HHS ISSUES FINAL RULE UPDATING FINANCIAL CONFLICT OF INTEREST RULES FOR INVESTIGATORS

On August 23, 2011, the U.S. Department of Health and Human Services ("HHS") issued the updated Final Rule on financial conflict of interest regulations for institutions applying for or receiving Public Health Service ("PHS") funding, including from the National Institutes of Health ("NIH"). The rule amends the 1995 PHS regulations "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94), and provides a guide for investigators on identifying and avoiding financial conflicts. The changes seek to address the needs of the rapidly expanding and increasingly complex field of biomedical and behavioral research and continue to enhance the integrity of research funded by the federal government.

Major changes to the regulations include:

- Requiring investigators to disclose all of their significant financial interests ("SFI") relating to the investigator's institutional responsibilities, including any reimbursed or sponsored travel. This requirement does not apply to travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institution affiliated with an institute of higher education.

- Lowering the minimum amount at which SFIs must be disclosed from $10,000 to $5,000. This requirement applies to payments for services and/or equity interests and equity interests in non-publicly traded entities.

- Excluding from the definition of SFIs any income from government agencies or higher education institutions in connection with seminars, lectures, teaching or service on advisory or review panels.

- Requiring institutions to provide mandatory training for investigators related to the regulations and the institution's financial conflict of interest policy at least every four years.

- Requiring institutions to post on a publicly accessible website or provide, upon written request, information about identified SFIs of senior/key personnel that constitute financial conflicts of interest before spending funds for PHS-supported research.

- Requiring institutions to provide more information to the PHS Awarding Component in addition to that required by the 1995 regulations, including the value of the financial interest, the nature of the conflict and how it relates to the PHS-funded research and the institution's plan for managing the conflict.

Institutions applying for or receiving PHS funding that is covered by the regulations must be in full compliance with the requirements no later than August 24, 2012 or immediately upon making its institutional financial conflict of interest policy publicly accessible.

The Final Rule can be viewed in its entirety here:

If you have any questions or would like further information, please contact Melissa L. Markey at 248.457.7853 or mmarkey@hallrender.com, Andrea B. Anantharam at 248.457.7822 or aanantharam@hallrender.com or your regular Hall Render attorney.