

of 684 Patients,” *Journal of Obstetrics and Gynecology Research*, 34(4):449–456, 2008.

5. Maher, C.F., et al., “Surgical Management of Pelvic Organ Prolapse in Women,” *Cochrane Database of Systematic Review*, 4: CD004014, 2010.

6. Diwadkar, G.B., et al., “Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair: A Systematic Review,” *Obstetrics & Gynecology*, 113(2 Pt. 1):67–73, 2009.

7. Maher, C.F., et al., “Laparoscopic Sacral Colpopexy Versus Total Vaginal Mesh for Vaginal Vault Prolapse: A Randomized Trial,” *American Journal of Obstetrics & Gynecology*, 204(4):360.e1–360.e7, 2011.

8. Altman, D., et al., “Anterior Colporrhaphy Versus Transvaginal Mesh for Pelvic-Organ Prolapse,” *New England Journal of Medicine*, 364:1826–1836, 2011.

9. Iglesia, C.B., et al., “Vaginal Mesh for Prolapse: A Randomized Controlled Trial,” *Obstetrics & Gynecology*, 116(2 Pt. 1):293–303, 2010.

10. Withagen, M.I., et al., “Trocarguided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse: A Randomized Controlled Trial,” *Obstetrics & Gynecology*, 117(2 Pt. 1):242–250, 2011.

11. Sung, V.W., et al., Society of Gynecologic Surgeons Systematic Review Group. “Graft Use in Transvaginal Pelvic Organ Prolapse and Urinary Incontinence,” *Obstetrics & Gynecology*, 112(5):1131–1142, 2008.

12. Hiltunen, R., et al., “Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse: A Randomized Controlled Trial,” *Obstetrics & Gynecology*, 110(2 Pt. 2):455–462, 2007.

13. Jia, X., et al., “Efficacy and Safety of Using Mesh or Grafts in Surgery for Anterior and/or Posterior Vaginal Wall Prolapse: Systematic Review and Meta-Analysis,” *British Journal of Obstetrics and Gynecology*, 115:1350–1361, 2008.

14. Sivaslioglu, A.A., E. Unlubilgin, and I. Dolen, “A Randomized Comparison of Polypropylene Mesh Surgery With Site-Specific Surgery in the Treatment of Cystocele,” *International Urogynecology Journal and Pelvic Floor Dysfunction*, 19(4):467–471, 2008.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 884.4910 to subpart E to read as follows:

§ 884.4910 Specialized surgical instrumentation for use with urogynecologic surgical mesh.

(a) *Identification.* Specialized surgical instrumentation for use with urogynecologic surgical mesh is a prescription device specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures. These procedures include transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of specialized surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device is not a manual gastroenterology-urology surgical instrument and accessories (§ 876.4730) or a manual surgical instrument for general use (§ 878.4800).

(b) *Classification.* Class II (special controls). The special controls for specialized surgical instrumentation for use with urogynecologic surgical mesh are:

(1) The device must be demonstrated to be biocompatible;

(2) The device must be demonstrated to be sterile and, if reusable, it must be demonstrated that the device can be adequately reprocessed;

(3) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;

(4) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and

(5) Labeling must include:

(i) Information regarding the mesh design that may be used with the device;

(ii) Detailed summary of the clinical evaluations pertinent to use of the device;

(iii) Expiration date; and

(iv) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31862 Filed 1–5–17; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2016–0396; FRL–9957–80–Region 5]

Air Plan Approval; Ohio; Redesignation of the Cleveland, Ohio Area to Attainment of the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) finds that the Cleveland-Akron-Lorain, Ohio area (Cleveland area) is attaining the 2008 ozone National Ambient Air Quality Standard (NAAQS or standard) and is redesignating the area to attainment for the 2008 ozone NAAQS, because the area meets the statutory requirements for redesignation under the Clean Air Act (CAA). The Cleveland area includes Ashtabula, Cuyahoga, Geauga, Lake, Lorain, Medina, Portage, and Summit counties. EPA is also approving, as a revision to the Ohio State Implementation Plan (SIP), the state’s plan for maintaining the 2008 ozone standard through 2030 in the Cleveland area. Finally, EPA finds adequate and is approving the state’s 2020 and 2030 volatile organic compound (VOC) and oxides of nitrogen (NO_x) Motor Vehicle Emission Budgets (MVEBs) for the Cleveland area. The Ohio Environmental Protection Agency (Ohio EPA) submitted the SIP revision and redesignation request on July 6, 2016.

DATES: This final rule is effective January 6, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2016–0396. All documents in the docket are listed in the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jenny Liljegren, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18)),

Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6832, Liljegren.Jennifer@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

I. What is being addressed in this document?

This rule takes action on the July 6, 2016 submission from Ohio EPA requesting redesignation of the Cleveland area to attainment for the 2008 ozone standard. The background for today’s action is discussed in detail in EPA’s proposal, dated October 17, 2016 (81 FR 71444). In that rulemaking, we noted that, under EPA regulations at 40 CFR part 50, the 2008 ozone NAAQS is attained in an area when the 3-year average of the annual fourth highest daily maximum 8-hour average concentration is equal to or less than 0.075 ppm, when truncated after the thousandth decimal place, at all of the ozone monitoring sites in the area. (See 40 CFR 50.15 and appendix P to 40 CFR part 50.) Under the CAA, EPA may redesignate nonattainment areas to attainment if sufficient complete, quality-assured data are available to determine that the area has attained the standard and if it meets the other CAA redesignation requirements in section 107(d)(3)(E). The proposed rule, dated October 17, 2016, provides a detailed discussion of how Ohio has met these CAA requirements.

As discussed in the proposed rule, quality-assured and certified monitoring data for 2013–2015 and preliminary data for 2016 show that the Cleveland area has attained and continues to attain the 2008 ozone standard. In the maintenance plan submitted for the area, Ohio has demonstrated that the ozone standard will be maintained in the area through 2030. Finally, Ohio has adopted 2020 and 2030 VOC and NO_x MVEBs for the Cleveland area that are supported by Ohio’s maintenance demonstration.

II. What comments did we receive on the proposed rule?

EPA provided a 30-day review and comment period for the October 17, 2016, proposed rule. The comment period ended on November 16, 2016. During the comment period, comments in support of the action were submitted on behalf of the Ohio Utility Group and its member companies. We received no adverse comments on the proposed rule.

III. What action is EPA taking?

EPA finds that the Cleveland nonattainment area is attaining the 2008 ozone standard, based on quality-assured and certified monitoring data for 2013–2015 and that the Ohio portion of this area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA. EPA is thus changing the legal designation of the Cleveland area from nonattainment to attainment for the 2008 ozone standard. EPA is also approving, as a revision to the Ohio SIP, the state’s maintenance plan for the area. The maintenance plan is designed to keep the Cleveland area in attainment of the 2008 ozone NAAQS through 2030. Finally, EPA finds adequate and is approving the newly-established 2020 and 2030 MVEBs for the Cleveland area.

In accordance with 5 U.S.C. 553(d), EPA finds there is good cause for these actions to become effective immediately upon publication. This is because a delayed effective date is unnecessary due to the nature of a redesignation to attainment, which relieves the area from certain CAA requirements that would otherwise apply to it. The immediate effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rulemaking actions may become effective less than 30 days after publication if the rule “grants or recognizes an exemption or relieves a restriction,” and section 553(d)(3), which allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” The purpose of the 30-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Today’s rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today’s rule relieves the state of planning requirements for this ozone nonattainment area. For these reasons, EPA finds good cause under 5 U.S.C. 553(d)(3) for these actions to become effective on the date of publication of these actions.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those

imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - 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);
 - Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
 - Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
 - Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of

Indian country, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on tribes, impact any existing sources of air pollution on tribal lands, nor impair the maintenance of ozone national ambient air quality standards in tribal lands.

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. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule 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).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 7, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition

for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 21, 2016.

Robert A. Kaplan

Acting Regional Administrator, Region 5.

■ Parts 52 and 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.1885 is amended by adding paragraph (pp)(3) to read as follows:

§ 52.1885 Control strategy: Ozone.

* * * * *

(pp) * * *

(3) Approval—On July 6, 2016, the Ohio Environmental Protection Agency submitted a request to redesignate the Cleveland area to attainment of the 2008 ozone NAAQS. As part of the redesignation request, the State submitted a maintenance plan as required by section 175A of the Clean Air Act. Elements of the section 175 maintenance plan include a contingency plan and an obligation to submit a subsequent maintenance plan revision in eight years as required by the Clean Air Act. The 2020 motor vehicle emissions budgets for the Cleveland area are 38.85 tons per summer day (TPSD) for VOC and 61.56 TPSD for NO_x. The 2030 motor vehicle emissions budgets for the Cleveland area are 30.80 TPSD for VOC and 43.82 TPSD for NO_x.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. Section 81.336 is amended by revising the entry for Cleveland-Akron-Lorain, OH in the table entitled “Ohio-2008 8-Hour Ozone NAAQS (Primary and secondary)” to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date ¹	Type	Date ¹	Type
* * * * *				
Cleveland, OH: ² Ashtabula County, Cuyahoga County, Geauga County, Lake County, Lorain County, Medina County, Portage County, Summit County.	1/6/2017	Attainment.	*	*
* * * * *				

¹ This date is July 20, 2012, unless otherwise noted.

² Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2016-31634 Filed 1-5-17; 8:45 am]

BILLING CODE 6560-50-P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE**45 CFR Parts 1230 and 2554****RIN 3045-AA67****Annual Civil Monetary Penalties Inflation Adjustment****AGENCY:** Corporation for National and Community Service.**ACTION:** Interim final rule.

SUMMARY: The Corporation for National and Community Service (CNCS) is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalties in its regulations, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective date:* This rule is effective January 15, 2017.

Comment due date: Technical comments may be submitted until February 6, 2017.

ADDRESSES: You may send your comments electronically through the Federal government's one-stop rulemaking Web site at www.regulations.gov. Also, you may mail or deliver your comments to Phyllis Green, Executive Assistant, Office of General Counsel, at the Corporation for National and Community Service, 250 E Street SW., Washington, DC 20525. Due to continued delays in CNCS's receipt of mail, we strongly encourage comments to be submitted online electronically. The TDD/TTY number is 800 833-3722. You may request this notice in an alternative format for the visually impaired.

FOR FURTHER INFORMATION CONTACT: Phyllis Green, Executive Assistant, Office of General Counsel, at 202-606-6709 or email to pgreen@cns.gov. Individuals who use a telecommunications device for the deaf (TTY-TDD) may call 800-833-3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:**I. Background**

The Corporation for National and Community Service (CNCS) is a federal agency that engages more than five million Americans in service through its AmeriCorps, Senior Corps, Social

Innovation Fund, and Volunteer Generation Fund programs to further its mission to improve lives, strengthen communities, and foster civic engagement through service and volunteering. For more information, visit NationalService.gov.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114-74) (the "Act"), which is intended to improve the effectiveness of civil monetary penalties and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

II. Method of Calculation

CNCS has two civil monetary penalties in its regulations. A civil monetary penalty under the Act is a penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law and is assessed or enforced by an agency pursuant to Federal law and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. (*See* 28 U.S.C. 2461 note).

The inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October of the year in which the amount of each civil money penalty was most recently established or modified. In the December 16, 2016, OMB Memo for the Heads of Executive Agencies and Departments, M-17-11, *Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*, OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2017, based on the CPI-U for the month of October 2016, not seasonally adjusted, is 1.01636.

CNCS identified two civil penalties in its regulations: (1) The penalty associated with Restrictions on Lobbying (45 CFR 1230.400) and (2) the penalty associated with the Program Fraud Civil Remedies Act (45 CFR 2554.1).

The civil monetary penalties related to Restrictions on Lobbying (Section 319, Pub. L. 101-121; 31 U.S.C. 1352) range from \$18,936 to \$189,361. Using the 2017 multiplier, the new range of possible civil monetary penalties is from \$19,246 to \$192,459.

The Program Fraud Civil Remedies Act of 1986 (Pub. L. 99-509) civil monetary penalty has an upper limit of \$10,781. Using the 2017 multiplier, the

new upper limit of the civil monetary penalty is \$10,957.

III. Summary of Final Rule

This final rule adjusts the civil monetary penalty amounts related to Restrictions on Lobbying (45 CFR 1230.400) and the Program Fraud Civil Remedies Act of 1986 (45 CFR 2554.1). The range of civil monetary penalties related to Restrictions on Lobbying increase from "\$18,936 to \$189,361" to "\$19,246 to \$192,459." The civil monetary penalties for the Program Fraud Civil Remedies Act of 1986 increase from "up to \$10,781" to "up to \$10,957."

IV. Regulatory Procedures*A. Determination of Good Cause for Publication Without Notice and Comment*

CNCS finds, under 5 U.S.C. 553(b)(3)(B), that there is good cause to except this rule from the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b). Because CNCS is implementing a final rule pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires CNCS to update its regulations based on a prescribed formula, CNCS has no discretion in the nature or amount of the change to the civil monetary penalties. Therefore, notice and comment for these proscribed updates is impracticable and unnecessary. As an interim final rule, no further regulatory action is required for the issuance of this legally binding rule. If you would like to provide technical comments, however, they may be submitted until February 6, 2017.

B. Review Under Procedural Statutes and Executive Orders

CNCS has determined that making technical changes to the amount of civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive Orders that govern rulemaking procedures.

V. Effective Date

This rule is effective January 15, 2017. The adjusted civil penalty amounts apply to civil penalties assessed on or after January 15, 2017, when the violation occurred after November 2, 2015. If the violation occurred prior to November 2, 2015, or a penalty was assessed prior to August 1, 2016, the pre-adjustment civil penalty amounts in effect prior to August 1, 2016, will apply.