

*Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects 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.

*Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects 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.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this interim final rule.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or

organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

*Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b) unless otherwise noted.

■ 2. In § 1308.14:

- a. Redesignate paragraphs (f)(11) through (13) as (f)(12) through (14); and
- b. Add new paragraph (f)(11).

The addition reads as follows:

**§ 1308.14 Schedule IV.**

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(f) \* \* \*

(11) Serdexmethylphenidate ..... 1729

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**D. Christopher Evans,**

*Acting Administrator.*

[FR Doc. 2021–09738 Filed 5–6–21; 8:45 am]

**BILLING CODE 4410–09–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket Number USCG–2021–0215]

RIN 1625–AA08

**Special Local Regulation; Clinch River, Oak Ridge, TN**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard establishes a temporary special local regulation for all navigable waters on the Clinch River from mile marker (MM) 48.5 to MM 52.0 during the U.S. Rowing Southeast Youth

Championship. This special local regulation prohibits non-participant persons and vessels from entering, transiting through, anchoring in, or remaining within the race area and prohibits vessels from transiting at speeds that cause wake within the spectator area unless authorized by Captain of the Port Sector Ohio Valley or a designated representative.

**DATES:** This rule is effective from 6 a.m. until 6 p.m. from May 8, 2021, to May 9, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2021–0215 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Petty Officer First Class Nicholas Jones, Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615–736–5421, email [Nicholas.J.Jones@uscg.mil](mailto:Nicholas.J.Jones@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**

The Coast Guard is issuing this temporary 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. We must establish this temporary safety zone by May 8, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

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 contrary to the public

interest of ensuring the safety of spectators and vessels during the event and immediate action is necessary to prevent possible loss of life and property.

### 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 Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the US Rowing Southeast Youth Championship marine event will be a safety concern, and is establishing a special local regulation from Mile Marker (MM) 48.5 to 52.0 on the Clinch River. This rule is needed to protect personnel and vessels on the navigable waters during the marine event.

### IV. Discussion of the Rule

This rule establishes a special local regulation from 6 a.m. until 6 p.m. from May 8, 2021, to May 9, 2021. The special local regulation will cover all navigable waters between MM 48.5 to MM 52.0 on the Clinch River. The duration of the zone is intended to ensure spectators and vessels' safety on these navigable waters for the duration of the event. All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or their designated representative. To seek permission to enter, contact the COTP or the COTP's representative by Sector Ohio Valley Command Center at 502-779-5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

### 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 the size, location, duration, and time-of-day of the special local regulation. This special local regulation restricts transit on a two and a half mile segment of the Clinch River for twelve hours on two days. Moreover, the Coast Guard would issue Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and Marine Safety Information Bulletins (MSIBs) about this special local regulation so that waterway users may plan accordingly for this short restriction on transit, and the rule would allow vessels to request permission to enter the zone.

#### 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 special local regulation 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 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 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

#### 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 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 a special local regulation lasting twelve hours that will prohibit entry from MM 48.5 to 52.0 on the Clinch River. It is categorically excluded from further review under paragraph L61 in Table 3-1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Memorandum for Record supporting this determination is available in the docket where indicated under **ADDRESSES**.

### 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 100

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

For the reasons discussed in this preamble, the Coast Guard amends 33 CFR part 100 as follows:

### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 46 U.S.C. 70041; 33 CFR 1.05-1.

■ 2. Add § 100.T08-0215 to read as follows:

#### § 100.T08-0215 Oak Ridge, TN. Clinch River mile 48.5 to 52.0.

(a) *Location.* The regulations in this section apply to the following area: All navigable waters of the Clinch River from mile 48.5 to mile 52.0, extending the entire width of the river.

(b) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by Sector Ohio Valley Command Center at 502-779-5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(c) *Enforcement period.* This section will be enforced from 6 a.m. to 6 p.m. from May 8, 2021 to May 9, 2021.

(d) *Information broadcast.* The COTP will issue Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and Marine Safety Information Bulletins (MSIBs) about this special local regulation so that waterway users may plan accordingly for this short restriction on transit, and the rule would allow vessels to request permission to enter the zone.

Dated: May 4, 2021.

**A.M. Beach,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.*

[FR Doc. 2021-09725 Filed 5-6-21; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 17

RIN 2900-AP64

### Adopting Standards for Laboratory Requirements

**AGENCY:** Department of Veterans Affairs.  
**ACTION:** Final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) adopts as final, with changes, a proposed rule amending its medical regulations to establish standards for VA clinical laboratories. The Department of Health and Human Services (HHS) has established standards for the staffing, management, procedures, and oversight of clinical laboratories that perform testing used for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. VA is required, in consultation with HHS, to establish standards equal to those applicable to other clinical laboratories. As a matter of policy and practice VA has applied HHS standards to its VA laboratory operations, and this rule formalizes this practice. In response to public comments this final rulemaking amends proposed language to more accurately reflect VA's utilization of CMS-deemed accreditation organizations in the process of inspection, oversight, and operational approval of VA clinical laboratories.

**DATES:** This final rule is effective June 7, 2021.

**FOR FURTHER INFORMATION CONTACT:** Quynh Vantu, Health Science Specialist, Pathology and Laboratory Service (1011DIAG2), Office of Clinical Care Services, Veterans Health

Administration, Department of Veterans Affairs, 810 Vermont Ave NW, Washington, DC 20420, (202) 632-8418. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** In a document published in the **Federal Register** on October 17, 2018, VA proposed to amend its medical regulations to establish standards for VA clinical laboratories. 83 FR 52345. We provided a 60-day comment period, which ended on December 17, 2018, and we received four comments.

The Clinical Laboratory Improvement Amendments of 1988 (Public Law (Pub. L.) 100-578) amended section 353 of the Public Health Service Act to establish legal requirements for the staffing, management, procedures, reporting of results and oversight of clinical laboratories that perform testing used for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. These statutory requirements are codified at 42 U.S.C. 263a. The Centers for Medicare & Medicaid Services (CMS), within HHS, has primary responsibility for the administration of the Clinical Laboratory Improvement Amendments (CLIA) program and implementing regulations for CLIA at 42 Code of Federal Regulations (CFR) part 493.

Section 101 of Pub. L. 102-139 (enacted October 28, 1991), required VA, within a specified time-frame and in consultation with HHS, to "establish standards [by regulation] equal to that [sic] applicable to other medical facility laboratories in accordance with the requirements of section 353(f) of the Public Health Service Act." VA's regulations must "include appropriate provisions respecting compliance with such requirements [set forth in section 353(f) of the Public Health Service Act]" and may include appropriate provisions respecting waivers and accreditations as described in section 353(d) and 353(e), respectively, of the Public Health Service Act. This final rule complies with the requirement for rulemaking by amending VA's medical regulations to reference the portions of 42 CFR part 493 adopted by VA as they apply to VA medical facility laboratories and clinics, and to clarify that these standards are subject to VA oversight and enforcement by VA only. In addition, this final rule allows VA laboratories to be accredited by an accreditation organization granted deeming authority by CMS under the CLIA program, in accordance with the accreditation requirements in the CLIA regulations at subpart E of 42 CFR part 493, and participate in an HHS approved proficiency testing program.