

eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

#### Drafting Information

The principal author of these regulations is Arturo Estrada, Office of the Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be 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 860F-4 issued under 26 U.S.C. 860G(e) and 26 U.S.C. 6230(k). \* \* \*

**Par. 2.** In § 1.860F-4, paragraph (a) is amended by adding a sentence at the end to read as follows:

#### § 1.860F-4 REMIC reporting requirements and other administrative rules.

(a) \* \* \* The identity of a holder of a residual interest in a REMIC is not treated as a partnership item with respect to the REMIC for purposes of subchapter C of chapter 63.

\* \* \* \* \*

**Nancy J. Jardini,**

*Acting Deputy Commissioner of Services and Enforcement.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 40 and 49

[REG-163909-02]

RIN 1545-BB75

#### Collected Excise Taxes; Duties of Collector

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulations.

**SUMMARY:** In this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the obligations of persons that receive payments for air transportation or communications services subject to excise tax when persons liable for the tax refuse to pay the tax. The text of those temporary regulations also serves as the text of these proposed regulations. These proposed regulations affect persons liable for those taxes and persons that receive payments subject to tax.

**DATES:** Written and electronic comments and requests for a public hearing must be received by November 8, 2004.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-163909-02), room 5203, Internal Revenue Service, POB 7604 Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-163909-02), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the IRS Internet site at [www.irs.gov/regs](http://www.irs.gov/regs), or via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (indicate IRS and REG-163909-02).

**FOR FURTHER INFORMATION CONTACT:** Concerning submissions, the Publication and Regulations Unit, (202) 622-7180; concerning the regulations, Taylor Cortright, (202) 622-3130 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background

These proposed regulations relate to the obligations of persons that receive payments for air transportation or communications services subject to excise tax when persons liable for the tax refuse to pay the tax. These proposed regulations would amend the Excise Tax Procedural Regulations (26 CFR part 40) and the Facilities and

Services Excise Tax Regulations (26 CFR part 49). The text of temporary regulations published in this issue of the **Federal Register** also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations.

#### Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the notice of proposed rulemaking does not impose a collection of information 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, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

#### Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

#### Drafting Information

The principal author of these regulations is Patrick S. Kirwan, Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

#### List of Subjects

26 CFR Part 40

Excise taxes, Reporting and recordkeeping requirements.

## 26 CFR Part 49

Excise taxes, Reporting and recordkeeping requirements, Telephone, Transportation.

### Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 40 and 49 are proposed to be amended as follows:

#### PART 40—EXCISE TAX PROCEDURAL REGULATIONS

**Paragraph 1.** The authority citation for part 40 continues to read, in part, as follows:

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

**Par. 2.** Section 40.6302(c)–3 is amended by revising paragraph (b)(2)(ii)(B) to read as follows:

#### § 40.6302(c)–3 Special rules for use of Government depositaries under chapter 33.

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(ii) \* \* \*

(B) [The text of this proposed paragraph is the same as the text of § 40.6302(c)–3T(b)(2)(ii)(B) published elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

#### PART 49—FACILITIES AND SERVICES EXCISE TAXES

**Par. 3.** The authority citation for part 49 continues to read in part as follows:

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

**Par. 4.** Section 49.4291–1 is amended by revising the fourth sentence to read as follows:

#### § 49.4291–1 Persons receiving payment must collect tax.

\* \* \* [The text of this proposed sentence is the same as the text of § 49.4291–1T published elsewhere in this issue of the **Federal Register**].  
\* \* \*

Approved: June 21, 2004.

**Mark E. Matthews,**

*Deputy Commissioner for Services and Enforcement.*

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 199

RIN 0720–AA88

#### TRICARE Program; Rare Diseases Definition and Partial List of Examples of Unproven Drugs, Devices, Medical Treatments or Procedures

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

**ACTION:** Proposed Rule.

**SUMMARY:** This proposed rule revises the definition of rare diseases, clarifies case-by-case review of benefits for rare diseases, and removes the partial list of examples of unproven drugs, devices, medical treatments or procedures.

**DATES:** Written comments received at the address indicated below by October 12, 2004, will be accepted.

**ADDRESSES:** Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission or e-mail. Mail written comments to the following address ONLY: TRICARE Management Activity, Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, CO 80011–9066. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

**FOR FURTHER INFORMATION CONTACT:** René Morrell, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676–3618.

**SUPPLEMENTARY INFORMATION:** TRICARE supplements the availability of health care in military hospitals and clinics.

#### Rare Diseases

On January 6, 1997, the Office of the Secretary of Defense published a final rule in the **Federal Register** (62 FR 627–631) clarifying the TRICARE exclusion of unproven drugs, devices, medical treatments and procedures and adding the TRICARE definition of rare diseases. This rule also added the provision for reviewing benefits for rare diseases on a case-by-case basis. Currently, TRICARE defines a rare disease as one which affects fewer than one in 200,000 Americans. The basis for this definition was not documented. Upon further review, we propose to revise our definition to be more in compliance with the definition of other Federal agencies and national organizations specializing in the identification of rare diseases. Our revised definition is based on the following:

(1) For the purpose of designating drugs for rare diseases or conditions, the

Food and Drug Administration defines the term rare disease, in part, as any disease or condition which affects less than 200,000 persons in the United States (21 U.S.C. 360(bb)(a)(2)).

2. Section 3 of the Rare Diseases Act of 2002, Public Law 107–28, defines a rare disease or condition as any disease or condition that affects less than 200,000 persons in the United States.

3. The National Institutes of Health Office of Rare Diseases considers an orphan or rare disease or condition to have a prevalence of less than 200,000 affected individuals in the United States.

4. The National Organization for Rare Disorders defines a rare or orphan disease as affecting fewer than 200,000 people in the United States.

We also propose to clarify the provision for review of benefits for rare diseases on a case-by-case basis. We are not removing the provision for case-by-case review only clarifying that case-by-case review is not required for treatment that has already been established as safe and effective.

#### Partial List of Examples of Unproven Drugs, Devices, Medical Treatment or Procedures

The current regulation and program policy exclude coverage of unproven drugs, devices, medical treatment or procedures. The current regulation and program policy provide a partial list of examples of unproven drugs, devices, medical treatment or procedures that are excluded from benefits. The intent of this partial list was to provide information on specific examples of emerging drugs, devices, medical treatment or procedures determined to be unproven by TRICARE based on review of current reliable evidence. Due to the rapid and extensive changes in medical technology it is not feasible to maintain this list in the regulation. Removal of the partial list of examples does not change the exclusion of unproven drugs, devices, medical treatment or procedures. Removal of the partial list of examples does not change the process TRICARE follows in determining for purposes of benefit coverage when a drug, device, medical treatment or procedure has moved from the status of unproven to proven medical effectiveness. Removal of the partial list of examples does not mean the drugs, devices, medical treatment or procedures cited in the partial list have now been determined to be proven. The intent of this revision is to ensure that benefit determinations are made based on current reliable evidence rather than relying on outdated regulatory provisions.