

believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is classifying this device into class I, the lowest level of control allowed. In addition, the device is exempt from premarket notification requirements. The agency, therefore, certifies that this final rule will not have a significant impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and 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. In addition, it will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VI. 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.

## VII. 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 (44 U.S.C. 3501–3520) is not required.

### List of Subjects in 21 CFR Part 878

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 878 is amended as follows:

### PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4025 is added to subpart E to read as follows:

#### § 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

(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 § 878.9.

Dated: July 28, 2004.

**Linda S. Kahan,**

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

[FR Doc. 04–18074 Filed 8–6–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900–AL59

### Compensation for Certain Cases of Bilateral Deafness

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

**SUMMARY:** This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning how to rate claims of veterans with bilateral hearing impairment when hearing loss in one ear is service connected and hearing loss in the other ear is not. The amendment is necessary to implement a statutory provision of the Veterans Benefits Act of 2002, which will now factor in nonservice-connected hearing loss of one ear when

hearing loss in the other ear is service connected and hearing loss manifests to a specified degree. This enables VA to pay compensation for such claims as if the combined hearing loss in both ears is service connected. These amendments are non-substantive because they are restatements of statutes and interpretive rules.

**DATES:** *Effective Date:* In accordance with statutory provisions, these amendments to 38 CFR 3.383(a)(3) are effective December 6, 2002.

**FOR FURTHER INFORMATION CONTACT:** Beth McCoy, Consultant, Regulations Staff, Compensation and Pension Service (211A), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave, NW., Washington, DC 20420 telephone (202) 273–7211.

**SUPPLEMENTARY INFORMATION:** On December 6, 2002, the Veterans Benefits Act of 2002, Public Law 107–330 (the Act), was enacted. Certain provisions of the Act directly affect the payment of VA compensation or pension benefits. Section 103 of the Act altered the level at which compensation is payable to a veteran for hearing impairment when both ears are affected.

When veterans have a specified degree of disability that is service connected in certain organs or extremities and there is nonservice-connected disability affecting the corresponding "paired" organ or extremity, section 1160 of title 38, United States Code, authorizes VA to pay disability compensation as if the combination of service- and non-service connected disabilities in those paired organs or extremities were service connected. Bilateral deafness is covered by this statute. Prior to the Act, 38 U.S.C. 1160(a)(3) authorized VA to pay compensation as if deafness in both ears were service connected when a veteran had service-connected *total* deafness in one ear along with *total* deafness in the other ear due to nonservice-connected disability and not the result of the veteran's willful misconduct.

Under the Act, Congress amended section 1160(a)(3) to eliminate the total deafness requirement. The statute now authorizes payment of compensation when a veteran has deafness in one ear compensable to a degree of 10 percent or more as a result of service-connected disability and deafness in the other ear as a result of nonservice-connected disability.

Congress amended 38 U.S.C. 1160(a)(3) to eliminate the extreme requirement that there be complete and total deafness in both ears before compensation is payable for this paired

organ combination. The legislative history reflects that the amendment was introduced as part of Senate Bill 2237 to correct a long-standing inequity in compensating veterans with paired organ hearing loss compared with the way VA compensates involvement of a veteran's other paired organs or paired extremities, such as eyes, kidneys, or hands. (148 Cong. Rec. S 3305, April 24, 2002.) The first version of the bill struck "total" from both places it appeared in section 1160(a)(3) so that the statute would compensate for paired organ hearing loss when a veteran had service-connected deafness in one ear and nonservice-connected deafness in the other ear. (148 Cong. Rec. S 3305-06, April 24, 2002.)

To mirror the exceptions made for other paired organ or extremity combinations in 38 U.S.C. 1160, a manager's amendment to the committee bill was substituted to allow VA to consider partial nonservice-connected hearing loss in one ear when rating disability for veterans with at least 10 percent compensable service-connected hearing loss in the other ear. (148 Cong. Rec. S 9556, September 26, 2002.) The revised language became section 103 of the Act, striking "total deafness" in its first occurrence and replacing it with "deafness compensable to a degree of 10 percent or more" for the service-connected ear and striking "total deafness" in the second occurrence and replacing it with "deafness" for the nonservice-connected ear.

Currently, "deafness" is not defined in VA regulations except in reference to the severest degrees of hearing loss. (See 38 CFR 3.350(a)(5), concerning entitlement to special monthly compensation for deafness of both ears based on absence of air and bone conduction, and 38 CFR 4.84a, Table IV, concerning rating of blindness combined with varying degrees of hearing loss, including total deafness.) *Dorland's Medical Dictionary*, 28th edition, defines "deafness" as "lack of the sense of hearing, or profound hearing loss. Moderate loss of hearing is often called hearing loss."

We understand that while Congress intended to eliminate the requirement of total deafness in both ears before applying the paired organ exception, a veteran must have a specified degree of hearing loss independently ratable in the service-connected ear, *i.e.*, 10 percent or more, before nonservice-connected hearing disability in the other ear can be considered for compensation.

In determining what constitutes hearing loss or impairment for the nonservice-connected ear, we also look to the common meaning of deafness,

which *Webster's New World Dictionary*, 3rd college edition, defines broadly as "totally or partially unable to hear." VA regulations specify the point at which hearing impairment is considered a disability for VA purposes in 38 CFR 3.385 based on the auditory thresholds in five specified frequencies and speech recognition scores. Thus, as to paired organ hearing loss in the nonservice-connected ear, we are applying the provisions of § 3.385 to define the point at which hearing impairment is considered a disability. However, we are not requiring that the degree of hearing loss in the nonservice-connected ear be ratable at 10 percent or more because Congress did not impose this requirement.

Because the legislative history of Senate Bill 2237 refers to "hearing loss" in discussing the changes to the paired organ rule and because Congress retained the term "deafness" in the revised statute but did not specify the degree of hearing loss required in the nonservice-connected ear, we understand the intent of the statute is to include any degree of hearing loss disability, including a 0 percent, manifested in the nonservice-connected ear.

We are amending § 3.383(a)(3) of title 38, Code of Federal Regulations, which is VA's implementing regulation, accordingly. Also, we are adding a Cross References paragraph at the end of § 3.383 to alert veterans and adjudicators to the provisions of § 3.385, Disability due to impaired hearing, and § 4.85, Evaluation of hearing impairment, which have bearing on the application of the paired organ rule for hearing disability. Since the above amendments involve the restatement and interpretation of the Act, they are non-substantive and do not require publication for notice and comment.

#### Administrative Procedure Act

Changes made by this final rule merely reflect and interpret new statutory provisions. Accordingly, there is a basis for dispensing with prior notice and comment and delayed effective date provisions of 5 U.S.C. 552 and 553.

#### Executive Order 12866

This document has been reviewed by the Office of Management and Budget under Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

#### Paperwork Reduction Act

This document contains no provisions constituting a collection of information

under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

#### Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any given year. This rule will have no such effect on State, local, or tribal governments, or the private sector.

#### Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The reason for this certification is that these amendments would not directly affect any small entities. Only VA beneficiaries and their survivors could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

#### Catalog of Federal Domestic Assistance

There is no Catalog of Federal Domestic Assistance program number for this benefit.

#### List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans.

Approved: June 2, 2004.

**Anthony J. Principi**,  
*Secretary of Veterans Affairs.*

■ For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

#### PART 3—ADJUDICATION

##### Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

■ 1. The authority citation for part 3, subpart A continues to read as follows:

**Authority:** 38 U.S.C. 501(a), unless otherwise noted.

- 2. Section 3.383 is amended by:
  - A. Revising paragraph (a)(3).
  - B. Revising the authority citation at the end of the section.
  - C. Adding a Cross References paragraph immediately after the authority citation at the end of the section.

The revisions and addition read as follows:

**§ 3.383 Special consideration for paired organs and extremities.**

(a) \* \* \*

(3) Hearing impairment in one ear compensable to a degree of 10 percent or more as a result of service-connected disability and hearing impairment as a result of nonservice-connected disability that meets the provisions of § 3.385 in the other ear.

\* \* \* \* \*

(Authority 38 U.S.C. 501(a), 1160(a)(3))

Cross-References: § 3.385 Disability due to impaired hearing; § 4.85 Evaluation of hearing impairment.

[FR Doc. 04-18105 Filed 8-6-04; 8:45 am]

BILLING CODE 8320-01-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[R04-OAR-2004-GA-0001-200420c; FRL-7798-7]

**Approval and Promulgation of Implementation Plans; Georgia: Approval of Revisions to the State Implementation Plan; Correction****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule; correction.

**SUMMARY:** The EPA published in the *Federal Register* of July 19, 2004 (69 FR 42880), a document concerning the Georgia Post-1999 Rate-of-Progress Plan. A volatile organic compound (VOC) motor vehicle emission budget (MVEB) of 160.68 was inadvertently stated in the July 19, 2004, document. This document corrects that error.

**DATES:** Effective on August 18, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mr. Scott M. Martin, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9036. Mr. Martin can also be reached via electronic mail at [martin.scott@epa.gov](mailto:martin.scott@epa.gov).

**SUPPLEMENTARY INFORMATION:** The EPA published a document in the *Federal Register* of July 19, 2004, (69 FR 42880) concerning the Georgia Post-1999 Rate-of-Progress Plan. A VOC MVEB of 160.68 was inadvertently stated in the July 19, 2004, document. The last sentence of the second paragraph in the first column of page 42882 should read as follows: "The new budget for VOCs is 160.80 tons per day (tpd) and 318.24 tpd of NO<sub>x</sub>."

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 27, 2004.

**A. Stanley Meiburg,***Acting Regional Administrator, Region 4.*

[FR Doc. 04-18025 Filed 8-6-04; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[VA146-5080a; FRL-7798-6]

**Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revised Major Stationary Source Applicability for Reasonably Available Control Technology in the Northern Virginia Ozone Nonattainment Area****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve a revision to the Commonwealth of Virginia State Implementation Plan (SIP). The revision specifies that the Northern Virginia Ozone Nonattainment Area is now subject to the severe major source permitting requirements and lowers the major stationary source threshold for nitrogen oxide (NO<sub>x</sub>) from 50 tons per year to 25 tons per year. EPA is approving this revision to the Commonwealth of Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** This rule is effective on October 8, 2004 without further notice, unless EPA receives adverse written comment by September 8, 2004. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the *Federal Register* and inform the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by VA146-5080 by one of the following methods:

A. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. E-mail: [morris.makeba@epa.gov](mailto:morris.makeba@epa.gov).

C. Mail: Makeba Morris, Chief, Air Quality Planning Branch Name, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. VA146-5080. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://regulations.gov) or e-mail. The federal [regulations.gov](http://regulations.gov) web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103, and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

**FOR FURTHER INFORMATION CONTACT:** Janice Lewis, (215) 814-2185, or by e-mail at [lewis.janice@epa.gov](mailto:lewis.janice@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

On January 24, 2003 (68 FR 3410), EPA issued a determination that the Metropolitan Washington, DC ozone nonattainment area (DC Area) failed to attain the ozone standard by the statutory date of November 15, 1999, and reclassified the area from "serious" to "severe" for one-hour ozone. As a