Regulatory Burden Provisions in 21st Century Cures

The *21st Century Cures Act* (H.R. 34), which was approved, 392-26, by the House on Nov. 30, 2016, and by the Senate, 94-5, on Dec. 7, 2016, and signed into law by the President December 13, 2016, includes a number of provisions related to reducing regulatory burden for researchers and research institutions. Many of these provisions are contained in Section 2034 of the Act, entitled "Reducing Administrative Burdens for Researchers," and were taken or adapted from Part One of a 2016 report from a Congressionally requested Committee on Federal Research Regulations and Reporting Requirements of the National Academies of Sciences, Engineering, and Medicine. The first part of this report, "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century," was issued in September 2015 after Senator Lamar Alexander (R-TN) requested an expedited set of recommendations from the Committee.

Requirements of Section 2034:

- **Review all conflict of interest regulations and policies of funding agencies** (§2034(a))
  - Specific elements the Secretary of Health and Human Services (HHS) must consider are: the minimum threshold for reporting financial conflicts of interest; the timeline for such reporting by NIH-funded institutions; whether reporting requirements are appropriate for, and relevant to, research funding awards; and whether training modules the NIH has created for financial interest disclosure should be updated.
  - This provision, which addresses one of the areas identified in the Academies' report as the most burdensome without evidence of intended impact, and one of the least consistent across funding agencies.
  - The Academies report recommended that Congress develop a single federal-wide conflict of interest policy for all research funding agencies. Congress took a more conservative approach by tasking the HHS Secretary with reviewing, revising as appropriate, and harmonizing existing regulations.

- **Reduce Burdens Related to Monitoring Subrecipients of NIH Funding** (§2034(b))
  - The NIH Director is directed to implement measures to reduce the burdens related to monitoring subrecipients of NIH grants.
  - Such measures could include granting exemptions to primary awardees when the subrecipient meets certain requirements and exploring new grant models such as multiple primary awardees that would obviate the need for subrecipient monitoring.

- **Evaluate Required Reporting to NIH of Financial Expenditures** (§2034(c))
    - The HHS Sectretary and NIH Director should take action to ensure that NIH funding recipients do not have duplicative or burdensome expenditure reporting requirements.

- **Review and revise NIH, FDA, USDA regulations and policies related to the care and use of laboratory animals** (§2034(d))
    - Within two years, the applicable regulations and policies must be reviewed and revised to reduce administrative burden for researchers while ensuring "integrity and credibility of research findings and protection of research animals."
    - The NIH Director is charged with identifying and eliminating or reducing regulations and policies that are duplicative, inconsistent, or overlapping and to take steps to make sure remaining regulations and policies are coordinated.

- **Clarify Uniform Guidance Requirements for HHS Grant Awardee Documentation of Personnel Expenses** (§2034(e))

- **Establish a Research Policy Board** (§2034(f))
    - The Board would be tasked with making recommendations for modifying and harmonizing policies and regulations across research funding agencies to minimize administrative burden. The Boards activities could include analyzing existing policies for possible improvements, creating a forum for discussion of regulatory gaps and overlaps, and assessing regulatory burden through the development of metrics.
    - Membership would consist of 4-10 Federal members from departments and agencies that support or regulate research and 9-12 representatives from non-Federal stakeholders communities including academic research institutions and other nonprofit institutions with relevant expertise.
    - The Board will submit two formal reports with its recommendations to the Office of Management and Budget (OMB), Office of Science and Technology Policy (OSTP), relevant Federal agency heads, the Senate Committee on Health, Education, Labor and Welfare, and the House Committee on Energy and Commerce before it terminates September 30, 2021.