4,5-(245-T) .....	2.28e+00	4.56e+01
Trichlorophenoxypropionic acid, 2,4,5-(Silvex) .....	1.00e+00	2.00e+01

(B) Organics	Maximum allowable leachate conc. (mg/l)	Maximum allowable total conc. (mg/kg)
Trichloropropane, 1,2,3- .....	7.69e-04	1.54e-02
Trinitrobenzene, sym- .....	6.49e+00	1.30e+02
Vinyl chloride .....	2.34e-03	4.68e-02
Xylenes (total) .....	3.20e+02	6.40e+03

(4) *Changes in Operating Conditions:* If GROWS significantly changes the treatment process or the chemicals used in the treatment process, GROWS may not manage the treatment sludge filter cake generated from the new process under this exclusion until it has met the following conditions: (a) GROWS must demonstrate that the waste meets the delisting levels set forth in Paragraph 3; (b) it must demonstrate that no new hazardous constituents listed in Appendix VIII of Part 261 have been introduced into the manufacturing or treatment process; and (c) it must obtain prior written approval from EPA and the Pennsylvania Department of Environmental Protection to manage the waste under this exclusion.

(5) *Reopener:*

(a) If GROWS discovers that a condition at the facility or an assumption related to the disposal of the excluded waste that was modeled or predicted in the petition does not occur as modeled or predicted, then GROWS must report any information relevant to that condition, in writing, to the Regional Administrator or his delegate and to the Pennsylvania Department of Environmental Protection within 10 days of discovering that condition.

(b) Upon receiving information described in paragraph (a) of this section, regardless of its source, the Regional Administrator or his delegate and the Pennsylvania Department of Environmental Protection will determine whether the reported condition requires further action. Further action may include repealing the exclusion, modifying the exclusion, or other appropriate response necessary to protect human health and the environment.

\* \* \* \* \*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Part 1001

RIN 0991-AB05

### Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule sets forth a safe harbor, as authorized under section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, to protect certain arrangements involving hospitals or other receiving facilities that replenish drugs and medical supplies used by ambulance providers (or first responders) when transporting patients to the hospitals or receiving facilities.

**EFFECTIVE DATE:** These regulations are effective on January 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** Vicki L. Robinson, Senior Counsel, Office of Counsel to the Inspector General, (202) 619-0335.

**SUPPLEMENTARY INFORMATION:**

### *Overview—Establishing a New Safe Harbor for Ambulance Restocking Arrangements*

This final regulation establishes safe harbor protection for ambulance restocking arrangements.<sup>1</sup> Ambulance restocking is the practice, commonplace in many parts of the country, of hospitals or other receiving facilities restocking ambulance providers<sup>2</sup> with drugs or supplies used during the transport of a patient to the hospital or receiving facility. (For simplicity, we sometimes use the shorthand “hospital” or “receiving hospital” in this preamble; such terminology is intended to include other types of receiving facilities, such as urgent care or community health care clinics that provide emergency care services). Restocking enables the ambulance to depart the hospital ready

<sup>1</sup> Because these arrangements are commonly known as “restocking,” we use that term in this preamble. As further discussed below, the regulations use the word “replenish” to make clear that the safe harbor only applies to the gifting or transfer of drugs and supplies that replace comparable drugs and supplies administered by the ambulance provider (or first responder) to a patient before the patient is delivered to the receiving facility. The rule is not applicable to any arrangements for the general stocking of the inventories of ambulance providers. Depending on the circumstances, such arrangements may fit into other safe harbors, such as the group purchasing organization safe harbor at § 1001.952(j) or the discount safe harbor at § 1001.952(h) of this part.

<sup>2</sup> In this preamble and regulations text, unless otherwise specified, the term “ambulance provider” compasses both independent ambulance suppliers and hospital-based providers, including “under arrangements” providers.

for the next emergency call, fully stocked with current medications, sanitary linens, and a full complement of appropriate medications and supplies, and helps ensure that supplies, such as intravenous tubing and catheters, are compatible with equipment used in local emergency rooms so as to expedite the transfer of critically ill or injured patients to emergency room systems. *Bona fide* restocking arrangements serve a significant public interest and are consistent with Federal policy established over the past 25 years.<sup>3</sup>

Set forth below is a brief background discussion addressing the anti-kickback statute and the proposed safe harbor for ambulance restocking; a summary of the provisions being adopted into the final regulations; and a review of the public

<sup>3</sup> See, e.g., Emergency Medical Services Systems Act of 1973, Public Law 93-154 (providing Federal funding for the development of regional Emergency Medical Services (EMS) systems at the State, regional, and local levels, and defining “emergency medical services system” as “a system which provides for the arrangement of personnel, facilities and equipment for the effective and coordinated delivery in an appropriate geographical area of health care services under emergency conditions \* \* \* and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system.”); Highway Safety Act of 1966, Public Law 89-594 (establishing an EMS program in the Department of Transportation); Emergency Medical Services for Children Program, under the Public Health Act, Public Law 98-555 (providing funds for enhancing pediatric EMS); and Trauma Care Systems Planning and Development Act of 1990, Public Law 101-590.