

E-ALERT | Health Care

June 2010

GUIDE TO APPLYING FOR THERAPEUTIC DISCOVERY PROJECT GRANTS AND TAX CREDITS

In an April 2010 alert entitled “Therapeutic Discovery Project Tax Credits and Grants for Small Employers,” we discussed section 9023 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (the Act), which establishes the grant and credit program (the Program). The Program provides to certain companies with no more than 250 employees a grant or nonrefundable tax credit for up to 50% of a “qualified investment” made in 2009 and 2010 in a “qualifying therapeutic discovery project.” As implemented by the Internal Revenue Service (IRS), the grant or credit is available for up to \$10 million in qualified investments per taxpayer, which is equivalent to \$5 million in grants/credits per taxpayer. Effective May 21, 2010, the IRS has issued guidance on the Program in the form of IRS Notice 2010-45 (the Notice). This alert discusses the application process set forth in the Notice and describes issues relating to the allocation of grants/credits under the Program. In addition, this alert addresses some considerations for potential applicants as they complete Form 8942 and the Project Information Memorandum (PIM), which comprise the application for the grant/credit.

I. Application Process

Applicants may submit applications once the IRS releases Form 8942, which will be released no later than June 21, 2010. Applications will be accepted until July 21, 2010. Between July 21 and September 30, 2010, the IRS will engage in a preliminary review of the applications to determine whether the applications are complete. All complete applications will be deemed submitted on October 1, 2010, and the IRS will approve or deny all applications by October 29. Because all applications will be deemed simultaneously submitted on October 1, there does not appear to be an advantage to submitting an application early in the application window.

The final approval of grants/credits will be based solely upon the factors described below. Other factors, such as the geographic location of the project within the United States, will not be considered. The IRS will be responsible for assessing the economic merits of an application, while the Department of Health and Human Services (HHS) will assess an application’s scientific and medical merit. It is our understanding that HHS will likely use panels of outside reviewers chosen on the basis of the expertise necessary to assess each project.

II. The Application

The application for project grants/credits consists of two components: (1) Form 8942, which asks several basic questions about the project, and (2) the PIM. These documents will be used by the IRS and HHS to determine whether a project meets the definition of a “qualifying therapeutic discovery project” and whether the expenditures should be certified as “qualified investments” eligible for a grant/credit.

The first part of the application is Form 8942. This form asks several questions about the applicant and the project so that the IRS can establish basic eligibility and assess a project's likelihood of creating jobs and infrastructure within the United States. For more information about issues that applicants should consider when completing Form 8942, please see attached Appendix A.

The second part of the application is the PIM. This part of the application provides an opportunity for the applicant to elaborate upon the details and scientific underpinnings of the project. For instance, the applicant must explain how the project meets the statutory definition of a "qualifying therapeutic discovery project" through demonstrating how it is designed to diagnose a disease or condition, determine molecular factors related to diseases and conditions in order to guide treatment decisions, develop a product to treat or prevent a disease or condition, or develop a product, process, or technology to aid the delivery of therapeutics. The PIM also provides an opportunity to explain how the project will fulfill the policy goals of the Program. For more information about issues that applicants should consider in drafting a PIM, please see attached Appendix B.

III. The Allocation of the Grants and Credits

The Notice creates a complex process for allocating the grants/credits. Only those expenditures that the IRS certifies as qualified investments will be eligible, and no more than \$5 million in grants/credits will be allocated per taxpayer. **To allocate the grants/credits, the IRS will pick an initial amount that it will allocate equally to all eligible projects.** The IRS will then engage in two stages of rebalancing to ensure statutory compliance: (1) it will reallocate the excess grant/credit from projects where qualified investments are less than the initial allocation, and (2) it will reallocate any excess from taxpayers whose grants/credits in the aggregate would exceed the \$5 million maximum per taxpayer.

For some projects, the IRS's initial grant/credit allocation will be larger than the qualified investment associated with the project can support, because a project can receive a grant/credit amounting to no more than 50% of its qualified investment. Under the first reallocation, any project where the qualified investments would support less than the initial allocation will be certified only up to the level of its qualified investments. The difference between the amount certified and the initial allocation will be reallocated to any projects where qualified investments would support a grant/credit in excess of the initial allocation. This reallocation will continue until no project is certified for a grant/credit of more than 50% of the qualified investments attributable to that project.

Under the second stage of reallocation, the IRS will ensure that no single taxpayer receives grants/credits that exceed \$5 million in the aggregate. If a taxpayer submits applications for multiple projects, the combined allocations for those projects could exceed the \$5 million statutory limit. Thus, the IRS will reduce the allocations for a taxpayer's projects such that the total of the grants/credits awarded to that taxpayer does not exceed the limit. The difference between the amount awarded and the amount the taxpayer would have received prior to this stage of reallocation will be reallocated among all taxpayers who have not yet hit the \$5 million cap and whose projects have qualified investments that would support larger grants/credits.

If, after the reallocations, the IRS has not yet awarded \$1 billion in grants/credits, it may initiate another round of applications, to be announced later.

IV. Defining a Qualifying Project

In some cases, such as work on a single compound for multiple indications, the applicant may have multiple teams pursuing separate research. Such work may arguably be classified as one or multiple projects. Because the IRS guidance does not define "project," in cases where it is uncertain if

research constitutes one or many projects, the applicant seems to have the discretion to present its work as one project or several. **Given the structure of the allocation process, an applicant will most likely fare better by submitting separate applications for projects that can be segregated into multiple qualified projects, instead of submitting an omnibus application for a single qualified project.** A single project, no matter how large the qualified investments, will be given the same initial allocation as every other project, whereas each separate qualified project will receive a separate initial allocation. Moreover, separate applications will enable applicants to provide greater detail regarding their projects within the constraints of the 250-word limitation on project descriptions, discussed in Appendix B.

While having multiple certified projects may maximize an applicant's ability to receive additional resources, applicants should bear in mind that certification decisions will be made on the basis of the strength of the application. Thus, where they may choose between submitting projects as one or separately, a single application may present a more compelling case for certification.

* * * * *

The therapeutic discovery project grant or tax credit is a unique and complex program. However, it has the potential to provide critical financial resources to small companies performing valuable research and development. We would be pleased to discuss this program and its potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

Anna Kraus	202.662.5320	akraus@cov.com
Demetrios Kouzoukas	202.662.5057	dkouzoukas@cov.com
Ellen Corenswet	212.841.1256	ecorenswet@cov.com
Rod DeArment	202.662.5900	rdearment@cov.com
Ryan Budish	202.662.5546	rbudish@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein. Under IRS standards of professional practice, certain tax advice must meet requirements as to form and substance. To assure compliance with these standards, we disclose to you that this communication is not intended or written to be used, and cannot be used, for the purpose of avoiding penalties.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2010 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.

APPENDIX A: FORM 8942

Form 8942 asks several questions about the applicant and the project so that the IRS can establish basic eligibility and assess a project's likelihood of creating jobs and infrastructure within the United States.

Questions 1 to 5: These questions ask about the ownership of the entity applying for the grant/credit and the number of people employed by the entity. Only taxpayers with 250 employees or fewer are eligible for the Program. Full-time and part-time employees count equally as employees, but leased employees are not included in the count.

Question 6: This question asks the applicant to elect between receiving a grant or a tax credit. Entities that do not expect to have enough net income to pay income tax would elect to receive a grant in lieu of a tax credit by checking the applicable box on Form 8942. For expenditures made during the 2010 taxable year, if the applicant initially applies for a credit but then does not have taxable income for the year, the applicant may subsequently file an amended Form 8942 requesting a grant by the due date (including extensions) for filing the applicant's 2010 tax return.

To receive a grant/credit, the applicant does not need to be a corporation. Limited liability companies and partnerships will be eligible to receive grants/credits, but will be eligible only if none of their direct or indirect members or partners are federal, state or local governments, 501(c) organizations, or cooperative energy companies under Section 54(j). The exclusion for certain types of partners applies only to partnerships or other pass-through entities.

Any applicant requesting a grant in lieu of a credit must have a Data Universal Numbering System (DUNS) number and must register with the Central Contractor Registration, as described in the Notice.

Question 7: This question asks the applicant to describe the qualified investments in the project for which it is seeking the grant/credit. These qualified investments may include, among others, wages, supplies and lab costs, depreciable property and outside contractor costs. In addition, it appears that patent license payments would also be qualified investments. Expenditures may be qualified investments even if they are made for products and development candidates that have been designated as orphan drugs.

Qualified investments, however, will not include compensation for the CEO and the four highest-paid officers. It is our understanding that this limitation applies equally to both public corporations and private entities. However, we also understand that the IRS is aware that this rule would exclude significant portions of smaller companies' expenditures and is currently considering how to address this problem. We will continue to monitor this issue for additional guidance from the IRS. Other expenses that are not considered qualified investments include interest expenses, facility maintenance expenses, and indirect costs related to administrative, service, or support departments (including personnel, accounting, data processing, security, and legal).

For an application that covers the 2010 taxable year, some of the qualified investments will likely be projected but not yet realized. In such circumstances, the application should provide an estimate that represents that applicant's fair and honest expectation of what it will spend, taking into account its current plans, resources, and funding opportunities.

Although a wide variety of expenditures can be qualified investments, applicants must be aware that the types of qualified investments claimed will be one factor upon which an application will be

judged as a qualifying project. The IRS will review applications to identify those that are most likely to create and sustain jobs in the United States and advance the United States' competitiveness in medical, biological and life sciences. For example, expenses related to clinical trials conducted in Canada or other foreign countries would likely be qualified investments. However, the fact that these trials are conducted outside the United States may suggest that the project is less likely to lead to jobs in the United States. On the other hand, even contracted research activities and other outsourced expenses (not just internal expenses) may demonstrate an ability to create additional jobs, as long as the outsourced work is being performed within the United States.

Questions 8 and 9: These questions ask for information regarding the number of, and compensation paid to, workers on the project in question. These questions cover full-time and part-time employees and outside contractors who work in the United States. The data will be used to determine "which projects have the greatest potential to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States."

Question 10: This question asks whether, as of the date of the application, the project is active, terminated or suspended. If the applicant has terminated or suspended the project because it failed a clinical trial, failed a pre-clinical research milestone or failed to secure FDA licensure, then it cannot be certified. It appears that projects that have experienced these kinds of setbacks, however, will be eligible for certification if the project is still ongoing. Termination or suspension for some other reason, such as a lack of funding, will not preclude the project from certification, although there is no guidance on how HHS or the IRS will weigh that factor in determining which projects to certify.

Question 11: This question asks whether the project will produce new or significantly improved technology and whether it will lead to the construction or use of a contract production facility within the next five years. This information will be used to determine which projects are most likely to advance the United States in competitiveness in life, biological, and medical sciences.

An applicant's answers on Form 8942 will comprise part of the basis for evaluating which projects to certify. The other, and equally important, component will be the information proffered in the Project Information Memorandum, described in Appendix B.

APPENDIX B: PROJECT INFORMATION MEMORANDUM

The second component of the application is the PIM. This part of the application provides an opportunity for the applicant to elaborate upon the scientific underpinnings of the project and explain how the project will fulfill the policy goals of the Program. In particular, the PIM provides an opportunity for the applicant to describe how the project meets the definition of a qualifying therapeutic discovery project, why it deserves to be certified over other projects, the scientific basis for believing the project will yield the expected outcomes, and the financial status of the project. These considerations will inform the HHS and the IRS decision regarding certification of the project.

I. Overview

The first part of the PIM asks for an overview of the project, which may not exceed 250 words. If a project involves a new therapy, the overview must include an explanation of why the therapy is novel.

II. Statutory Qualifications

The second part of the PIM relates to proving that the project satisfies the statutory threshold for a qualifying therapeutic discovery project. **To establish that the project meets the statutory qualifications, the applicant must establish that it meets at least one of the following four criteria, and provide a 50-word statement justifying each affirmative response:**

(1) The project is designed to develop a product to treat or prevent a disease or condition by conducting pre-clinical activities, clinical trials, or clinical studies, or by carrying out research protocols for the purpose of securing approval of an NDA or BLA. For purposes of this question, generic drugs and biosimilar products do not qualify. Similarly, dietary supplements and most cosmetics do not qualify.

(2) The project is designed to diagnose a disease or condition. For purposes of this question, any product that diagnoses a disease or condition would qualify, regardless of whether the test is based upon molecular diagnostics, as described in Question 3. An example of a qualifying product might be one that provides point-of-care diagnostics for infectious agents.

(3) The project is designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions. This might include, for example, a test that would determine which patients with a particular disease or condition would be likely to respond best to a particular drug or device.

(4) The project is designed to develop a product, process or technology to further the delivery or administration of therapeutics. For purposes of this question, a drug-eluting stent or infusion pump would be an example of a product that furthers the delivery or administration of a drug and would meet the requirements of this provision. 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 requirements of this provision. For instance, products, processes or technologies that assist in the delivery of speech, physical, and cognitive therapies would not qualify. In addition, a project to provide health IT software would not meet the statutory definition and could not be certified.

III. Certification Criteria

Not all projects that meet the statutory criteria for a qualifying therapeutic discovery project will be certified. Instead, HHS will select for certification those projects that best meet the statutory goals. The answers to questions 5 through 11 provide the basis for making that determination.

Questions 5 through 8 serve to ensure that projects meet the Act's specific statutory selection criteria. **An applicant must answer "yes" to one or more of the following questions and substantiate each affirmative response with a 50-word statement:**

Question 5: Is the project likely to result in one or more new therapies? For purposes of this question, the therapy must be novel and meaningfully distinguishable from current treatments. Thus, a therapy in the same class as existing therapies would not qualify unless such therapy is expected to offer a significant enhancement in safety or effectiveness.

Question 6: If the answer to Question 5 is "yes," is the new therapy expected to: (a) treat areas of unmet medical need, or (b) prevent, detect, or treat chronic or acute diseases or conditions? For purposes of this question, qualifying products would include "novel influenza vaccine technologies, broad spectrum anti-viral medications, novel antibiotics, and platform vaccine technologies." In addition, "products that detect or prevent diseases and conditions are also covered by this provision."

Question 7: Is the project likely to reduce long-term health care costs in the United States? The applicant must explain how the project is likely to lead to *actual* cost reductions and should provide a reasonable estimate of these savings.

Question 8: Is the project likely to significantly advance the goal of curing cancer within the next 30 years?

On the basis of the applicant's answers to these questions, HHS will determine whether a project meets the Act's specific statutory selection criteria.

IV. Reasonable Potential to Achieve Statutory Goals

If HHS determines that the project meets the statutory certification criteria covered in questions 5 through 8, then HHS must determine whether the information provided supports the conclusion that there is a reasonable potential that the project will achieve one or more of the statutory goals. The IRS does not define "reasonable potential," nor is it a term commonly used in grant determinations. This vague standard, therefore, leaves HHS with considerable flexibility in determining which projects are most likely to satisfy the statutory goals. Accordingly, if HHS wishes to limit the number of qualifying projects, it may be able to set a high bar for meeting the "reasonable potential" standard. Questions 9 through 11 seek to elicit the information that HHS will need to determine which projects are most likely to succeed. Applicants' responses may not exceed 250 words for each question.

Question 9: This question asks for data regarding the scientific rationale for the project. Applicants may establish the project's scientific basis by reference to prior work, explaining the research plan, and describing any peer review of the project. Although the IRS does not provide any additional guidance on this question, presumably HHS will use applicants' responses to this question to choose those projects with the greatest chance of success, based upon their scientific underpinnings. One of the factors that HHS will consider is whether the project has been subject to peer review.

Question 10: This question asks applicants to describe the current stage of the project's development. Information relevant to this question includes pre-clinical and clinical trial results, the status of any applications with the FDA or other relevant regulatory approvals, results of any human testing, and a description of the planned research and development strategy. Although the IRS does not provide any additional guidance on this question, presumably HHS will use applicants' responses to this question to select those projects that are closest to being complete. Accordingly, projects that have successfully completed later stage clinical trials may be more likely to receive certification than pre-clinical development programs and projects that have completed earlier stage clinical trials.

Question 11: This question concerns an applicant's capacity to bring the project to fruition. Information relevant to this question includes a description of the applicant's resources and experience, the project's revenue levels for the past three years, revenue levels and funding sources for the proposed research plan outlined in response to Question 10, a description of significant venture capital investments and strategic partnerships, and whether the project is currently ongoing.

The Notice states only that HHS will use applicants' responses to this question to select those projects with that are best able to bring their projects to fruition. While the IRS does not explain which factors HHS must consider in making that determination, it appears that this criterion will favor those projects that are already well funded. In addition, the criterion appears to favor more established companies that have a stronger organizational structure. However, this question will provide an opportunity for smaller or newer companies to showcase their competencies and demonstrate how they will be able to bring their project to successful completion.

On the basis of the answers to these questions, HHS will determine which projects are most likely to fulfill the Act's statutory goals and should be certified.