

The rationale for requiring blood and blood components, including fresh frozen plasma collected by an apheresis procedure, to be collected by a single uninterrupted venipuncture is to help ensure minimal tissue damage which could activate the coagulation cascade. This is also a requirement for Platelet collection. Under 21 CFR 640.22(d), the regulation states that Platelet phlebotomy shall be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue. FDA does not anticipate, in the near future, any change in the policy for using a sterile connecting device to attach a sterile needle to a collection set in the event of a blood flow interruption.

List of Subjects

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated by the Commissioner of Food and Drugs, 21 CFR part 640 is amended as follows:

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

■ 1. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 2. Section 640.4 is amended by revising paragraph (h) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(h) *Storage.* Whole Blood must be placed in storage at a temperature between 1 and 6 °C immediately after collection unless the blood is to be further processed into another component or the blood must be transported from the donor center to the processing laboratory. If transported, the blood must be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a temperature range between 1 and 10 °C until arrival at the processing laboratory. At the processing laboratory, the blood must be stored at a temperature between 1 and 6 °C. Blood from which a component is to be prepared must be held in an environment maintained at a temperature range specified for that component in the directions for use for

the blood collecting, processing, and storage system approved for such use by the Director, CBER.

§ 640.24 [Amended]

■ 3. Section 640.24 is amended in the first sentence of paragraph (d) by removing “6.0” and adding in its place “6.2”.

Dated: February 1, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8-2322 Filed 2-7-08; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9379]

RIN 1545-BG35

Time and Manner for Electing Capital Asset Treatment for Certain Self-Created Musical Works

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulation.

SUMMARY: This document contains a temporary regulation that provides the time and manner for making an election to treat the sale or exchange of musical compositions or copyrights in musical works created by the taxpayer (or received by the taxpayer from the works' creator in a transferred basis transaction) as the sale or exchange of a capital asset. The regulation reflects changes to the law made by the Tax Increase Prevention and Reconciliation Act of 2005 and the Tax Relief and Health Care Act of 2006. The regulation affects taxpayers making the election under section 1221(b)(3) of the Internal Revenue Code (Code) to treat gain or loss from such a sale or exchange as capital gain or loss. The text of this temporary regulation also serves as the text of the proposed regulation (REG-153589-06) set forth in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* This regulation is effective on February 8, 2008.

Applicability Dates: For dates of applicability, see § 1.1221-3T(d).

FOR FURTHER INFORMATION CONTACT: Jamie Kim, (202) 622-4950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 1221(a) of the Internal Revenue Code (Code) generally provides

that capital assets include all property held by a taxpayer with certain specified exclusions. Section 1221(a)(1) excludes from the definition of a capital asset inventory property or property held by a taxpayer primarily for sale to customers in the ordinary course of the taxpayer's trade or business. Section 1221(a)(3) excludes from the definition of a capital asset copyrights, literary, musical, or artistic compositions, letters or memoranda, or similar property held by a taxpayer whose personal efforts created the property (or held by a taxpayer whose basis in the property is determined by reference to the basis of such property in the hands of the taxpayer whose personal efforts created the property).

Section 1221(b)(3) of the Code, added by section 204 of the Tax Increase Prevention and Reconciliation Act of 2005 (Public Law 109-222, 120 Stat. 345) and amended by section 412 of the Tax Relief and Health Care Act of 2006 (Public Law 109-432, 120 Stat. 2922), provides that, at the election of a taxpayer, the section 1221(a)(1) and (a)(3) exclusions from capital asset status do not apply to musical compositions or copyrights in musical works sold or exchanged by a taxpayer described in section 1221(a)(3). Thus, if a taxpayer who owns a musical composition or copyright in a musical work created by the taxpayer (or transferred to the taxpayer by the work's creator in a section 1221(a)(3)(C) transferred basis transaction) elects the application of this provision, gain or loss from the sale or exchange of the musical composition or copyright is treated as capital gain or loss.

Explanation of Provisions

This temporary regulation provides rules regarding the time and manner for making an election under section 1221(b)(3) to treat gain or loss from the sale or exchange of certain musical compositions or copyrights in musical works as gain or loss from the sale or exchange of a capital asset.

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 also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. For application of the Regulatory Flexibility Act (5 U.S.C. Chapter 6) please refer to the cross reference notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section

7805(f) of the Internal Revenue Code, this regulation has been 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 Jamie Kim of the Office of Associate Chief Counsel (Income Tax & Accounting). 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.

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 continues to read in part as follows:

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

■ **Par. 2.** Section 1.1221-3T is added to read as follows:

§ 1.1221-3T Time and manner for electing capital asset treatment for certain self-created musical works (temporary).

(a) *Description.* Section 1221(b)(3) allows an electing taxpayer to treat the sale or exchange of a musical composition or copyright in a musical work created by the taxpayer's personal efforts (or having a basis determined by reference to the basis of such property in the hands of a taxpayer whose personal efforts created such property) as the sale or exchange of a capital asset. As a consequence, gain or loss from the sale or exchange is treated as capital gain or loss. An election may be made for sales and exchanges in taxable years beginning after May 17, 2006.

(b) *Time and manner for making the election.* An election described in this section is made separately for each musical composition (or copyright in a musical work) sold or exchanged during the taxable year. An election must be made on or before the due date (including extensions) of the income tax return for the taxable year of the sale or exchange. An election is to be made on Schedule D, "Capital Gains and Losses," of the appropriate income tax form (for example, Form 1040, "U.S. Individual Income Tax Return;" Form 1065, "U.S. Return of Partnership Income;" Form 1120, "U.S. Corporation Income Tax Return") by treating the sale or exchange as the sale or exchange of a

capital asset, in accordance with the form and its instructions.

(c) *Revocability of election.* An election described in this section is revocable with the consent of the Commissioner. To seek consent to revoke an election, a taxpayer must submit a request for a letter ruling under the appropriate revenue procedure. See, for example, Rev. Proc. 2007-1, 2007-1 CB 1 (updated annually). Alternatively, an automatic extension of 6 months from the due date of the taxpayer's income tax return (excluding extensions) is granted to revoke an election, provided the taxpayer timely filed the taxpayer's income tax return and, within this 6-month extension period, the taxpayer files an amended income tax return that treats the sale or exchange as the sale or exchange of property that is not a capital asset. See § 601.601(d)(2)(ii)(b) of this Chapter.

(d) *Effective/applicability date.* (1) The rules of this section apply to sales and exchanges in taxable years beginning after May 17, 2006.

(2) *Expiration date.* This section expires on February 7, 2011.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

Approved: January 28, 2008.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E8-2309 Filed 2-7-08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2007-1054; A-1-FRL-8524-9]

Approval and Promulgation of Air Quality Implementation Plans; Maine; Transportation Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Maine. This revision establishes transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. The intended effect of this action is to approve State criteria and procedures to govern transportation conformity determinations. This action

is being taken in accordance with the Clean Air Act.

DATES: This direct final rule will be effective April 8, 2008, unless EPA receives adverse comments by March 10, 2008. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R01-OAR-2007-1054 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail:* arnold.anne@epa.gov.

3. *Fax:* (617) 918-0047.

4. *Mail:* "Docket Identification Number EPA-R01-OAR-2007-1054", Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, Suite 1100 (mail code CAQ), Boston, MA 02114-2023.

5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, 11th floor, (CAQ), Boston, MA 02114-2023. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R01-OAR-2007-1054. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov, or e-mail, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you