

COUNCIL ON GOVERNMENTAL RELATIONS

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National Academies Panel on Reforming Regulation and Reporting Requirements - Lisa Nichol's Remarks on Behalf of the Council on Governmental Relations

COGR is an association of over 190 research universities, academic medical centers and research institutes that conduct over \$60 billion in R&D activities annually. We appreciate the opportunity to highlight our concerns regarding Federal regulations and reporting requirements and their impact on member institutions.

A number of reports and articles have detailed the various facets of Federal regulatory burden and other challenges to the research enterprise. Each of the reports highlight some of the fundamental issues that COGR, AAU, and APLU address on a daily basis. Specific to this initiative, the issues include:

- the proliferation of significant regulations, policies and guidance;
- a lack of standardization of regulations, policies, guidance, systems and forms across federal agencies; and,
- a lack of central authority and a standing process for addressing standardization and reform both retrospectively and prospectively.

Growing Regulatory Burden

COGR keeps a running list of federal regulatory changes since 1991, the year the 26 percent cap on F&A was imposed. In the last year there have been a number of new or proposed regulations and policies; including eight in just the last 6 months.

COGR has worked with federal agencies where possible to address proposed policies and limit associated administrative burden. As an example, David Kennedy and members of COGR's Costing Policy Committee have worked closely with OMB staff throughout the development of the Uniform Guidance and have continued to work with them to address concerns with the final policy and its implementation.

COGR is planning to document agency deviations from the Uniform Guidance in the coming months. Some interim rules are thought to exceed the scope of the Guidance. Further, while some agencies, including NIH and NSF are working together to revise their research terms and conditions, other funding agencies such as DOD have opted out.

The Cost of Regulation

New regulations and policies can be costly in terms of faculty and administrative staff time. As an example, the estimated annualized burden hours for the reporting requirements associated with the 2011 revisions to the Public Health Services financial conflict of interest regulations, which are currently up for renewal, is 676,130 hours at an estimated cost of \$23,664,550 annually. This is just one policy change, and affects only one major funding agency, NIH.

COGR and APLU are engaged in the AAU/Yale effort to evaluate and assess the cost and effectiveness of specific regulations, including the 2011 PHS FCOI requirements which anecdotally have not led to a notable increase in COI to manage. Surveys will be distributed to member institutions next week.

The Role of Audit/Inspectors General

Another facet of regulatory burden and area that COGR and AAU have recently addressed involves federal audits. Policy disputes between NSF management and the NSF Inspector General's Office on the issue of two-month or summer salary have led to protracted and costly audits and resolution periods. AAU and COGR staff met with the NSF inspector general to discuss this issue in October and policy clarifications were made to the 2015 NSF Proposal and Award Policies and Procedures Guide. Nonetheless, the issues are not entirely resolved as resolutions are pending for a number of audits with related findings.

Inspectors General can also heavily influence reform efforts. Regarding effort reporting, the Uniform Guidance seeks to lessen the administrative work associated with confirming salaries and wages and provides standards for internal controls. However, institutions must develop their own systems for supporting the charges and there is uncertainty regarding what constitutes an auditable system. The Federal Demonstration Partnership has piloted automated payroll certification systems at four institutions.

NSF and HHS IGs have reviewed three of the four FDP pilots and the results are expected in March. Early indications are that IGs are concerned that expenditures do not match Federal Financial Reports. The results of the reviews will have a large impact on the implementation of the Guidance as it relates to compensation. If the IGs do not endorse payroll certification or offer a pathway forward, institutions are more likely to maintain their current reporting systems.

AAU and COGR staff will schedule a meeting with the NSF and HHS IGs following publication of the reviews and address this issue with OMB. Indications are that federal agency officials and institutions are aligned on this issue and believe that, per the NSB report, OMB should identify a means by which the payroll certification approach can be used by universities and accepted by auditors and issue a Memo of Clarification indicating that the approach is acceptable to the Federal Government.

Mechanisms for Addressing Reform

In terms of a process for addressing research regulatory reform, several reports have recommended that the Federal Government review and modify or eliminate burdensome and inefficient policies and address variation among agencies. The reports, and the Research and Development Efficiency Act passed by the House in July 2014, have called for OSTP and OMB/OIRA to lead this effort and included provisions for stakeholder input.

Another potential and possibly parallel direction is a standing mechanism or process within OMB/OIRA to oversee the development and coordination of agency regulations, policies and guidance as well as reform efforts. From our perspective a lack of central authority and a standing process for addressing standardization and reform prevents real reform from taking hold and leaves institutions open to escalating regulatory burden.

OMB/OIRA ostensibly has the authority to play a major role in the oversight and reform of Federal agency regulations and guidance per executive orders 12866, 13563, 13610 and 13422 in addition to Agency Good Guidance Practices, The Paperwork Reduction Act and other authorities to oversee and coordinate rulemaking. These orders direct OIRA to review individual regulations, oversee regulatory planning and retrospective review of existing regulations, coordinate review of agency rulemaking, and engage stakeholders.

Much of what we would be seeking mechanistically is contained within these executive orders. However, they apply to agencies with “significant domestic regulatory responsibility”, not to NIH and NSF, and have a greater focus on the needs of state, local and tribal governments. The policies and guidance developed by key research funding agencies have not been subject to retrospective review and other aspects of these orders. There is a real need for regulatory planning and review that is specific to research and research funding agencies that also applies to significant policies and guidance and follows the guidelines laid out for regulatory planning.

Regarding public participation, we note that the notice-and-comment approach required under the Administrative Procedure Act can lack the timeliness needed to establish good policy. Federal officials are reaching out to the stakeholder community informally for real-time feedback and discussion, but in an ad hoc manner and not always at the optimal time.

Greater engagement by OMB/OIRA in the development, coordination and reform of major research regulations, policies and guidance and a process for gaining timely stakeholder feedback could lead to significant improvements and, per the R&D Efficiency Act, allow “a higher proportion of taxpayer dollars to flow into direct research activities.”

How can we get OIRA and OMB to act? How will they respond to resistance from agencies and IGs?

Next Steps in Reform Efforts

AAU and COGR took up these issues with the OIRA administrator Howard Shelanski, and will follow-up with a meeting in March or April. We have also discussed these issues with the Chairman of the Administrative Conference of the United States, Paul Verkuil.

For those of you not familiar with ACUS, it is an independent federal agency that seeks to improve federal agency procedures. Paul Verkuil will speak about the agency and its initiatives at the March COGR meeting. In our December meeting, AAU, COGR and ACUS staff discussed a potential study aimed at achieving greater research regulatory efficiency. The timeline for completion of the study would be less than one year.

Again, COGR appreciates the opportunity to address this Committee today. We believe that the scope of this Committee's work and the depth of analysis proposed will compliment previous initiatives and ongoing efforts by COGR, AAU and APLU.