

**§ 416.926a [Amended]**

■ 4. Amend § 416.926a by removing paragraph (m)(1) and redesignating paragraphs (m)(2) through (6) as (m)(1) through (5).

[FR Doc. 2016-13275 Filed 6-8-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**21 CFR Part 14**

[Docket No. FDA-2016-N-0001]

**Advisory Committee; Transmissible Spongiform Encephalopathies Advisory Committee; Termination**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the termination of the Transmissible Spongiform Encephalopathies Advisory Committee. This document removes the Transmissible Spongiform Encephalopathies Advisory Committee from the Agency's list of standing advisory committees.

**DATES:** This rule is effective June 9, 2016.

**FOR FURTHER INFORMATION CONTACT:** Bryan Emery, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993-0002, 240-402-8054, FAX: 301-595-1307, or [bryan.emery@fda.hhs.gov](mailto:bryan.emery@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Transmissible Spongiform Encephalopathies Advisory Committee (the Committee) was established on June 9, 1995 (60 FR 31311, June 14, 1995; 21 CFR 14.100 erroneously lists the date of establishment as June 21, 1995). The Committee reviews and evaluates available scientific data concerning the safety of products that may be a risk for transmission of spongiform encephalopathies having an impact on the public health as determined by the Commissioner of Food and Drugs. The Committee makes recommendations to the Commissioner regarding the regulation of such products. In recent years, the number of issues requiring Committee advice has declined, and the Committee has met very infrequently. Therefore, the effort and expense of maintaining this advisory committee is no longer justified. Any relevant

Transmissible Spongiform Encephalopathy issues in the future could be addressed by the Agency's other advisory committees, such as the Agency's Blood Products Advisory Committee, with additional augmentation of expertise by appropriate subject matter experts serving as temporary members on the committee.

The Committee is no longer needed and will be terminated on June 9, 2016.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40 (d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Transmissible Spongiform Encephalopathies Advisory Committee from the list of standing advisory committees in 21 CFR 14.100.

Therefore, the Agency is amending 21 CFR 14.100(b) as set forth in the regulatory text of this document.

**List of Subjects in 21 CFR Part 14**

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

**PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE**

■ 1. The authority citation for part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155.

**§ 14.100 [Amended]**

■ 2. In § 14.100, redesignate paragraph (b)(5) as (b)(4) and remove paragraph (b)(6).

Dated: June 6, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-13705 Filed 6-8-16; 8:45 am]

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**DEPARTMENT OF THE INTERIOR**
**Office of Natural Resources Revenue**
**30 CFR Part 1241**

[Docket No. ONRR-2016-0002; DS63644000 DR2PS0000.CH7000167D0102R2]

RIN 1012-AA17

**Civil Monetary Penalties Inflation Adjustment**

**AGENCY:** Office of the Secretary, Office of Natural Resources Revenue, Interior.

**ACTION:** Interim final rule.

**SUMMARY:** The Office of Natural Resources Revenue (ONRR) publishes this interim final rule to adjust the amount of our civil monetary penalties (CMPs) for inflation with an initial "catch-up" adjustment under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

**DATES:** This rule is effective July 11, 2016. Comments will be accepted until August 8, 2016.

**ADDRESSES:** You may submit comments to ONRR by one of the following three methods. (Please reference the Regulation Identifier Number (RIN) 1012-AA17 in your comments.). See also Public Availability of Comments under Procedural Requirements.

1. Electronically, go to [www.regulations.gov](http://www.regulations.gov). In the entry titled "Enter Keyword or ID," enter "ONRR-2016-0002," and then click "Search." Follow the instructions to submit public comments. ONRR will post all comments.

2. Mail comments to Luis Aguilar, Regulatory Specialist, ONRR, P.O. Box 25165, MS 64400B, Denver, Colorado 80225.

3. Hand-carry comments, or use an overnight courier service to the Office of Natural Resources Revenue, Building 53, Entrance E-20, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225.

**FOR FURTHER INFORMATION CONTACT:** For comments or questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, by telephone at (303) 231-3418 or email to [luis.aguilar@onrr.gov](mailto:luis.aguilar@onrr.gov). For questions on technical issues, contact Geary Keeton, Chief of Enforcement, by telephone at (303) 231-3096 or email to [geary.keeton@onrr.gov](mailto:geary.keeton@onrr.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background
- II. Method of Calculation
- III. Summary of Final Rule
- IV. Procedural Requirements

**I. Background**

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the Act). The Act requires Federal agencies to adjust each CMP amount with an initial catch-up adjustment through rulemaking and then make subsequent annual inflationary adjustments. The new CMP amounts must be published by July 1, 2016, and take effect no later than August 1, 2016. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to foster compliance with the law.

The Act provides that any increase in a CMP due to the calculated inflation adjustments shall apply only to a violation that occurs after the date when the increase takes effect and states that the initial inflation adjustment may not exceed 150 percent of the amount of the CMP on November 2, 2015.

**II. Method of Calculation**

OMB issued guidance on calculating the catch-up adjustments. See February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*. Under this guidance, the Department of the Interior (Department) has identified applicable CMPs and calculated the catch-up adjustments. A CMP is any assessment with a dollar amount that is levied for

a violation of a Federal civil statute or regulation and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A CMP does not include a penalty levied for violation of a criminal statute, fees for services, licenses, permits, or other regulatory review.

Under the Act, the inflation adjustment for each applicable CMP is determined by increasing the maximum CMP amount per violation by the cost-of-living adjustment. The cost-of-living adjustment is defined as the percent by which the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October of the calendar year preceding the adjustment exceeds the CPI-U for the month of October of the year in which the amount of such CMP was last set or adjusted pursuant to law.

The maximum CMP amounts for ONRR penalties under 30 U.S.C. 1719(a)–(d) were established in 1983 in the Federal Oil and Gas Management Act (FOGRMA). Since we have not updated the maximum CMP amounts for inflation since their establishment, we must calculate a new maximum CMP with an initial catch-up adjustment. The inflation adjustment amount for each maximum CMP amount is calculated by multiplying the 1983 maximum CMP amount by the 2016 CMP catch-up adjustment multiplier for 1983, which is 2.35483. In accordance with the Act, the new maximum CMP amount is rounded to the nearest dollar. For example:

- The maximum CMP amount under 30 U.S.C. 1719(a) established in 1983 is \$500.

- The 2016 CMP catch-up adjustment multiplier for 1983 is 2.35483.

- Therefore,  $\$500 \times 2.35483 = \$1,177.415$ , which rounds to \$1,177.

- The new maximum CMP amount is \$1,177.

Pursuant to the Act, in the event that a violation took place prior to the effective date of the new penalty amount—and we assess a penalty after the effective date—the new penalty amount is assessed in a manner consistent with the new maximum CMP calculation. As the Act applies to penalties assessed after the effective date of the applicable adjustment, the Act adjusts penalties prospectively. The Act does not retrospectively change previously assessed or enforced penalties that we are actively collecting or have collected. The Act does not alter our statutory authority to assess penalties below the maximum amount.

**III. Summary of Final Rule**

This final rule adjusts the maximum CMP amount within each of the four established civil penalty tiers specified in 30 U.S.C. 1719(a)–(d). The following list summarizes the existing ONRR regulations containing CMPs, as well as the penalties before and after adjustment. The increases in maximum CMP amounts contained in this final rule may not necessarily affect the amount of any CMP that we may seek for a particular violation; we will calculate each CMP on a case-by-case basis.

ONRR Regulation containing CMPs	Current maximum CMP amount	Catchup adjustment multiplier	Adjusted maximum CMP amount
30 CFR 1241.53(a) .....	500	2.35483	1,177
30 CFR 1241.53(b) .....	5,000	2.35483	11,774
30 CFR 1241.60(a) .....	10,000	2.35483	23,548
30 CFR 1241.60(b) .....	25,000	2.35483	58,871

**Note:** The CMP amounts under 30 CFR 1241 are authorized by 30 U.S.C. 1719(a)–(d).

**IV. Procedural Requirements**

*1. Regulatory Planning and Review (Executive Orders 12866 and 13563)*

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in OMB will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the Nation’s regulatory system to promote predictability, to reduce uncertainty,

and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public, where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open

exchange of ideas. We developed this rule in a manner consistent with these requirements.

*2. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and

604(a). The Federal Civil Penalties Adjustment Act of 2015 requires agencies to adjust civil penalties with an initial catch-up adjustment through an interim final rule. An interim final rule does not include first publishing a proposed rule. Thus, the RFA does not apply to this rulemaking.

### 3. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

- a. Does not have an annual effect on the economy of \$100 million or more.
- b. Will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, local government agencies; or geographic regions.
- c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

### 4. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than \$100 million per year. This rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, we are not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) requires because this rule is not an unfunded mandate.

### 5. Takings (E.O. 12630)

Under the criteria in section 2 of E.O. 12630, this rule does not have any significant takings implications. This rule will not impose conditions or limitations on the use of any private property. Therefore, this rule does not require a takings implication assessment.

### 6. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. Therefore, this rule does not require a Federalism summary impact statement.

### 7. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

- a. Meets the criteria of section 3(a), which requires that we review all

regulations to eliminate errors and ambiguity and to write them to minimize litigation.

- b. Meets the criteria of section 3(b)(2), which requires that we write all regulations in clear language using clear legal standards.

### 8. Consultation With Indian Tribal Governments (E.O. 13175)

The Department strives to strengthen its government-to-government relationship with the Indian Tribes through a commitment to consultation with the Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. Under the Department's consultation policy and the criteria in E.O. 13175, we evaluated this rule and determined that it will have no substantial direct effects on Federally-recognized Indian Tribes and does not require consultation.

### 9. Paperwork Reduction Act

This rule:

- (a) Does not contain any new information collection requirements.
- (b) Does not require a submission to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). See 5 CFR 1320.4(a)(2).

### 10. National Environmental Policy Act of 1969 (NEPA)

This rule does not constitute a major Federal action, significantly affecting the quality of the human environment. We are not required to provide a detailed statement under NEPA because this rule qualifies for categorical exclusion under 43 CFR 46.210(i) in that this rule is “. . . of an administrative, financial, legal, technical, or procedural nature. . . .” We also have determined that this rule is not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

### 11. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211 and, therefore, does not require a Statement of Energy Effects.

### 12. Clarity of This Regulation

We are required by E.O. 12866 (section 1(b)(12)), E.O. 12988 (section 3(b)(1)(B)), and E.O. 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized.
- (b) Use the active voice to address readers directly.
- (c) Use common, everyday words and clear language rather than jargon.

(d) Be divided into short sections and sentences.

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

### 13. Public Availability of Comments

ONRR will post all comments, including the name and address of a respondent, at [www.regulations.gov](http://www.regulations.gov). Before including Personally Identifiable Information (PII), such as your address, phone number, email address, or other personal information in your comments, you should be aware that your entire comment (including PII) may be made available to the public at any time. While you may ask us, in your comment, to withhold PII from public view, we cannot guarantee that we will be able to do so.

### 14. Administrative Procedure Act (APA)

In accordance with § 553(b), ONRR generally publishes a rule in a proposed form and solicits public comment on it before issuing the final rule. However, § 553(b)(3)(B) provides an exception to the public comment requirement if the agency finds good cause to omit advance notice and public participation. Good cause is shown when public comment is “impracticable, unnecessary, or contrary to the public interest.”

ONRR finds that there is good cause to promulgate this rule without first providing for public comment. We are promulgating this final rule to implement the statutory directive in the Act, which requires agencies to publish an interim final rule and to update the CMP amounts by applying a specified formula. ONRR has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for pre-promulgation public comment on this rule. Also, it would not be possible to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Thus, pre-promulgation notice and public comment is unnecessary and impracticable. These technical changes,

required by law, do not substantively alter the existing regulatory framework nor in any way effect the terms under which ONRR assesses civil penalties.

#### List of Subjects in 30 CFR Part 1241

Administrative practice and procedure, Civil penalties, Coal, Geothermal, Inflation, Mineral resources, Natural gas, Notices of non-compliance, oil.

Dated: June 1, 2016.

**Kristen J. Sarri,**

*Principal Deputy Assistant Secretary for Policy, Management and Budget.*

#### Authority and Issuance

For the reasons discussed in the preamble, ONRR amends 30 CFR part 1241 as set forth below:

#### PART 1241—PENALTIES

■ 1. The authority citation for part 1241 is revised to read as follows:

**Authority:** 25 U.S.C. 396 *et seq.*, 396a *et seq.*, 2101 *et seq.*; 30 U.S.C. 181 *et seq.*, 351 *et seq.*, 1001 *et seq.*, 1701 *et seq.*; 43 U.S.C. 1301 *et seq.*, 1331 *et seq.*, 1801 *et seq.* and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

#### § 1241.53 [Amended]

■ 2. Amend § 1241.53 by:

- A. In paragraph (a), remove “\$500” and add in its place “\$1,177.”
- B. In paragraph (b), remove “\$5,000” and add in its place “\$11,774.”

#### § 1241.60 [Amended]

■ 3. Amend § 1241.60 by:

- A. In paragraph (a), remove “\$10,000” and add in its place “\$23,548.”
- B. In paragraph (b), remove “\$25,000” and add in its place “\$58,871.”

[FR Doc. 2016–13462 Filed 6–8–16; 8:45 am]

BILLING CODE 4335–30–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG–2015–0854]

#### Special Local Regulations and Safety Zones; Recurring Marine Events and Fireworks Displays Within the Fifth Coast Guard District

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations for a marine event taking place in the Tred Avon

River, between Bellevue, MD and Oxford, MD on June 12, 2016. The date of this enforcement action has changed because the event was postponed by the sponsor due to inclement weather. This action is necessary to ensure safety of life on navigable waters during this event. Our regulation for Recurring Marine Events within the Fifth Coast Guard District identifies the regulated area for this marine event. During the enforcement period, the Coast Guard Patrol Commander or designated Marine Event Patrol may forbid and control the movement of all vessels in the regulated area.

**DATES:** The regulations in 33 CFR 100.501, listed as event (b)14 in the Table to 33 CFR 100.501 will be enforced from 9 a.m. to 11 a.m. on June 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email Mr. Ron Houck, U.S. Coast Guard Sector Maryland-National Capital Region (WWM); telephone 410–576–26742, email [Ronald.L.Houck@uscg.mil](mailto:Ronald.L.Houck@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the regulated area in 33 CFR 100.501 from 9 a.m. until 11 a.m. on June 12, 2016, for the Oxford-Bellevue Sharkfest Swim. The date of this enforcement action has changed because the event was postponed by the sponsor due to inclement weather. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for Recurring Marine Events within the Fifth Coast Guard District, § 100.501, specifies the location of the regulated area for this event that includes all waters of the Tred Avon River from shoreline to shoreline, within an area bounded on the east by a line drawn from latitude 38°42′25″ N., longitude 076°10′45″ W., thence south to latitude 38°41′37″ N., longitude 076°10′26″ W., and bounded on the west by a line drawn from latitude 38°41′58″ N., longitude 076°11′04″ W., thence south to latitude 38°41′25″ N., longitude 076°10′49″ W., thence east to latitude 38°41′25″ N., longitude 076°10′30″ W., located at Oxford, MD. Only designated marine event participants and their vessels and official patrol vessels are authorized to enter the regulated area. As specified in § 100.501(c), during the enforcement period, the Coast Guard Patrol Commander or designated Marine Event Patrol may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel in these areas shall immediately comply with the directions given. Failure to do so

may result in expulsion from the area, citation for failure to comply, or both. The operator of any vessel in the regulated area shall: (i) Stop the vessel immediately when directed to do so by any Official Patrol and then proceed only as directed; (ii) All persons and vessels shall comply with the instructions of the Official Patrol; (iii) When authorized to transit the regulated area, all vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the race course. The Coast Guard may be assisted by other Federal, state or local law enforcement agencies in enforcing this regulation. If the Captain of the Port or his designated on-scene Patrol Commander determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

This notice of enforcement is issued under authority of 33 CFR 100.501(f), Special Local Regulations and Safety Zones; Recurring Marine Events and Fireworks Displays Within the Fifth Coast Guard District and 5 U.S.C. 552(a). In addition to this notification in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners and the Local Notice to Mariners. The Captain of the Port, Sector Maryland-National Capital Region, or a designated on-scene representative may be contacted via Channel 16, VHF–FM.

Dated: May 23, 2016.

**Michael W. Batchelder**

*Commander, U.S. Coast Guard, Acting Captain of the Port, Maryland-National Capital Region.*

[FR Doc. 2016–13707 Filed 6–8–16; 8:45 am]

BILLING CODE 9110–04–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG–2016–0402]

#### Drawbridge Operation Regulation; Saugatuck River, Saugatuck, CT

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Metro-North “SAGA” Bridge across the Saugatuck River, mile 1.1, at Saugatuck,