

performance characteristics must be tested:

- (i) Tensile testing of joints and materials;
 - (ii) Mechanical integrity testing;
 - (iii) Friction testing;
 - (iv) Flush testing;
 - (v) Air leakage and liquid leakage testing;
 - (vi) Latching and unlatching testing;
 - (vii) Kink and bend testing;
 - (viii) Insertion force testing;
 - (ix) Torque testing;
 - (x) Corrosion testing; and
 - (xi) Dimensional tolerance testing.
- (3) Performance data must support the sterility and pyrogenicity of the device components intended to be provided sterile.
- (4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
- (5) The patient contacting components of the device must be demonstrated to be biocompatible.
- (6) Software verification, validation, and hazard analysis must be performed.
- (7) Performance data must demonstrate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety.
- (8) Human factors performance evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.
- (9) Labeling must include:
- (i) Instructions for use;
 - (ii) A shelf life and storage conditions;
 - (iii) Compatible procedures;
 - (iv) A sizing table; and
 - (v) Quantification of blood detected.

Dated: June 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DoD-2020-HA-0040; and DoD-2020-HA-0050]

RIN 0720-AB81; 0720-AB82; and 0720-AB83

TRICARE Coverage and Reimbursement of Certain Services Resulting From Temporary Program Changes in Response to the COVID-19 Pandemic; Correction

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD).

ACTION: Final rule; correction.

SUMMARY: The DoD is correcting a final rule that appeared in the **Federal Register** on June 1, 2022. The Assistant Secretary of Defense for Health Affairs issued this final rule related to certain provisions of three TRICARE interim final rules (IFRs) with request for comments issued in 2020 in response to the novel coronavirus disease 2019 (COVID-19) public health emergency (PHE). Subsequent to publication of the final rule, DoD discovered an error in the preamble. This document corrects that error.

DATES: This final rule correction is effective on July 1, 2022.

FOR FURTHER INFORMATION CONTACT:

Erica Ferron, Defense Health Agency, Medical Benefits and Reimbursement Section, 303-676-3626 or erica.c.ferron.civ@mail.mil. Sharon Seelmeyer, Defense Health Agency, Medical Benefits and Reimbursement Section, 303-676-3690 or Sharon.I.seelmeyer.civ@mail.mil, Diagnosis Related Groups, Hospital Value Based Purchasing, Long Term Care Hospitals, and New Technology Add-On Payments.

SUPPLEMENTARY INFORMATION: In FR Doc. 2022-10545 appearing at 87 FR 33001-33015 in the **Federal Register** of Wednesday, June 1, 2022, the following corrections are made: On page 33007, in the third column, in section III.B.a.1, correct the first paragraph to read: "The IFR temporarily waived the regulatory requirement that an individual be an inpatient of a hospital for not less than three consecutive calendar days before discharge from the hospital (three-day prior hospital stay) for coverage of a SNF admission for the duration of the COVID-19 national emergency, consistent with a similar waiver under Medicare and TRICARE's statutory requirement to have a SNF benefit like Medicare's. The waiver will terminate when the President's national emergency for COVID-19 is terminated."

Dated: June 2, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022-12263 Filed 6-7-22; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2022-0444]

RIN 1625-AA08

Special Local Regulation; Lake of the Ozarks MM 1-6, Lake Ozark, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for the navigable waters of the Lake of the Ozarks within a 50-yard radius of all vessels participating in a boat parade starting at the foremost vessel in the World's Largest Parade marine event and extending to the last vessel in the parade. This special local regulation will follow the vessels until the parade's conclusion. The special local regulation is needed to protect personnel, vessels, and the marine environment from potential hazards created by the gathering of participant vessels during the Parade. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Upper Mississippi River.

DATES: This rule is effective from 10:30 a.m. through 1 p.m. June 10, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0444 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 Lieutenant Commander Stephanie Moore, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314-269-2560, email Stephanie.R.Moore@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of The Port Sector Upper Mississippi River
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. Sector Upper Mississippi River received the marine event application on May 25, 2022, prompting the creation of this rule due to the nature of the event. We must establish this special local regulation immediately 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 this rule would be contrary to public safety due to potential hazards for participants of the event and those transiting in the area around it.

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 Upper Mississippi River (COTP) has determined that potential hazards associated with this marine parade will be a safety concern for anyone operating or transiting within the lake of the Ozarks from MM 6 through MM 1. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the special local regulation while the parade is occurring.

IV. Discussion of the Rule

The World’s Largest Boat Parade is a gathering of over 1000 boats in an attempt to break a world record for the largest parade. It will occur on June 10, 2022 from 10:30 a.m. until 1 p.m. on the Lake of the Ozarks from MM 6 through MM 1. This special local regulation is a moving limited access area that follows the participants of the parade as they transit the parade route between MM 6 through MM 1. All spectator vessels and vessels not participating in this parade will not be allowed to transit within a 50 yard radius surrounding the area that includes vessels at the front of the parade extending to the vessels transiting at the end of the parade. Vessels other than those directly involved in the event will only be

allowed to safely transit the regulated area when the Coast Guard Patrol Commander has deemed it safe to do so.

No vessel or person will be permitted to enter the area without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF-FM channel 16, or through USCG Sector Upper Mississippi River at 314-269-2332. Persons and vessels permitted to enter the area must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the special local regulation as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), as appropriate.

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.

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 a special local regulation located on the Lake of the Ozarks at MM 6 through MM 1. The regulation is expected to be active only during the hours of 10:30 a.m. to 1:00 p.m. on June 10, 2022.

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 area 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 special local regulation is a moving limited access area that follows the participants of the parade as they transit the parade route between MM 6 through MM 1. All spectator vessels and vessels not participating in this parade will not be allowed to transit within a 50 yard radius surrounding the area that includes vessels at the front of the parade extending to the vessels transiting at the end of the parade. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the 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.T08–0444 to read as follows:

§ 100.T08–0444 Special Local Regulation; Lake of the Ozarks MM 1–6, Lake Ozark, MO.

(a) *Regulated areas.* All waters on the Lake of the Ozarks within MM 6 through MM 1.

(b) *Definitions.* (1) Coast Guard Patrol Commander means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port Sector Upper Mississippi River (COTP).

(2) Participant means all persons and vessels participating in The World's Largest Boat Parade under the auspices of the Marine Event Permit issued to the sponsor approved by the COTP.

(3) Spectator means all persons and vessels not registered with the event sponsor as participants or official patrol who are present on the water to observe the event.

(c) *Special local regulations.* (1) The World's Largest Boat Parade will occur on June 10, 2022 from 10:30 a.m. through 1 p.m. on the Lake of the Ozarks from MM 6 through MM 1. This special local regulation is a moving limited access area that follows the participants of the parade as they transit the parade route between MM 6 through MM 1. All spectator vessels and vessels not participating in this parade will not be allowed to transit within a 50 yard radius surrounding the area that includes vessels at the front of the parade extending to the vessels transiting at the end of the parade. Vessels other than spectator vessels and those directly involved in the event will only be allowed to safely transit the regulated area when the Coast Guard Patrol Commander has deemed it safe to do so. No vessel or person will be permitted to enter the area without obtaining permission from the COTP or a designated representative.

(2) The Coast Guard Patrol Commander may forbid and control the movement of all vessels and persons in

the regulated area. When hailed or signaled by an official patrol vessel, a vessel or person in the regulated area 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.

(3) The Coast Guard Patrol Commander may terminate the event, or the operation of any participant in the event, at any time it is deemed necessary for the protection of life or property.

(4) All Coast Guard vessels enforcing this regulated area can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz).

(5) Only participants and official patrol vessels are allowed to enter the parade route area.

Dated: June 3, 2022.

R.M. Scott,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2022–12325 Filed 6–7–22; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0330]

RIN 1625–AA00

Safety Zone; Potomac River, Between Charles County, MD and King George County, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; effective date extension and request for comment.

SUMMARY: The Coast Guard is extending the duration of a temporary safety zone on certain waters of the Potomac River. This action is necessary to provide for the safety of persons, and the marine environment from the potential safety hazards associated with construction operations at the new Governor Harry W. Nice/Senator Thomas “Mac” Middleton Memorial (US–301) Bridge, through July 1, 2022. This rule prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port, Maryland-National Capital Region or a designated representative.

DATES: The effective period of 33 CFR 165.T05–0330, published at 87 FR 28776 on May 11, 2022, which was set to expire at 8 p.m. on June 18, 2022, is extended through 8 p.m. on July 1, 2022.