List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Section 870.5310 is amended by revising the section heading and paragraphs (a) and (c) to read as follows:

§ 870.5310 Automated external defibrillator system.

(a) *Identification.* An automated external defibrillator (AED) system consists of an AED and those accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock (*e.g.,* battery, pad electrode, adapter, and hardware key for pediatric use). An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA will be required to be submitted to the Food and Drug Administration by April 29, 2015, for any AED that was in commercial distribution before May 28, 1976, or that has, by April 29, 2015, been found to be substantially equivalent to any AED that was in commercial distribution before May 28, 1976. A PMA will be required to be submitted to the Food and Drug Administration by April 29, 2015, for any AED accessory described in paragraph (a) that was in commercial distribution before May 28, 1976, or that has, by April 29, 2015, been found to be substantially equivalent to any AED accessory described in paragraph (a) that was in commercial distribution before May 28, 1976. Any other AED and AED accessory described in paragraph (a), shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: January 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01619 Filed 1–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9709]

RIN 1545–BK64

Application for Recognition as a 501(c)(29) Organization

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations authorizing the IRS to prescribe the procedures by which certain entities may apply to the IRS for recognition of exemption from Federal income tax. These regulations affect qualified nonprofit health insurance issuers participating in the Consumer Operated and Oriented Plan program established by the Centers for Medicare and Medicaid Services that seek exemption from federal income tax under the Internal Revenue Code.

DATES: *Effective date:* These regulations are effective on January 29, 2015.

Applicability date: For date of applicability, see § 1.501(c)(29)–1(c).

FOR FURTHER INFORMATION CONTACT: Martin Schäffer, (202) 317–5800 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 501(c)(29) of the Internal Revenue Code (Code) provides requirements for tax exemption under section 501(a) for qualified nonprofit health insurance issuers (QNHIIs). Section 501(c)(29) was added to the Code by section 1322(h)(1) of the Patient Protection and Affordable Care Act, Public Law 111–148 (March 23, 2010) (Affordable Care Act).

Section 1322 of the Affordable Care Act directs the Centers for Medicare and Medicaid Services (CMS) to establish the Consumer Operated and Oriented Plan (CO–OP) program. The purpose of the CO–OP program is to foster the creation of member-governed QNHIIs that will operate with a strong consumer focus and offer qualified health plans in the individual and small group markets. CMS provides loans and repayable grants (collectively, loans) to organizations applying to become QNHIIs to help cover start-up costs and meet any solvency requirements in States in which the organization is licensed to issue qualified health plans. For each loan, CMS issues a Notice of Award and Loan Agreement to the QNHII. The appropriate officer of the QNHII or of the QNHII's board of directors must sign and return the loan agreement to CMS. On December 13, 2011, CMS issued final regulations implementing the CO–OP program at 76 FR 77392.

The CMS final regulations define a QNHII as an entity that, within specified time frames, satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and in the CMS final regulations. The entity will constitute a QNHII until such time as CMS determines the entity does not satisfy or cannot reasonably be expected to satisfy these standards. Section 1322(c) of the Affordable Care Act imposes a number of requirements, including that a QNHII be organized as a nonprofit member corporation under State law and that substantially all its activities consist of the issuance of qualified health plans in the individual and small group markets in each State in which it is licensed to issue such plans.

Section 501(c)(29)(A) of the Code provides that a QNHII (within the meaning of section 1322(c) of the Affordable Care Act) which has received a loan or grant under the CO–OP program may be recognized as exempt from taxation under section 501(a), but only for periods for which the organization is in compliance with the requirements of section 1322 of the Affordable Care Act and any loan or grant agreement with the Secretary of Health and Human Services. Section 501(c)(29)(B) provides that a QNHII will not qualify for tax-exemption unless it meets four additional requirements. First, the QNHII must give notice to the Secretary of the Treasury, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of exemption as an organization described in section 501(c)(29). Second, no part of the QNHII's net earnings may inure to the benefit of any private shareholder or individual, except to the extent permitted by section 1322(c)(4) of the Affordable Care Act (which requires that any profits be used to lower premiums, to improve benefits, or for other programs intended to improve the quality of health care delivered to the organization's members). Third, no substantial part of the QNHII's activities

may consist of carrying on propaganda, or otherwise attempting, to influence legislation. Finally, the QNHII may not participate in or intervene in (including the publishing or distributing of statements) any political campaign on behalf of (or in opposition to) any candidate for public office. As required by section 1322(b)(2)(C)(iii) of the Affordable Care Act, CMS must notify the IRS of any determination of a failure to comply with the CO–OP program standards, including any loan agreement, that may affect a QNHII's tax-exempt status under section 501(c)(29) of the Code.

Section 6033 requires a QNHII to file an annual information return. Section 6033(m), added to the Code by section 1322(h)(2) of the Affordable Care Act, further requires a QNHII to provide additional information on the amount of reserves required by each state in which the QNHII is licensed to issue qualified health plans and the amount of reserves on hand. These requirements are met by filing a Form 990 for each tax year in which the QNHII claims tax-exempt status, including tax years prior to receipt of a determination letter from the IRS recognizing its tax-exempt status. See Notice 2011–23, § 8, 2011–13 IRB 588, as well as Instructions for Form 990–EZ, ''Short Form Return of Organization Exempt from Income Tax.''

On February 7, 2012, temporary regulations (TD 9574) authorizing the IRS to prescribe the procedures by which certain entities may apply to the IRS for recognition of exemption from Federal income tax were published in the **Federal Register** (77 FR 6005). On the same date, and under the authority of the temporary regulations, the IRS issued Rev. Proc. 2012–11, 2012–7 IRB 368, providing instructions on how an organization should apply for recognition of exemption as an organization described in section 501(c)(29). The IRS intends to reissue Rev. Proc. 2012–11 (with a 2015 designation) under the authority of the final regulations.

A notice of proposed rulemaking (REG–135071–11) cross-referencing the temporary regulations was also published in the **Federal Register** on February 7, 2012 (77 FR 6027). No public hearing was requested or held. Two comments responding to the notice of proposed rulemaking were received and are available at *www.regulations.gov* (Docket Number IRS–2012–0007). After consideration of the two comments, the proposed regulations are adopted without revision, and the corresponding temporary regulations are removed.

Summary of Comments and Explanation of Provisions

Section 501(c)(29)(B)(i) of the Code provides that a QNHII which has received a loan through the CO–OP program established under the Affordable Care Act by the Centers for Medicare and Medicaid Services may be recognized as exempt from taxation under section 501(a) only if, among other things, the QNHII gives notice to the IRS, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition as an organization described in section 501(c)(29). These final regulations provide that the Commissioner has the authority to prescribe the application procedures that a QNHII seeking such recognition must follow. These final regulations expressly authorize the Commissioner to recognize a QNHII as exempt effective as of a date prior to the date of its application, provided that the application is submitted in the manner and within the time prescribed by the Commissioner and that the QNHII's prior purposes and activities were consistent with the requirements for exempt status under section 501(c)(29).

Neither of the comments received addressed the proposed rule authorizing the IRS to prescribe the procedures by which certain entities may apply for recognition of exemption from Federal income tax as organizations described in section 501(c)(29). One commenter suggested that the final rule clarify that the failure of a QNHII to meet the requirements of state insurance laws may be grounds for the denial or revocation of the entity's tax-exempt status. In addition, the commenter suggested that the application for a section 501(c)(29) determination letter, as described in Rev. Proc. 2012–11, should include an affirmation by the entity seeking an exemption that it meets all applicable state requirements for a qualified health insurer, including solvency and licensing standards.

The final regulations do not incorporate these suggestions. Section 501(c)(29)(A) provides for recognition of a QNHII that has received a loan or grant under the CO–OP program for periods for which the organization is in compliance with the requirements of the Affordable Care Act and of any CO–OP program loan or grant. An entity that CMS has determined qualifies as a QNHII remains a QNHII until CMS determines that it does not satisfy or cannot reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and the CMS final regulations. CMS must notify the IRS if a QNHII fails to comply with the CO–OP program standards, including any loan agreement. If CMS determines that an organization no longer qualifies as a QNHII, it will lose its tax-exempt status under section 501(c)(29) of the Code. Because the commenter's suggestions relate to an organization's qualification as a QNHII, rather than to the requirements for a QNHII to be recognized as tax-exempt, these suggestions were not adopted.

Another commenter recommended that the final rule make it clear that all state and federal laws and regulations that currently apply to 501(c) organizations—including those related to transparency, reporting, and the treatment of assets upon dissolution—apply also to organizations recognized under section 501(c)(29), noting particularly the requirement to file a Form 990, ''Return of Organization Exempt From Income Tax,'' and related documents on an annual basis. The commenter further recommended that the final rule specifically address aspects of the Affordable Care Act that are not within the jurisdiction of the Treasury Department.

The final regulations do not incorporate these suggestions. With respect to the Code, different requirements apply to different types of organizations described in section 501(c). Section 501(c)(29)(B) sets forth the conditions that a QNHII must satisfy for exemption from Federal income tax. Section 6033 and the regulations thereunder generally requires all organizations exempt from taxation under section 501(a), including QNHIIs exempt under section 501(c)(29), to file Form 990, unless an organization qualifies for an exception from the filing requirement. With respect to section 1322 of Affordable Care Act, CMS issued final regulations in December 2011 implementing the CO–OP program and providing the basic standards that an organization must meet to be a QNHII and participate in the program. Those requirements are outside the jurisdiction of the Treasury Department. For these reasons no additional regulatory guidance is needed.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It has been determined, also, that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply, and because no collection of information is imposed on small entities, the

provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. Pursuant to section 7805(f) of the Code, the NPRM preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Martin Schäffer of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), although other persons in the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.501(c)(29)–1 also issued under 26 U.S.C. 501(c)(29)(B)(i). * * *

■ **Par. 2.** Section 1.501(c)(29)–1 is added to read as follows:

§ 1.501(c)(29)–1 CO–OP Health Insurance Issuers.

(a) *Organizations must notify the Commissioner that they are applying for recognition of section 501(c)(29) status.* An organization will not be treated as described in section 501(c)(29) unless the organization has given notice to the Commissioner that it is applying for recognition as an organization described in section 501(c)(29) in the manner prescribed by the Commissioner in published guidance.

(b) *Effective date of recognition of section 501(c)(29) status.* An organization may be recognized as an organization described in section 501(c)(29) as of a date prior to the date of the notice required by paragraph (a) of this section if the notice is given in the manner and within the time prescribed by the Commissioner and the organization's purposes and activities prior to giving such notice were consistent with the requirements for exempt status under section 501(c)(29). However, an organization may not be recognized as an organization described in section 501(c)(29) before the later of its formation or March 23, 2010.

(c) *Effective/applicability date.* Paragraphs (a) and (b) of this section are applicable beginning February 7, 2012.

§ 1.501(c)(29)–1T [Removed]

■ **Par. 3.** Section 1.501(c)(29)–1T is removed.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: January 22, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury.

[FR Doc. 2015–01677 Filed 1–26–15; 4:15 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2014–0713; FRL–9919–42–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to Administrative Rules of Montana—Prevention of Significant Deterioration

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve State Implementation Plan (SIP) revisions submitted by the State of Montana on June 4, 2013. This submission revises the Administrative Rules of Montana that pertain to the issuance of Montana air quality permits. The June 4, 2013 revisions contain amended and renumbered rules that, among other things, address the proper treatment of air pollutants under the State's prevention of significant deterioration (PSD) program. In this rulemaking, we are taking final action on all of the June 4, 2013 submittal, with the exception of one small portion. This action is being taken under section 110 of the Clean Air Act (CAA).

DATES: This final rule is effective March 2, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2014–0713. All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air Program, Mailcode 8P–AR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6227, or *leone.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background
II. What are the changes that EPA is taking final action to approve?
III. Response to Comments
IV. What action is EPA taking today?
V. Statutory and Executive Orders Review

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The initials *ARM* mean or refer to the Administrative Rules of Montana.

(iii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iv) The initials *FIP* mean or refer to Federal Implementation Plan.

(v) The initials *MDEQ* mean or refer to the Montana Department of Environmental Quality.

(vi) The initials NO_X mean or refer to nitrogen oxides.

(vii) The initials *NSR* mean or refer to New Source Review.

(viii) The initials $PM_{2.5}$ mean or refer to particulate matter equal to or less than 2.5 microns in diameter.

(ix) The initials *PSD* mean or refer to Prevention of Significant Deterioration.

(x) The initials *SIP* mean or refer to State Implementation Plan.

(xi) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

I. Background

EPA is taking final action to approve (with one exception) the revisions to Title 17, Chapter 8, subchapter 8 of the Administrative Rules of Montana (ARM) submitted by the State on June 4, 2013, that relate to the State's PSD program. The revisions to the State PSD SIP were adopted by the Montana Department of