

in parts 210 and 211 will be reduced under this direct final rule.

The OMB-approved hourly burden to comply with the information collection requirements in parts 210 and 211 (control number 0910-0139) is 848,625 hours. FDA estimates that, under the direct final rule, approximately 7,315 drugs will be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. Based on this number and the total number of drugs that are subject to parts 210 and 211, FDA estimates that the burden hours approved under control number 0910-0139 will be reduced by approximately 50,493 hours. Thus, as a result of the direct final rule, the amended burden hours in control number 0910-0139 will be approximately 798,132 hours.

VII. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 210

Drugs, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 210 is amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

■ 1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. Section 210.2 is amended by adding paragraph (c) to read as follows:

§ 210.2 Applicability of current good manufacturing practice regulations.

* * * * *

(c) An investigational drug for use in a Phase 1 study, as defined in § 312.21(a) of this chapter, is subject to the statutory requirements set forth at 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in part 211 of this chapter. However, this exemption does not apply to an investigational drug for use in a Phase 1 study once the investigational drug has been made available for use by or for the sponsor in a Phase 2 or Phase 3 study, as defined in § 312.21(b) and (c) of this chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a Phase 2 or 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with part 211.

Dated: January 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-353 Filed 1-12-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9240]

RIN 1545-BF15

Guidance Under Subpart F Relating to Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations providing guidance under subpart F relating to partnerships. The temporary regulations add rules for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal

holding company income under the exception contained in section 954(i). These temporary regulations will affect CFCs that are qualified insurance companies, as defined in section 953(e)(3), that have an interest in a partnership and U.S. shareholders of such CFCs. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective January 17, 2006.

Applicability Date: For dates of applicability, see § 1.954-2T(a)(5)(v).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Kate Y. Hwa, (202) 622-3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 relating to the rules under section 954(i) of the Internal Revenue Code (Code) for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i).

Need for Changes

On July 23, 2002, the IRS and the Treasury Department published in the **Federal Register** (TD 9008, 67 FR 48020) final regulations under section 702 and subpart F. Since the publication of TD 9008, the IRS and the Treasury Department have received several comments relating to the rule in the final regulations regarding the application of section 954(i) (special rule for income derived in the active conduct of an insurance business). These temporary regulations modify this rule in response to these comments.

Explanation of Revisions

Section 1.954-2(a)(5)(ii) sets forth special rules for determining the extent to which a CFC's distributive share of an item of income of a partnership is foreign personal holding company income. Section 1.954-2(a)(5)(ii)(C) addresses the exception contained in section 954(i) for income derived in the active conduct of an insurance business. Investment income that is excluded from insurance income as exempt insurance income under section 953(e) may nevertheless be treated as subpart F income if it falls within the definition of foreign personal holding company income under section 954(c) and the exception contained in section 954(i) is

not satisfied. Section 1.954-2(a)(5)(ii)(C) provides that a CFC's distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i) only if the CFC is a qualifying insurance company, generally as defined in section 953(e)(3), and the partnership, of which the CFC is a partner, generates qualified insurance income within the meaning of section 954(i)(2), taking into account only the income of the partnership. Qualified insurance income is defined under section 954(i)(2) as income of a qualifying insurance company that is derived from investment of certain of its reserves or surplus if certain other requirements are satisfied.

Commentators expressed concern that § 1.954-2(a)(5)(ii)(C) would never permit a CFC's distributive share of partnership income to qualify for the exclusion under section 954(i). Section 7701(a)(3) and the regulations provide that any entity that is an insurance company is treated as a corporation for Federal tax purposes. See Rev. Rul. 83-132 (1983-2 C.B. 270). Thus, any entity engaged in an active insurance business generally would be treated as a corporation and therefore would not be subject to the rule in § 1.954-2(a)(5)(ii)(C).

Commentators also distinguished section 954(i) from the other exceptions to foreign personal holding company income in section 954, arguing that those exceptions do not provide the appropriate model for section 954(i). The special rules in the regulations regarding the exception to foreign personal holding company income contained in section 954(c), or the exception for income derived from the active conduct of a banking or similar business contained in section 954(h), turn on whether the income was generated from certain active business activities. In contrast, income that is excluded under section 954(i) may be generated from purely passive investments as long as the amount of the investments satisfies the requirements set forth in section 954(i). Commentators asked for clarification of the regulations to take into account the purposes of section 954(i).

In response to these comments, these temporary regulations provide that a CFC's distributive share of partnership income will qualify for the exception contained in section 954(i) if the CFC is a qualifying insurance company and the income of the partnership would have been qualified insurance income under section 954(i) if received by the CFC directly. Thus, whether the CFC partner's distributive share of

partnership income is qualified insurance income is determined at the CFC partner level.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this temporary regulation will be 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 Kate Y. Hwa of the Office of the Associate Chief Counsel (International), IRS. However, other personnel from 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 26 CFR part 1 continues to read, in part, as follows:

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

■ **Par. 2.** Section 1.954-2 is amended by revising paragraphs (a)(5)(ii)(C) and (a)(5)(iii) *Example 2*, to read as follows:

§ 1.954-2 Foreign personal holding company income.

(a) * * *

(5) * * *

(C) [Reserved]. For further guidance, see § 1.954-2T(a)(5)(ii)(C).

* * * * *

(iii) * * *

Example 2. [Reserved]. For further guidance, see § 1.954-2T(a)(5)(iii) *Example 2*.

* * * * *

■ **Par. 3.** Section 1.954-2T is added as follows:

§ 1.954-2T Foreign personal holding company income (temporary).

(a)(1) through (5)(ii)(B) [Reserved]. For further guidance, see § 1.954-2(a)(1) through (5)(ii)(B).

(C) A controlled foreign corporation's distributive share of partnership income will not be excluded from foreign personal holding company income under the exception contained in section 954(i) unless the controlled foreign corporation is a qualifying insurance company, as defined in section 953(e)(3), and the income of the partnership would have been qualified insurance income, as defined in section 954(i)(2), if received by the controlled foreign corporation directly. See § 1.952-1(g)(1).

(iii) *Examples.* [Reserved] For further guidance, see § 1.954-2(a)(5)(iii).

Example 1. [Reserved] For further guidance, see § 1.954-2(a)(5)(iii) *Example 1*.

Example 2. D Corp, a Country F corporation, is a controlled foreign corporation within the meaning of section 957(a). D Corp is a qualifying insurance company, within the meaning of section 953(e)(3), that is engaged in the business of issuing life insurance contracts. D Corp has reserves of \$100x, all of which are allocable to exempt contracts, and \$10x of surplus, which is equal to 10 percent of the reserves allocable to exempt contracts. D Corp contributed the \$100x of reserves and \$10x of surplus to DJ Partnership in exchange for a 40-percent partnership interest. DJ Partnership is an entity organized under the laws of Country G and is treated as a partnership under the laws of Country G and Country F. DJ Partnership earns \$30x of investment income during the taxable year that is received from persons who are not related persons with respect to D Corp, within the meaning of section 954(d)(3). D Corp's distributive share of this investment income is \$12x. This income is treated as earned by D Corp in Country F under the tax laws of Country F and meets the definition of exempt insurance income in section 953(e)(1). This \$12x of investment income would be qualified insurance income, under section 954(i)(2), if D Corp had received the income directly, because the \$110x invested by D Corp in DJ Partnership is equal to D Corp's reserves allocable to exempt contracts under section 954(i)(2)(A) and allowable surplus under section 954(i)(2)(B)(ii). Thus, D Corp's distributive share of DJ Partnership's income will be excluded from foreign personal holding company income under section 954(i).

(iv) [Reserved].

(v) *Effective date.* [Reserved]. See § 1.954-2(a)(5)(v).

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Eric Solomon,

Acting Deputy Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 06-355 Filed 1-13-06; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AM11

Elimination of Copayment for Smoking Cessation Counseling

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rule adopts as final, without change, the interim final rule published in the **Federal Register** (70 FR 22595) on May 2, 2005. The Department of Veterans Affairs (VA) is publishing this final rule to designate smoking cessation counseling (individual and group sessions) as a service that is not subject to copayment requirements.

DATES: *Effective Date:* January 17, 2006.

FOR FURTHER INFORMATION CONTACT:

Eileen P. Downey, Program Analyst, Policy Development, Chief Business Office (16), (202) 254-0347 or Dr. Kim Hamlet-Berry, Director, Public Health National Prevention Program, Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273-8929. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: An interim final rule amending VA's medical regulations to set forth a rule designating smoking cessation counseling (individual and group sessions) as a service that is not subject to copayment requirements was published in the **Federal Register** on May 2, 2005 (70 FR 22595).

We provided a 60-day comment period that ended July 1, 2005. Twelve comments were received and all supported the rule. Based on the rationale set forth in the interim final rule, we now adopt the interim final rule as a final rule.

Administrative Procedure Act

In the May 2, 2005, **Federal Register** notice, we determined that there was a basis under the Administrative Procedure Act for issuing the interim

final rule with immediate effect. We invited and received public comment on the interim final rule. This document merely affirms the interim final rule as a final rule without change.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This final rule will not directly affect any small entities. Only individuals could be directly affected. Accordingly, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug

abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: November 22, 2005

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

PART 17—MEDICAL

Accordingly, the interim final rule amending 38 CFR part 17, which was published at 70 FR 22595 on May 2, 2005, is adopted as a final rule without change.

[FR Doc. 06-373 Filed 1-13-06; 8:45 am]

BILLING CODE 8320-01-P

POSTAL RATE COMMISSION

39 CFR Part 3001

[Docket No. RM2004-1; Order No. 1449]

Definition of Postal Service

AGENCY: Postal Rate Commission.

ACTION: Final rule.

SUMMARY: This document addresses adding a definition of the term "postal service" to the rules of practice. This change is prompted by the Postal Service's action with respect to nonpostal initiatives. There is often controversy and uncertainty regarding the postal character of the services provided under those initiatives. The definition provides guidance to the Postal Service and the general public concerning services that are subject to sections 3622 and 3623 of the Postal Reorganization Act.

DATES:

1. *Effective Date:* February 16, 2006.
2. Deadline for (optional) Postal Service motion to dismiss Docket No. C2004-1: January 17, 2006.
3. Deadline for (optional) Postal Service update on 14 services identified in Consumer Action petition: February 17, 2006.
4. Deadline for Postal Service updates on postal and nonpostal services: June 1, 2006.

ADDRESSES: File all documents referred to in this order electronically via the Commission's Filing Online system at <http://www.prc.gov>.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, 202-789-6818.