

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Parts 40, 41, 44, and 45

[Docket No. TTB-2009-0002; Notice No. 95; Re: T.D. TTB-78]

RIN 1513-AB72

#### Implementation of Statutory Amendments Requiring the Qualification of Manufacturers and Importers of Processed Tobacco and Other Amendments Related to Permit Requirements, and the Expanded Definition of Roll-Your-Own Tobacco

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Notice of proposed rulemaking; cross-reference to temporary rule.

**SUMMARY:** Elsewhere in this issue of the **Federal Register**, the Alcohol and Tobacco Tax and Trade Bureau is issuing a temporary rule to implement certain changes made to the Internal Revenue Code of 1986 by the Children's Health Insurance Program Reauthorization Act of 2009. The principal changes involve permit and related requirements for manufacturers and importers of processed tobacco and an expansion of the definition of roll-your-own tobacco. The text of the regulations in the temporary rule published in the Rules and Regulations section of this issue of the **Federal Register** serves as the text of the proposed regulations.

**DATES:** Comments must be received on or before August 21, 2009.

**ADDRESSES:** You may send comments on this notice to one of the following addresses:

- <http://www.regulations.gov> (via the online comment form for this notice as posted within Docket No. TTB-2009-0001 at "Regulations.gov," the Federal e-rulemaking portal);
- Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and

Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412; or

• *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, any comments received, and the related temporary rule at <http://www.regulations.gov>. A direct link to the appropriate Regulations.gov docket is also available under Notice No. 95 on the TTB Web site at [http://www.ttb.gov/regulations\\_laws/all\\_rulemaking.shtml](http://www.ttb.gov/regulations_laws/all_rulemaking.shtml). You also may view copies of these documents by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202-927-2400.

**FOR FURTHER INFORMATION CONTACT:** For questions concerning processed tobacco permit and authorization procedures, contact the National Revenue Center, Alcohol and Tobacco Tax and Trade Bureau (1-877-882-3277); for other questions concerning this document, contact Amy Greenberg, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau (202-927-8210).

#### SUPPLEMENTARY INFORMATION:

##### Background

In the Rules and Regulations section of this issue of the **Federal Register**, we are publishing a temporary rule setting forth regulatory amendments to implement certain provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3, 123 Stat. 8). The principal changes made by CHIPRA that are the basis for the regulatory amendments contained in this document involve permit and related requirements for manufacturers and importers of processed tobacco and an expansion of the definition of roll-your-own tobacco.

The temporary regulations published elsewhere in this issue of the **Federal Register** involve amendments to parts 40, 41, 44, and 45 of the TTB regulations (27 CFR parts 40, 41, 44, and 45). The text of the temporary regulations serves as the text of these proposed

regulations. The preamble to the temporary regulations explains the proposed regulations.

#### Public Participation

##### Comments Invited

We invite comments from interested members of the public on this proposed rulemaking.

##### Submitting Comments

You may submit comments on this notice by one of the following three methods:

- *Federal e-Rulemaking Portal:* You may electronically submit comments on this notice through "Regulations.gov," the Federal e-rulemaking portal. A direct link to the Regulations.gov docket containing this notice and its related comment submission form is available on the TTB Web site at [http://www.ttb.gov/regulations\\_laws/all\\_rulemaking.shtml](http://www.ttb.gov/regulations_laws/all_rulemaking.shtml) under Notice No. 95. You may also reach this notice and its related comment form via the Regulations.gov search page at <http://www.regulations.gov>. Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on "User Guide" under "How to Use this Site."

- *Mail:* You may send written comments to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412.

- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 95 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. We do not acknowledge receipt of comments, and we consider all comments as originals.

If you are commenting on behalf of an association, business, or other entity, your comment must include the entity's name as well as your name and position title. If you comment via <http://www.regulations.gov>, please enter the

entity's name in the "Organization" blank of the comment form. If you comment via mail, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

#### *Confidentiality*

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

#### *Public Disclosure*

On the Federal e-rulemaking portal, Regulations.gov, we will post, and you may view, copies of this notice, any electronic or mailed comments we receive about this proposal, and the related temporary rule. A direct link to the Regulations.gov docket containing this notice and the comments received on this proposal is available on the TTB Web site at [http://www.ttb.gov/regulations\\_laws/all\\_rulemaking.shtml](http://www.ttb.gov/regulations_laws/all_rulemaking.shtml) under Notice No. 95. You may also reach the relevant docket through the Regulations.gov search page at <http://www.regulations.gov>.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including e-mail addresses. We may omit voluminous attachments or material that we consider unsuitable for posting.

You also may view copies of this notice, any electronic or mailed comments we receive about this proposal, and the related temporary rule by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact our information specialist at the above address or by telephone at 202-927-2400 to schedule an appointment or to request copies of comments or other materials.

#### **Regulatory Flexibility Act, Paperwork Reduction Act, and Executive Order 12866**

Since the regulatory text proposed in this notice of proposed rulemaking is identical to that contained in the companion temporary rule published elsewhere in this issue of the **Federal Register**, the analyses contained in the preamble of the temporary rule concerning the Regulatory Flexibility Act, the Paperwork Reduction Act, and

Executive Order 12866 also apply to this proposed rule.

#### **Drafting Information**

Amy Greenberg of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document. However, other personnel participated in its development.

#### **List of Subjects**

##### *27 CFR Part 40*

Cigars and cigarettes, Claims, Electronic funds transfers, Excise taxes, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Tobacco.

##### *27 CFR Part 41*

Cigars and cigarettes, Claims, Customs duties and inspection, Electronic funds transfers, Excise taxes, Imports, Labeling, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Surety bonds, Tobacco, Virgin Islands, Warehouses.

##### *27 CFR Part 44*

Aircraft, Armed forces, Cigars and cigarettes, Claims, Customs duties and inspection, Excise taxes, Exports, Foreign trade zones, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Tobacco, Vessels, Warehouses.

##### *27 CFR Part 45*

Administrative practice and procedure, Authority delegations (Government agencies), Cigars and cigarettes, Excise taxes, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Tobacco.

#### **Proposed Amendments to the Regulations**

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR, chapter I, parts 40, 41, 44, and 45 as follows:

#### **PART 40—MANUFACTURE OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES**

1. The authority citation for part 40 is revised to read as follows:

**Authority:** 26 U.S.C. 5142, 5143, 5146, 5701–5705, 5711–5713, 5721–5723, 5731, 5741, 5751, 5753, 5761–5763, 6061, 6065, 6109, 6151, 6301, 6302, 6311, 6313, 6402, 6404, 6423, 6676, 6806, 7011, 7212, 7325, 7342, 7502, 7503, 7606, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

2. [The proposed amendatory instructions and the proposed amended

regulatory text for part 40 are the same as the amendatory instructions and the amended regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**.]

#### **PART 41—IMPORTATION OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES**

3. The authority citation for part 41 is revised to read as follows:

**Authority:** 26 U.S.C. 5701–5705, 5708, 5712, 5713, 5721–5723, 5741, 5754, 5761–5763, 6301, 6302, 6313, 6402, 6404, 7101, 7212, 7342, 7606, 7651, 7652, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

4. [The proposed amendatory instructions and the proposed amended regulatory text for part 41 are the same as the amendatory instructions and the amended regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**.]

#### **PART 44—EXPORTATION OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES, WITHOUT PAYMENT OF TAX, OR WITH DRAWBACK OF TAX**

5. The authority citation for part 44 is revised to read as follows:

**Authority:** 26 U.S.C. 5701–5705, 5708, 5711–5713, 5721–5723, 5731, 5741, 5751, 5754, 6061, 6065, 6151, 6402, 6404, 6806, 7011, 7212, 7342, 7606, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

6. [The proposed amendatory instructions and the proposed amended regulatory text for part 44 are the same as the amendatory instructions and the amended regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**.]

#### **PART 45—REMOVAL OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES, WITHOUT PAYMENT OF TAX, FOR USE OF THE UNITED STATES**

7. The authority citation for part 45 is revised to read as follows:

**Authority:** 26 U.S.C. 5702–5705, 5723, 5741, 5751, 5762, 5763, 6313, 7212, 7342, 7606, 7805; 44 U.S.C. 3504(h).

8. [The proposed amendatory instructions and the proposed amended regulatory text for part 45 are the same as the amendatory instructions and the amended regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**.]

Signed: April 15, 2009.

**John J. Manfreda,**  
Administrator.

Approved: May 26, 2009.

**Timothy E. Skud,**  
Deputy Assistant Secretary (Tax, Trade, and  
Tariff Policy).

[FR Doc. E9-14548 Filed 6-19-09; 8:45 am]

BILLING CODE 4810-31-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 199

[DOD-2009-HA-0051]

RIN 0720-AB31

#### TRICARE; Coverage of National Cancer Institute (NCI) Sponsored Phase I Studies

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule adds coverage of National Cancer Institute (NCI) sponsored Phase I studies for certain beneficiaries. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe.

**DATES:** Written comments received at the address indicated below by August 21, 2009 will be accepted.

**ADDRESSES:** You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

*Instructions:* All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:**  
Colonel John Kugler, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681-0064.

**SUPPLEMENTARY INFORMATION:** This proposed rule adds the coverage of a subset of National Cancer Institute (NCI) sponsored Phase I trials for certain TRICARE patients. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe. A Phase I trial usually enrolls only a small number of patients, sometimes as few as a dozen. A Phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer. A Phase III trial tests a new drug, a new combination of drugs, or a new surgical procedure in comparison to the current standard. A participant will usually be assigned to the standard group or the new group at random. Phase III trials often enroll large numbers of people and may be conducted at many doctors' offices, clinics, and cancer centers nationwide.

This proposed rule adds coverage only of NCI sponsored Phase I trials with clinical or preclinical data providing a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative. Additionally, only those TRICARE patients for whom standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative, would be eligible for these additional trials. TRICARE has covered NCI sponsored Phase II and III trials since 1996. The NCI estimates that Phase I trial participants represent about 3.4 percent of overall Phase II and III participants combined. Based on the history of DoD participation in these studies, it is estimated that there would be a maximum of one thousand new patients annually enrolling in Phase I trials. It is estimated that the net cost to TRICARE of adding Phase I treatment trials will increase costs by 12.8 percent of the total gross costs (approximately \$150,000 in FY09). Currently ten states mandate coverage of at least some Phase I trials.

#### Regulatory Procedures

*Executive Order 12866, "Regulatory Planning and Review"*

Section 801 of title 5, United States Code (U.S.C.), and Executive Order (E.O.) 12866 requires certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result

in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

*Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"*

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

*Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)*

The Regulatory Flexibility Act (RFA) requires each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule will not significantly affect a substantial number of small entities for purposes of the RFA.

*Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)*

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

*Executive Order 13132, "Federalism"*

This proposed rule has been examined for its impact under E.O. 13132 and it does not contain policies that have federalism implications that would 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; therefore, consultation with State and local officials is not required.

#### List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended as follows:

#### PART 199—[AMENDED]

1. The authority citation for Part 199 continues to read as follows:

**Authority:** 5 U.S.C. 301; 10 U.S.C. Chapter 55.

2. Section 199.4 is amended by: