

TREASURY ANNOUNCES RULES FOR THERAPEUTIC DISCOVERY PROJECT TAX CREDIT AND GRANT PROGRAM

On May 21, 2010, the US Department of the Treasury issued Notice 2010-45, establishing the rules for the therapeutic discovery project tax credit and associated grant program under the Patient Protection and Affordable Care Act of 2010 (PPACA). The rules clarify eligibility criteria outlined in PPACA, set maximum amounts allowable for individual applicants, and set a timetable for the application process. While the pre-printed Internal Revenue Service (IRS) form might not be available until June 20, 2010, the Notice provides sufficient guidance to start preparing applications now.

The salient features of the program include:

- Applicants are limited to a maximum of US\$5 million in credits or grants for all projects undertaken in 2009 and 2010.
- All initial applications must be filed during the window of June 21, 2010 through July 21, 2010.
- All applications submitted during the initial window will be deemed submitted as of October 1, 2010 and decisions will be made on or before October 29, 2010. Only if the entire US\$1 billion in credits and grants is not approved during the initial process will there be a second round of applications.
- The development of diagnostic devices is eligible for consideration, but the category of other eligible medical device development projects is limited to technologies used to deliver pharmaceuticals or other medical devices. The development of devices that are themselves therapeutic is not eligible for consideration.
- The application will require a "Project Information Memorandum" following a specified format, with strict limits on the number of words in answers to 11 questions listed in the Notice. No attachments or exhibits are permitted and no outside materials may be incorporated by reference. Up to five citations to published scientific literature may be included. Since those details have been released, applicants can start drafting now.
- The individual merits of applications will be evaluated by the US Department of Health and Human Services. Pre-filing conferences or other pre-filing

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communications with the IRS are prohibited. (The government may request additional information, but the taxpayer may not send in any information after filing the application unless requested by the government.)

- The government will determine which budget line items in a submission are allowable and which are not, but it appears that the government will not otherwise determine the amount of a credit or grant based on the relative merits of the particular projects. Equal allocations are to be made to all qualifying projects to the extent of their qualified investments, subject to the US\$5 million cap per applicant.
- Decisions are final and not subject to any appeal process.

The procedure for claiming credits or grants has two steps. The first step is the application for certification of the project, which must be delivered to the IRS no later than July 21, 2010. The application will cover amounts expended or expected to be expended. The form will contain an election as to whether the applicant wishes to claim the credit or receive a grant. In the case of the credit, the applicant will then report the credit on its tax return for the year in question (2009 or 2010), to the extent that it has actually paid or incurred the amounts that were certified. In the case of the grant, the applicant will file a claim for the grant between the day after the last day of the relevant taxable year for which the expenditures are claimed and the due date (including extensions) for that year's tax return, also based on its actual expenditures during that year. If the applicant previously elected to take the credit, but wishes to elect a grant instead, the applicant is permitted to amend its application for certification to make that election.

We hope you find this advisory helpful. If you would like more information, please feel free to contact your Arnold & Porter attorney or:

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