

(11) After a De Novo request is accepted for review under § 860.230(b), the requester makes significant unsolicited changes to the device's:

(i) Indications for use; or

(ii) Technological characteristics.

(d) An order declining a De Novo request will inform the requester of the deficiencies in the De Novo request, including each applicable ground for declining the De Novo request.

(e) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to grant or decline a De Novo request. FDA may use information other than that submitted by the requester in making such determination.

Dated: September 30, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021-21677 Filed 10-4-21; 8:45 am]

BILLING CODE 4164-01-P

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1400

RIN 3076-AA19

Outside Employment, Business Activities, or Interests Regulation

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule; rescission of regulation.

SUMMARY: On August 7, 1992, the Office of Government Ethics (OGE) published a final rule entitled “Supplemental Agency Regulations” requiring Federal agencies creating supplemental ethics regulations to submit such regulations to OGE for concurrence and joint issuance within their regulations. In accordance with “Supplemental Agency Regulations,” this final rule rescinds the current Federal Mediation and Conciliation Service (FMCS) supplemental ethics regulation “Outside employment, business activities, or interests”.

DATES: This final rule is effective October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Alisa Silverman, Attorney-Advisor, Office of General Counsel, Federal Mediation and Conciliation Service, 250 E St. SW, Washington, DC 20427; Office/Fax/Mobile 202-606-5488; asilverman@fmcs.gov.

SUPPLEMENTARY INFORMATION:

I. Discussion

On April 13, 1968, at 33 FR 5765, the Federal Mediation and Conciliation

Service (FMCS) published a final rule entitled “Outside employment, business activities, and interests.” This final rule implemented ethics regulations concerning outside activities.

On August 7, 1992, at 57 FR 35042, the Office of Government Ethics (OGE) published a rule “Supplemental Agency Regulations” requiring Federal agencies creating supplemental ethics regulations to submit such regulations to OGE for concurrence and joint issuance within title 5 of the Code of Federal Regulations.

In accordance with 5 CFR 2635.105, FMCS is working jointly with OGE to develop new supplemental agency regulations to be published by OGE within title 5 of the Code of Federal Regulations. Therefore, FMCS is issuing this final rule, which rescinds the current rule on outside employment, business activities, and interests within title 29 of the Code of Federal Regulations.

II. Final Rule

FMCS has determined that this rule is suitable for final rulemaking. The revisions to FMCS' policies and requirements surrounding outside activities are purely internal matters of agency management, as well as the agency's procedure, and practice. Accordingly, FMCS is not required to engage in a notice and comment process to issue this rule under the Administrative Procedures Act, See U.S.C. 553(a)(2), 553(b)(A). Furthermore, because this rule is procedural rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable. FMCS also finds good cause to provide an immediate effective date for this rule because it imposes no obligations on parties outside the Federal Government and therefore no advance notice is required to enable employers or other private parties to come into compliance.

List of Subjects in 29 CFR Part 1400

Administrative practice and procedure.

For the reasons discussed in the preamble, and under the authority 29 U.S.C. 172 of Taft Harley Act of 1947, and 5 U.S.C. 7301, FMCS amends 29 CFR chapter XII as follows:

PART 1400—STANDARDS OF CONDUCT, RESPONSIBILITIES, AND DISCIPLINE

■ 1. The authority citation for part 1400 continues to read as follows:

Authority: E.O. 11222, 30 FR 6469, 3 CFR, 1965 Supp.; 5 CFR 735.104.

§ 1400.735-12 [Removed]

■ 2. Remove § 1400.735-12.

Issued in Washington, DC.

Sarah Cudahy,

General Counsel.

[FR Doc. 2021-21716 Filed 10-4-21; 8:45 am]

BILLING CODE 6732-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2020-0647]

RIN 1625-AA09

Drawbridge Operation Regulation; New Jersey Intracoastal Waterway, Point Pleasant, NJ; Correction

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Correcting amendments.

SUMMARY: The Coast Guard published a final rule in the **Federal Register** on August 23, 2021, which was effective on September 22, 2021, announcing changes to the Route 88 (Veterans Memorial) Bridge and Route 13 (Lovelandtown) Bridge across the NJICW at Point Pleasant Canal, mile 3.0 and 3.9, respectively at Point Pleasant, NJ. The amendatory instruction within that final rule was incorrect and the changes could not be incorporated into the CFR. This correcting amendment incorporates those changes into the CFR.

DATES: The correction is effective on October 5, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2020-0647. In the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Mickey Sanders, Bridge Administration Branch, Fifth District, U.S. Coast Guard, telephone (757) 398-6587, email Mickey.D.Sanders2@uscg.mil.

SUPPLEMENTARY INFORMATION:

Correction

On August 23, 2021, the Coast Guard published a final rule titled “Drawbridge Operation Regulation; New