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.

[FR Doc. 04–18161 Filed 8–9–04; 8:45 am]

BILLING CODE 4830–01–P

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.

Regulatory Procedures

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically 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.

The Regulatory Flexibility Act (RFA) requires that 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 rule has been designated as significant and has been reviewed by the Office Management and Budget as required under the provisions of E.O. 12866 however, it would not have a significant impact on small entities. The changes set forth in the proposed rule are minor revisions to the existing regulation. In addition, this proposed rule does not impose new information collection requirements for purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511).

This is a proposed rule. Public comments are invited.

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 199.2, paragraph (b) is proposed to be amended by revising the definition of ''Rare Diseases'' to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Rare Diseases. TRICARE defines a rare disease as any disease or condition that affects less than 200,000 persons in the United States.

* * * * *

3. Section 199.4 is proposed to be amended by revising paragraph (g)(15)(ii) and removing paragraph (g)(15)(iv) as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) * * *

(15) * * *

(ii) CHAMPUS benefits for rare diseases are reviewed on a case-by-case basis by the Director, TRICARE Management Activity, or a designee. Case-by-case review is not required for drugs, devices, medical treatments and procedures that have already been established as safe and effective for treatment of rare diseases. In reviewing the case, the Director, or a designee, may consult with any or all of the following sources to determine if the proposed therapy is considered safe and effective.

* * * * *

Dated: August 4, 2004.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–18182 Filed 8–9–04; 8:45 am]

BILLING CODE 5001–06–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R04–OAR–2003–SC–0001–200416(b); FRL–7799–4]

Approval and Promulgation of Implementation Plans; South Carolina: Source Testing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve the State Implementation Plan (SIP) revisions submitted by the South Carolina Department of Health and Environmental Control (SC DHEC) on September 4, 2002, and July 25, 2003. The proposed revisions are to establish, standardize, and clarify source testing requirements. South Carolina is also changing the title of Regulation 62.1 to reflect that it contains general provisions. In the Final Rules section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no significant, material, and adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before September 9, 2004.

ADDRESSES: Comments may be submitted by mail to: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Comments may also be submitted electronically, or through hand delivery/courier. Please follow the detailed instructions described in the direct final rule, **ADDRESSES** section which is published in the Rules Section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can also be reached via electronic mail at *ward.nacosta@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the Rules section of this **Federal Register**.

Dated: July 27, 2004.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 04–18138 Filed 8–9–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7799–2]

National Oil and Hazardous Substance Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of Intent to Delete the San Fernando Valley Basin Area 3, Verdugo Study Area Superfund Site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) Region IX is publishing this Notice of Intent to Delete the San Fernando Valley Basin Area 3, Verdugo Study Area Superfund Site (Site) from the National Priorities List (NPL), and requests public comments on this