

Health Alert

IRS Releases Guidance on Therapeutic Discovery Tax Credit Program

May 21, 2010

On May 21, 2010, the Internal Revenue Service (IRS) released Notice 2010-45, providing detailed guidance regarding the therapeutic discovery tax credit program established by the Patient Protection and Affordable Care Act. The program is aimed at producing new therapies, creating jobs and advancing U.S. competitiveness. The Notice describes the procedures that companies must follow in order to apply for a credit or a grant under the program and sets forth important filing dates for the 2009-2010 allocation round.

Under Section 9023 of the Act, Congress created a new section 48D of the Internal Revenue Code to provide a tax credit or grant to each eligible company that makes a “qualified investment” in a “qualifying therapeutic discovery project” in the amount of 50 percent of the investment, up to a cap of \$10 million. To be eligible to participate in the program, a company with no more than 250 employees must make, or have made, such an investment in a qualifying project during 2009 or 2010.

In general, a qualified investment is the aggregate amount of the costs paid or incurred for expenses necessary for, and directly related to, the conduct of the project. Certain costs are specifically excepted from the program, including executive compensation, interest payments, facility maintenance expenses, overhead and other expenses to be determined by the secretary of the Treasury.

A qualifying therapeutic discovery project is a project designed to treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials and clinical studies, or by carrying out research protocols, for the purpose of securing federal approval of a drug or biologic. It also includes projects intended to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or projects to develop a product, process or technology to further the delivery or administration of therapeutics.

The IRS must certify a company’s qualified investment before the company can be eligible for a credit or grant under the program. A qualifying investment will be certified by the IRS only if the Department of Health and Human Services (HHS) determines that the project is a qualifying therapeutic discovery project and that the project shows a reasonable potential to (a) result in new therapies, treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions; (b) reduce long-term health care costs in the United States; or (c) significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010. In addition, the IRS must determine that the project is among those that have the greatest potential to create high-quality, high-paying jobs in the United States and to advance the United States’ competitiveness in the fields of life, biological and medical sciences. The IRS will make its certification decisions after HHS has completed its review of all applications submitted, but in no case will formal determinations occur later than October 29, 2010.

One significant limitation set forth in the guidance concerns the cap on the aggregate amount of credits or grants available to a single company under the program. The IRS will not certify more than \$10 million as a qualified investment for any single company during the initial 2009-2010 allocation round. As a result, no company will be allocated more than \$5 million in credits or grants in the aggregate for 2009 and 2010, regardless of the number of projects that the company sponsors. If any portion of the \$1 billion available under the program remains unallocated after the primary allocation, additional allocation rounds may be conducted.



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Applications for certification must be made on Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program." Separate applications must be filed for each qualifying therapeutic discovery project for which a company is seeking certification of a qualified investment. The application and accompanying filing instructions will be released by the IRS no later than June 21, 2010. In the interim, Appendix A to Notice 2010-45 contains a description of the basic questions that applicants will be expected to answer, along with information that must be included and detailed word limitations. Applications on Form 8942 must be filed no later than July 21, 2010, to qualify for the primary 2009-2010 allocation round.

Please click [here](#) to view a copy of Notice 2010-45.

A fact sheet on the credit is available by clicking [here](#).

A Treasury news release is available by clicking [here](#).

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