

the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The special controls established by this final rule create “requirements” to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

#### V. How does this rule comply with the paperwork reduction Act of 1995?

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required.

#### VI. What references are on display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Neuronetics, Inc., May 23, 2007.

#### List of Subjects in 21 CFR Part 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 part 882 is amended as follows:

#### PART 882—NEUROLOGICAL DEVICES

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

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

■ 2. Section 882.5805 is added to subpart F to read as follows:

#### § 882.5805 Repetitive transcranial magnetic stimulation system.

(a) *Identification.* A repetitive transcranial magnetic stimulation system is an external device that delivers transcranial repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms

of major depressive disorder without inducing seizure in patients who have failed at least one antidepressant medication and are currently not on any antidepressant therapy.

(b) *Classification.* Class II (special controls). The special control is FDA’s “Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation System.” See § 882.1(e) for the availability of this guidance document.

Dated: July 20, 2011.

**Nancy K. Stade,**

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

[FR Doc. 2011–18806 Filed 7–25–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 54

[TD 9532]

RIN 1545–BK30

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### 29 CFR Part 2590

RIN 1210–AB45

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### 45 CFR Part 147

[CMS–9993–CN]

RIN 0938–AQ66

### Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes; Correction

**AGENCIES:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**ACTION:** Correction of amendment to interim final rules with request for comments.

**SUMMARY:** This document corrects technical errors that appeared in the June 24, 2011 amendment to the interim final rules (76 FR 37208) entitled, “Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes.”

**DATES:** *Effective Date:* July 22, 2011.

**FOR FURTHER INFORMATION CONTACT:** Ellen Kuhn, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492–4263; Amy Turner, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; or Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

##### A. Introduction

In FR Doc. 2011–15890 of June 24, 2011 (76 FR 37208), there were technical errors that are identified in the “Summary of Errors” section and corrected in the “Correction of Errors” section below. The provisions in this correction notice are effective as if they had been included in the June 24, 2011 interim final rule with request for comments entitled, “Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes.” Accordingly, the corrections are effective July 22, 2011.

##### B. Regulations Overview

On July 23, 2010, the Departments of Health and Human Services (HHS), Labor (DOL), and the Treasury (collectively, the Departments) issued interim final rules implementing section 2719 of the Public Health Service (PHS) Act (75 FR 43330) (July 2010 regulations), regarding internal claims and appeals and external review processes for group health plans and health insurance issuers offering coverage in the group and individual markets.<sup>1</sup> The Departments issued an amendment to the interim final rules that was published in the **Federal Register** on June 24, 2011 (76 FR 37208) (June 2011 amendments). Below, we summarize the errors in the June 2011 amendments and describe the corrections we are making in this notice.

#### II. Summary of Errors

##### A. Error in the Preamble

In the **FOR FURTHER INFORMATION CONTACT** section of the June 2011 amendments (page 37208), we listed an incorrect telephone number for Ellen Kuhn, Centers for Medicare & Medicaid Services, Department of Health and Human Services. We are correcting the telephone number.

<sup>1</sup> The requirements of PHS Act section 2719 and the July 2010 regulations do not apply to health plans grandfathered under section 1251 of the Affordable Care Act.

B. Errors in the Regulations Text

In the June 2011 amendments (page 37231), we inadvertently made a typographical error in the DOL regulations text that could cause confusion. The text pertains to the effective date of the suspension of the general rule defining the scope of what is appealable in external review. We are correcting this typographical error. We note that the regulation text for HHS and the Department of the Treasury were correct and therefore are unchanged.

In the joint preamble to the June 2011 amendments (pages 37209 through 37215), we explain that the July 2010 regulations established requirements for group health plans and health insurance issuers offering both individual and group health coverage and that the June 2011 amendments were modifying those requirements. However, the regulations text in the June 2011 amendments only reflected the changes to the group market provisions, which appear in all three Departments' regulations (pages 37228 through 37229; 37230 through 37231; and 37232 through 37233). Requirements that apply to the individual market only appear in HHS regulations, and conforming amendments to those requirements were inadvertently omitted from the regulation text of the June 2011 amendments. In the regulations text at 45 CFR 147.136, HHS is correcting this technical error. Specifically, we are reorganizing § 147.136(b)(3)(ii) and adding language to clarify that these amendments apply to health insurance issuers offering individual health coverage. These changes relate to internal claims and appeals processes requirements for individual health insurance issuers in the HHS regulations text. We note that the regulations text for the DOL and the Department of the Treasury were correct and therefore are unchanged.

III. Waiver of Proposed Rulemaking and Waiver of the Delay in Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), while a general notice of proposed rulemaking and an opportunity for public comment is generally required before the promulgation of regulations, this is not required when an agency, for good cause, finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the reasons for that finding in the notice.

The APA also generally requires that a final rule be effective no sooner than 30 days after the date of publication in the Federal Register. This 30-day delay in effective date can be waived, however, if an agency finds good cause why the effective date should not be delayed, and the agency incorporates a statement of the findings and its reasons in the rule issued.

This document merely corrects technical errors made in the June 2011 amendments published in the Federal Register on June 24, 2011 (76 FR 37208), which will be effective on July 22, 2011. The corrections contained in this document are consistent with and do not make substantive changes to the policies adopted in the June 2011 amendments. The preamble to the June 2011 amendments correctly refers to and discusses the substance of the sections affected by this technical correction. Therefore, we find for good cause that it is unnecessary and would be contrary to the public interest to undertake further notice and comment procedures to incorporate these corrections. Furthermore, we note that the June 2011 amendments were published, for good cause, as interim final rules, and that all the reasons stated in the June 2011 amendments for waiving notice and comment procedures with respect to the June 2011 amendments are applicable to this correction notice.

We are also waiving the 30-day delay in effective date for these corrections. We believe that it is in the public interest to ensure that the June 2011 amendments setting forth requirements for group health plans and health insurance issuers relating to internal claims and appeals and external review processes accurately states our policies as of the date they take effect. Therefore, we find that delaying the effective date of these corrections beyond the effective date of the June 2011 amendments would be contrary to the public interest. In doing so, we find good cause to waive the 30-day delay in the effective date.

IV. Correction of Errors

In FR Doc. 2011-15890 of June 24, 2011 (76 FR 37208), make the following corrections:

A. Correction to the Preamble

On page 37208, in the third column, under the **FOR FURTHER INFORMATION CONTACT** section, the telephone number "(301) 492-4100" for Ellen Kuhn, Centers for Medicare & Medicaid Services, Department of Health and Human Services, is corrected to read "(301) 492-4263."

B. Correction to the Regulations Text  
29 CFR 2590.715-2719 [Corrected]

1. On page 37231, in the third column, in paragraph (d)(1)(ii), the phrase "with respect to claims for which external review has not been initiated before the effective date of this paragraph (d)(1) (September 20, 2011)," is corrected to read "with respect to claims for which external review has not been initiated before September 20, 2011,".

45 CFR 147.136 [Corrected]

2. On page 37232, in the third column, after the amendatory instruction 3. and before the phrase "The revisions and additions read as follows", add the following amendatory instructions to read as follows:

"4. Revising paragraphs (b)(3)(ii)(B), (b)(3)(ii)(E)(1), and (b)(3)(ii)(F)."

"5. Redesignating paragraphs (b)(3)(ii)(E)(2), (b)(3)(ii)(E)(3), and (b)(3)(ii)(E)(4), as (b)(3)(ii)(E)(3), (b)(3)(ii)(E)(4), and (b)(3)(ii)(E)(5), respectively."

"6. Adding a new paragraph (b)(3)(ii)(E)(2)."

3. On page 37233, in the second column, after the five asterisks "\* \* \* \* \*" and before the paragraph "(c) \* \* \*," add the following:

- (b) \* \* \*
- (3) \* \* \*
- (ii) \* \* \*

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503-1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

\* \* \* \* \*  
(E) \* \* \*

(1) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the

treatment code and its corresponding meaning).

(2) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

\* \* \* \* \*

(F) *Deemed exhaustion of internal claims and appeals processes*—(1) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(2) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(2) Notwithstanding paragraph (b)(3)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(1) of this section on the basis that the issuer met the standards for the exception under this

paragraph (b)(3)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

Signed this 15th day of July 2011.

**Diane O. Williams,**

*Federal Register Liaison, Internal Revenue Service, Department of the Treasury.*

Signed this 20th day of July 2011.

**Daniel J. Maguire,**

*Director, Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Department of Labor.*

Signed this 20th day of July 2011.

**Dawn Smalls,**

*Executive Secretary to the Department, Department of Health and Human Services.*

[FR Doc. 2011-18820 Filed 7-22-11; 4:15 pm]

**BILLING CODE 4820-01-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R09-OAR-2011-0042;FRL-9279-3]

#### Revisions to the California State Implementation Plan, Northern Sierra Air Quality Management District, Sacramento Metropolitan Air Quality Management District, and South Coast Air Quality Management District

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the Northern Sierra Air Quality Management District (NSAQMD), Sacramento Metropolitan Air Quality Management District (SMAQMD), and South Coast Air Quality Management District (SCAQMD) portions of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from gasoline dispensing facilities, polyester resin operations, and spray booth facilities. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** This rule is effective on September 26, 2011 without further notice, unless EPA receives adverse

comments by August 25, 2011. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

**ADDRESSES:** Submit comments, identified by docket number EPA-R09-OAR-2011-0198, by one of the following methods:

1. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions.

2. *E-mail:* [steckel.andrew@epa.gov](mailto:steckel.andrew@epa.gov).

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

*Instructions:* All comments will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through <http://www.regulations.gov> or e-mail. <http://www.regulations.gov> is an "anonymous access" system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. 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.

*Docket:* The index to the docket for this action is available electronically at <http://www.regulations.gov> and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** David Grounds, EPA Region IX, (415) 972-3019, [grounds.david@epa.gov](mailto:grounds.david@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, "we," "us," and "our" refer to EPA.