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Details on Therapeutic Discovery Tax Credit for Small Employers Released

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The Affordable Care Act (the "Act")[1] enacted a “"ualified therapeutic discovery tax credit" for small employers. The purpose of the credit is to encourage investment in product development that will enhance medical care and at the same time promote economic growth and create jobs. The credit, contained in a new Section 48D of the Internal Revenue Code, provides a 50 percent tax credit for expenditures for developing therapeutic products and methods. The credit applies only to expenditures made in taxable years beginning in 2009 and 2010 and is limited to an aggregate total over both years of $1 billion. The Department of the Treasury was required by the Act to release guidance on the program within 60 days of enactment. On May 21, 2010, the Department of the Treasury released Notice 2010-45, which describes the application process for obtaining credits and explains how the total credit amount will be allocated among applicants. A news release and a link to the Notice are available at http://www.ustreas.gov/press/releases/tg712.htm. Section 9023(e) of the Act also provides that qualified recipients can receive grants in lieu of credits; in this analysis, requirements for the grant are the same as those indicated for the credit unless otherwise specified.

What Is a Qualifying Therapeutic Discovery Project.

The Act prescribes four categories of qualifying projects:

- A project designed 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 by the FDA of a new drug application or a biologic license application;
- A project designed to diagnose diseases or conditions (the Notice uses as an example point of care diagnostics for infectious agents);
- A project designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions (the Notice uses

as an example a test that would determine which patients would be likely to respond to a particular drug or device); and

- A project designed to develop a product, process or technology that furthers the delivery or administration of therapeutics.

New drugs and biologics are thus by definition included as qualifying projects in the first category. The Notice points out that medical devices are not included in the first category but can be qualifying projects if they fall within one of the other three categories. Similarly, generic drugs, biosimilar products, dietary supplements, and most cosmetics would also not be included in the first category because they are generally not the subject of a new drug or biologic license application.

The fourth category is a product, process or technology that furthers the delivery or administration of therapeutics. The Notice explains that "therapeutics" are drugs or medical devices, a narrower category than "therapies." Drug-eluting stents and infusion pumps are examples of qualifying products. 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 fall within this category. Products, processes or technologies that deliver other therapies which are not therapeutics, such as speech or physician therapy, are not included in this category.

Timetable and Application Process.

The Notice explains that there will be a primary allocation round this summer and fall to allocate available credit amounts. This round will cover expenditures made (or to be made) in tax years beginning in both 2009 and 2010. If any of the $1 billion credit amount is not allocated in the primary round, subsequent allocation rounds will be held.

A separate application must be submitted for each project; a single taxpayer may submit several applications. Applications for certification must be submitted to the IRS by July 21, 2010 to be considered in the primary allocation round. (Applications are to be submitted on a new IRS Form 8942, to be released by June 21, 2010.) Between that time and September 30, 2010, the IRS will conduct a preliminary review to determine that the applicant is eligible for the credit and that the application is complete.

Substantive review by the Department of Health and Human Services ("HHS") will take place during October, 2010 and will determine whether each submitted project meets or does not meet the certification criteria. Apparently each project will receive a "yes-no" decision; the projects will not be ranked or rated. The IRS will approve or deny the application for certification no later than October 29, 2010.

Applicants have no right to a conference with reviewers or to an appeal of a negative decision.

Allocation of Available Credits.

Once all qualifying projects in the initial round are determined by the IRS and HHS, the IRS will certify each program for a specified amount of qualifying investments. The total amount of investment certified is not to exceed $2 billion (credits for 50 percent of $2 billion in investments equals the $1 billion available). The IRS will start by certifying an equal amount of qualifying investments for each project in the pool. For example, a project with $2 million in qualifying investments would receive the same dollar allocation amount as a project with $200,000 in qualifying investments. If a project is allocated an amount greater than its anticipated qualifying investments, the excess will be allocated among all projects where investments exceed their allocation.

The Notice provides, however, that no single taxpayer, regardless of the number of projects, will be certified for a total of more than $10 million in qualified investments. Thus, no taxpayer can receive a credit of more than $5 million.

Each successful applicant taxpayer will receive a certification for a specified dollar amount of credit and of qualified investment eligible for the credit. If the taxpayer’s actual amount of qualified investment in tax years 2009 and 2010 is less than the allocated amount, the taxpayer’s allocated credit amount is reduced by 50 percent of the shortfall.

Qualifying Recipients.

A qualifying recipient can have no more than 250 full- or part-time employees at the time of the application. The Notice clarifies that leased employees are not included as employees in this count. Related entities, including foreign entities, will be aggregated for purposes of determining whether the 250-employee threshold is exceeded. Thus, while a United States taxpayer with a foreign parent is eligible for the credit, the employees of the foreign parent and its subsidiaries will be included in determining whether the employee limit is exceeded.

Governmental entities, tax-exempt organizations, and pass-through entities owned to any extent by either governmental entities or tax-exempt organizations are not qualifying recipients of grants but can receive credits. A pass-through entity must determine if any of its partners or other holders of equity or profits interests are governmental or exempt before applying for a grant.

Information to Be Submitted in Application for Certification

Although the application form, Form 8942, has not yet been released, the Notice indicates in an appendix what the questions will be. The application is to include a Form 8942, to be reviewed by the IRS, and an attached Program Information Memorandum, to be reviewed by HHS.

The IRS must determine that the project is among those with the greatest potential to create and sustain high quality, high-paying jobs in the United States, and to advance United States competitiveness in the fields of life, biological, and medical sciences. Among other items, information on the Form 8942 is to include:

- The number of employees in the United States whose work is directly billed to the project and the average salaries of such employees, along with the number of contractors in the United States paid for work on the project the average monthly hours and compensation of such contractors. This information will be used to determine which projects have the greatest potential to create high quality, high-paying jobs in the United States.
- Whether the project is active, and if not, the reason why. A project that is terminated or suspended because it failed a clinical trial, failed a pre-clinical research milestone, or failed to secure FDA licensure will be ineligible for certification because it has insufficient potential to advance United States competitiveness in life sciences.

- Whether the project is expected to lead to the construction or use of a contract production facility in the United States in the next five years. This information will be used to determine which projects have the greatest potential to advance United States competitiveness in life sciences.

The Program Information Memorandum is to include the following information, subject to strict word count limits.

- In 250 words, an overview of the project, including, if the project involves a new therapy, why the therapy is novel.
- In 250 words, the scientific rationale underlying the project, including the research and development plan and the scientific evidence. Five literature citations may be included.
- In 250 words, the project's stage of development, including the status of any FDA approvals and a summary schedule for development of the project, including timelines and milestones.
- In 250 words, the applicant's resources, management experience, revenue levels and sources for the project over the past three years and in the future, and investments by others in the development or commercialization of the project.

HHS will use this information to determine whether the project is a qualifying type of project and shows a reasonable potential of achieving one of the three statutory goals described below.

Determination of Qualifying Projects.

HHS must determine that the project falls within one of the four prescribed categories of qualifying projects described above. Further, based on the information included in the Program Information Memorandum, HHS must determine that the project has a reasonable potential of developing new therapies, lowering United States long-term health care costs, or significantly advancing the goal of curing cancer within thirty years (the three goals set forth in the statute).

Publicity of Information

The Notice provides that the identity and the amount of the credit for successful applicants will be publicly disclosed. In addition, in the case of applicants receiving 2009 grants, or applicants receiving credit or 2010 grant approval who have consented to disclosure, the IRS will also make public the type and location of the project, as permitted by the statute. The IRS will ask, but not require, in the application process that applicants for credits, or for 2010 grants, execute a consent to the IRS's disclosure of this information. No information on unsuccessful applications will be made public. Information that is to be made public will be available through the Freedom of Information Act ("FOIA") process.

The Notice indicates that if information contained the Program Information Memorandum (to be attached to the Form 8942) is considered to be a trade secret, confidential, or otherwise exempt from disclosure under FOIA, the claim of exemption must be asserted in the application in a specified manner.

Receiving Grants Instead of Tax Credits.

The statute permits applicants to apply for grants rather than tax credits, enabling quicker receipt of funds. The Notice provides that if an applicant so elects on the Form 8942, an application for a credit will be treated as an application for a grant. The grant can be requested for 2009 only, for 2010 only, or for both 2009 and 2010. An application for a 2010 grant will be considered effective the day after the last day of the taxpayer's 2010 tax year. In this way, the program has enabled applications for grants for both 2009 and 2010 to be submitted in the first allocation round (despite that statutory provision that an application for a grant for 2010 can be submitted no earlier than the end of that tax year). If the taxpayer's filed Form 8942 requested a credit, the taxpayer can file an amended 8942 requesting a grant. For a 2009 grant, this amended form must be filed no later than the due date (including extensions) for the 2009 return.

If the taxpayer's Form 8942 for tax year 2009 elected to receive a grant, or if an amended form requesting a grant is filed on or by September 30, 2010, the grant will be authorized for payment no later than October 29, 2010 if the amount of qualified investment reported as incurred by September 30, 2010 on the Form 8942 is at least equal to the certified amount of qualified investment. Grants for 2009 not meeting these conditions will generally be paid within 30 days after the end of the tax year or the amended form filing, as applicable. Grants for tax year 2010 will generally be paid 30 days after the end of the taxpayer's 2010 tax year.

To make an election to apply for a grant, the applicant must have a Data Universal Numbering System (DUNS) number from Dunn and Bradstreet and be registered with the government's Central Contractor Registration.

Next Steps.

Even though the actual application form is not yet available, taxpayers who believe they have qualifying projects should start crafting answers now. The strict limits on length of narrative responses make it imperative that projects and their ability to meet statutory standards be described clearly and concisely. Being able to explain the significance of highly technical matters in terms that are easy to understand will be at a premium. Applications should be submitted by July 21 but under the approval and allocation process set forth in the Notice, there is no advantage to submitting an application earlier to have it "first in line." Separate applications should be submitted for as many projects as possible.

[1] "Affordable Care Act" means The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010 (HCERA).

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