

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 271**

[FRL-9464-4]

Ohio: Final Authorization of State Hazardous Waste Management Program Revision**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: Ohio has applied to EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Ohio's application with regards to Federal requirements, and is proposing to authorize the State's changes.

DATES: Comments on this proposed rule must be received on or before October 14, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-RCRA-2011-0530 by one of the following methods:

http://www.regulations.gov: Follow the on-line instructions for submitting comments.

E-mail: westefer.gary@epa.gov.

Mail: Gary Westefer, Ohio Regulatory Specialist, LR-8J, U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Instructions: Direct your comments to Docket ID Number EPA-R05-RCRA-2011-0530. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in

the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epagov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some of the information is not publicly available, e.g., CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy. You may view and copy Ohio's application from 9 a.m. to 4 p.m. at the following addresses: U.S. EPA Region 5, LR-8J, 77 West Jackson Boulevard, Chicago, Illinois, contact: Gary Westefer (312) 886-7450; or Ohio Environmental Protection Agency, Lazarus Government Center, 50 West Town Street, Suite 700, Columbus, Ohio, contact: Kit Arthur (614) 644-2932.

FOR FURTHER INFORMATION CONTACT: Gary Westefer, Ohio Regulatory Specialist, U.S. EPA Region 5, LR-8J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-7450, e-mail westefer.gary@epa.gov.

SUPPLEMENTARY INFORMATION:**A. Why are revisions to State programs necessary?**

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and request EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What decisions have we made in this rule?

We conclude that Ohio's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we propose to grant Ohio final authorization to operate its hazardous waste program with the changes described in the authorization application. Ohio has responsibility for permitting treatment, storage, and disposal facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Ohio, including issuing permits, until the State is granted authorization to do so.

C. What is the effect of this authorization decision?

The effect of this decision, once finalized, is that a facility in Ohio subject to RCRA would have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. Ohio has enforcement responsibilities under its State hazardous waste program for RCRA violations, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

1. Do inspections, and require monitoring, tests, analyses or reports;
2. Enforce RCRA requirements and suspend or revoke permits; and
3. Take enforcement actions regardless of whether the State has taken its own actions.

This action will not impose additional requirements on the regulated community because the regulations for which Ohio is being authorized are already effective, and will not be changed by EPA's final action.

D. What happens if EPA receives adverse comments on this action?

If EPA receives adverse comments on this authorization, we will address all public comments in a later **Federal Register**. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

E. What has Ohio previously been authorized for?

Ohio initially received final authorization on June 28, 1989, effective June 30, 1989 (54 FR 27170) to implement the RCRA hazardous waste management program. We granted authorization for changes to their program on April 8, 1991, effective June 7, 1991 (56 FR 14203) as corrected June 19, 1991, effective August 19, 1991 (56 FR 28088); July 27, 1995, effective

September 25, 1995 (60 FR 38502); October 23, 1996, effective December 23, 1996 (61 FR 54950); January 24, 2003, effective January 24, 2003 (68 FR 3429); January 20, 2006, effective January 20, 2006 (71 FR 3220), and October 29, 2007, effective October 29, 2007 (72 FR 61063).

F. What changes are we proposing with today's action?

On May 9, 2011, Ohio submitted a final complete program revision

application, seeking authorization of their changes in accordance with 40 CFR 271.21. We are now proposing to authorize, subject to receipt of written comments that oppose this action, Ohio's hazardous waste program revision. We propose to grant Ohio final authorization for the following program changes:

OHIO'S ANALOGS TO THE FEDERAL REQUIREMENTS

Description of Federal requirement (include checklist number, if relevant)	Federal Register date and page (and/or RCRA statutory authority)	Analogous State authority
Amendments to Land Disposal Restrictions for First Third Scheduled Wastes; Checklist 50.1.	February 27, 1989, 54 FR 8264	OAC 3745-59-41(A); Effective June 29, 1990.
Changes to Part 124 Not Accounted for by Present Checklists; Checklist 70.	April 1, 1983, 48 FR 14146 June 30, 1983, 48 FR 30113 July 26, 1988, 53 FR 28118	OAC 3745-50-21; Effective July 14, 1997, amended September 5, 2010. OAC 3745-50-40; Effective July 14, 1997, amended February 16, 2009.
NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors; Technical Corrections; Checklist 188.1.	September 26, 1988, 53 FR 37396 January 4, 1989, 54 FR 246 May 14, 2001, 66 FR 24270	50-39; 50-51; Effective July 14, 1997, amended September 5, 2010. OAC 3745-50-41; Effective February 16, 2009.
NESHAPS: Interim Standards for Hazardous Air Pollutants for Hazardous Waste Combustors (Interim Standards Rule); Checklist 197.	February 13, 2002, 67 FR 6792	OAC 3745-50-44; 3745-50-66; 3745-50-235; 3745-57-40; 3745-266-100; Effective February 16, 2009.
NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors; Final Rule; Checklist 198.	February 14, 2002, 67 FR 6968	OAC 3745-50-51; 3745-266-100; Effective December 7, 2004.
Hazardous Waste Management System; Definition of Solid Waste; Toxicity Characteristic; Checklist 199.	March 13, 2002, 67 FR 11251	OAC 3745-51-02; 3745-51-04; 3745-51-24; Effective December 7, 2004.
NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors—Corrections; Checklist 202.	December 19, 2002, 67 FR 77687	OAC 3745-50-44(C)(7); 3745-50-44(C)(9); 3745-50-62; 3745-50-66; Effective February 16, 2009.
Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards; Checklist 203.	July 30, 2003, 68 FR 44659	OAC 3745-51-05; 3745-279-10; 3745-279-74; Effective February 16, 2009.
Hazardous Waste—Nonwastewaters From Production of Dyes, Pigments, and Food, Drug and Cosmetic Colorants; Mass Loadings-Based Listing; Final Rule; Checklist 206.	February 24, 2005, 70 FR 9138	OAC 3745-51-04; 3745-51-11; 3745-51-30; 3745-51-32; 3745-270-20; 3745-270-40; Effective February 16, 2009.
Hazardous Waste—Nonwastewaters From Production of Dyes, Pigments, and Food, Drug and Cosmetic Colorants; Mass Loadings-Based Listing; Correction; Checklist 206.1.	June 16, 2005, 70 FR 35032	OAC 3745-51-32; Effective February 16, 2009.
Hazardous Waste Management System, Modification of the Hazardous Waste Manifest System; Final Rule; Checklist 207.	March 4, 2005, 70 FR 10776	OAC 3745-50-10; 3745-51-07; 3745-52-20; 3745.52-21; 3745-52-27; 3745-52-32; 3745-52-33; 3745-52-34; 3745-52-45; 3745-52-60; 3745-53-20; 3745-53-21; 3745-54-70; 3745-54-71; 3745-54-72; 3745-54-76; 3745-65-70; 3745-65-71; 3745-65-72; 3745-65-76; Effective February 16, 2009.
Hazardous Waste Management System, Modification of the Hazardous Waste Manifest System; Correction; Checklist 207.1.	June 16, 2005, 70 FR 35034	OAC 3745-52-20; 3745-52-33; Effective February 16, 2009.

OHIO'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

Description of Federal requirement (include checklist number, if relevant)	Federal Register date and page (and/or RCRA statutory authority)	Analogous State authority
Waste Management System; Testing and Monitoring Activities; Final Rule: Methods Innovation Rule and SW-846 Final Update IIIB; Checklist 208.	June 14, 2005, 70 FR 34538	OAC 3745-50-11; 3745-50-44(C)(7); 3745-50-44(C)(9); 3745-50-62; 3745-50-66; 3745-51-03; 3745-51-20; 3745-51-21; 3745-51-22; 3745-51-35; 3745-51-38; 3745-55-90; 3745-57-14; 3745-66-90; 3745-68-14; 3745-266-100; 3745-266-102; 3745-266-103; 3745-266-106; 3745-266-112; 3745-270-40; 3745-270-48; 3745-279-10; 3745-279-44; 3745-279-53; 3745-279-63; Effective February 16, 2009.
Waste Management System; Testing and Monitoring Activities; Final Rule: Methods Innovation Rule and SW-846 Final Update IIIB; Correction; Checklist 208.1.	August 1, 2005, 70 FR 44150	OAC 3745-54-98; Effective February 16, 2009.
Revision of Wastewater Treatment Exemptions for Hazardous Waste Mixtures ("Headworks Exemptions"); Checklist 211.	October 4, 2005, 70 FR 57769	OAC 3745-51-03; Effective February 16, 2009.
National Emission Standards for Hazardous Air Pollutants: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors (Phase I Final Replacement Standards and Phase II); Checklist 212.	October 12, 2005, 70 FR 59402	OAC 3745-50-10; 3745-50-11; 3745-50-44(C)(7); 3745-50-44(C)(9, 10, 11); 3745-50-51; 3745-50-62; 3745-50-66; 3745-50-235; 3745-57-40; 3745-68-40; 3745-266-100; Effective February 16, 2009.
Hazardous Waste and Used Oil; Corrections to Errors in the Code of Federal Regulations; Checklist 214.	July 14, 2006, 71 FR 40254	OAC 3745-50-27; 3745-50-28; 3745-50-40; 3745-50-41; 3745-50-42; 3745-50-43; 3745-50-44; 3745-50-45; 3745-50-50; 3745-50-51; 3745-51-02; 3745-51-03; 3745-51-04; 3745-51-06; 3745-51-11; 3745-51-21; 3745-51-24; 3745-51-30; 3745-51-31; 3745-51-32; 3745-51-33; 3745-51-38; 3745-52-34; 3745-52-53; 3745-52-56; 3745-52-58; 3745-52-70; 3745-52-81; 3745-52-82; 3745-52-83; 3745-52-84; 3745-52-87; 3745-54-01; 3745-54-13; 3745-54-17; 3745-54-18; 3745-54-73; 3745-54-97; 3745-54-98; 3745-54-99; 3745-54-101; 3745-55-11; 3745-55-12; 3745-55-15; 3745-55-16; 3745-55-18; 3745-55-19; 3745-55-40; 3745-55-42; 3745-55-43; 3745-55-45; 3745-55-47; 3745-55-51; 3745-55-75; 3745-55-93; 3745-56-21; 3745-56-23; 3745-56-26; 3745-56-51; 3745-56-52; 3745-56-59; 3745-56-80; 3745-56-83; 3745-57-03; 3745-57-04; 3745-57-06; 3745-57-14; 3745-57-17; 3745-57-44; 3745-57-72; 3745-57-73; 3745-57-74; 3745-57-75; 3745-57-83; 3745-57-90; 3745-57-91; 3745-205-101; 3745-65-01; 3745-65-12; 3745-65-14; 3745-65-16; 3745-65-19; 3745-65-56; 3745-65-73; 3745-65-90; 3745-66-10; 3745-66-12; 3745-66-13; 3745-66-17; 3745-66-19; 3745-66-40; 3745-66-42; 3745-66-45; 3745-66-47; 3745-66-74; 3745-66-93; 3745-66-94; 3745-66-97; 3745-66-99; 3745-66-101; 3745-67-21; 3745-67-24; 3745-67-28; 3745-67-29; 3745-67-55; 3745-67-59; 3745-67-80; 3745-67-81; 3745-68-02; 3745-68-03; 3745-68-05; 3745-68-12; 3745-68-14; 3745-68-16; 3745-69-05; 3745-69-41; 3745-69-43; 3745-69-45; 3745-256-100; 3745-256-101; 3745-266-70; 3745-266-80; 3745-266-100; 3745-266-102; 3745-266-103; 3745-266-106; 3745-266-107; 3745-266-109; 3745-266-112; 3745-270-02; 3745-270-04; 3745-270-06; 3745-270-07; 3745-270-40; 3745-270-42; 3745-270-44; 3745-270-45; 3745-270-48; 3745-270-49; 3745-270-50; 3745-273-09; 3745-273-13; 3745-273-14; 3745-273-34; 3745-279-01; 3745-279-10; 3745-279-11; 3745-279-43; 3745-279-44; 3745-279-45; 3745-279-52; 3745-279-55; 3745-279-56; 3745-279-57; 3745-279-59; 3745-279-63; 3745-279-64; 3745-279-70; Effective February 16, 2009.

TABLE 2—EQUIVALENT STATE INITIATED CHANGES

Ohio amendment	Description of change	Sections affected and effective date
Rule Review per 119.032 ... Housekeeping Rules Set I	OAC 3745-50-31; 3745-50-47; 3745-54-56; 3745-54-77 Effective May 13, 2007. OAC 3745-50-10; 3745-50-11; 3745-50-40 3745-50-51; 3745-50-235; 3745-51-03; 3745-51-04; 3745-51-05; 3745-51-20; 3745-51-22; 3745-51-24; 3745-51-30; 3745-51-35; 3745-51-38; 3745-52-10; 3745-52-21; 3745-52-27; 3745-52-32; 3745-52-33; 3745-52-34; 3745-52-41; 3745-52-54; 3745-53-20; 3745-53-21; 3745-54-18; 3745-54-71; 3745-54-72; 3745-54-98; 3745-55-47; 3745-55-90; 3745-55-99; 3745-57-14; 3745-57-83; 3745-57-91; 3745-65-72; 3745-66-41; 3745-66-90; 3745-67-73; 3745-68-14; 3745-68-40; 3745-256-100; 3745-266-80; 3745-266-103; 3745-266-106; 3745-270-01; 3745-270-40; 3745-270-48; 3745-279-44; 3745-279-53; 3745-279-55; 3745-279-63 Effective February 16, 2009.

G. Which revised State rules are different from the Federal rules?

Ohio has excluded the non-delegable Federal requirements at 40 CFR 268.5, 268.6, 268.42(b), 268.44, and 270.3. EPA will continue to implement those requirements. In this action, because Ohio has not received statutory authority for Subparts AA, BB and CC of 40 CFR part 264, they have not adopted the rules for the 40 CFR subpart BB portion in checklist 212 (located in the table above). This will be added at a later date. Checklist 214 in the above table appeared in the **Federal Register** on July 14, 2006 (71 FR 40254) as a Federal regulation that corrected numerous errors that had appeared in the *Code of Federal Regulations* over several years. Not all of the amendments in the July 14 **Federal Register** are reflected in this Ohio rules effective date or in the current Authorization Revision Application. Since the July 14 **Federal Register** includes several hundred amendments, it was broken into several rule-makings in Ohio. This is the first of these rule-makings. Subsequent rule-makings will address the balance of the corrections. A number of these Federal corrections had already been made in the State rules, so not all the Federal changes made in the July 14 FR resulted or will result in Ohio rule amendments attributable to the July 14 FR. Ohio has corrected the errors in the sections cited in Checklist 214 above, additional corrections will be noted in future **Federal Registers** as State Initiated Changes to Checklist 214.

H. Who handles permits after the authorization takes effect?

Ohio will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization until they expire or are terminated. We will not issue any more

new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Ohio is not yet authorized.

I. How does today's action affect Indian Country (18 U.S.C. 1151) in Ohio?

Ohio is not authorized to carry out its hazardous waste program in "Indian Country," as defined in 18 U.S.C. 1151. Indian Country includes:

1. All lands within the exterior boundaries of Indian Reservations within or abutting the State of Ohio;
2. Any land held in trust by the U.S. for an Indian tribe; and
3. Any other land, whether on or off an Indian reservation that qualifies as Indian Country.

Therefore, EPA retains the authority to implement and administer the RCRA program in Indian Country.

J. What is codification and is EPA codifying Ohio's Hazardous Waste Program as authorized in this rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized State rules in 40 CFR part 272. Ohio's rules, up to and including those revised June 7, 1991, as corrected August 19, 1991, have previously been codified through the incorporation-by-reference effective February 4, 1992 (57 FR 4162). We reserve the amendment of 40 CFR part 272, subpart KK for the codification of Ohio's program changes until a later date.

K. Statutory and Executive Order Reviews

This proposed rule only authorizes hazardous waste requirements pursuant to RCRA 3006 and imposes no requirements other than those imposed by State law (see **SUPPLEMENTARY**

INFORMATION, Section A. Why are Revisions to State Programs Necessary?). Therefore this rule complies with applicable executive orders and statutory provisions as follows:

1. Executive Order 18266: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

The Office of Management and Budget has exempted this rule from its review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821 January 21, 2011).

2. Paperwork Reduction Act

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.*).

3. Regulatory Flexibility Act

This rule authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those required by State law. Accordingly, I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

4. Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

5. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) does not apply to this rule because it will not have federalism implications (*i.e.*, 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).

6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this rule because it will not have tribal implications (*i.e.*, substantial direct effects on one or more Indian tribes, or on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes).

7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866 and because the EPA does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action as defined in Executive Order 12866.

9. National Technology Transfer Advancement Act

EPA approves State programs as long as they meet criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a State program, to require the use of any particular voluntary consensus standard in place of another standard that meets requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply to this rule.

10. Executive Order 12988

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

11. Executive Order 12630: Evaluation of Risk and Avoidance of Unanticipated Takings

EPA has complied with Executive Order 12630 (53 FR 8859, March 18,

1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the executive order.

12. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

Because this rule proposes authorization of pre-existing State rules and imposes no additional requirements beyond those imposed by State law and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994).

13. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: August 28, 2011.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011-23553 Filed 9-13-11; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

Office of the Secretary

45 CFR Part 164

[CMS-2319-P]

RIN 0938-AQ38

CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS; Office for Civil Rights (OCR), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient's request, the laboratory may provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. Subject to conforming amendments, the proposed rule would retain the existing provisions that provide for release of test reports to authorized persons and, if applicable, the individuals (or their personal representative) responsible for using the test reports and, in the case of reference laboratories, the laboratory that initially requested the test. In addition, this proposed rule would also amend the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals the right to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 14, 2011.

ADDRESSES: In commenting, please refer to file code CMS-2319-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation