Cutting-Edge Research and Development Receives Boost from Health Care Reform: An Overview of the Cures Acceleration Network

April 30, 2010

HEALTHCARE ALERT - APRIL 30, 2010

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As provisions of the Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, are implemented to expand coverage and improve the quality of health care, it is important for the health care industry to be aware of another provision in PPACA – the Cures Acceleration Network, which will be a valuable tool to fund the development of cutting edge drugs, diagnostics, biologics, and medical devices.

Cures Acceleration Network

PPACA establishes the Cures Acceleration Network (CAN) within the Office of the Director of the NIH. Subject to the recommendations of the CAN Review Board, the CAN is directed to engage in a number of activities to support "revolutionary advances" in translating scientific discoveries from bench to bedside and to accelerate the development of "high need cures."

The CAN Review Board is composed of 24 private members appointed by the Secretary of Health and Human Services as well as government representatives from the NIH, the Office of the Assistant Secretary of Defense for Health Affairs, the Office of the Undersecretary of Health for the VHA, the National Science Foundation, and the FDA, who serve as ex officio members. The 24 private members will be selected from the following sectors: venture capital and private equity, biotechnology and pharmaceuticals, disease advocacy, basic research, medicine, discovery and delivery of medical products, bioinformatics and gene therapy, medical instrumentation, and regulatory review and approval of medical products.

Most importantly, PPACA authorizes the CAN to award grants to eligible entities to develop "high need cures" and specifically directs the CAN to coordinate with the Food and Drug Administration (FDA) regarding review and approval of high need cures, including by establishing regular communication with FDA regarding CAN activities and ensuring that CAN activities are synchronized with the approval requirements of FDA. A "high need cure" is a drug, biological product, or device as those terms are defined by the FDA, that, in the determination of the Director of NIH:

- is a priority to diagnose, mitigate, prevent or treat harm from any disease or condition; and
- for which the incentives of the commercial market are "unlikely to result in its adequate or timely development."

PPACA specifically authorizes three types of CAN grants which may be awarded to eligible entities (public or private) such as institutes of higher education, medical centers, biotechnology or pharmaceutical companies, disease or patient advocacy organizations, or academic research institutions who submit an appropriate application for a grant to the NIH.

- Partnership Awards are in the amount of $15 million for the first year of funding, with the possibility of extension for additional years at $15 million per year. The grant recipient must contribute $1 for every $3 of federal funding, unless the Director of NIH waives or modifies the matching requirement for the recipient.
- Grant Awards are also in the amount of $15 million for the first year of funding, with the possibility of extension for additional years at $15 million per year. Unlike Partnership Awards, there is no matching requirement for Grant Awards.
- In addition to Partnership and Grant Awards, NIH is provided with "other transactions" authority to achieve the goals of the CAN, if the Director of the NIH determines that the goals and objectives of the CAN cannot be met by contract, grant, or cooperative agreement. The Director of the NIH may not expend more than 20% of total CAN funding per fiscal year for "other transactions" authority.

The bill authorizes $500 million for the CAN for fiscal year 2010, and such sums as necessary for subsequent fiscal years. However, it is important to remember that Congress has not yet appropriated the funds for the CAN, thus the program will not be operational until the funding is received by the NIH.

Future Outlook

Importantly, and building off of a new NIH-FDA collaboration, the CAN is designed to facilitate the development and approval of CAN-funded projects from conception all the way through to FDA approval. This could be a signal of improved communication between the two agencies, and better success rates at bringing new therapies to patients. The CAN also represents new potential funding for the NIH and the possibility to at least begin to shore up the agency's deficit after the $10 billion in stimulus funding runs out in fiscal year 2011.

Congress, however, must still act to appropriate the $500 million for the CAN during the annual appropriations cycle before it is operational. Champions for this funding increase are emerging on Capitol Hill; interested parties should monitor the progress closely and watch for establishment of the CAN if the funds are appropriated.