

(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