

§ 1.28-0

26 CFR Ch. I (4-1-02 Edition)

for that quarter; the issuer is not required to file any subsequent reports with respect to that program. See section 6709(c) for the penalties with respect to failure to file a report.

(ii) The report shall be submitted on Form 8330 and shall contain the information required therein, including—

(A) The name, address, and TIN of the issuer of the mortgage credit certificates,

(B) The date of the issuer's election not to issue qualified mortgage bonds with respect to the mortgage credit certificate program and the nonissued bond amount of the program,

(C) The sum of the products determined by multiplying—

(1) The certified indebtedness amount of each qualified mortgage credit certificate issued under that program during the calendar quarter, by

(2) The certificate credit rate with respect to such certificate, and

(D) A listing of the name, address, and TIN of each holder of a qualified mortgage credit certificate which has been revoked during the calendar quarter.

(c) *Extensions of time for filing reports.* The Commissioner may grant an extension of time for the filing of a report required by this section if there is reasonable cause for the failure to file such report in a timely fashion.

(d) *Place for filing.* The reports required by this section are to be filed at the Internal Revenue Service Center, Philadelphia, Pennsylvania 19225.

(e) *Cross reference.* See section 6709 and the regulations thereunder with respect to the penalty for failure to file a report required by this section.

[T.D. 8023, 50 FR 19354, May 8, 1985]

§ 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.
- (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 percent 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 sec-

tion, 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 retains no substantial rights in the clinical testing under the agreement providing for the clinical testing the taxpayer's clinical testing expenses are treated as fully funded for purposes of section 28(b)(1)(C). Thus, for example, if the taxpayer incurs clinical testing expenses under an agreement that confers on another person the exclusive right to exploit the results of the clinical testing, those expenses do not constitute qualified clinical testing expenses because they are fully funded under this paragraph (b)(3)(ii). Incidental benefits to the taxpayer from the conduct of the clinical testing (for example, increased experience in the field of human clinical testing) do not constitute substantial rights in the clinical testing.

(iii) *Clinical testing in which taxpayer retains substantial rights—*(A) *In general.* If a taxpayer conducting clinical testing with respect to the designated drug for another person retains substantial rights in the clinical testing under the agreement providing for the clinical testing, the clinical testing expenses are funded to the extent of the payments (and fair market value of any