(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2019–0039.

(h) Exceptions to EASA AD 2019–0039

(1) Where EASA AD 2019–0039 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2019–0039 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information required by EASA AD 2019–0039 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not require the ''Remarks'' section of EASA AD 2019–0039.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2019–0039 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the helicopter can be modified, provided the OEI rating is prohibited on the right-hand engine.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(l) Related Information

For more information about this AD, contact Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2019–0039, dated February 20, 2019.

(ii) [Reserved]

(3) For EASA AD 2019–0039, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0687.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 14, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25213 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0332]

RIN 1625–AA09

Drawbridge Operation Regulation; Indiana Harbor Canal, East Chicago, IN

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

ACTION: Final rule.

SUMMARY: The Coast Guard is altering the operating schedule that governs the Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal at East Chicago, Indiana. Indiana Department of Transportation, the owner and operator of the bridge, has requested to stop continual drawtender service to the bridge due to a lack of openings.

DATES: This rule is effective December 20, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type USCG–2021–0332 in the ''SEARCH'' box and click ''SEARCH.'' In the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email: Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
IGLD85 International Great Lakes Datum of 1985
INDOT Indiana Department of Transportation
LWD Low Water Datum based on IGLD85
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking
§ Section
USACE United States Army Corps of Engineers
U.S.C. United States Code
USEPA United States Environmental Protection Agency

II. Background Information and Regulatory History

On July 28, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Drawbridge Operation Regulation; Indiana Harbor Canal, East Chicago, IN,'' in the **Federal Register** (86 FR 40388). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this regulatory change. During the comment period that ended on September 27, 2021, we did not receive any comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is a double leaf bascule bridge that provides a horizontal clearance of 68-feet and a vertical clearance of 12-feet in the closed position with an unlimited vertical clearance in the open position based on low water datum (LWD). The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is required to open on signal, and there are no previous rulemakings for this bridge to discuss. The Indiana Harbor Canal is a 3-mile long commercial waterway that serves several industries near the City of East Chicago, Indiana, including the largest integrated steelmaking facility in North America and the 1,400 acre Whiting Refinery that includes the site of the former 1889 Standard Oil of

Indiana refinery at the head of navigation. The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is the last drawbridge before the head of navigation. Once the 1889 Standard Oil of Indiana refinery was torn down the bridge lost its purpose for regular openings, and the waterway silted in around the bridge preventing vessels from approaching. Approximately thirty years after the removal of the refinery, the U.S. Environmental Protection Agency (EPA) and the U.S. Army Corps of Engineers (USACE) partnered to remove polluted sediments form the waterway and established a contaminated dredge spoils area above the bridge. The EPA and USACE contracted dredging company is working a few weeks each season and is the only commercial vessel requesting the bridge to open. There are no records of recreational vessels using the Indiana Harbor Canal.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided a comment period of 60 days and no comments were received.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard did not receive any comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V. A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.400, add paragraph (c) to read as follows:

§ 117.400 Indiana Harbor Canal.

* * * * *

(c) The Indianapolis Boulevard Bridge, mile 2.59, at East Chicago, shall open on signal if at least twelve hours' notice is given.

M.J. Johnston.

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2021–25268 Filed 11–18–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2482–F2]

RIN 0938–AT82

Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to a value based purchasing (VBP) arrangement, of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'', published in the December 31, 2020 **Federal Register** to July 1, 2022. This final rule will also delay for 9 months the April 1, 2022 effective date of inclusion (hereinafter referred to as the inclusion date) of the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) in the amended regulatory definitions of ''States'' and ''United States'' for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, ''Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States'', published in the November 25, 2019 **Federal Register** to January 1, 2023. We requested public comment on the proposed delays of the applicable effective date and inclusion date and discuss the comments received in this final rule.

DATES: These regulations are effective on December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786–4578.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of Proposed Delays in Effective and Inclusion Dates of Certain Regulation Provisions

In the ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States'' proposed rule that published in the May 28, 2021 **Federal Register** (86 FR 28742) (hereinafter referred to as the proposed rule), CMS made two proposals. First, CMS proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' (85 FR 87000) (hereinafter referred to as the December 31, 2020 final rule), for 6 months to July 1, 2022. Second, CMS proposed to delay the April 1, 2022, inclusion date in the amended regulatory definitions of ''States'' and ''United States'', adopted in the interim final rule with comment period entitled ''Medicaid Program; Covered Outpatient Drugs; Further Delay of Inclusion of Territories in Definitions of States and United States'' (84 FR 64783), for 2 years until April 1, 2024, or in the alternative, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments.

B. Proposed Delay of Effective Date of Amendatory Instruction 10.a.

The December 31, 2020 final rule advanced CMS' efforts to support state flexibility to enter into innovative value-based purchasing (VBP) arrangements with drug manufacturers for new and innovative, and often costly therapies, such as gene therapies, and codified new approaches required by section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) and the existing Medicaid DUR program to improve the clinical use of opioids and reduce the potential for abuse in Medicaid patients. In addition, it codified in regulation several changes made in recent legislation and clarified other provisions of regulations relating to the Medicaid Drug Rebate Program (MDRP).

The regulations included in the December 31, 2020 final rule went into effect on March 1, 2021, except for certain amendatory instructions, including instruction 10.a., which is effective on January 1, 2022. In the proposed rule, we proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule on manufacturer reporting of multiple best prices connected to a VBP arrangement, to July 1, 2022, and sought public comment on the proposed delay. As discussed in the proposed rule, we believed a delay of 6 months is warranted to assure that stakeholders have the ability to implement the new VBP policy in a manner that assures patient access and quality of care are protected. We sought public comments on this proposed delay in the effective date, including the impact of this delay on affected beneficiaries. The primary reason for the original delay, and the proposed delay, was to provide more time for CMS, states, and manufacturers to make the complex system changes necessary to implement the new best price and VBP program, and assure patient access and quality of care, given the current need to devote resources to the public health emergency (PHE) relating to COVID–19 that has been in effect, and will likely remain in effect at least through 2021. On April 21, 2021, the Secretary of Health and Human Services (the Secretary) renewed the PHE initially declared on January 31,