

TABLE 1—IDENTIFIED RISKS AND REQUIRED MITIGATIONS—Continued

Identified risks	Required mitigations
A false negative test result for an individual may lead to a potential delay in treatment.	Labeling. The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of <i>Clostridium difficile</i> ,” which addresses this risk through: Specific Device Description Requirements. Performance Studies.
Failure of the test to be used or perform properly	Labeling. The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of <i>Clostridium difficile</i> ,” which addresses this risk through: Labeling.
Failure to properly interpret the test results	The FDA document entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of <i>Clostridium difficile</i> ,” which addresses this risk through: Labeling.

FDA believes that the measures set forth in the special controls guideline entitled “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of *Clostridium difficile*” are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

A *C. difficile* toxin gene amplification assay is a prescription device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the *C. difficile* toxin gene amplification assay they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 866.3130 to subpart D to read as follows:

§ 866.3130 *Clostridium difficile* toxin gene amplification assay.

(a) *Identification.* A *Clostridium difficile* toxin gene amplification assay is a device that consists of reagents for the amplification and detection of target sequences in *Clostridium difficile* toxin genes in fecal specimens from patients suspected of having *Clostridium difficile* infection (CDI). The detection of clostridial toxin genes, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of CDI caused by *Clostridium difficile*.

(b) *Classification.* Class II (special controls). The special controls are set forth in FDA’s guideline document entitled: “Class II Special Controls Guideline: Toxin Gene Amplification Assays for the Detection of *Clostridium difficile*; Guideline for Industry and Food and Drug Administration Staff.” See § 866.1(e) for information on obtaining this document.

Dated: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9731]

RIN 1545–BM11

Allocation of W–2 Wages in a Short Taxable Year and in an Acquisition or Disposition

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to the allocation of W–2 wages for purposes of the W–2 wage limitation on the amount of a taxpayer’s deduction related to domestic production activities. Specifically, the temporary regulations provide guidance on: the allocation of W–2 wages paid by two or more taxpayers that are employers of the same employees during a calendar year; and the determination of W–2 wages if the taxpayer has a short taxable year. The text of the temporary regulations

also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking (REG-136459-09) on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on August 27, 2015.

Applicability Date: For dates of applicability, see § 1.199-8T(i)(10).

FOR FURTHER INFORMATION CONTACT: James A. Holmes 202-317-4137 (not a toll free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 199(b) of the Internal Revenue Code (Code). Section 199(b) was enacted by the American Jobs Creation Act of 2004 (Pub. L. 108-357, 118 Stat. 1418 (2004)). Subsequent amendments to section 199(b) were made by the Gulf Opportunity Zone Act of 2005 (Pub. L. 109-135, 119 Stat. 25 (2005)), the Tax Increase Prevention and Reconciliation Act of 2005 (Pub. L. 109-222, 120 Stat. 345 (2005)), the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Pub. L. 110-343, 122 Stat. 3765 (2008)), and the Tax Increase Prevention Act of 2014 (Pub. L. 113-295, 128 Stat. 4010 (2014)).

Under section 199(b)(1), the amount of the deduction allowable under section 199(a) for any taxable year shall not exceed 50 percent of the W-2 wages of the taxpayer for the taxable year. Section 199(b)(2)(A) generally defines W-2 wages, with respect to any person for any taxable year of such person, as the sum of amounts described in section 6051(a)(3) and (8) paid by such person with respect to employment of employees by such person during the calendar year ending during such taxable year. Section 199(b)(3), after its amendment by section 219(b) of the Tax Increase Prevention Act of 2014, provides that the Secretary shall provide for the application of section 199(b) in cases of a short taxable year or where the taxpayer acquires, or disposes of, the major portion of a trade or business, or the major portion of a separate unit of a trade or business during the taxable year. Section 219(d) of the Tax Increase Prevention Act of 2014 provides that the amendments made by section 219 shall take effect as if included in the provision of the American Jobs Creation Act of 2004 to which they relate. Section 1.199-2(c) provides the current rule for acquisitions and dispositions.

Section 1.199-2(c) currently provides that if a taxpayer (a successor) acquires a trade or business, the major portion of

a trade or business, or the major portion of a separate unit of a trade or business from another taxpayer (a predecessor), then, for purposes of computing the respective section 199 deduction of the successor and of the predecessor, the W-2 wages paid for that calendar year shall be allocated between the successor and the predecessor based on whether the wages are for employment by the successor or for employment by the predecessor. Thus, the W-2 wages are allocated based on whether the wages are for employment for a period during which the employee was employed by the predecessor or for employment by a period during which the employee was employed by the successor. The W-2 wage allocation under the current regulations is made regardless of which permissible method is used by a predecessor or a successor for reporting wages on Form W-2, as provided in Rev. Proc. 2004-53 (2004-2 CB 320) (see § 601.601(d)(2) of this chapter). Section 1.199-2(e)(1) provides that under section 199(b)(2), the term *W-2 wages* means, with respect to any person for any taxable year of such person, the sum of the amounts described in section 6051(a)(3) and (8) paid by such person with respect to employment of employees by such person during the calendar year ending during such taxable year.

Rev. Proc. 2006-47 (2006-2 CB 869) (see § 601.601(d)(2)) is the currently effective guidance providing methods of calculating W-2 wages and related rules for purposes of section 199(b). Section 6.02(A) of Rev. Proc. 2006-47 provides that the amount of W-2 wages for a taxpayer with a short taxable year includes only those wages subject to Federal income tax withholding that are reported on Form W-2, "Wage and Tax Statement," for the calendar year ending with or within that short taxable year.

In certain situations, a short taxable year may not include a calendar year ending within such short taxable year. Section 1.199-2(c) of the current regulations does not address these situations and does not reflect the amendment made by the Tax Increase Prevention Act of 2014. In order to provide guidance on the application of section 199(b)(3) to a short taxable year that does not include a calendar year ending within the short taxable year, the IRS and the Treasury Department are revising the regulations to address these situations. To provide immediate effect, the IRS and the Treasury Department are issuing these regulations as temporary regulations. These temporary regulations apply solely for purposes of section 199.

Explanation of Provisions

The final regulations issued in connection with these temporary regulations remove the current language of § 1.199-2(c) and replace it with a cross reference to these temporary regulations. In the place of the current language, these temporary regulations provide rules for calculating W-2 wages for purposes of the W-2 wage limitation in the case of an acquisition or disposition of a trade or business, the major portion of a trade or business, the major portion of a separate unit of a trade or business during the taxable year, or a short taxable year. Specifically, these temporary regulations provide a rule for acquisitions and dispositions if one or more taxpayers may be considered the employer of the employees of the acquired or disposed of trade or business during that calendar year. In that case, the temporary regulations provide that the W-2 wages paid during the calendar year to employees of the acquired or disposed of trade or business are allocated between each taxpayer based on the period during which the employees of the acquired or disposed of trade or business were employed by the taxpayer.

These temporary regulations also provide a rule to apply in the case of a short taxable year in which there is no calendar year ending within such short taxable year (short-taxable-year rule). Wages paid by a taxpayer during the short taxable year to employees for employment by such taxpayer are treated as W-2 wages for such short taxable year for purposes of section 199(b)(1).

These temporary regulations also describe types of transactions that are considered either an acquisition or disposition for purposes of section 199(b)(3). Specifically, these temporary regulations provide that an acquisition or disposition includes an incorporation, a formation, a liquidation, a reorganization, or a purchase or sale of assets.

These regulations also contain cross references to § 1.199-2(a), (b), (d), and (e). The IRS and the Treasury Department observe that these rules continue to apply to taxpayers that use these temporary regulations. For example, the non-duplication rule of § 1.199-2(d) applies such that a taxpayer that includes wages as W-2 wages based on these temporary regulations, including by filing an amended return for a short taxable year, may not treat those wages as W-2 wages for any other taxable year. Also, wages qualifying as W-2 wages of one taxpayer

based on these temporary regulations cannot be treated as W–2 wages of another taxpayer.

The temporary regulations are applicable for taxable years beginning on or after August 27, 2015 and expire on August 24, 2018. A taxpayer may apply § 1.199–2T(c) to taxable years for which the limitations for assessment of tax has not expired beginning before August 27, 2015.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866 of, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 533(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6) refer to the Special Analyses section of the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is James A. Holmes, Office of Associate Chief Counsel (Passthroughs and Special Industries). 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.

Adoption of Amendment to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

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

Section 1.199–2T also issued under 26 U.S.C. 199(b)(3).

* * * * *

Par. 2. Section 1.199–0 is amended by revising the entry for § 1.199–2(c) and adding entries for §§ 1.199–2(c)(1), (c)(2), and (c)(3), and 1.199–8(i)(10) to read as follows:

§ 1.199–0 Table of contents.

* * * * *

§ 1.199–2 Wage limitation.

* * * * *

(c) Acquisitions, dispositions, and short taxable years.

(1) Allocation of wages between more than one taxpayer.

(2) Short taxable years.

(3) Operating rules.

(i) Acquisition or disposition.

(ii) Trade or business.

* * * * *

§ 1.199–8 Other rules.

* * * * *

(i) * * *

(10) Acquisitions, dispositions, and short taxable years.

* * * * *

Par. 3. Section 1.199–2 is amended by revising paragraph (c) to read as follows:

§ 1.199–2 Wage limitation.

* * * * *

(c) [Reserved]. For further guidance see § 1.199–2T(c).

* * * * *

Par. 4. Section 1.199–2T is added to read as follows:

§ 1.199–2T Wage limitation (temporary).

(a) through (b) [Reserved]. For further guidance, see § 1.199–2(a) through (b).

(c) *Acquisitions, dispositions, and short taxable years*—(1) *Allocation of wages between more than one taxpayer.*

For purposes of computing the section 199 deduction of a taxpayer, in the case of an *acquisition or disposition* (as defined in paragraph (c)(3)(i) of this section) of a *trade or business* (as defined in paragraph (c)(3)(ii) of this section) that causes more than one taxpayer to be an employer of the employees of the acquired or disposed of trade or business during the calendar year, the W–2 wages of the taxpayer for the calendar year of the acquisition or disposition are allocated between each taxpayer based on the period during which the employees of the acquired or disposed of trade or business were employed by the taxpayer, regardless of which permissible method is used for reporting W–2 wages on Form W–2, “Wage and Tax Statement.” For this purpose, the period of employment is determined consistently with the principles for determining whether an individual is an employee described in § 1.199–2(a)(1).

(2) *Short taxable years.* If a taxpayer has a short taxable year that does not contain a calendar year ending during such short taxable year, wages paid to employees for employment by such taxpayer during the short taxable year

are treated as W–2 wages for such short taxable year for purposes of § 1.199–2(a)(1) (if the wages would otherwise meet the requirements to be W–2 wages under § 1.199–2 but for the requirement that a calendar year must end during the short taxable year).

(3) *Operating rules*—(i) *Acquisition or disposition.* For purposes of this paragraph (c), the term *acquisition or disposition* includes an incorporation, a reorganization, or a purchase or sale of assets.

(ii) *Trade or business.* For purposes of this paragraph (c), the term *trade or business* includes a trade or business, the major portion of a trade or business, or the major portion of a separate unit of a trade or business.

(iii) *Application to section 199 only.* The provisions of this section apply solely for purposes of section 199 of the Internal Revenue Code.

(d) through (e) [Reserved]. For further guidance, see § 1.199–2(d) through (e).

Par. 5. Section 1.199–8 is amended by adding paragraph (i)(10) to read as follows:

§ 1.199–8 Other rules.

* * * * *

(i) * * *

(10) *Acquisitions, dispositions, and short taxable years.* [Reserved]. For further guidance, see § 1.199–8T(i)(10).

Par. 6. Section 1.199–8T is added to read as follows:

§ 1.199–8T Other rules (temporary).

(a) through (h) [Reserved]. For further guidance, see § 1.199–8(a) through (h).

(i) *Effective/applicability dates.* (1) through (9) [Reserved]. For further guidance, see § 1.199–8(i)(1) through (9).

(10) *Acquisitions, dispositions, and short taxable years.* Section 1.199–2T(c) is applicable for taxable years beginning on or after August 27, 2015. A taxpayer may apply § 1.199–2T(c) to taxable years for which the limitations for assessment of tax has not expired beginning before August 27, 2015.

(11) *Expiration date.* The applicability of § 1.199–2T(c) expires on August 24, 2018.

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: May 29, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

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