Cooley

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There are a number of steps a life sciences company can take to be ready to apply for cash grants or tax credits under the $1 billion program authorized by the new healthcare reform law.[1] Early preparation is key as the program is expected to have tight submission deadlines and be highly competitive. In addition, for companies new to the federal financing arena, there are several legal and procedural issues to consider and discuss with counsel before an application is submitted. Cooley's guidance is based on experience advising multiple companies regarding federal grant and tax credit programs for clean energy companies—programs that were significantly oversubscribed and subject to similar uncertainty at the outset of the program. The Treasury Department is expected to publish detailed guidelines for this program during the third week of May, or soon after.

- **Confirm that your company qualifies as an "eligible taxpayer":** Eligible companies performed qualified research and development during 2009 and 2010, and have not more than 250 employees in all businesses at the time of submission.

  TIP The first level of government review is typically for responsiveness. Therefore, each eligibility criterion should be explicitly addressed in the application.

- **Consider your eligible project(s):** It appears that companies will be able to submit applications on a project-by-project basis. Compile a list of all eligible projects for 2009 and 2010, and be prepared to prioritize them based on the scoring criteria that will be detailed in the upcoming guidelines. The new legislation has generally identified "Qualified Therapeutic Discovery Projects" as:
  - clinical trials, pre-clinical activities, clinical studies and research protocols undertaken to secure FDA product approval; or
  - projects designed to diagnose diseases or determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or
  - development of a product, process, or technology to further the delivery or administration of therapeutics.

- **Prioritize projects that will score higher:** For each eligible project, prepare arguments addressing the following selection criteria. Each application will need to address *at least one* of items 1 through 4 and *both* of items A and B.

  1. How would the project result in new therapies to treat areas of unmet medical need?
  2. How would the project prevent, detect or treat chronic or acute diseases and conditions?
  3. How would the project reduce long-term health care costs in the U.S.?
  4. How would the project significantly advance the goal of curing cancer within 30 years?

  1. How would the project create and sustain (directly or indirectly) high quality, high-paying jobs in the U.S.?

     TIP Under comparable federal financing programs, "direct" jobs are jobs created or sustained by the applicant in relation to the project, and "indirect" jobs are jobs created or sustained by materials, equipment, and service providers to the project.

  2. How would the project advance U.S. competitiveness in the fields of life, biological, and medical sciences?

     TIP Projects that significantly advance multiple federal goals (i.e., address multiple items in 1-4) are likely to score higher than projects that merely demonstrate that they are "qualified" by addressing at least one item of 1-4.

- **Review proposed "qualified investment" expenses with tax and accounting teams:** The program provides a tax credit or grant in respect of expenditures that already have been made by the applicant. Applicants will need to provide a precise breakdown of their eligible expenditures. This will typically require detailed accounting. Accordingly, either in-house or outside accounting advisors will need to be involved early in the preparation and application process.

- **Review potential confidentiality issues with counsel:** As with other government financing application processes, we expect that the submitted application will be subject to disclosure under the Freedom of Information Act (FOIA), meaning that all or any part of the application can be disclosed upon the request of a member of the public (which includes media and competitors), unless an exemption applies. To minimize the risk of disclosure, each applicant should carefully review the FOIA rules and regulations for the relevant agency with counsel and follow applicable instructions for marking sensitive business information *before* submitting the application.

  TIP Be sensitive to projects that involve third parties (e.g., as customers or collaborators). Confirm whether any third-party information (including names) may be confidential *before* submitting the application.

In conjunction with your accounting team, Cooley life sciences, government financing and tax experts are available to provide legal counsel at all stages of the application process.

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Notes

1 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 9023. For more information, *see Cooley Alert: Healthcare Reform Law Will Provide Cash Grants and Tax Credits for Qualifying Life Sciences Companies*. The program provides for a 50% tax credit, or an elective 50% cash grant, for qualifying expenditures on eligible projects certified for acceptance by the Treasury Department in consultation with the Department of Health and Human Services.

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