

reorganization described in section 368(a)(1)(E).”.

36. On page 3522, column 3, § 1.358-2(i) *Example 5*(ii), line 10, the language “is not dividend equivalent, such terms” is corrected to read “does not have the effect of a dividend, such terms”.

37. On page 3523, column 1, § 1.358-2(i) *Example 6*(i), line 8, the language “reorganization under section 368(a)(1)(A).” is corrected to read “reorganization described in section 368(a)(1)(A).”.

38. On page 3523, column 1, § 1.358-2(i) *Example 7*(i), line 6, the language “of Corporation X in a reorganization under” is corrected to read “of Corporation X in a reorganization described in”.

39. On page 3523, column 2, § 1.358-2(i) *Example 8*(ii), line 5, the language “liability of J, the rules of paragraph (g) this” is corrected to read “liability of J, the rules of paragraph (g) of this”.

40. On page 3523, column 2, § 1.358-2(i) *Example 9*(i), lines 9 through 11, the language “Corporation X in a reorganization under section 368(a)(1)(D). Pursuant to the terms of the plan of reorganization, J surrenders J’s” is corrected to read “Corporation X in a reorganization described in section 368(a)(1)(D). Pursuant to the terms of the plan of reorganization, J surrenders”.

41. On page 3523, column 2, § 1.358-2(i) *Example 9*(ii), line 5 from the bottom of the column, the language “recapitalized in a reorganization under” is corrected to read “recapitalized in a reorganization described in”.

42. On page 3523, column 3, § 1.358-2(i) *Example 10*(i), lines 12 thru 14, the language “Corporation X in a reorganization under section 368(a)(1)(D). Pursuant to the terms of the plan of reorganization, J surrenders J’s” is corrected to read “Corporation X in a reorganization described in section 368(a)(1)(D). Pursuant to the terms of the plan of reorganization, J surrenders”.

43. On page 3523, column 3, § 1.358-2(i) *Example 10*(ii), line 10 from the bottom of the column, the language “be recapitalized in a reorganization under” is corrected to read “be recapitalized in a reorganization described in”.

44. On page 3524, column 2, § 1.358-2(i) *Example 13*(i), line 9, the language “reorganization under section 368(a)(1)(A).” is corrected to read “reorganization described in section 368(a)(1)(A).”.

45. On page 3524, column 3, § 1.358-2(i) *Example 14*(i), line 9, the language “reorganization under section

368(a)(1)(A).” is corrected to read “reorganization described in section 368(a)(1)(A).”.

46. On page 3525, column 1, § 1.358-2(i) *Example 15*(ii), line 3 from the bottom of the paragraph, the language “each has a basis of \$6 and is treated as having” is corrected to read “each has a basis of \$5 and is treated as having”.

47. On page 3525, column 1, § 1.358-2(i) *Example 16*(i), line 4, the language “Shares of Corporation Y in an exchange to” is corrected to read “Shares of Corporation Y stock in an exchange to”.

48. On page 3525, column 1, § 1.358-2(i) *Example 17*(i), line 2, the language “*Facts*. The facts are the same as Example 1.” is corrected to read “*Facts*. The facts are the same as Example 16.”.

§ 1.358-6 [Corrected]

49. On page 3525, column 2, § 1.358-6(f)(3), line 4 from the bottom of the paragraph, the language “1 revised April 1, 2008 for the year” is corrected to read “1 revised April 1 for the year”.

§ 1.861-12 [Corrected]

50. On page 3525, column 3, § 1.861-12(c)(2)(vi), lines 1 through 3, the language “Adjustments in respect of redeemed stock for taxpayers using the tax book value method. Solely for” is corrected to read “*Adjustments in respect of redeemed stock for taxpayers using the tax book value method. Solely for*”.

51. On page 3525, column 3, § 1.861-12(c)(2)(vi), lines 13 through 15, the language “taken into account under § 1.302-5(a)(3) as of the close of the redeemed shareholder’s taxable year (unrecovered” is corrected to read “taken into account under § 1.302-5 as of the close of the redeemed shareholder’s taxable year (deferred”.

52. On page 3525, column 3, § 1.861-12(c)(2)(vi), line 4 from the bottom of the column, the language “unrecovered loss (and allocated among” is corrected to read “deferred loss (and allocated among”.

§ 1.1001-6 [Corrected]

53. On page 3526, column 2, § 1.1001-6(c), line 10 from the top of the column, the language “still unliquidated. Solely for purposes of” is corrected to read “still unliquidated investment. Solely for purposes of”.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-144615-02]

RIN 1545-BI47

Section 482: Methods To Determine Taxable Income in Connection With a Cost Sharing Arrangement; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains corrections to a notice of proposed rulemaking by cross-reference to temporary regulations (REG-144615-02) that was published in the **Federal Register** on Monday, January 5, 2009 providing further guidance and clarification regarding methods under section 482 to determine taxable income in connection with a cost sharing arrangement in order to address issues that have arisen in administering the current regulations. These temporary regulations potentially affect controlled taxpayers within the meaning of section 482 that enter into cost sharing arrangements as defined therein.

FOR FURTHER INFORMATION CONTACT: Kenneth P. Christman, (202) 435-5265 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 482 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking by cross-reference to temporary regulations (REG-144615-02) published January 5, 2009 (74 FR 236), contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking by cross-reference to temporary regulations (REG-144615-02), which was the subject of FR Doc. E8-30712, is corrected as follows:

1. On page 236, in the document headings, under the caption **ACTION:**, the language “Notice of proposed rulemaking by cross-reference to temporary regulations, notice of proposed rulemaking, and notice of

public hearing.” is corrected to read “Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.”.

2. On page 236, column 3, in the preamble, under the paragraph heading “Special Analyses”, last line of the column, the language “sharing agreements. Few small entities” is corrected to read “sharing arrangements. Few small entities”.

3. On page 237, column 1, in the preamble, under the paragraph heading “Special Analyses”, first paragraph of the column, line 2, the language “agreements, as defined by these” is corrected to read “arrangements, as defined by these”.

4. On page 237, column 1, in the preamble, under the paragraph heading “Comments and Public Hearing”, third paragraph, line 1, the language “The rules of 26 CFR 601.601(a)(93)” is corrected to read “The rules of 26 CFR 601.601(a)(3)”.

§ 1.482–2 [Corrected]

5. On page 237, column 3, § 1.482–2(f)(2), the language “Election to apply paragraph (b) of this section to earlier taxable years.” is corrected to read “Election to apply paragraph (b) to earlier taxable years.”.

LaNita Van Dyke,

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

[FR Doc. E9–4687 Filed 3–4–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

Office for Human Research Protections; Institutional Review Boards

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Advanced notice of proposed rulemaking; request for comments.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science is seeking information and comments on whether OHRP should pursue a notice of proposed rulemaking (NPRM) to enable OHRP to hold institutional review boards (IRB) and the institutions or organizations operating the IRBs, hereafter referred to as the IRB organizations (IORG), directly accountable for meeting certain

regulatory requirements of the Department of Health and Human Services (HHS) regulations for the protection of human subjects. OHRP is contemplating this regulatory change to encourage institutions to rely on IRBs that are operated by another institution or organization, when appropriate. Historically, OHRP has only enforced compliance with 45 CFR part 46 through the institutions that were engaged in human subjects research. This has been the case even in circumstances when a regulatory violation was directly related to the responsibilities of an external IRB that was designated on the engaged institution’s assurance of compliance with OHRP. OHRP is considering whether to pursue a regulatory change that would enable the Department to hold IRBs and IORGs directly accountable for compliance with the provisions of 45 CFR part 46 that relate to an IRB’s or IORG’s responsibilities. OHRP believes that such a regulatory change in its enforcement authority may address one of the main disincentives institutions have cited as inhibiting them from exercising the regulatory flexibility that currently permits institutions to implement a variety of cooperative review arrangements and to rely on the review of an IRB operated by another institution or organization. If institutions become more willing to rely on cooperative review arrangements and on review of IRBs operated by other institutions or organizations, OHRP believes that this will reduce administrative burdens such as the time associated with IRB review for multi-site studies, the time devoted by IRB staff and investigators to duplicative IRB review, and the time and personnel costs associated with operating an IRB for those institutions that choose not to establish an internal IRB—without diminishing human subject protections. This request for information and comments stems from interest in this issue from the Secretary’s Advisory Committee on Human Research Protections (SACHRP) and others, as well as two meetings on alternative IRB models that OHRP co-sponsored in November 2005 and November 2006 along with the National Institutes of Health (NIH), the Association of American Medical Colleges (AAMC), and the American Society of Clinical Oncology (ASCO).

DATES: Submit written or electronic information and comments by June 3, 2009.

ADDRESSES: You may submit comments by any of the following methods:

- *E-mail:* IRBaccountability@hhs.gov. Include “IRB Accountability RFI” in the subject line.

- *Fax:* 301–402–2071.

- *Mail/Hand Delivery/Courier [For paper, disk, or CD-ROM submissions]:* Julie Kaneshiro, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

FOR FURTHER INFORMATION CONTACT: Julie Kaneshiro, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 240–453–6900; e-mail julie.kaneshiro@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

HHS, through OHRP, regulates research involving human subjects conducted or supported by HHS in regulations codified at 45 CFR part 46. The HHS regulations at 45 CFR part 46 identify requirements that pertain to several different entities, including the IRB and the institution engaged in non-exempt human subjects research. The IRB is an administrative body that takes the form of a board, committee, or group, and is responsible for conducting initial and continuing review of research involving human subjects. The IRB must have authority to approve, require modification in (in order to secure approval), or disapprove all research activities covered by the HHS regulations (45 CFR 46.109(a)). An IRB’s primary purpose in reviewing research is to ensure the protection of the rights and welfare of human research subjects.

Requirements for an Assurance of Compliance

The HHS regulations for the protection of human subjects require that each institution engaged in non-exempt human subjects research conducted or supported by HHS provide a written assurance satisfactory to the Secretary of Health and Human Services that it will comply with the requirements of the HHS regulations (45 CFR 46.103(a)). OHRP reviews and approves such assurances on behalf of HHS. The Federalwide Assurance (FWA) is now the only type of assurance accepted and approved by OHRP. An FWA commits the entire institution (including institutional officials, IRBs designated in the assurance, research investigators, and all other employees or agents) to compliance with the HHS regulations whenever the institution is engaged in HHS-conducted or