

Treasury Releases Guidance on Tax Credits and Grants Available for Certain Pharmaceutical, Biotechnology, Medical Device, and Other Healthcare Companies

BY SAMANTHA H. ELDREDGE, JEFFREY T. HARTLIN, ROB R. CARLSON, & MICHAEL G. MCKINNON

On May 21, 2010, the U.S. Department of the Treasury issued Notice 2010-45, which establishes the qualifying therapeutic discovery project program under Section 48D of the Internal Revenue Code included as part of the Patient Protection and Affordable Care Act of 2010. The Notice also provides details about completing and submitting applications for a tax credit or grant under the program. As discussed in our previous client alert, "Tax Credits and Grants Available for Certain Pharmaceutical, Biotechnology, and Other Healthcare Companies: Applicants Should Prepare Now," available at http://www.paulhastings.com/assets/publications/1586.pdf?wt.mc_ID=1586.pdf, pharmaceutical, biotechnology, medical device and other healthcare companies with 250 or fewer employees may be eligible to apply for a tax credit or grant with respect to certain "qualifying therapeutic discovery projects" under the program.

The Application Process

Under Notice 2010-45 (available at <http://www.irs.gov/pub/irs-drop/n-10-45.pdf>), applicants must prepare and file an application on IRS Form 8942, "Application for Certification of Qualified Investment Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Program." IRS Form 8942 is expected to be publicly released on or before June 21, 2010 and will be available at www.irs.gov. Applications may be submitted to the IRS beginning on the date IRS Form 8942 is released, but must be postmarked no later than July 21, 2010. Applicants must prepare a separate IRS Form 8942 for each project for which they seek a tax credit or grant. The Notice also includes the following key details about the program:

- A single taxpayer may not be allocated more than a total of \$5 million in tax credits or grants under the program for 2009 and 2010 combined, regardless of the number of projects for which the taxpayer has submitted an application for a tax credit or grant.
- The IRS will certify an equal amount of qualified investment per project, which means that, regardless of its size, each certified project will receive the same amount of tax credit or grant as each other certified project. However, in no case will the amount certified exceed the actual amount of qualified investment for each project. The IRS estimates that 1,200 taxpayers will apply for a tax credit or grant under the program.

- If the amount certified for a project exceeds the actual amount of qualified investment for such project, the excess amount will be reapportioned pro rata across all other projects that otherwise would receive a certification for only a portion of their respective qualified investments.

Accordingly, tax credits and grants under the program will not be awarded on a “first-come, first-served” basis. Applicants should therefore focus more on preparing thorough and persuasive applications for each project rather than submitting their applications at the very beginning of the filing period. No additional information may be submitted after the July 21, 2010 deadline unless specifically requested by the IRS, so it is especially important that applicants submit complete applications to the IRS by the deadline.

Following the July 21, 2010 deadline, the IRS will first conduct and complete a preliminary review of each application that was timely filed. The purpose of the preliminary review is to determine whether the applicant is an eligible taxpayer and whether the application is otherwise complete. All preliminary reviews will be completed by September 30, 2010. After this time, the IRS, in consultation with the U.S. Department of Health and Human Services, will review the individual merits of the applications. Applicants will receive determination letters as to the amount of the tax credit or grant awarded for each project (if any) from the IRS by no later than October 29, 2010. All decisions will be final and not subject to appeal.

The Application

Notice 2010-45 states that each application must consist of a completed IRS Form 8942, a Project Information Memorandum and, for applicants seeking a *grant* for the 2009 tax year, a consent to public disclosure of certain information included in the application. (Applicants seeking a grant for the 2010 tax year or a tax credit for 2009 or 2010 may, but are not required to, submit an optional consent to public disclosure.) No additional materials may be submitted unless expressly requested by the IRS. Specifically, applicants are prohibited from including brochures or other presentations as part of the application. However, applicants will be required to notify the IRS of any significant changes in the information set forth in the application, including any new developments with respect to each project for which they are seeking a tax credit or grant.

While IRS Form 8942 and the related instructions are not yet available, Notice 2010-45 indicates that the following information will be required on IRS Form 8942:

- general information about the applicant, including: name, address, taxpayer identification number, entity type, ownership information, and a contact person for the applicant;
- whether the applicant is requesting a grant in lieu of a tax credit;
- a description and the amounts of the applicant’s qualified investments for 2009, 2010, or both;
- the number of full-time and part-time employees employed by the applicant;
- the number of full-time and part-time employees and contractors in the U.S. whose work is directly billed to the project, and their average salary and compensation information;

- the current status of the project, such as whether the project is active, terminated, or suspended; and
- whether the project will produce a new or significantly improved technology, or a new application or significant improvement to existing technology, and whether the project is expected to lead to the construction or use of a contract production facility in the U.S. in the next five years.

The Notice also sets forth the format of, and information required to be included in, the Project Information Memorandum. In addition to following strict formatting guidelines, applicants must adhere to word limits in answering several questions relating to how the project satisfies the criteria for qualifying therapeutic discovery projects set forth in Section 48D of the Internal Revenue Code. Moreover, each Project Information Memorandum must include short statements, not to exceed 250 words each, in response to the following:

- the scientific rationale, research and development plan and scientific evidence relied upon by the applicant in determining that the proposed project satisfies the criteria;
- the state of development of the project, including a description of pre-clinical and clinical trial results that are relevant to the proposal; and
- the resources, management experience, and organizational capacity of the applicant and how the applicant believes that such resources, experience and capacity will support successful completion of the project.

In addition, each applicant seeking a grant in lieu of a tax credit will need a Data Universal Numbering System (DUNS) from Dun and Bradstreet and also will need to register with the Central Contractor Registration (CCR). A DUNS number may be requested at no cost by calling the toll-free DUNS Number request line at 1-866-705-5711. CCR registration can be completed at [Central Contractor Registration \(CCR\)](#).

Certain Medical Device Companies May Qualify

Notice 2010-45 confirms the availability of the program for certain medical devices. For a medical device to qualify, it must be a product, process, or technology that furthers the delivery or administration of therapeutics. "Therapeutics" means drugs, as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (FFDCA), or medical devices, as defined in Section 201(h) of the FFDCA. Biologics that are licensed under the Public Health Service Act generally will be either drugs or medical devices. As an example, projects focused on drug-eluting stents or infusion pumps would constitute qualifying programs. However, a medical device, or other product, process, or technology that does not further the delivery or administration of a drug or medical device would not meet the program requirements because it does not deliver or administer a therapeutic.

Public Disclosure

The identity of all tax credit and grant recipients will be publically disclosed, along with the amount of the tax credit or grant. In addition, the IRS will publish the type and location of the qualifying project for 2009 tax year grant recipients, subject to certain Freedom of Information Act (FOIA) protections for trade secrets and other confidential commercial and financial information. The IRS will publish the

type and location of the qualifying project for 2010 tax year grant recipients and tax credit recipients only if the recipient has provided its consent.

To protect trade secret, confidential, or privileged information contained in an application from disclosure under FOIA, an applicant should assert a claim of exemption from FOIA under 5 U.S.C. § 552 on the first page of its Project Information Memorandum. In addition, each line or paragraph of the memorandum that contains trade secrets, confidential, privileged, or otherwise exempt information must be specifically identified and marked as such in the application.

Advice for Applicants

Notice 2010-45 states that the estimated average time for preparing an application for a tax credit or grant under the program is approximately 12 hours. *Accordingly, we recommend that companies interested in applying for the program begin gathering the information and supporting materials and preparing a Project Information Memorandum for each potential qualifying project as soon as possible.* As part of this process, applicants are encouraged to begin coordinating with their tax professionals or auditors, as well as outside advisors, to determine their eligibility to participate in the program and collect relevant supporting data. Applicants also should read carefully Notice 2010-45 along with the program fact sheet published by the Department of the Treasury (available at <http://www.ustreas.gov/press/releases/reports/5.21.10%20therapeutic%20discovery%20fact%20sheet.pdf>).



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

Atlanta

Michael D. Haun
404-815-2279
michaelhaun@paulhastings.com

Philip J. Marzetti
404-815-2258
philmarzetti@paulhastings.com

Los Angeles

Rob R. Carlson
213-683-6220
robcarlson@paulhastings.com

Alexander M. Lee
213-683-6160
alexanderlee@paulhastings.com

Orange County

Michael G. McKinnon
714-668-6240
michaelmckinnon@paulhastings.com

San Francisco

Samantha H. Eldredge
415-856-7098
samanthaeldredge@paulhastings.com

Jeffrey T. Hartlin
415-856-7024
jeffhartlin@paulhastings.com