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CLIENT ALERT

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IRS Issues Guidance on Qualifying Therapeutic Discovery Project Program

On May 21, 2010, the Internal Revenue Service ("IRS") issued Notice 2010-45 (the "Notice"), establishing the qualifying therapeutic discovery project program under Section 48D of the Internal Revenue Code and setting forth the procedures for applying for IRS certification of an applicant's qualified investment and eligibility for a tax credit or grant. Section 48D was recently enacted as part of H.R. 3590, the Patient Protection and Affordable Care Act. Read Notice 2010-45. Read our prior client alert describing the Section 48D statutory requirements. Read the formal announcement of the program guidance by Treasury Secretary Timothy Geithner and National Institutes of Health (NIH) Director Francis Collins and a fact sheet released with the announcement.

Timing of Application and Review

Contrary to concerns, the application and review process is not on a "first-come, first-serve basis." Rather, applicants must submit their applications by July 21, 2010, and Health and Human Services ("HHS") and the IRS will review the applications based on prescribed timeframes. The timeframes are set forth below.

Date	Event
May 21, 2010	Issuance of Notice 2010-45
June 21, 2010	Issuance of IRS Form 8942 and first day to submit applications
July 21, 2010	Deadline for submission of applications
July 22 - Sept. 30, 2010	Preliminary review of applications
October 1, 2010	Applications deemed submitted
October 29, 2010	Deadline for approval or denial

Applications can be filed no earlier than the issuance of new IRS Form 8942, which is expected to be issued on or about and no later than June 21, 2010. Thus, applicants will have approximately 2 months to complete and file their applications.

Application Process

The application will consist of (i) the Form 8942 and (ii) a Project Information Memorandum. The Form 8942 has not yet been issued. The Notice (pp. 26-28) provides details of the information that will be required to complete Form 8942. Of importance, the Notice indicates that the IRS will be reviewing information set forth on the Form 8942 regarding (i) the applicant's tax and entity characteristics; (ii) information

relating to employment for purposes of determining whether the project is a project that has the "greatest potential" to create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States, and (iii) information relating to the nature of the project and whether it has the "greatest potential" to advance United States competitiveness in the fields of life, biological, and medical sciences.

With respect to jobs creation, the Notice indicates that Form 8942 will require information on full-time and part-time employees, leased employees, and contractors with respect to the project. With respect to competitiveness, the Notice indicates that the IRS will review information relating to whether the project is active, terminated, or suspended in determining whether it has the greatest potential to advance United States competitiveness. A project that has been terminated or suspended because the project failed a clinical trial, failed a preclinical research milestone, or failed to secure FDA licensure will be determined to have insufficient potential to advance United States competitiveness in the fields of life, biological and medical sciences and thus will be determined to be ineligible for certification.

The Notice also indicates that the IRS will consider, with respect to competitiveness, whether the project:

a. will produce a new or significantly improved technology, or a new application or significant improvement to existing technology, as compared to commercial technologies currently in service; and

b. is expected to lead to the construction or use of a contract production facility in the United States in the next five years.

Appendix A of the Notice (pp. 28-35) sets forth the format for the Project Information Memorandum and the information to be contained in the Project Information Memorandum. In particular, the format will follow a question-and-answer format keyed to certain of the statutory requirements and discretionary factors. Each question will require the applicant to provide a brief narrative, illustrating why the applicant's project satisfies each factor. The Notice provides strict word limitations for each question in the Project Information Memorandum. Appendices, brochures, and other materials are not permitted except where specifically noted. The Notice indicates that HHS will be reviewing the Project Information Memorandum as part of its review responsibilities under the program.

Certification Process

The Notice states that a primary allocation round will be conducted to issue certifications for both qualified investments made in taxable years beginning in 2009 and qualified investments made in taxable years beginning in 2010. If any portion of the $1 billion available under the program for allocation remains unallocated after this primary allocation, one or more additional allocation rounds may be conducted.

The Notice notes that the aggregate amount of qualified investments that will be certified by the IRS will not exceed $2 billion (i.e., $1 billion of credits or grants). The Notice states that the IRS will certify an *equal amount* of qualified investment for each successful project. However, the applicant is only entitled to have its qualified investment attributable to a project certified . Consequently, if the applicant's qualified investment is lower than the "equal amount" set by the IRS for each project, the IRS will certify the actual qualified investment. Any unused certification amount will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments (i.e., their actual qualified investment exceeds the "equal amount" set by the IRS). This reapportionment will continue until no project receives certification for an amount that exceeds its actual qualified investment.

Cap on Qualified Investment

Section 5.02(7) of the Notice provides that the IRS will not certify more than $10 million for a single taxpayer, such that no taxpayer will be allocated more than $5 million in credits or grants in the aggregate for 2009 and 2010, regardless of the number of projects the taxpayer sponsors. If a taxpayer would otherwise receive certification for an amount of qualified investment that exceeds this $10 million threshold, the amount in excess of

$10 million will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments. Such reapportionment will continue until no taxpayer receives certification for an amount that exceeds the $10 million threshold.

Qualifying Therapeutic Discovery Project

The Notice (pp. 32-35) provides additional guidance on the meaning of a "qualifying therapeutic discovery project" and the three threshold criteria for qualifying as such a project. Under Section 48D, a "qualifying therapeutic project" is a project designed (A) 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 under Section 505(b) of the Food, Drug and Cosmetic Act or Section 351(a) of the Public Health Services Act, (B) to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions or (C) to develop a product, process or technology to further the delivery or administration of therapeutics.

In order to satisfy item (A), the Notice provides that the project must be designed to treat or prevent diseases or conditions. It must be designed to do so by conducting pre-clinical activities, clinical trials, or clinical studies or by carrying out a clinical protocol. It must also be for the purpose of obtaining approval of a product under one of two statutory provisions — Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (a new drug application) or Section 351(a) of the Public Health Service Act (PHSA) (a biologic license application). Generic drugs, which are approved under Section 505(j) of the FFDCA, andbiosimilar products, which are approved under Section 351(k) of the PHSA, would be excluded, as are dietary supplements and most cosmetics, because they are generally not the subject of a new drug or biologic license application.

Item (B) is a product to diagnose a disease or condition. Any product that diagnoses a disease or condition would meet this criterion, whether or not it determines molecular factors or is a molecular diagnostic. Item (B) also covers a product that determines 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.

The Notice provides more detail on the broader category in item (C). To qualify under item (C), a product, process, or technology must further the delivery or administration of therapeutics. The Notice states that for this purpose, the term "therapeutics" means drugs or medical devices, as those terms are defined in Section 201(g) and (h) of the FFDCA, 21 U.S.C. 321(g) and (h). Biologics that are licensed under the PHSA will generally be either drugs or medical devices. Thus, 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 because such products do not deliver or administer a therapeutic for purposes of item (C). The term "therapeutic" is narrower than the term "therapy," which appears elsewhere in Section 48D, and products, processes or technologies that deliver other therapies that are not therapeutics, such as speech, physical, and cognitive therapies, would for the same reasons be excluded.

Discretionary Factors

The Notice (pp. 33-35) indicates that HHS will determine whether the project has a "reasonable potential" to meet certain discretionary factors set forth in the statute; i.e., the project must be designed and demonstrate a reasonable potential (i) to result in new therapies (I) to treat areas of unmet need or (II) to prevent, detect or treat chronic or acute diseases and conditions, (ii) to reduce long-term health care costs in the United States or (iii) to significantly advance the goal of curing cancer within a 30-year period.

In order to qualify as a "new therapy," the Notice states that the therapy must be novel and cannot be the same as, or difficult to meaningfully distinguish from, a therapy currently on the market. For example, this means the therapy should not be in the same class as existing therapies, unless such therapy is expected to offer a significant enhancement in safety or effectiveness. The Notice also states that "unmet medical needs," for purposes of this factor, would include novel influenza vaccine technologies, broad-spectrum anti-viral medications, novel antibiotics, and platform vaccine technologies. The Notice further notes that, in addition to new therapies that treat diseases and conditions, such products that detect or prevent diseases and conditions are also covered by this provision.

The Notice provides that the applicant's response should explain how the project is likely to reduce health care costs, including a description of how the project will lead to actual cost reductions, not just substituting one cost for another, and the basis of this determination. The narrative should provide a reasonable estimate of savings and demonstrate a reasonable potential to achieve these savings.

Assuming HHS determines that the applicant's responses satisfy one or more of these criteria, HHS will then evaluate whether there is a reasonable potential that the project will achieve one or more of these statutory goals considering (i) the scientific rationale for the project, (ii) the current stage of development of the project, and (iii) the evidence that the applicant has the capacity to bring the project to fruition.

Multiple Projects

The Notice provides that a complete application must be submitted for each qualifying therapeutic discovery project that the applicant sponsors for which the applicant is requesting a credit or a grant.

Investment Tax Credit Rules

Section 2.05 of the Notice states that the at-risk rules in Section 49 of the Code and the recapture and other special rules in Section 50 of the Code apply to the qualifying therapeutic discovery project credit.

Grants Reduce Qualified Investment

Section 4.01 of the Notice states that an applicant's qualified investment should be reduced by the amount of any grant excluded from gross income under Section 61 of the Code, unless the grant can only be used for costs not included in the definition of a qualified investment.

Grant in Lieu of Tax Credit

The taxpayer is permitted to elect to take a grant in lieu of the tax credit. If such an election is made, the grant is required to be paid during the 30-day period beginning on the later of (i) the date of the application for the grant, or (ii) the date the qualified investment, for which the grant is being made, is made. In the case of an application for a taxable year beginning in 2010, the application must be submitted (i) not earlier than the day after the last day of the taxable year, and (ii) not later than the due date (including extensions) for filing the tax return for such taxable year.

The Notice indicates that the grant election is affirmatively made on the Form 8942 for a grant for 2009 or 2010. In the case of an election for the 2010 taxable year, the election will be considered effective the day after the last day of the taxpayer's 2010 taxable year, even though the certification process will have been completed by such time. Generally, payment for the 2009 taxable year is required to be made no later than October 29, 2010. However, if the applicant's 2009 taxable year is a fiscal year and ends after September 30, 2010, the grant will be paid by October 29, 2010, in an amount equal to 50 percent of the applicant's qualified investment that has been paid or incurred by September 30, 2010. The remaining amount of the grant will be paid within 30 days after the end of the applicant's 2009 taxable year. Any grant for the 2010 taxable year will be paid during the 30-day period beginning on the day after the last day of the 2010 taxable year.

It is likely that this program will be oversubscribed. That, combined with the relatively short time frame that the IRS and HHS have to review and evaluate applications, means applicants must ensure that their applications are clear, concise and compelling. Successful applications will be those that make the most compelling case.

Our tax lawyers at Hunton & Williams specialize in programs similar to the new program for qualifying therapeutic discovery projects. Our tax lawyers routinely advise clients in all areas involving tax credits, including investment tax credits similar to this new credit, and have advised and successfully represented a number of clients in their applications for grants in lieu of tax credits under the 2009 stimulus act. We also have advised and represented clients in tax credit allocation programs preceding this new credit. Our tax lawyers will coordinate and work with lawyers in our Food and Drug practice group and Intellectual Property group, as appropriate, to help clients evaluate the tax credit/grant program, determine eligibility, and prepare applications.