

26 USC 45C: Clinical testing expenses for certain drugs for rare diseases or conditions

Text contains laws through Pub. L. 113-271, except Pub. L. 113-235

Pending Updates: Pub L. 113-295 (12/19/2014) [[View Details](#)]**From Title 26-INTERNAL REVENUE CODE**

Subtitle A-Income Taxes

CHAPTER 1-NORMAL TAXES AND SURTAXES

Subchapter A-Determination of Tax Liability

PART IV-CREDITS AGAINST TAX

Subpart D-Business Related Credits

Jump To:[Source Credit](#)[References In Text](#)[Amendments](#)[Effective Date](#)**§45C. Clinical testing expenses for certain drugs for rare diseases or conditions****(a) General rule**

For purposes of section 38, the credit determined under this section for the taxable year is an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year.

(b) Qualified clinical testing expenses

For purposes of this section-

(1) Qualified clinical testing expenses**(A) In general**

Except as otherwise provided in this paragraph, the term "qualified clinical testing expenses" means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

(B) Modifications

For purposes of subparagraph (A), subsection (b) of section 41 shall be applied-

- (i) by substituting "clinical testing" for "qualified research" each place it appears in paragraphs (2) and (3) of such subsection, and
- (ii) by substituting "100 percent" for "65 percent" in paragraph (3)(A) of such subsection.

(C) Exclusion for amounts funded by grants, etc.

The term "qualified clinical testing expenses" shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

(D) Special rule

For purposes of this paragraph, section 41 shall be deemed to remain in effect for periods after June 30, 1995, and before July 1, 1996, and periods after December 31, 2013.

(2) Clinical testing**(A) In general**

The term "clinical testing" means any human clinical testing-

- (i) which is carried out under an exemption for a drug being tested for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section),
- (ii) which occurs-
 - (I) after the date such drug is designated under section 526 of such Act, and
 - (II) before the date on which an application with respect to such drug is approved under section 505(b) of such Act or, if the drug is a biological product, before the date on which a license for such drug is issued under section 351 of the Public Health Service Act; ¹ and
- (iii) which is conducted by or on behalf of the taxpayer to whom the designation under such section

526 applies.

(B) Testing must be related to use for rare disease or condition

Human clinical testing shall be taken into account under subparagraph (A) only to the extent such testing is related to the use of a drug for the rare disease or condition for which it was designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

(c) Coordination with credit for increasing research expenditures

(1) In general

Except as provided in paragraph (2), any qualified clinical testing expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

(2) Expenses included in determining base period research expenses

Any qualified clinical testing expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

(d) Definition and special rules

(1) Rare disease or condition

For purposes of this section, the term "rare disease or condition" means any disease or condition which-

(A) affects less than 200,000 persons in the United States, or

(B) affects more than 200,000 persons in the United States but for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.

Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date such drug is designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

(2) Special limitations on foreign testing

(A) In general

No credit shall be allowed under this section with respect to any clinical testing conducted outside the United States unless-

(i) such testing is conducted outside the United States because there is an insufficient testing population in the United States, and

(ii) such testing is conducted by a United States person or by any other person who is not related to the taxpayer to whom the designation under section 526 of the Federal Food, Drug, and Cosmetic Act applies.

(B) Special limitation for corporations to which section 936 applies

No credit shall be allowed under this section with respect to any clinical testing conducted by a corporation to which an election under section 936 applies.

(3) Certain rules made applicable

Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

(4) Election

This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.

(Added Pub. L. 97-414, §4(a), Jan. 4, 1983, 96 Stat. 2053, §44H; renumbered §28 and amended Pub. L. 98-369, div. A, title IV, §§471(c), 474(g), title VI, §612(e)(1), July 18, 1984, 98 Stat. 826, 831, 912; Pub. L. 99-514, title II, §§231(d)(3)(A), 232, title VII, §701(c)(2), title XII, §1275(c)(4), title XVIII, §1879(b)(1), (2), Oct. 22, 1986, 100 Stat. 2178, 2180, 2340, 2599, 2905; Pub. L. 100-647, title I, §1018(q)(1), title IV, §4008(c)(1), Nov. 10, 1988, 102 Stat. 3585, 3653; Pub. L. 101-239, title VII, §7110(a)(3), Dec. 19, 1989, 103 Stat. 2323; Pub. L. 101-508, title XI, §§11402(b)(2), 11411, Nov. 5, 1990, 104 Stat. 1388-473, 1388-479; Pub. L. 102-227, title I, §§102(b), 111(a), Dec. 11, 1991, 105 Stat. 1686, 1688; Pub. L. 103-66, title XIII, §13111(a)(2), (b), Aug. 10, 1993, 107 Stat. 420; renumbered §45C and amended Pub. L. 104-188, title I, §§1204(e), 1205(a)(1), (b), (d)(1), (2), Aug. 20, 1996, 110 Stat. 1775, 1776; Pub. L. 105-34, title VI, §§601(b)(2), 604(a), Aug. 5, 1997, 111 Stat. 862, 863; Pub. L. 105-115, title I, §125(b)(2)(O), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 105-277, div. J, title I, §1001(b), Oct. 21, 1998, 112 Stat. 2681-888; Pub. L. 106-170, title V,

§502(a)(2), Dec. 17, 1999, 113 Stat. 1919 ; Pub. L. 108–311, title III, §301(a)(2), Oct. 4, 2004, 118 Stat. 1178 ; Pub. L. 109–432, div. A, title I, §104(a)(2), Dec. 20, 2006, 120 Stat. 2934 ; Pub. L. 110–343, div. C, title III, §301(a)(2), Oct. 3, 2008, 122 Stat. 3865 ; Pub. L. 111–312, title VII, §731(b), Dec. 17, 2010, 124 Stat. 3317 ; Pub. L. 112–240, title III, §301(a)(2), Jan. 2, 2013, 126 Stat. 2326.)

REFERENCES IN TEXT

Sections 505(b), (i) and 526 of the Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(2)(A) and (d)(1), (2)(A)(ii), are classified to sections 355(b), (i) and 360bb, respectively, of Title 21, Food and Drugs.

Section 351 of the Public Health Service Act, referred to in subsec. (b)(2)(A)(ii)(II), is classified to section 262 of Title 42, The Public Health and Welfare.

AMENDMENTS

2013-Subsec. (b)(1)(D). Pub. L. 112–240 substituted "December 31, 2013" for "December 31, 2011".

2010-Subsec. (b)(1)(D). Pub. L. 111–312 substituted "December 31, 2011" for "December 31, 2009".

2008-Subsec. (b)(1)(D). Pub. L. 110–343 substituted "December 31, 2009" for "December 31, 2007".

2006-Subsec. (b)(1)(D). Pub. L. 109–432 substituted "2007" for "2005".

2004-Subsec. (b)(1)(D). Pub. L. 108–311 substituted "December 31, 2005" for "June 30, 2004".

1999-Subsec. (b)(1)(D). Pub. L. 106–170 substituted "June 30, 2004" for "June 30, 1999".

1998-Subsec. (b)(1)(D). Pub. L. 105–277 substituted "June 30, 1999" for "June 30, 1998".

1997-Subsec. (b)(1)(D). Pub. L. 105–34, §601(b)(2), substituted "June 30, 1998" for "May 31, 1997".

Subsec. (b)(2)(A)(ii)(II). Pub. L. 105–115 struck out "or 507" after "505(b)".

Subsec. (e). Pub. L. 105–34, §604(a), struck out subsec. (e) which read as follows:

"(e) Termination.-This section shall not apply to any amount paid or incurred-

"(1) after December 31, 1994, and before July 1, 1996, or

"(2) after May 31, 1997."

1996-Pub. L. 104–188, §1205(a)(1), renumbered section 28 of this title as this section.

Subsec. (a). Pub. L. 104–188, §1205(d)(1), substituted "For purposes of section 38, the credit determined under this section for the taxable year is" for "There shall be allowed as a credit against the tax imposed by this chapter for the taxable year".

Subsec. (b)(1)(D). Pub. L. 104–188, §1204(e), inserted ", and before July 1, 1996, and periods after May 31, 1997" after "June 30, 1995".

Subsec. (d)(2) to (5). Pub. L. 104–188, §1205(d)(2), redesignated pars. (3) to (5) as (2) to (4), respectively, and struck out former par. (2) which read as follows: "Limitation based on amount of tax.-The credit allowed by this section for any taxable year shall not exceed the excess (if any) of-

"(A) the regular tax (reduced by the sum of the credits allowable under subpart A and section 27), over

"(B) the tentative minimum tax for the taxable year."

Subsec. (e). Pub. L. 104–188, §1205(b), amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: "Termination.-This section shall not apply to any amount paid or incurred after December 31, 1994."

1993-Subsec. (b)(1)(D). Pub. L. 103–66, §13111(a)(2), substituted "June 30, 1995" for "June 30, 1992".

Subsec. (e). Pub. L. 103–66, §13111(b), substituted "December 31, 1994" for "June 30, 1992".

1991-Subsec. (b)(1)(D). Pub. L. 102–227, §102(b), substituted "June 30, 1992" for "December 31, 1991".

Subsec. (e). Pub. L. 102–227, §111(a), substituted "June 30, 1992" for "December 31, 1991".

1990-Subsec. (b)(1)(D). Pub. L. 101–508, §11402(b)(2), substituted "December 31, 1991" for "December 31, 1990".

Subsec. (e). Pub. L. 101–508, §11411, substituted "December 31, 1991" for "December 31, 1990".

1989-Subsec. (b)(1)(D). Pub. L. 101–239 substituted "1990" for "1989".

1988-Subsec. (b)(1)(D). Pub. L. 100–647, §4008(c)(1), substituted "1989" for "1988".

Subsec. (b)(2)(A)(ii)(II). Pub. L. 100–647, §1018(q)(1), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: "before the date on which an application with respect to such drug is approved under section 505(b) of such Act or, if the drug is a biological product, before the date on which a license for such drug is issued under section 351 of the Public Health Services Act, and".

1986-Subsec. (b)(1). Pub. L. 99–514, §231(d)(3)(A)(i), (iv), substituted "41" for "30" in subpars. (A), (B), and (D), and substituted "1988" for "1985" in subpar. (D).

Subsec. (b)(2)(A)(ii)(I). Pub. L. 99–514, §1879(b)(1)(A), substituted "the date such drug" for "the date of such drug".

Subsec. (b)(2)(A)(ii)(II). Pub. L. 99–514, §1879(b)(1)(B), inserted "or, if the drug is a biological product, before the date on which a license for such drug is issued under section 351 of the Public Health Services Act".

Subsec. (c). Pub. L. 99–514, §231(d)(3)(A)(i), (ii), substituted "41" for "30" in pars. (1) and (2) and "41(b)" for "30(b)" in par. (2).

Subsec. (d)(1). Pub. L. 99–514, §1879(b)(2), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "For purposes of this section, the term 'rare disease or condition' means any disease or condition which occurs so infrequently in the United States that there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date such drug is designated under section 526 of the Federal Food, Drug, and Cosmetic Act."

Subsec. (d)(2). Pub. L. 99–514, §701(c)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "The credit allowed by this section for any taxable year shall not exceed the taxpayer's tax liability for the taxable year (as defined in section 26(b)), reduced by the sum of the credits allowable under subpart A and section 27."

Subsec. (d)(3)(B). Pub. L. 99–514, §1275(c)(4), struck out "934(b) or" before "936" in heading and amended text generally. Prior to amendment, text read as follows: "No credit shall be allowed under this section with respect to any clinical testing conducted by a corporation to which section 934(b) applies or to which an election under section 936 applies."

Subsec. (d)(4). Pub. L. 99–514, §231(d)(3)(A)(iii), substituted "section 41(f)" for "section 30 (f)".

Subsec. (e). Pub. L. 99–514, §232, substituted "1990" for "1987".

1984-Pub. L. 98–369, §471(c), renumbered section 44H of this title as this section.

Subsec. (b)(1)(A), (B), (D). Pub. L. 98–369, §474(g)(1)(A), substituted "section 30" for "section 44F".

Subsec. (c)(1). Pub. L. 98–369, §474(g)(1)(A), substituted "section 30" for "section 44F".

Subsec. (c)(2). Pub. L. 98–369, §474(g)(1)(A), (B), substituted "section 30" for "section 44F" and "section 30(b)" for "section 44F(b)".

Subsec. (d)(2). Pub. L. 98–369, §612(e)(1), substituted "section 26(b)" for "section 25(b)".

Pub. L. 98–369, §474(g)(2), amended par. (2) generally, substituting "shall not exceed the taxpayer's tax liability for the taxable year (as defined in section 25(b), reduced by the sum of the credits allowable under subpart A and section 27" for "shall not exceed the amount of the tax imposed by this chapter for the taxable year reduced by the sum of the credits allowable under a section of this subpart having a lower number or letter designation than this section, other than the credits allowable by sections 31, 39, and 43. For purposes of the preceding sentence, the term 'tax imposed by this chapter' shall not include any tax treated as not imposed by this chapter under the last sentence of section 53(a)".

Subsec. (d)(4). Pub. L. 98–369, §474(g)(1)(C), substituted "section 30(f)" for "section 44F(f)".

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 112–240 applicable to amounts paid or incurred after Dec. 31, 2011, see section 301(d)(1) of Pub. L. 112–240, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–312 applicable to amounts paid or incurred after Dec. 31, 2009, see section 731(c) of Pub. L. 111–312, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–343 applicable to amounts paid or incurred after Dec. 31, 2007, see section 301(e)(2) of Pub. L. 110–343, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by Pub. L. 109–432 applicable to amounts paid or incurred after Dec. 31, 2005, see section 104(a)(3) of Pub. L. 109–432, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 2004 AMENDMENT

Amendment by Pub. L. 108–311 applicable to amounts paid or incurred after June 30, 2004, see section 301(b) of Pub. L. 108–311, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–170 applicable to amounts paid or incurred after June 30, 1999, see section 502(a)(3) of Pub. L. 106–170, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–277 applicable to amounts paid or incurred after June 30, 1998, see section 1001(c) of Pub. L. 105–277, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 601(b)(2) of Pub. L. 105–34 applicable to amounts paid or incurred after May 31, 1997, see section 601(c) of Pub. L. 105–34, set out as a note under section 41 of this title.

Pub. L. 105–34, title VI, §604(b), Aug. 5, 1997, 111 Stat. 863 , provided that: "The amendment made by subsection (a) [amending this section] shall apply to amounts paid or incurred after May 31, 1997."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by section 1204(e) of Pub. L. 104–188 applicable to taxable years ending after June 30, 1996, and not to be taken into account under section 6654 or 6655 of this title in determining amount of any installment required to be paid for a taxable year beginning in 1997, see section 1204(f) of Pub. L. 104–188, set out as a note under section 41 of this title.

Amendment by section 1205(a)(1), (b), (d)(1), (2) of Pub. L. 104–188 applicable to amounts paid or incurred in taxable years ending after June 30, 1996, see section 1205(e) of Pub. L. 104–188, set out as a note under section 45K of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, §13111(c), Aug. 10, 1993, 107 Stat. 421 , provided that: "The amendments made by this section [amending this section and section 41 of this title] shall apply to taxable years ending after June 30, 1992."

EFFECTIVE DATE OF 1991 AMENDMENT

Pub. L. 102–227, title I, §102(c), Dec. 11, 1991, 105 Stat. 1686 , provided that: "The amendments made by this section [amending this section and section 41 of this title] shall apply to taxable years ending after December 31, 1991."

Pub. L. 102–227, title I, §111(b), Dec. 11, 1991, 105 Stat. 1689 , provided that: "The amendment made by this section [amending this section] shall apply to taxable years ending

after December 31, 1991."

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title XI, §11402(c), Nov. 5, 1990, 104 Stat. 1388–473 , provided that: "The amendments made by this section [amending this section and section 41 of this title and repealing provisions set out as a note under section 41 of this title] shall apply to taxable years beginning after December 31, 1989."

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 1018(q)(1) of Pub. L. 100–647 effective, except as otherwise provided, as if included in the provision of the Tax Reform Act of 1986, Pub. L. 99–514, to which such amendment relates, see section 1019(a) of Pub. L. 100–647, set out as a note under section 1 of this title.

Amendment by section 4008(c)(1) of Pub. L. 100–647 applicable to taxable years beginning after Dec. 31, 1988, see section 4008(d) of Pub. L. 100–647, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 231(d)(3)(A) of Pub. L. 99–514 applicable to taxable years beginning after Dec. 31, 1985, see section 231(g) of Pub. L. 99–514, set out as a note under section 41 of this title.

Amendment by section 701(c)(2) of Pub. L. 99–514 applicable to taxable years beginning after Dec. 31, 1986, with certain exceptions and qualifications, see section 701(f) of Pub. L. 99–514, set out as an Effective Date note under section 55 of this title.

Amendment by section 1275(c)(4) of Pub. L. 99–514 applicable to taxable years beginning after Dec. 31, 1986, with certain exceptions and qualifications, see section 1277 of Pub. L. 99–514, set out as a note under section 931 of this title.

Pub. L. 99–514, title XVIII, §1879(b)(3), Oct. 22, 1986, 100 Stat. 2906 , provided that: "The amendments made by this subsection [amending this section] shall apply to amounts paid or incurred after December 31, 1982, in taxable years ending after such date."

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 474(g) of Pub. L. 98–369 applicable to taxable years beginning after Dec. 31, 1983, and to carrybacks from such years, see section 475(a) of Pub. L. 98–369, set out as a note under section 21 of this title.

Amendment by section 612(e)(1) of Pub. L. 98–369, applicable to interest paid or accrued after December 31, 1984, on indebtedness incurred after December 31, 1984, see section 612 (g) of Pub. L. 98–369, set out as an Effective Date note under section 25 of this title.

EFFECTIVE DATE

Pub. L. 97–414, §4(d), Jan. 4, 1983, 96 Stat. 2056 , provided that: "The amendments made by this section [enacting this section and amending sections 280C and 6096 of this title] shall apply to amounts paid or incurred after December 31, 1982, in taxable years ending after such date."

APPLICABILITY OF CERTAIN AMENDMENTS BY PUBLIC LAW 99–514 IN RELATION TO TREATY OBLIGATIONS OF UNITED STATES

For applicability of amendment by section 701(c)(2) of Pub. L. 99–514 notwithstanding any treaty obligation of the United States in effect on Oct. 22, 1986, with provision that for such purposes any amendment by title I of Pub. L. 100–647 be treated as if it had been included in the provision of Pub. L. 99–514 to which such amendment relates, see section 1012(aa)(2), (4) of Pub. L. 100–647, set out as a note under section 861 of this title.

PLAN AMENDMENTS NOT REQUIRED UNTIL JANUARY 1, 1989

For provisions directing that if any amendments made by subtitle A or subtitle C of title XI [§§1101–1147 and 1171–1177] or title XVIII [§§1800–1899A] of Pub. L. 99–514 require an

amendment to any plan, such plan amendment shall not be required to be made before the first plan year beginning on or after Jan. 1, 1989, see section 1140 of Pub. L. 99-514, as amended, set out as a note under section 401 of this title.

¹ *So in original. The semicolon probably should be a comma.*