

Health Care Reform Advisory: How to Apply for a Billion-Dollar Tax Credit and Grant Opportunity - New Guidance from the IRS

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On May 21, 2010, the IRS issued highly anticipated rules on the Qualifying Therapeutic Discovery Project credit. In recent advisories, we reported that the Patient Protection and Affordable Care Act (a/k/a – the health care reform bill) includes \$1 billion in tax credits and grants to defray the costs of therapeutic research for small and mid-size life sciences companies, including drug, therapeutic, and diagnostic companies. The new, temporary program offers a choice between an income tax credit and a cash grant (not to exceed \$5 million per company) for up to 50% of a company's costs paid or incurred in 2009 and 2010 and directly related to a "qualifying therapeutic discovery project" (QTDP). On May 21, 2010, the IRS issued Notice 2010-45 describing the application procedures.

The full text of the IRS notice can be found [here](#), and an IRS fact sheet [here](#). For our advisory describing the credit and its eligibility criteria, see [here](#). For our advisory on how you may prepare in advance for the application process, see [here](#).

The program is competitive. Your application will be evaluated with all others received, and only those that demonstrate both therapeutic and economic benefits for the U.S. are likely to be approved. Therefore, in addition to compiling accounting information concerning your company's investment in therapeutic technologies, it will be essential that your application for certification also demonstrates sound technical merit and a business case.

Timeline for Applications, Review, and Certification

There is only a *one-month* application window. Applications may be submitted beginning June 21, 2010, and applications must be postmarked no later than July 21, 2010. The program guidance does not authorize electronic filing of applications. The IRS will conduct a preliminary review of all timely filed applications by September 30, 2010 to eliminate applications that are incomplete or from unqualified taxpayers. Finally, the IRS will issue certification notices to recipients by October 29, 2010.

Application Process

Companies must submit a separate application for each QTDP for which they seek a credit or grant. If you are conducting more than one QTDP, multiple applications are permitted. A

complete application will consist of three components: (1) a Project Information Memorandum; (2) an IRS Form 8942; and (3) a consent to disclose certain information to permit publication of information concerning program awards.

The Project Information Memorandum will describe scientific details of the project. The Department of Health and Human Services (HHS) will review the memorandum to determine whether a project meets the definition of a QTDP and shows a reasonable potential to meet one or more the goals specified in the statute. As we previously reported, a QTDP is a project designed to achieve any of the following objectives:

- to 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 by the Food & Drug Administration or Public Health Service,
- to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or
- to develop a product, process, or technology to further the delivery or administration of therapeutics.

A project also must show a reasonable potential to meet one or more of the following goals:

- to develop new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions,
- to reduce long-term health care costs in the U.S., or
- to significantly advance the goal of curing cancer within the next 30 years.

The Form 8942 will require information about the company's ownership, number of employees working on the QTDP, basic information about the status of the QTDP, and information concerning the company's qualified investments for 2009 and 2010, including salary costs, lab costs, contractor costs, and other qualified investments.

The IRS will review the Form 8942 to determine which projects (a) have the greatest potential to create and sustain high-quality, high-paying jobs in the U.S., (b) have the greatest potential to advance U.S. competitiveness in the life, biological, and medical sciences, and (c) have the greatest potential to produce a new or significantly improved technology as compared to existing commercial technologies, and will lead to the construction or use of a production facility in the U.S. within the next five years. *The Form 8942 is not yet available.* The IRS is expected to release this new form by June 21, 2010.

If HHS determines that the project meets the therapeutic goals of the statute, and the IRS determines that, compared to the submissions of other taxpayers, it is more likely to advance the employment and U.S. competitiveness goals of the statute, then a certification will be awarded.

There is no right to appeal a denial of or the amount of a credit or grant. Applicants must meet all qualifying requirements and demonstrate the merits of their QTDP in their initial submissions.

Additional Details on Applying for a Grant

The taxpayer may elect to apply for a grant in lieu of a tax credit when filing the Form 8942. If the taxpayer applies for and receives certification for a credit, it may file an amended Form 8942 later if it wishes to receive a grant instead of a tax credit. If the applicant requests a grant in its initial Form 8942 and receives certification for 2009, it will receive payment of the grant by October 29, 2010. Payment of the 2010 portion of the grant will be made after close of the taxpayer's 2010 tax year. Applicants seeking grants instead of a tax credit also must obtain a DUNS number and register on the government's Central Contractor Registration database before filing their application. These are administrative steps that should be completed before filing the Form 8942.

Mintz Levin's health law, tax, and government grants and contracts attorneys are prepared to help you submit the most effective application for this competitive program.

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For further information regarding this or any issue related to Health Care Reform, please contact one of the professionals listed below or the Mintz Levin attorney who ordinarily handles your legal affairs.

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