	Value	Source
Total ED Visits, Injury-related	39,395,000	Ref. 25
Total ED Visits, Injury-related due to Medication Adverse Effects	716,000	Ref. 25
Total ED Visits, Admitted	14,641,000	Ref. 25
Total ED Visits, Admitted with Asthma	158,000	Ref. 25
Total Hospital Discharges	34,369,000	Ref. 18
Total Hospital Discharges, Asthma	456,000	Ref. 18
Mortality, Asthma	3,447	Ref. 11

[FR Doc. 2011–18347 Filed 7–25–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2011–N–0466]

Medical Devices; Neurological Devices; Classification of Repetitive Transcranial Magnetic Stimulation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the repetitive transcranial magnetic stimulation (rTMS) system into class II (special controls). The Agency is classifying this device type into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This final rule is effective August 25, 2011.

FOR FURTHER INFORMATION CONTACT: Ann H. Costello, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2460, Silver Spring, MD 20993–0002, 301–796–6493.

SUPPLEMENTARY INFORMATION:

I. What is the background of this rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of FDA's regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA must, within 60 days of receiving such a request, classify the device by written order. This classification will be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification (section 513(f)(2) of the FD&C Act).

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 27, 2007, classifying the NeuroStar® TMS System for the treatment of major depressive disorder in patients who have failed to receive benefit from one antidepressant trial into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On May 23, 2007, Neuronetics, Inc., submitted a petition requesting classification, under section 513(f)(2) of the FD&C Act, of the NeuroStar® TMS System for the treatment of major depressive disorder in patients who have failed to receive benefit from one antidepressant trial. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the rTMS system can be classified into class II with the establishment of special controls. FDA believes that these special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled ''Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation System,'' which will serve as the special control for rTMS systems.

The device is assigned the generic name ''Repetitive Transcranial Magnetic Stimulation System.'' 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.

FDA has identified the risks to health associated with this type of device as follows:

- Failure to identify correct patient population;
- Ineffective treatment;
- Seizure;
- Scalp discomfort, scalp burn, or other adverse effects;
- Magnetic field effects on functioning of other medical devices;
- Adverse tissue reaction;
- Hazards associated with electrical equipment;
- Hazards caused by electromagnetic interference and electrostatic discharge hazards; and
- Hearing loss.

FDA believes that the class II special controls guidance document will aid in

mitigating the potential risks to health as described in table 1 of this document.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Mitigation measures
Failure to identify correct patient population	Clinical testing. Labeling.
Ineffective treatment	Nonclinical analysis and testing. Software life cycle and risk management. Clinical testing. Labeling.
Seizure	Nonclinical analysis and testing. Clinical testing. Labeling.
Scalp discomfort, scalp burn, or other adverse effects	Nonclinical analysis and testing. Software life cycle and risk management. Clinical testing. Labeling.
Magnetic field effects on functioning of other medical devices	Non-clinical analysis and testing. Labeling.
Adverse tissue reaction	Biocompatibility.
Hazards associated with electrical equipment	Electrical equipment safety. Labeling.
Hazards caused by electromagnetic interference and electrostatic discharge hazards	Electromagnetic compatibility. Labeling.
Hearing loss	Labeling.

FDA believes that the special controls, in addition to general controls, address the risks to health identified previously in this document and provide reasonable assurances of the safety and effectiveness of the device type. Thus, on October 7, 2008, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 882.5805.

Following the effective date of the final classification rule, manufacturers will need to address the issues covered in the special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the rTMS system they intend to market.

II. What is the environmental impact of this rule?

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Thus, neither an environmental assessment nor an environmental impact statement is required.

III. What is the economic impact of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II 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), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic 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 $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does this final rule have federalism implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under

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.[1] 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.

[1] 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.