

\$2,000 for qualified tuition and related expenses for a 16-hour work load for the 1998 Spring semester. Prior to beginning classes, Student A withdraws from 6 course hours. On February 15, 1998, Student A receives a \$750 refund from University X. In September 1998, Student A pays University X \$1,000 to enroll half-time for the 1998 Fall semester. Prior to beginning classes, Student A withdraws from a 2-hour course, and she receives a \$250 refund in October 1998. Student A computes the amount of qualified tuition and related expenses she may claim for 1998 by:

- (i) Adding all qualified expenses paid during the taxable year ($\$2,000 + \$1,000 = \$3,000$);
- (ii) Adding all refunds of qualified tuition and related expenses received during the taxable year ($\$750 + \$250 = \$1,000$); and, then
- (iii) Subtracting paragraph (ii) of this *Example 1* from paragraph (i) of this *Example 1* ($\$3,000 - \$1,000 = \$2,000$). Therefore, Student A's qualified tuition and related expenses for 1998 are \$2,000.

Example 2. (i) In December 1998, Student B, a senior at College Y, pays \$2,000 for qualified tuition and related expenses for a 16-hour work load for the 1999 Spring semester. Prior to beginning classes, Student B withdraws from a 4-hour course. On January 15, 1999, Student B files her 1998 income tax return and claims a \$400 Lifetime Learning Credit for the \$2,000 qualified expenses paid in 1998, which reduces her tax liability for 1998 by \$400. On February 15, 1999, Student B receives a \$500 refund from College Y.

- (ii) Student B calculates the increase in tax for 1999 by—
 - (A) Calculating the redetermined qualified expenses for 1998 ($\$2,000 - \$500 = \$1,500$);
 - (B) Calculating the redetermined credit for the redetermined qualified expenses ($\$1,500 \times .20 = \300); and
 - (C) Calculating the difference in tax liability for 1998 resulting from the redetermined credit. Because Student B's tax liability for 1998 was reduced by the full amount of the \$400 education tax credit claimed on her 1998 income tax return, the difference in tax liability can be determined by subtracting the redetermined credit from the credit claimed in 1998 ($\$400 - \$300 = \$100$).

(iii) Therefore, Student B must increase the tax on her 1999 federal income tax return by \$100.

Example 3. In September 1998, Student C pays College Z \$1,200 in qualified tuition and related expenses to attend evening classes during the 1998 Fall semester. Student C is an employee of Company R. On January 15, 1999, Student C files a federal income tax return for 1998 claiming a Lifetime Learning Credit of \$240 ($.20 \times \$1,200$), which reduces Student C's tax liability for 1998 by \$240. Pursuant to an educational assistance program described in section 127(b), Company R reimburses Student C in February 1999 for the \$1,200 of qualified tuition and related ex-

penses paid by Student C in 1998. The \$240 education tax credit claimed by Student C for 1998 is subject to recapture. Because Student C paid no net qualified tuition and related expenses for 1998, the redetermined credit for 1998 is zero. Student C must increase the amount of Student C's 1999 tax by the recapture amount, which is \$240 (the difference in tax liability for 1998 resulting from the redetermined credit for 1998 (\$0)). Because the \$1,200 reimbursement relates to expenses for which the taxpayer claimed an education tax credit in a prior year, the reimbursement does not reduce the amount of any qualified tuition and related expenses that Student C paid in 1999.

[T.D. 9034, 67 FR 78691, Dec. 26, 2002; 68 FR 15940, Apr. 2, 2003]

§ 1.28-0 Credit for clinical testing expenses for certain drugs for rare diseases or conditions; table of contents.

In order to facilitate use of § 1.28-1, this section lists the paragraphs, subparagraphs, and subdivisions contained in § 1.28-1.

- (a) General rule.
- (b) Qualified clinical testing expenses.
 - (1) In general.
 - (2) Modification of section 41(b).
 - (3) Exclusion for amounts funded by another person.
 - (i) In general.
 - (ii) Clinical testing in which taxpayer retains no rights.
 - (iii) Clinical testing in which taxpayer retains substantial rights.
 - (A) In general.
 - (B) Drug by drug determination.
 - (iv) Funding for qualified clinical testing expenses determinable only in subsequent taxable years.
 - (4) Special rule governing the application of section 41(b) beyond its expiration date.
 - (c) Clinical testing.
 - (1) In general.
 - (2) Definition of "human clinical testing".
 - (3) Definition of "carried out under" section 505(i).
 - (d) Definition and special rules.
 - (1) Definition of "rare disease or condition".
 - (i) In general.
 - (ii) Cost of developing and making available the designated drug.
 - (A) In general.
 - (B) Exclusion of costs funded by another person.
 - (C) Computation of cost.
 - (D) Allocation of common costs. Costs for developing and making available the designated drug for both the disease or condition for which it is designated and one or more other diseases or conditions.
 - (iii) Recovery from sales.

§ 1.28-1

26 CFR Ch. I (4-1-04 Edition)

- (iv) Recordkeeping requirements.
- (2) Tax liability limitation.
 - (i) Taxable years beginning after December 31, 1986.
 - (ii) Taxable years beginning before January 1, 1987, and after December 31, 1983.
 - (iii) Taxable years beginning before January 1, 1984.
 - (3) Special limitations on foreign testing.
 - (i) Clinical testing conducted outside the United States—In general.
 - (ii) Insufficient testing population in the United States.
 - (A) In general.
 - (B) “Insufficient testing population”.
 - (C) “Unrelated to the taxpayer”.
 - (4) Special limitations for certain corporations.
 - (i) Corporations to which section 936 applies.
 - (ii) Corporations to which section 934(b) applies.
 - (5) Aggregation of expenditures.
 - (i) Controlled group of corporations: organizations under common control.
 - (A) In general.
 - (B) Definition of controlled group of corporations.
 - (C) Definition of organization.
 - (D) Determination of common control.
 - (ii) Tax accounting periods used.
 - (A) In general.
 - (B) Special rule where the timing of clinical testing is manipulated.
 - (iii) Membership during taxable year in more than one group.
 - (iv) Intra-group transactions.
 - (A) In general.
 - (B) In-house research expenses.
 - (C) Contract research expenses.
 - (D) Lease payments.
 - (E) Payments for supplies.
 - (6) Allocations.
 - (i) Pass-through in the case of an S corporation
 - (ii) Pass-through in the case of an estate or a trust.
 - (iii) Pass-through in the case of a partnership.
 - (A) In general.
 - (B) Certain partnership non-business expenditures.
 - (C) Apportionment.
 - (iv) Year in which taken into account.
 - (v) Credit allowed subject to limitation.
 - (7) Manner of making an election.

[T.D. 8232, 53 FR 38710, Oct. 3, 1988; 53 FR 40879, Oct. 19, 1988]

§ 1.28-1 Credit for clinical testing expenses for certain drugs for rare diseases or conditions.

(a) *General rule.* Section 28 provides a credit against the tax imposed by chapter 1 of the Internal Revenue Code. The amount of the credit is equal to 50 per-

cent of the qualified clinical testing expenses (as defined in paragraph (b) of this section) for the taxable year. The credit applies to qualified clinical testing expenses paid or incurred by the taxpayer after December 31, 1982, and before January 1, 1991. The credit may not exceed the taxpayer's tax liability for the taxable year (as determined under paragraph (d)(2) of this section).

(b) *Qualified clinical testing expenses—*
(1) *In general.* Except as otherwise provided in paragraph (b)(3) of this section, the term “qualified clinical testing expenses” means the amounts which are paid or incurred during the taxable year which would constitute “qualified research expenses” within the meaning of section 41(b) (relating to the credit for increasing research activities) as modified by section 28(b)(1)(B) and paragraph (b)(2) of this section. For example, amounts paid or incurred for the acquisition of depreciable property used in the conduct of clinical testing (as defined in paragraph (c) of this section) are not qualified clinical testing expenses.

(2) *Modification of section 41(b).* For purposes of paragraph (b)(1) of this section, section 41(b) is modified by substituting “clinical testing” for “qualified research” each place it appears in paragraph (2) of section 41(b) (relating to in-house research expenses) and paragraph (3) of section 41(b) (relating to contract research expenses). In addition, “100 percent” is substituted for “65 percent” in paragraph (3)(A) of section 41(b).

(3) *Exclusion for amounts funded by another person—*(i) *In general.* The term “qualified clinical testing expenses” shall not include any amount which would otherwise constitute qualified clinical testing expenses, to the extent such amount is funded by a grant, contract, or otherwise by another person (or any governmental entity). The determination of the extent to which an amount is funded shall be made in light of all the facts and circumstances. For a special rule regarding funding between commonly controlled businesses, see paragraph (d)(5)(iv) of § 1.28-1.

(ii) *Clinical testing in which taxpayer retains no rights.* If a taxpayer conducting clinical testing with respect to the designated drug for another person