

quality systems would include complaint-handling procedures. FDA's QS requirements are flexible and FDA believes that these manufacturers will be able to conform their systems to FDA requirements with little difficulty or cost. Manufacturers are already required to report to FDA whenever they learn that their device may have caused or contributed to a death or serious injury to a patient. The costs of complying with these requirements will be relatively small, but will vary depending on the number and nature of the devices manufactured and the state of the firm's existing quality system. Based on our understanding that the industry generally has in place measures to ensure quality, we believe most firms will be able to adapt their systems to meet FDA's QS and MDR regulations for not more than \$20,000. This cost would not be imposed by this final rule; it is an existing burden that manufacturers may not have fully incurred because of FDA's exercise of enforcement discretion with manufacturers of MDDSs.

Because manufacturers have not been required to register and list, we cannot be positive all firms have existing measures to ensure quality, and we cannot rule out the possibility that some manufacturers will face greater costs. If a manufacturer has no quality system in place, we estimate that it would cost less than \$20,000 to establish a quality system plus the annual cost of a full-time employee to manage such a system. Comments to the proposed rule estimated the cost of such an employee, including benefits, to be \$143,000 per year.

#### F. Premarket Notification

With the issuance of this final rule and the classification of MDDSs into class I, a manufacturer of an MDDS would not need to comply with the PMA requirement that applies to class III devices or submit a premarket notification. For those MDDSs that exceed the limitations on 510(k) exemptions found in § 880.9, the required premarket notification for an MDDS will be far less complex than submission of a PMA. The cost of preparing and submitting such a notification would be several thousand dollars. The user fees for a premarket notification would be \$4,348 for FY 2011, increasing to \$4,717 in 2012. In contrast, the cost of submitting a PMA can reach \$1,000,000, plus user fees of an additional \$236,298 in FY 2011, increasing to \$256,384 in FY 2012.

In summary, this device reclassification final rule will substantially reduce an existing legal

burden on the manufacturers of MDDSs. The burden of compliance with the general controls provisions applicable to the manufacturers of all class I devices is attributable to statutory requirements that already apply but in the past have not been enforced for MDDSs. Because continued exercise of enforcement discretion may not be a viable long-term regulatory alternative, this final rule reduces the ultimate regulatory burden for manufacturers of MDDSs. Considering the cost of submitting a PMA plus the relevant user fees, the reduction could be \$1,000,000 per device.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of the affected devices from class III to class I will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

#### VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

#### PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for 21 CFR part 880 continues to read as follows:

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

■ 2. Section 880.6310 is added to subpart G to read as follows:

#### § 880.6310 Medical device data system.

(a) *Identification.* (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

Dated: February 9, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-3321 Filed 2-14-11; 8:45 am]

**BILLING CODE 4160-01-P**

#### PENSION BENEFIT GUARANTY CORPORATION

#### 29 CFR Part 4022

#### Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2011. Interest assumptions are also published on PBGC's Web site (<http://www.pbgc.gov>).

**DATES:** Effective March 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

**SUPPLEMENTARY INFORMATION:** PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the

financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for March 2011.<sup>1</sup>

The March 2011 interest assumptions under the benefit payments regulation will be 2.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for February 2011, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during March 2011, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

**List of Subjects in 29 CFR Part 4022**

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

**PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS**

■ 1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 209, as set forth below, is added to the table.

**Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments**

\* \* \* \* \*

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i <sub>1</sub>	i <sub>2</sub>	i <sub>3</sub>	n <sub>1</sub>	n <sub>2</sub>
* 209	* 3-1-11	* 4-1-11	* 2.50	* 4.00	* 4.00	* 4.00	* 7	* 8

■ 3. In appendix C to part 4022, Rate Set 209, as set forth below, is added to the table.

**Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments**

\* \* \* \* \*

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i <sub>1</sub>	i <sub>2</sub>	i <sub>3</sub>	n <sub>1</sub>	n <sub>2</sub>
* 209	* 3-1-11	* 4-1-11	* 2.50	* 4.00	* 4.00	* 4.00	* 7	* 8

<sup>1</sup> Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing

benefits under terminating covered single-employer plans for purposes of allocation of assets under

ERISA section 4044. Those assumptions are updated quarterly.

Issued in Washington, DC, on this 8th day of February 2011.

**Vincent K. Snowbarger,**

*Deputy Director for Operations, Pension Benefit Guaranty Corporation.*

[FR Doc. 2011-3403 Filed 2-14-11; 8:45 am]

BILLING CODE 7709-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2010-1093]

RIN 1625-AA08

#### Special Local Regulation; Mavericks Surf Competition, Half Moon Bay, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation on certain navigable waters of Half Moon Bay in support of the Mavericks Surf Competition. This special local regulation is necessary to ensure the safety of participants and spectators during the event. Entry into this zone is prohibited unless authorized by the Captain of the Port San Francisco, CA.

**DATES:** This rule is effective from February 15, 2011 through February 28, 2011.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-1093 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-1093 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call Lieutenant Junior Grade Liezl Nicholas at (415) 399-7436, or e-mail [D11-PF-MarineEvents@uscg.mil](mailto:D11-PF-MarineEvents@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202)366-9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

The Coast Guard is issuing this temporary final 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 immediate action is needed to provide for the safety of life and property on navigable waters. Because of the dangers posed by the surf conditions during the Mavericks Surf Competition, the special local regulation is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

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**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the surf conditions during the Mavericks Surf Competition.

##### Basis and Purpose

The Mavericks Surf Competition is a one day "Big Wave" surfing competition consisting of the top 24 big wave surfers and only occurs when 15-20 foot waves are sustained for over 24 hours and are combined with mild easterly winds of no more than 5-10 knots. Because weather conditions are integral to the occurrence of the Maverick Surf Competition, the exact date of the event cannot be determined in advance. The rock and reef ridges that make up the sea floor of the Pillar Point area combined with just the right weather conditions create the large waves that Mavericks is known for. Due to the treacherous terrain and un-navigable areas surrounding Pillar Point, the Coast Guard is establishing a special local regulation within a 1,000 yard radius of Pillar Point that restricts navigation near the surf competition area and neighboring treacherous terrain and identifies the safest area for spectator viewing on the water.

##### Discussion of Rule

The Coast Guard is establishing a special local regulation within a 1,000 yard radius of Pillar Point in Half Moon Bay. The Mavericks Surf Competition will occur in the vicinity of Pillar Point in the navigable waters of Half Moon

Bay, and the spectator viewing area will be located inside the following coordinates: 37°29.265' N 122°30.165' W, 37°29.248' N 122°29.978' W, and 37°29.406' N 122°30.081' W (NAD 83). Competitors, participating agencies (Coast Guard, San Mateo Police Marine Patrol, Pillar Point Harbor Patrol, San Mateo Fire Marine Patrol) and the public (to include but not restricted to: Commercial sightseeing vessels, photographer platforms and recreational boaters) will be given 48 hours notice prior to the start of the one day competition. This action is necessary to ensure the safety of participants and spectators during the event. During the enforcement period, unauthorized persons (persons not classified as spectators, participants or participating agencies) or vessels are prohibited from transiting through, anchoring, blocking, or loitering in the regulated area without permission of the Captain of the Port (COTP) or their designated representative.

The effect of the temporary special local regulation will be to regulate navigation in the vicinity of Pillar Point while the Mavericks Surf Competition is taking place. Except for persons or vessels authorized by the Coast Guard Patrol Commander (persons classified as spectators, participants or participating agencies), no person or vessel may transit within the bounds of the regulated area. These regulations are needed to keep spectators and vessels a safe distance away from the event participants and the un-navigable waters surrounding Pillar Point and to ensure the safety of participants, spectators, and transiting vessels.

The Coast Guard will enforce the temporary special local regulation from 8 a.m. to 3 p.m. on a date to be determined. Notification of the enforcement of the special local regulation will be provided to the public via broadcast notice to mariners, as well as through advertising on local media.

##### Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

##### Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and