

benefits, before proposing "any rule that includes any Federal mandate that may 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 one year." The current threshold after adjustment for inflation is \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The burden hours required for § 884.5320(c), included in the collection entitled "Pre-market Approval of Medical Devices—21 CFR Part 814," are reported and approved under OMB control number 0910–0231. Therefore, clearance by OMB under the PRA is not required.

List of Subjects in 21 CFR Parts 868, 870, and 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 868, 870, and 882 are amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 868 continues to read as follows:

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

■ 2. Section 868.1120 is amended by revising paragraph (c) to read as follows:

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to an indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976. Any other indwelling blood oxyhemoglobin concentration analyzer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 870—CARDIOVASCULAR DEVICES

■ 3. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 4. Section 870.4320 is amended by revising paragraph (c) to read as follows:

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976. Any other cardiopulmonary bypass pulsatile flow generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

■ 5. The authority citation for 21 CFR part 882 continues to read as follows:

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

■ 6. Section 882.1790 is amended by revising paragraph (c) to read as follows:

§ 882.1790 Ocular plethysmograph.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any ocular plethysmograph that was in commercial distribution before May 28, 1976. Any other ocular plethysmograph shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 14, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14126 Filed 6–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AA60

Health Care Continuation Coverage, Correction

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Final rule, technical corrections.

SUMMARY: The Department published in the **Federal Register** of May 26, 2004, (69 FR 30084) final rules implementing the notice requirements of the health care continuation coverage (COBRA) provisions of part 6 of title I of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). This document makes technical corrections to one of the final rules and to a model notice published in an appendix to one of the final rules.

DATES: *Effective date:* The regulations that are being corrected are effective on July 26, 2004, and these corrections are effective July 26, 2004.

Applicability date: The regulations that are being corrected apply to notice obligations arising under the COBRA provisions of part 6 of title I of ERISA on or after the first day of the first plan year beginning on or after the date that is six months after May 26, 2004.

FOR FURTHER INFORMATION CONTACT: Lisa M. Alexander or Suzanne M. Adelman, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693-8500. this is not a toll-free number.

SUPPLEMENTARY INFORMATION: On May 26, 2004, the Department of Labor published final regulations on the notice provisions of part 6 of title I of ERISA. The regulations comprise four sections. Section 2590.606–1 establishes the time frames within which the general notice of continuation coverage must be provided and describes the specific information that the general notice must contain. Paragraph (d) of § 2590.606–1 permits delivery of a single notice addressed to a covered employee and the covered employee's spouse at their joint residence, provided that the plan's latest information indicates that both reside at that address. paragraph (d) states, on page 30097, that "nothing in this section shall be construed to create a requirement to provide a separate notice to dependent children who share a residence with a covered employer or a covered employee's spouse to whom notice is provided in accordance with

this section.” The term “covered employer” in this sentence is an inadvertent error and should instead be “covered employee.”

In an appendix to § 2590.606–4, the Department also published a Model COBRA Continuation Coverage Election Notice for use by single-employer group health plans. The section of the model notice entitled “Important Information About Your COBRA Continuation Coverage Rights” states, on page 30108, that continuation coverage will be terminated before the end of the maximum period if, among other things, “a covered employee becomes entitled

to Medicare benefits (under part A, Part B, or both) after electing continuation coverage.” The term “covered employee” on this page is an inadvertent error and should be changed “qualified beneficiary.”

This correction replaces two phrases with the correct terminology to prevent confusion and improve the clarity of the regulation and model notice.

■ Accordingly, in the Health Care Continuation Coverage Final Rule, FR Doc. 04–11796, published in the **Federal Register** on May 26, 2004, on pages 30084–112, make the following corrections:

§ 2590.606–1 [Corrected]

■ 1. On page 30097, in the third column, in paragraph (d), which is entitled *Single notice rule*, in the last sentence, remove the words “covered employer” and add in their place the words “covered employee.”

Appendix to § 2590.606–4 [Corrected]

■ 2. On page 30108, in the appendix to § 2590.606–4, the page titled “Important Information About Your COBRA Continuation Coverage Rights” is revised to read as follows:

BILLING CODE 4510–29–M

IMPORTANT INFORMATION
ABOUT YOUR COBRA CONTINUATION COVERAGE RIGHTS

What is continuation coverage?

Federal law requires that most group health plans (including this Plan) give employees and their families the opportunity to continue their health care coverage when there is a “qualifying event” that would result in a loss of coverage under an employer’s plan. Depending on the type of qualifying event, “qualified beneficiaries” can include the employee (or retired employee) covered under the group health plan, the covered employee’s spouse, and the dependent children of the covered employee.

Continuation coverage is the same coverage that the Plan gives to other participants or beneficiaries under the Plan who are not receiving continuation coverage. Each qualified beneficiary who elects continuation coverage will have the same rights under the Plan as other participants or beneficiaries covered under the Plan, including [*add if applicable: open enrollment and*] special enrollment rights.

How long will continuation coverage last?

In the case of a loss of coverage due to end of employment or reduction in hours of employment, coverage generally may be continued only for up to a total of 18 months. In the case of losses of coverage due to an employee’s death, divorce or legal separation, the employee’s becoming entitled to Medicare benefits or a dependent child ceasing to be a dependent under the terms of the plan, coverage may be continued for up to a total of 36 months. When the qualifying event is the end of employment or reduction of the employee's hours of employment, and the employee became entitled to Medicare benefits less than 18 months before the qualifying event, COBRA continuation coverage for qualified beneficiaries other than the employee lasts until 36 months after the date of Medicare entitlement. This notice shows the maximum period of continuation coverage available to the qualified beneficiaries.

Continuation coverage will be terminated before the end of the maximum period if:

- any required premium is not paid in full on time,
- a qualified beneficiary becomes covered, after electing continuation coverage, under another group health plan that does not impose any pre-existing condition exclusion for a pre-existing condition of the qualified beneficiary,
- a qualified beneficiary becomes entitled to Medicare benefits (under Part A, Part B, or both) after electing continuation coverage, or
- the employer ceases to provide any group health plan for its employees.

Continuation coverage may also be terminated for any reason the Plan would terminate coverage of a participant or beneficiary not receiving continuation coverage (such as fraud).

[If the maximum period shown on page 1 of this notice is less than 36 months, add the following three paragraphs:]

Signed at Washington, DC, this 15th day of June, 2004.

Ann L. Combs,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. 04-13949 Filed 6-22-04; 8:45 am]

BILLING CODE 4510-29-C

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 4, 19, 84, 101, 104, 118, 127, 140, 154, 161, 164, 169, 174, 181, and 183

[USCG-2004-18057]

RIN 1625-ZA02

Navigation and Navigable Waters; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This rule makes non-substantive changes throughout the Code of Federal Regulations. The purpose of this rule is to update organization names and addresses and make conforming amendments and technical corrections to Coast Guard navigation and navigable water regulations. This rule will have no substantive effect on the regulated public.

DATES: This rule is effective June 30, 2004.

ADDRESSES: Any comments and material received from the public will be made part of docket, USCG-2004-18057, and will be available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Robert S. Spears, Coast Guard, telephone 202-267-1099. If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202-366-0271.

SUPPLEMENTARY INFORMATION:

Regulatory History

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under both 5 U.S.C.

553(b)(A) and (b)(B), the Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements because some of these changes involve agency organization and practices, and good cause exists for not publishing an NPRM for all revisions in the rule because they are all non-substantive changes. This rule consists only of corrections and editorial, organizational, and conforming amendments. These changes will have no substantive effect on the public; therefore, it is unnecessary to publish an NPRM. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Discussion of the Rule

Each year title 33 of the Code of Federal Regulations is updated on July 1. This rule, which becomes effective June 30, 2004, corrects organization names and addresses, and makes other technical and editorial corrections throughout title 33. This rule does not create any substantive requirements.

Some of the revisions in this rule are not necessarily self-explanatory changes. For example, in § 4.02 we updated the listing of approved collections of information based on information requirements in Title 33. In parts 101 and 104, we replaced SOLAS "Chapter XI" references with "Chapter XI-1 or Chapter XI-2" to conform these chapter references to the **Federal Register** approved reference, used in the relevant incorporation by reference section, § 101.115(b). In §§ 118.3, 127.003, 140.7, 154.106, 164.03, 181.4, and 183.5, we changed references to material incorporated by reference as being "available for inspection" rather than merely "on file" to align these sections with other incorporation by reference sections.

Regulatory Evaluation

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 Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. As this rule involves internal agency practices and

procedures and non-substantive changes, it will not impose any costs on the public.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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. This rule does not require a general NPRM and, therefore, is exempt from the requirements of the Regulatory Flexibility Act. Although this rule is exempt, we have reviewed it for potential economic impact on small entities.

This rule will have no substantive effect on the regulated public. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

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). We note, however, that in 33 CFR 4.02, this rule updates the listing of approved collections of information based on information requirements contained in title 33.

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 or more in any one year. Though this rule will not result in an expenditure of this magnitude, we do discuss the effects of this rule elsewhere in this preamble.