

PUBLICATION

Spotlight on Health Care Reform: IRS Provides Guidance on Tax Credit for Drug-Related Studies and Trials

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On May 21, 2010, the Internal Revenue Service (IRS) issued Notice 2010-45 establishing the program requirements and procedures for filing applications and obtaining certifications for the therapeutic discovery project tax credit under newly enacted § 48D of the Internal Revenue Code (IRC). Under Section 48D, eligible taxpayers making qualified investments in certain therapeutic projects receive a tax credit (or grant in lieu of a credit) of 50% of the qualified investment if the project is certified by the IRS (in consultation with the Department of Health and Human Services). Notice 2010-45 describes the requirements and procedures for the application and certification process.

Program Overview

IRS Notice 2010-45 establishes the Qualifying Therapeutic Discovery Project Tax Credit Program and spells out program specifications and requirements, timelines, application procedures for grants in lieu of the tax credit, disclosure of information, and related tax consequences. The tax credit program allows eligible taxpayers to take a 50% credit on qualifying investments in certified qualifying therapeutic discovery projects.

A "qualifying therapeutic discovery project" is a project that is designed to:

1. Treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) or section 351(a) of the Public Health Service Act (PHSA);
2. Diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or
3. Develop a product, process, or technology to further the delivery or administration of therapeutics.

An eligible taxpayer must affirmatively elect on Form 8942, Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program, whether it is applying for a tax credit or grant in lieu of a tax credit. However, if an eligible taxpayer's Form 8942 is approved and receives a certification for a tax credit, it may file an amended Form 8942 by the due date for the taxpayer's 2010 tax return requesting a grant in lieu of the tax credit.

An "eligible taxpayer" is a taxpayer that employs 250 employees or less, determined based on the "single employer" rules of IRC §§ 52(a) or (b) or 414(m) or (o). The IRS will count full-time and part-time employees, but not leased employees, toward the 250 employee maximum.

A "qualified investment" is the aggregate amount of the costs paid or incurred in 2009 or 2010 for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project. Certain executive compensation, interest expenses, facility maintenance expenses (mortgage or rent payments, insurance on the facility, utility and maintenance costs, and costs of employing maintenance personnel), and services costs (i.e., SG&A expenses) are not included in "qualified investment."

Program Specifications and Timelines

Initially, the IRS will host one application and certification round. Additional rounds will only be held if there are unallocated credits after the initial round. The IRS will certify an equal amount of qualified investment for each qualifying project, up to the total qualifying investment amount for such project. Therefore, the credit allocation will not be made on a first-come, first-served basis.

An application for certification (Form 8942 and accompanying information) must be postmarked by July 21, 2010. The IRS will release Form 8942 no later than June 21, 2010. Earlier filed applications will not receive any different consideration than applications postmarked July 21, 2010.

The following are the highlights of the program specifications:

4. A taxpayer must file with the IRS a separate Form 8942 for each qualifying therapeutic discovery project for which it is seeking certification of the qualified investment.
5. The IRS will perform a preliminary review of each Form 8942 submitted to determine that the taxpayer-applicant is an eligible taxpayer and whether the application is complete. **Preliminary review of timely-filed applications will end on September 30, 2010.**
6. The IRS will approve or deny an application **no later than October 29, 2010.**
7. The IRS will approve or deny an application only after HHS has completed its review of all applications submitted by eligible taxpayers.
8. The aggregate amount of qualified investments that will be certified by the IRS will not exceed \$2 billion. In addition, the IRS will not certify more than \$10 million as a qualified investment for any single taxpayer. As a result, no single taxpayer will be allocated more than \$5 million in tax credits or grants in the aggregate for 2009 and 2010 (the credit or grant is 50% of the qualified investment).
9. An eligible taxpayer must inform the IRS of a significant change in plans of a qualifying therapeutic discovery project. According to Notice 2010-45, a "significant change" is "any change, including any change that would affect the continuing accuracy of a statement made in the application, that a reasonable person would conclude might have influenced HHS's evaluation."

If an eligible taxpayer applies for a grant in lieu of the tax credit, it must also provide on Form 8942 its Data Universal Numbering System (DUNS) number from Dunn and Bradstreet and register with the Central Contractor Registration (CCR).

If the IRS denies an eligible taxpayer's application for certification, the taxpayer has no right to a conference or right to appeal the decision (including the amount of credit or grant allocated to the project).

Submission Information for Certification

A complete application for certification includes Form 8942, an attached Project Information Memorandum, and a consent to disclosure. Form 8942 will consist of 11 questions requesting general information about the eligible taxpayer-applicant, description of qualified investments, and employees and contractors. The IRS will use the answers to the first 10 questions for its preliminary review, described above.

Question 11 of Form 8942 will request information on whether the project:

10. Will produce a new or significantly improved technology, or a new application or significant improvement to existing technology, as compared to commercial technologies currently in service; and

11. Is expected to lead to the construction or use of a contract production facility in the U.S. within five years.

After HHS completes its review of the Project Information Memorandum and determines the project is a qualifying therapeutic discovery project and shows a reasonable potential to achieve statutory goals, the IRS will then review the information responding to question 11 of Form 8942 to determine which projects have the greatest potential to advance U.S. competitiveness in the fields of life, biological, and medical sciences.

The Project Information Memorandum will consist of narrative answers to 11 questions. HHS will review the eligible taxpayer-applicant's Project Information Memorandum to determine whether the project is a "qualifying therapeutic discovery project," based on information provided related to: treatment or prevention of diseases or conditions, pre-clinical activities, clinical trials, or clinical studies aimed at developing a new drug application under FFDCFA § 505(b) or biological license application under PHSA § 351(a); diagnoses of diseases and conditions; determination of molecular factors related to diseases or conditions; and delivery or administration of therapeutics.

If HHS determines that the project satisfies the basic qualifications, it will consider whether the applicant has demonstrated that its project is designed to have a "reasonable potential" to meet one or more of the goals specified in IRC § 48D. The determination will be made based on whether the therapy is novel and not the same as a therapy currently on the market, whether the therapy treats areas of unmet medical need or prevents, detects, or treats chronic or acute diseases or conditions, how the project will lead to actual cost reductions, or whether the project will significantly advance the goal of curing cancer within 30 years.

Last, if HHS is satisfied that the project is designed to meet statutory goals, it will assess whether there is a reasonable potential that the project will actually achieve one or more of the statutory goals. That determination will be based on the scientific rationale, research and development plans, scientific evidence, stage of development, resources, management experience and organizational capacity of the applicant.

Appendix A to Notice 2010-45 also sets forth the required format of the Project Information Memorandum, including word limits. Brochures and other presentations are not permitted and will not be considered.

Disclosure

The amount of the tax credit or grant in lieu of a tax credit, the identity of the eligible taxpayer, and the description of the qualified investment are not tax return information under IRC § 6103 pursuant to IRC § 48D(d)(4). Therefore, the IRS will publicly disclose this information upon making a certification for credit or grant, including the type and location of the project. As part of filing Form 8942, an eligible taxpayer will also be required to submit a declaration consenting to public disclosure by the IRS of the type and location of the project.

In addition to the information that the IRS is authorized by IRC § 48D(d)(4) to publicly disclose, other parties could seek other information and records under the Freedom of Information Act (FOIA). If elements of the information provided with Form 8942 and the Project Information Memorandum, other than what the IRS is authorized to disclose, are considered trade secrets, confidential, privileged or otherwise exempt from disclosure under FOIA, the eligible taxpayer must assert the exemption at the time of application, place a specific statement text in the Project Information Memorandum, and identify the page(s) of the application that should be restricted.

If a project is not approved for a tax credit or grant, the IRS will not publicly disclose information that it has received during the application process.

Other Tax Consequences

For eligible taxpayers undertaking qualifying therapeutic discovery projects, one of the immediate tax considerations is whether to apply for a § 48D tax credit or grant in lieu of a tax credit. If the taxpayer is not in a taxable position for its 2009 or 2010 taxable years, a grant may be more valuable than a tax credit since the taxpayer would not have a 2009 or 2010 federal income tax liability to offset. Nonetheless, an eligible taxpayer's taxable income projections also enter into the tax credit versus grant decision. The therapeutic discovery project tax credit is included as one of the sum of credits listed by IRC § 46 as the investment tax credit. In turn, as an investment tax credit, the therapeutic discovery project tax credit is also a business tax credit under IRC § 38. Therefore, to the extent the therapeutic discovery project tax credit is not utilized in 2009 or 2010, it is eligible for the one-year carryback and 20-year carryforward rules of IRC § 39.

Additional tax consequences should also be considered in advance of applying for the § 48D tax credit, including the following:

The therapeutic discovery project tax credit will be subject to the recapture and other special rules of IRC § 50, as well as the IRC § 49 at risk rules.

1. To the extent the § 48D credit is allowed for an expenditure related to depreciable property, the basis of that property is reduced by the amount of the credit.
2. The § 48D credit will not be allowed for any investment in property eligible for bonus depreciation under IRC § 168(k).
3. Expenses taken into account for determining the "qualified investment" are not taken into account for purposes of the eligible taxpayer's research credit under IRC § 41 (although the expenses are taken into account in determining base period research expenses for § 41) or the credit for clinical testing expenses under IRC § 45C.
4. A grant in lieu of the tax credit is excluded from the eligible taxpayer's gross income. Based on Notice 2010-45, the amount of the "qualified investment" is reduced by any grant in lieu of the tax credit that is excluded from the eligible taxpayer's gross income, unless the grant can only be used for costs not included in "qualified investment."

Despite the short time frame for eligible taxpayers to prepare and submit applications for this tax credit, it is not first-come, first-served, and applicants must take the time and appropriately address all selection criteria. A team with the relevant tax, health law, and therapeutic project expertise should be assembled.

If you would like to discuss the Qualifying Therapeutic Discovery Project Tax Credit Program, please contact one of the members of our Tax and Health Law Departments.