

and Drugs, 21 CFR parts 882 and 1270 are amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

§ 882.5975 [Removed]

■ 2. Remove § 882.5975.

PART 1270—[REMOVED]

■ 3. Under the authority of 42 U.S.C. 216, 243, 264, 271, part 1270 is removed.

Dated: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022-00492 Filed 1-12-22; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0022]

RIN 1625-AA00

Safety Zones; Delaware River Dredging, Marcus Hook, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is re-establishing temporary safety zones on the waters of the Delaware River in portions of Marcus Hook Range and Anchorage 7 off Marcus Hook Range. The safety zones temporarily restrict vessel traffic from transiting or anchoring in portions of the Delaware River while maintenance dredging is being conducted within the Delaware River. The safety zones are needed to protect personnel, vessels, and the marine environment from hazards created by dredging operations. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the COTP or his designated representatives.

DATES: This rule is effective without actual notice from January 13, 2022 through January 31, 2022. For the purposes of enforcement, actual notice will be used from January 6, 2022, until January 13, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-

0022 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Jennifer Padilla, Waterways Management Branch, U.S. Coast Guard Sector Delaware Bay; telephone (215) 271-4889, email Jennifer.I.padilla@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On September 2, 2021, the Coast Guard established temporary safety zones on the waters of the Delaware River in portions of Marcus Hook Range and Anchorage 7 off Marcus Hook Range to temporarily restrict vessel traffic from transiting or anchoring in portions of the Delaware River in association with maintenance dredging within the Delaware River (86 FR 49241, Sept. 2, 2021). That rule expired November 2, 2021. On January 6, 2022, the dredging company informed the Coast Guard about additions to the original contract and the need to extend the project. The new estimated completion date is January 31, 2022.

The Coast Guard is issuing this rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. There is insufficient time to allow for a reasonable comment period prior to the start date for dredging operations. The rule must be in force by January 6, 2022, to serve its purpose of ensuring the safety of the public from hazards associated with dredging operations such as submerged and floating pipeline, booster pumps, head sections and vessels with a restricted ability to maneuver.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to mitigate the potential safety hazards associated with dredging operations in these locations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that there are potential hazards associated with dredging operations. The purpose of this rulemaking is to ensure the safety of personnel, vessels, and the marine environment within a 250-yard radius of dredging operations and all associated pipeline and equipment.

IV. Discussion of the Rule

This rule re-establishes the safety zones established on September 2, 2021, (86 FR 49241, Sept. 2, 2021). The re-established zones will be in effect from January 6, 2022, through January 31, 2022. This change is reflected in a revised enforcement paragraph, paragraph (e). This rule makes no other changes to the previous rule. The locations and restrictions of the safety zones established by the September rule remain the same.

The safety zones are necessary to facilitate annual maintenance dredging of the Delaware River in the vicinity of Marcus Hook Range and Anchorage 7 off Marcus Hook Range (as described in 33 CFR 110.157(a)(8)). Dredging will most likely be conducted with the dredge ESSEX, though other dredges may be used, along with associated dredge pipeline and boosters. The pipeline consists of a combination of floating hoses immediately behind the dredge and submerged pipeline leading to upland disposal areas. Due to the hazards related to dredging operations, the associated pipeline, and the location of submerged pipeline, safety zones are being established in the following areas:

(1) Safety zone one includes all navigable waters within 250 yards of the dredge displaying lights and shapes for vessels restricted in ability to maneuver as described in 33 CFR 83.27, and all related dredge equipment when the dredge is operating in Marcus Hook Range, and Anchorage 7. This safety zone is being established for the duration of the maintenance project. Vessels requesting to transit the safety zone must contact the dredge on VHF channel 13 or 16 at least 1 hour prior

to arrival to arrange safe passage. At least one side of the main navigational channel will be kept clear for safe passage of vessels in the vicinity of the safety zone. At no time will the entire main navigational channel be closed to vessel traffic. Vessels should avoid meeting in these areas where one side of the main navigational channel is open and proceed per this rule and the Rules of the Road (33 CFR subchapter E).

(2) Safety zone two includes all the waters of Anchorage 7 off Marcus Hook Range, as described in 33 CFR 110.157(a)(8). Vessels wishing to anchor in Anchorage 7 off Marcus Hook Range while this rule is in effect must obtain permission from the COTP at least 24 hours in advance by calling (215) 271-4807. Vessels requesting permission to anchor within Anchorage 7 off Marcus Hook must be at least 650 feet in overall length. The COTP will permit, at minimum, only one vessel to anchor at a time on a “first-come, first-served” basis. Vessels will only be allowed to anchor for a 12 hour period. Vessels that require an examination by the Public Health Service, Customs, or Immigration authorities will be directed to an anchorage by the COTP for the required inspection. Vessels are encouraged to use Anchorage 9 near the entrance to Mantua Creek, Anchorage 10 at Naval Base, Philadelphia, and Anchorage 6 off Deepwater Point Range as alternative anchorages.

Preference is being given to vessels at least 650 feet in length in the Anchorage 7 while this rule is in effect, because vessels of this size are limited in their ability to utilize other anchorages due to draft. The depth of Anchorage 7 provides an acceptable depth for large vessels to bunker and stage for facility arrival. Smaller vessels maintain a host of other options to include, but are not limited to Anchorage 9 and 10 as recommended above.

Entry into, transiting, or anchoring within safety zone one is prohibited unless vessels obtain permission from the COTP or make satisfactory passing arrangements with the operating dredge per this rule and the Rules of the Road (33 CFR subchapter E). The COTP may issue updates regarding the vessel and equipment being utilized for these dredging operations via Marine Safety Information Bulletin and Broadcast Notice to Mariners.

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 protestors.

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, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration, and traffic management of the safety zones. The safety zones will be enforced in an area and in a manner that does not conflict with transiting commercial and recreational traffic. At least one side of the main navigational channel will be open for vessels to transit at all times. Moreover, the Coast Guard will work in coordination with the pilots to ensure vessel traffic can transit the area safely.

Although this regulation will restrict access to regulated areas, the effect of this rule will not be significant because there are a number of alternate anchorages available for vessels to anchor. Furthermore, vessels may transit through the safety zones with the permission of the COTP or make satisfactory passing arrangements with the dredge ESSEX, or other dredge(s) that may be used in accordance with this rule and the Rules of the Road (33 CFR subchapter E). The Coast Guard will notify the maritime public about the safety zones through maritime advisories, allowing mariners to alter their plans accordingly.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 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 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 safety zone 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 (Pub. L. 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 call or email 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 will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 involves safety zones to protect waterway users that would prohibit entry within 250 yards of dredging operations, within Marcus Hook Anchorage and will close only one side of the main navigation channel. It is categorically excluded from further review under paragraph L[60a] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email 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 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T05–0022, to read as follows:

§ 165.T05–0022 Safety Zones, Delaware River Dredging; Marcus Hook, PA.

(a) *Location.* The following areas are safety zones:

(1) Safety zone one includes all waters within 250 yards of the dredge displaying lights and shapes for vessels restricted in ability to maneuver as described in 33 CFR 83.27, as well as all related dredge equipment, while the dredge is operating in Marcus Hook Range. For enforcement purposes Marcus Hook Range includes all navigable waters of the Delaware River shoreline to shoreline, bound by a line drawn perpendicular to the center line of the channel at the farthest upriver point of the range to a line drawn perpendicular to the center line of the channel at the farthest downriver point of the range.

(2) Safety zone two includes all the waters of Anchorage 7 off Marcus Hook Range, as described in 33 CFR 110.157(a)(8) and depicted on U. S. Nautical Chart 12312.

(b) *Definitions.* As used in this section, *designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to assist with enforcement of the safety zone described in paragraph (a) of this section.

(c) *Regulations.* (1) Entry into or transiting within the safety zone one is prohibited unless vessels obtain permission from the Captain of the Port via VHF–FM channel 16 or 215–271–4807, or make satisfactory passing arrangements via VHF–FM channel 13 or 16 with the operating dredge per this section and the rules of the Road (33 CFR subchapter E). Vessels requesting to transit shall contact the operating dredge via VHF–FM channel 13 or 16 at least 1 hour prior to arrival.

(2) Vessels desiring to anchor in safety zone two, Anchorage 7 off Marcus Hook Range, must obtain permission from the COTP at least 24 hours in advance by calling (215) 271–4807. The COTP will permit, at minimum, one vessel at a time to anchor on a “first-come, first-served” basis. Vessels will only be allowed to anchor for a 12 hour period. Vessels that require an examination by the Public Health Service, Customs, or Immigration authorities will be directed to an anchorage for the required inspection by the COTP.

(3) Vessels desiring to anchor in safety zone two, Anchorage 7 off Marcus Hook Range, must be at least 650 feet in length overall.

(4) This section applies to all vessels except those engaged in the following operations: Enforcement of laws, service of aids to navigation, and emergency response.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by federal, state and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This rule will be enforced from January 6, 2022, through January 31, 2022, unless cancelled earlier by the Captain of the Port.

Dated: January 6, 2022.

Jonathan D. Theel,

Captain, U. S. Coast Guard, Captain of the Port, Delaware Bay.

[FR Doc. 2022–00560 Filed 1–12–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6081–N]

Medicare Program; Updates to Lists Related to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Conditions of Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Updates to and selection of certain codes.

SUMMARY: This document announces the updated Healthcare Common Procedure Coding System (HCPCS) codes on the Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements. It also announces the initial selection of HCPCS codes on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and the updates the HCPCS codes on the Required Prior Authorization List.

DATES: The implementation is effective on April 13, 2022. Prior authorization will be implemented in 3 incremental phases, with the final phase being national implementation. Phase 1 includes 1 state per jurisdiction and is effective April 13, 2022, Phase 2 includes 4 States per jurisdiction and is effective July 12, 2022, and Phase 3 is nationwide and is effective October 10, 2022.

FOR FURTHER INFORMATION CONTACT:

Susan Billet, (410) 786–1062.