

(C) The method comparison study must include predefined maximum acceptable differences between the test and comparator method across all primary outcome measures in the clinical study protocol.

(D) The final release test results for each lot used in the clinical study.

Dated: September 15, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–20716 Filed 9–17–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–109755–19]

RIN 1545–BP31

#### Certain Medical Care Arrangements; Hearing

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

**ACTION:** Proposed rule; notification of hearing.

**SUMMARY:** This document provides a notice of public hearing on proposed regulations relating to section 213 of the Internal Revenue Code (Code) regarding the treatment of amounts paid for certain medical care arrangements, including direct primary care arrangements, health care sharing ministries, and certain government sponsored health care programs.

**DATES:** The public hearing is being held on Wednesday, October 7, 2020, at 1:30 p.m. The IRS must receive speakers' outlines of the topics to be discussed at the public hearing by Friday, September 25, 2020. If no outlines are received by September 25, 2020, the public hearing will be cancelled.

**ADDRESSES:** The public hearing is being held by teleconference. Individuals who want to testify (by telephone) at the public hearing must send an email to [publichearings@irs.gov](mailto:publichearings@irs.gov) to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number [REG–109755–19] and the word TESTIFY. For example, the subject line may say: Request to TESTIFY at Hearing for REG–109755–19. The email should include the name of the speaker. Send outline submissions electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG–109755–19). The email must be received by September 25, 2020.

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, contact Richard C. Gano IV of the Office of Associate Chief Counsel (Income Tax and Accounting), (202) 317–7011 (not a toll-free call); concerning the preamble discussion of health reimbursement arrangements or health savings accounts, call William Fischer of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), (202) 317–5500 (not a toll-free call); concerning submissions of comments, the hearing, and the access code to attend the hearing by teleconferencing, Regina Johnson at (202) 317–5177 (not toll-free numbers) or [publichearings@irs.gov](mailto:publichearings@irs.gov). If emailing please put Attend, Testify, or Agenda Request and [REG–109755–19] in the email subject line.

**SUPPLEMENTARY INFORMATION:** The subject of the public hearing is the notice of proposed rulemaking REG–109755–19 that was published in the **Federal Register** on Wednesday, June 19, 2020, 85 FR 35398.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments telephonically at the hearing that submitted written comments by August 10, 2020, must submit an outline of the topics to be addressed and the amount of time to be devoted to each topic by September 25, 2020.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, on [Regulations.gov](http://Regulations.gov), search IRS and REG–109755–19, or by emailing your request to [publichearings@irs.gov](mailto:publichearings@irs.gov). Please put “REG–109755–19” Agenda Request” in the subject line of the email.

Individuals who want to attend (by telephone) the public hearing must also send an email to [publichearings@irs.gov](mailto:publichearings@irs.gov) to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number [REG–109755–19] and the word ATTEND. For example, the subject line may say: Request to ATTEND Hearing for REG–109755–19. The email requesting to attend the public hearing must be received by 5:00 p.m. two (2) business days before the date that the hearing is scheduled.

The telephonic hearing will be made accessible to people with disabilities. To request special assistance during the telephonic hearing please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel

(Procedure and Administration) by sending an email to [publichearings@irs.gov](mailto:publichearings@irs.gov) (preferred) or by telephone at (202) 317–5177 (not a toll-free number) at least three (3) days prior to the date that the telephonic hearing is scheduled.

Any questions regarding speaking at or attending a public hearing may also be emailed to [publichearings@irs.gov](mailto:publichearings@irs.gov).

**Crystal Pemberton,**

*Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. 2020–20326 Filed 9–17–20; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–132766–18]

RIN 1545–BP53

#### Small Business Taxpayer Exceptions Under Sections 263A, 448, 460 and 471; Correction

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

**ACTION:** Correction to a notice of proposed rulemaking.

**SUMMARY:** This document contains a correction to a notice of proposed rulemaking (REG–132766–18) that was published in the **Federal Register** on August 5, 2020. The proposed regulations to implement legislative changes to sections 263A, 448, 460, and 471 of the Internal Revenue Code (Code) that simplify the application of those tax accounting provisions for certain businesses having average annual gross receipts that do not exceed \$25,000,000, adjusted for inflation.

**DATES:** Written or electronic comments and requests for a public hearing are still being accepted and must be received by September 14, 2020.

**ADDRESSES:** Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (indicate IRS and REG–132766–18) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any

comments submitted on paper will be considered to the extent practicable. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket. *Send paper submissions to:* CC:PA:LPD:PR (REG-132766-18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

**FOR FURTHER INFORMATION CONTACT:**

Concerning proposed §§ 1.460-1 through 1.460-6, Innessa Glazman, (202) 317-7006; concerning all other proposed regulations in this document, Anna Gleysteen, (202) 317-7007; concerning submissions of comments and requests for a public hearing, Regina L. Johnson, (202) 317-5177 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

The proposed regulations that are the subject of this correction are under sections 263A, 448, 460, and 471 of the Internal Revenue Code.

**Need for Correction**

As published, the notice of proposed regulations (REG-132766-18) contains errors which may prove to be misleading and need to be clarified.

**Correction of Publication**

Accordingly, the notice of proposed rulemaking (REG-132766-18) that was the subject of FR Doc. 2020-16364, published at 85 FR 47508 (August 5, 2020), is corrected to read as follows:

1. On page 47513, the second column, the fifth line from the bottom of the first full paragraph under the heading “ii. De Minimis Exception to Look-Back Rules,” the language, “Proposed § 1.460-3(b)(3)” is corrected to read “Proposed § 1.460-6(b)(3)”.

2. On page 47530, the first column, in § 1.460-3, the eighth line of paragraph (b)(3)(ii)(B), the language “receipts the” is corrected to read “receipts of the”.

**Crystal Pemberton,**

*Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. 2020-20606 Filed 9-16-20; 4:15 pm]

**BILLING CODE 4830-01-P**

**DEPARTMENT OF THE TREASURY**

**Office of the Secretary**

**31 CFR Part 1**

**RIN 1505-AC66**

**Committee on Foreign Investment in the United States Case Management System Privacy Act of 1974; Proposed Implementation**

**AGENCY:** Departmental Offices, Department of the Treasury.

**ACTION:** Proposed rule.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of the Treasury, Departmental Offices (DO) gives notice of a proposed exemption for a new system of records entitled “Department of the Treasury, Departmental Offices .227—Committee on Foreign Investment in the United States (CFIUS) Case Management System,” maintained by the Committee on Foreign Investment in the United States from certain provisions of the Privacy Act. The exemption is intended to comply with the legal prohibitions against the disclosure of certain kinds of information and to protect certain information maintained in this system of records.

**DATES:** Written comments must be received by October 19, 2020.

**ADDRESSES:** Written comments on this proposal may be submitted electronically through the Federal government eRulemaking portal at <http://www.regulations.gov>. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department of the Treasury (Treasury) to make the comments available to the public. Please note that comments submitted through <https://www.regulations.gov> will be public, and can be viewed by members of the public. Due to COVID-19-related restrictions, Treasury has temporarily suspended its ability to receive public comments by mail.

In general, Treasury will post all comments to <https://www.regulations.gov> without change, including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. All comments received, including attachments and other supporting material, will be part of the public record and subject to public disclosure. You should only submit information that you wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:** For questions about this proposed rule and privacy issues, contact: Deputy Assistant Secretary for Privacy, Transparency, and Records at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622-5710.

**SUPPLEMENTARY INFORMATION:** As background, in 2018, the Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA), Subtitle A of Title XVII of Public Law 115-232, 132 Stat. 2173, was enacted. FIRRMA amends section 721 of the Defense Production Act of 1950, as amended (Section 721), which delineates the authorities and jurisdiction of the Committee on Foreign Investment in the United States (CFIUS). FIRRMA maintains CFIUS’s jurisdiction over any transaction that could result in foreign control of any U.S. business, and broadens the authorities of the President and CFIUS under Section 721 to review and take action to address any national security concerns arising from certain non-controlling investments and certain real estate transactions involving foreign persons.

Executive Order 13456, 73 FR 4677 (January 23, 2008), directs the Secretary of the Treasury to issue regulations implementing Section 721. On January 17, 2020, Treasury published two rules broadly implementing FIRRMA, and those rules took effect on February 13, 2020. 85 FR 3112 and 85 FR 3158. Subsequent amendments were made to the regulations in 2020. 85 FR 8747 and 85 FR 45311.

In addition to the exemptions proposed below, pursuant to section 721(c) of the Defense Production Act of 1950, as amended, 50 U.S.C. 4565(c) and subject to certain exceptions provided therein, any information or documentary material filed with CFIUS under Section 721 is exempt from disclosure under the Freedom of Information Act, as amended (FOIA), 5 U.S.C. 552, and no such information or documentary material may be made public.

Treasury is publishing separately the proposed rule of the new system of records to be maintained by CFIUS.

Under 5 U.S.C. 552a(k)(1), the head of a Federal agency may promulgate rules to exempt a system of records from certain provisions of 5 U.S.C. 552a if the system of records is subject to the exemption contained in section 552(b)(1) of this title. (Freedom of Information Act, exemption (b)(1) protects from disclosure information that has been deemed classified “under criteria established by an Executive