

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kristin Davis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993, 301-796-0418.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 1, 2016 (81 FR 60299), FDA published a notification of public hearing on firm communications regarding unapproved uses of approved or cleared medical products. FDA is currently engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved or cleared medical products, and the comments on the notification of public hearing will inform FDA's policy development in this area.

Interested persons were originally given until January 9, 2017, to comment on the topics discussed in the notification of public hearing.

At the public hearing on November 9 and 10, 2016, a number of speakers presented legal views regarding the application of First Amendment principles to firm communications regarding unapproved uses of approved or cleared medical products. Some expressed the view that FDA had not sufficiently discussed the First Amendment in the notification of public hearing. In response to these comments, FDA is now placing the Memorandum in the docket for the public hearing to provide additional background on the issues it is considering as part of its review of its rules and policies relating to firm communications regarding unapproved uses of approved or cleared medical products, including a discussion of First Amendment considerations. In the notification of public hearing, FDA requested comments on a number of specific issues and questions identified throughout the document. The Memorandum is intended to help advance the discussion of these topics, and FDA is seeking input on the information in the Memorandum as it relates to these issues and questions in the notification of public hearing.

Furthermore, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers," which provides answers to common questions regarding the communication of health care economic information about approved prescription drugs by medical product firms to payors, formulary committees, or other similar entities. The draft guidance also provides answers to common questions related to firms' communications about investigational drugs and devices (investigational products) to payors before FDA approval or clearance of such products.

Additionally, in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers." The guidance provides information for medical product firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.

FDA is harmonizing the comment periods for the notification of public hearing and the two draft guidances, as all three documents relate to the overarching topic of firm communications regarding medical products, and interested persons may wish to review all the documents before submitting comments to any of the relevant dockets. FDA is requesting comments on both draft guidances by April 19, 2017.

To allow interested parties an opportunity to review the Memorandum and the two draft guidances, FDA is reopening the comment period for the notification of public hearing for an additional 90 days, until April 19, 2017. The Agency believes reopening the comment period for an additional 90 days for the notification of public hearing will allow adequate time for interested persons to submit comments without significantly delaying Agency decision making and policy development on these important issues.

Dated: January 6, 2017.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-127203-15]

RIN 1545-BN81

#### Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners

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

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

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**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, temporary regulations are being issued under sections 197, 704, 721(c), and 6038B of the Internal Revenue Code (Code) that address transfers of appreciated property by U.S. persons to partnerships with foreign partners related to the transferor. The temporary regulations affect U.S. partners in domestic or foreign partnerships. The text of the temporary regulations also serves as the text of these proposed regulations.

**DATES:** Written or electronic comments and requests for a public hearing must be received by April 19, 2017.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-127203-15), Internal Revenue Service, Room 5203, P.O. Box 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-127203-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-127203-15).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Ryan A. Bowen, (202) 317-6937; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317-6901 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background

The temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** contain regulations under sections 197, 704, 721(c), and 6038B of the Code. The temporary regulations contain rules described in Notice 2015-54, 2015-34 I.R.B. 210, and override nonrecognition of gain under section 721(a) for transfers of property to a partnership with related foreign partners and with substantial related-party ownership unless certain requirements are satisfied. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and the corresponding proposed regulations.

##### Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It is hereby certified that the collection of information contained in this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This conclusion is based on the fact that the proposed regulations include a \$1,000,000 de minimis exception for certain transfers, and tangible property with built-in gain that does not exceed \$20,000 is excluded from the application of the

regulations. In addition, the regulations only apply when a U.S. transferor contributes property to a partnership with a related foreign partner, and persons related to the U.S. transferor own 80 percent or more of the interests in the partnership. Accordingly, the Treasury Department and the IRS expect that these regulations primarily will affect large domestic corporations. Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

##### Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at [www.regulations.gov](http://www.regulations.gov) or upon request. 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 proposed regulations is Ryan A. Bowen, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS 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 entries to read in part as follows:

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

Section 1.721(c)-1 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-2 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-3 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-4 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-5 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-6 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-7 also issued under 26 U.S.C. 721(c).

\* \* \* \* \*

■ **Par. 2.** Section 1.197-2 is amended by adding paragraphs (h)(12)(vii)(C) and (l)(5) to read as follows:

##### § 1.197-2 Amortization of goodwill and certain other intangibles.

\* \* \* \* \*

(h) \* \* \*

(12) \* \* \*

(vii) \* \* \*

(C) [The text of proposed § 1.197-2(h)(12)(vii)(C) is the same as the text of § 1.197-2T(h)(12)(vii)(C) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

(l) \* \* \*

(5) [The text of proposed § 1.197-2(l)(5) is the same as the text of § 1.197-2T(l)(5) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

■ **Par. 3.** Section 1.704-1 is amended by adding paragraph (b)(2)(iv)(f)(6) following the undesignated paragraph at the end of paragraph (b)(2)(iv)(f)(5) and adding paragraph (f) to read as follows:

##### § 1.704-1 Partner's distributive share.

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(iv) \* \* \*

(f) \* \* \*

(6) [The text of proposed § 1.704-1(b)(2)(iv)(f)(6) is the same as the text of § 1.704-1T(b)(2)(iv)(f)(6) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

(f) [The text of proposed § 1.704-1(f) is the same as the text of § 1.704-1T(f) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

■ **Par. 4.** Section 1.704-3 is amended by adding paragraphs (a)(13), (d)(5)(iii), and (g) to read as follows:

##### § 1.704-3 Contributed property.

(a) \* \* \*

(13) [The text of proposed § 1.704-3(a)(13) is the same as the text of § 1.704-3T(a)(13) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

(d) \* \* \*

(5) \* \* \*

(iii) [The text of proposed § 1.704-3(d)(5)(iii) is the same as the text of § 1.704-3T(d)(5)(iii) published

elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

(g) [The text of proposed § 1.704–3(g) is the same as the text of § 1.704–3T(g) published elsewhere in this issue of the **Federal Register**].

■ **Par. 5.** Section 1.721(c)–1 is added to read as follows:

**§ 1.721(c)–1 Overview, definitions, and rules of general application.**

[The text of proposed § 1.721(c)–1 is the same as the text of § 1.721(c)–1T published elsewhere in this issue of the **Federal Register**].

■ **Par. 6.** Section 1.721(c)–2 is added to read as follows:

**§ 1.721(c)–2 Recognition of gain on certain contributions of property to partnerships with related foreign partners.**

[The text of proposed § 1.721(c)–2 is the same as the text of § 1.721(c)–2T published elsewhere in this issue of the **Federal Register**].

■ **Par. 7.** Section 1.721(c)–3 is added to read as follows:

**§ 1.721(c)–3 Gain deferral method.**

[The text of proposed § 1.721(c)–3 is the same as the text of § 1.721(c)–3T published elsewhere in this issue of the **Federal Register**].

■ **Par. 8.** Section 1.721(c)–4 is added to read as follows:

**§ 1.721(c)–4 Acceleration events.**

[The text of proposed § 1.721(c)–4 is the same as the text of § 1.721(c)–4T published elsewhere in this issue of the **Federal Register**].

■ **Par. 9.** Section 1.721(c)–5 is added to read as follows:

**§ 1.721(c)–5 Acceleration event exceptions.**

[The text of proposed § 1.721(c)–5 is the same as the text of § 1.721(c)–5T published elsewhere in this issue of the **Federal Register**].

■ **Par. 10.** Section 1.721(c)–6 is added to read as follows:

**§ 1.721(c)–6 Procedural and reporting requirements.**

[The text of proposed § 1.721(c)–6 is the same as the text of § 1.721(c)–6T published elsewhere in this issue of the **Federal Register**].

■ **Par. 11.** Section 1.721(c)–7 is added to read as follows:

**§ 1.721(c)–7 Examples.**

[The text of proposed § 1.721(c)–7 is the same as the text of § 1.721(c)–7T published elsewhere in this issue of the **Federal Register**].

■ **Par. 12.** Section 1.6038B–2 is amended by:

- 1. Revising paragraph (a)(3).
- 2. Adding paragraphs (a)(1)(iii), (c)(8), and (c)(9).
- 3. Revising paragraph (h)(3).
- 4. Adding paragraphs (j)(4) and (j)(5).

**§ 1.6038B–2 Reporting of certain transfers to foreign partnerships.**

(a) \* \* \*

(1) \* \* \*

(iii) [The text of proposed § 1.6038B–2(a)(1)(iii) is the same as the text of § 1.6038B–2T(a)(1)(iii) published elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

(3) [The text of proposed § 1.6038B–2(a)(3) is the same as the text of § 1.6038B–2T(a)(3) published elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

(c) \* \* \*

(8) [The text of proposed § 1.6038B–2(c)(8) is the same as the text of § 1.6038B–2T(c)(8) published elsewhere in this issue of the **Federal Register**].

(9) [The text of proposed § 1.6038B–2(c)(9) is the same as the text of § 1.6038B–2T(c)(9) published elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

(h) \* \* \*

(3) [The text of proposed § 1.6038B–2(h)(3) is the same as the text of § 1.6038B–2T(h)(3) published elsewhere in this issue of the **Federal Register**].

\* \* \* \* \*

(j) \* \* \*

(4) [The text of proposed § 1.6038B–2(j)(4) is the same as the text of § 1.6038B–2T(j)(4) published elsewhere in this issue of the **Federal Register**].

(5) [The text of proposed § 1.6038B–2(j)(5) is the same as the text of § 1.6038B–2T(j)(5) published elsewhere in this issue of the **Federal Register**].

**John Dalrymple,**

*Deputy Commissioner for Services and Enforcement.*

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Parts 1 and 301**

**[REG–137604–07]**

**RIN 1545–BI35**

**Definition of Dependent**

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

**ACTION:** Withdrawal of notice of proposed rulemaking and notice of proposed rulemaking.

**SUMMARY:** This document withdraws proposed regulations relating to the definition of an authorized placement agency for purposes of a dependency exemption for a child placed for adoption that were issued prior to the changes made to the law by the Working Families Tax Relief Act of 2004 (WFTRA). This document contains proposed regulations that reflect changes made by WFTRA and by the Fostering Connections to Success and Increasing Adoptions Act of 2008 (FCSIAA) relating to the dependency exemption. This document also contains proposed regulations that, to reflect current law, amend the regulations relating to the surviving spouse and head of household filing statuses, the tax tables for individuals, the child and dependent care credit, the earned income credit, the standard deduction, joint tax returns, and taxpayer identification numbers for children placed for adoption. These proposed regulations change the IRS's position regarding the category of taxpayers permitted to claim the childless earned income credit. In determining a taxpayer's eligibility to claim a dependency exemption, these proposed regulations change the IRS's position regarding the adjusted gross income of a taxpayer filing a joint return for purposes of the tiebreaker rules and the source of support of certain payments that originated as governmental payments. These regulations provide guidance to individuals who may claim certain child-related tax benefits.

**DATES:** Written or electronic comments and requests for a public hearing must be received by April 19, 2017.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG–137604–07), Room 5203, Internal Revenue Service, P.O. Box 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–137604–07), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG–137604–07).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Victoria J. Driscoll, (202) 317–4718; concerning the submission of comments and requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free calls).

**SUPPLEMENTARY INFORMATION:**