Compliance Focus on Time and Effort Reporting

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Recently, there has been a flurry of federal enforcement activity relating to accounting for and reporting of researchers' time and effort under federal grants. The False Claims Act (31 U.S.C. § 3729 et seq.) (FCA) has proven to be an effective tool of the U.S. Department of Justice (DOJ) for enforcement in the area of time and effort reporting. Federal authorities, in partnership with whistleblower qui tam plaintiffs, have taken the position that submitting erroneous time and effort reports violates the FCA.

Organizations are much more likely to receive favorable treatment in the conduct of a federal investigation if they maintain compliance programs that have proven effective at preventing violations, detecting, and remedying them when they occur. Conversely, organizations that lack an effective compliance program may be vulnerable to charges that they acted in reckless disregard of standards for claims submitted to the government.

This article first provides a brief introduction to the recent federal scrutiny of research grant management. After outlining the regulatory framework for time and effort reporting, the article enumerates some "hot spots" of compliance problems that arise from these accounting and reporting rules. The article concludes by suggesting steps compliance officers can take to review and improve their practices of charging costs to federal grants.

Federal Enforcement Activity

Over the past three years, at least five major academic institutions have entered into highly publicized, multi-million dollar settlements with the DOJ of allegations of false reporting of researchers' time and effort. The institutions were charged with a variety of improper activities, including overstating effort charged to research grants, improperly documenting salary costs attributable to federal grants, charging unreasonable costs to grants, or otherwise not complying with federal regulations governing time and effort reporting.

Submitting erroneous time and effort reports violates the False Claims Act

Several common themes run through the settlement agreements. First, organizations whose researchers or staff knowingly or recklessly violate the rules governing research grant reimbursement, or falsely certify time and effort reports place themselves squarely in line for FCA enforcement activity. Second, because institutions are granted a good deal of leeway in structuring systems for tracking payroll distribution and because there is no one federally mandated effort reporting system, the federal government is likely to focus on institutions whose own accounting and reporting policies are ineffective or inconsistently applied. Third, organizations will be faulted if they do not maintain an adequate compliance program to monitor and improve adherence to organizational time and effort reporting policies. (See the Exhibit accompanying this article for a more detailed discussion of the circumstances and allegations involved in the federal enforcement actions.)

The Office of Inspector General (OIG) at the U.S. Department of Health and Human Services, in addition to actively partnering with the DOJ in these federal enforcement actions, has also engaged in independent investigative activities with respect to time and effort reporting. In April 2004, the OIG issued a report of an audit of Northeastern University's claimed research costs to determine whether they were allowable, allocable, and reasonable. The report largely focused on Northeastern's salary costs, finding that the institution's reported time sheets did not consistently contain required time and effort reporting information, and that the institution had at times overstated effort in its claims for reimbursement. The OIG found that these conditions occurred because the institution did not have adequate controls in place to ensure that estimated and actual effort were consistently reported and reconciled, and it did not maintain documents adequate to support claims for reimbursement. In its Work Plan for 2005, the OIG indicated that it would continue this line of investigative activity by conducting a review to determine whether major universities committed more than 100 percent of researchers' time when applying for grants, resulting in the inflation of grant awards. The OIG plans to determine how, and the extent to which ,organizational audit programs, required by the Office of Management and Budget (OMB) Circular A-133, assess universities' time and effort reporting systems. The OIG also noted in its 2005 Work Plan that it would continue to work with the DOJ to develop and pursue FCA cases against grantee institutions.

Time and Effort Reporting: General Principles

Standards for compliant time and effort reporting are laid out in the Code of Federal Regulations (CFR) and in OMB Circulars. Specifically, OMB Circular A-21 sets out cost reporting principles for

educational institutions, OMB Circular A-122 governs non-profit organizations, and 45 CFR Part 74, App. E applies to hospitals.

In general, the standards provide that the total reimbursed cost of a federal research award is the sum of allowable direct costs and allocable indirect costs, less any applicable credits. With respect specifically to the salaries of research personnel, costs are allowable if; (1) the total compensation to individual employees is reasonable for the services rendered and conforms to the established policy of the organization, consistently applied both to federal and non-federal activities; and (2) salary charges to awards are determined and supported as required by the standards laid out for effort reporting. Moreover, costs must be adequately documented in such a way as to recognize the principle of after-the-fact confirmation or determination of effort, so that reimbursed costs represent actual costs incurred by the institution in relation to grant personnel.

Under the time and effort reporting standards, compensation for personal services that can be charged to a grant is calculated from an underlying determination of the percentage of overall effort from all activities conducted at the grantee organization. For example, at educational institutions, reimbursement is determined by multiplying research effort by the organization-reported Institutional Base Salary (IBS), subject to a salary limitation (currently $180,100). By not setting precise definitions with respect to such elements as the total hours that research personnel are deemed to work, or the additional activities that research personnel may engage in at the grantee institution (such as clinical, teaching and administration), the standards attempt to accommodate the great variety among grantee institutions in compensation arrangements. They therefore largely rely on organizational accounting standards and compliance activities to ensure consistency and fairness in federal research grant reimbursement.

Hospitals and non-profit organizations must prepare effort reports for their professional staff members at least monthly. Universities may prepare effort reports less frequently (generally every academic term), but they must be prepared at least every six months. Compensation cost allocation by educational institutions must be based on payrolls documented in accordance with Generally Accepted Accounting Principles); such payrolls must be incorporated into the official records of the institution and must reasonably reflect the activity for which the researcher is compensated by the institution. Circular A-21 enumerates examples of payroll distribution methods that would meet the required criteria. The plan-confirmation method is based on planned work activity accompanied by verifications that such activity was performed and modification or updates, as appropriate. The after-the-fact recording system is based on the submission and certification of activity reports that reasonably reflect compensated activities at the institution. In all cases, effort reports must be signed by the investigator or by a supervisor who has first-hand knowledge of the researcher's activities.

Organizations expending more than $500,000 per year in federal awards must adhere to compliance procedures as set forth in OMB Circular A-133, including annual audits.

Time and Effort Reporting Compliance "Hot Spots"

The allegations underlying each of the recent settlement agreements make it clear that one of the central areas of scrutiny in time and effort reporting is with respect to the accurate reporting of effort of investigators as a percentage of their overall activity. In particular, organizations face exposure to enforcement activity when they:

- Overstate effort by increasing IBS to include clinical activities, but then excluding those same clinical activities in calculating effort devoted to grants;
- Overstate effort by omitting time spent on other professional activities at the grantee institution;
- Fail to reconcile estimated effort with actual effort devoted to grant activities; or
- Fail to ensure that effort reports are always signed by individuals who have first-hand knowledge of the actual effort expended.

Academic medical centers in particular should pay special attention to the rules governing calculation of IBS. When investigators are compensated from two separate entities for their research and clinical practice activities (e.g., by a university for the former and a separately-organized faculty practice plan for the latter), these income streams may be aggregated only if their percentage effort is also aggregated, and if additional conditions are met; namely:

- Clinical practice compensation must be "set by the [grantee] institution;"
- Clinical practice activity must be shown on the grantee institution's payroll or salary appointment forms and records approved by the institution;
- Clinical practice compensation must be paid through or at the direction of the grantee institution;
- Clinical practice activity must be included and accounted for in the grantee institution's effort reporting or payroll distribution system; and
- The grantee institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to National Institute of Health (NIH) grants are retained and made available to federal officials consistent with the records retention requirements applicable to grantee institutions (found at OMB Circular A-110, Subpart C, section 53).

For purposes of the above conditions, "set by the institution" means that:

- The grantee institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator; and
- The IBS does not vary based on the specific clinical services provided by the investigator within the periods for which total IBS is certified by the grantee institution.

These conditions are the result of a recent reevaluation of the policy governing separate compensation arrangements.[1] In light of these revised guidelines, institutions should carefully assess their IBS calculations, the structure of clinical practice compensation to clinical faculty members at the institution, and their effort reporting systems to determine whether it is feasible or appropriate to include clinical practice compensation in investigators'

IBS, and to track the associated clinical effort accordingly.

Another area of compliance scrutiny is in the administration of NIH-supported career development awards (so-called "K awards"). K awards require that grant recipients devote a specified minimum percentage of their full-time effort (usually 75 percent) to the goals of the K award. In August 2004, NIH changed its policy governing determination of total professional effort for K's when the recipient maintains a commitment to an outside institution. Under the new policy, a K award recipient will meet the required commitment of total professional effort as long as: (1) the individual has a full-time appointment with the applicant organization; and (2) the minimum percentage of the candidate's commitment required for the proposed career award experience (e.g., 75 percent) is covered by that appointment.

Essential Compliance Steps in an Era of Increased Scrutiny

At this point, with multiple reported recent settlements on charges related to time and effort reporting, organizations that do not take certain basic efforts required to ensure compliance with effort reporting standards are easy targets for enforcement actions.

In 1991, the United States Sentencing Commission adopted Organizational Sentencing Guidelines offering reduced sanctions for violations of the law where organizations can show that they have instituted an effective compliance program. To assist healthcare organizations in developing effective compliance programs that are relevant to the particular legal and regulatory regime to which they are subject, the OIG has published a series of Compliance Program Guidance documents tailored to particular healthcare industry segments. In producing these compliance guidance documents, the OIG has identified seven fundamental elements to an effective compliance program, which generally track principles originally laid out in the U.S. Organizational Sentencing Guidelines. They are:

1. Implementing written policies, procedures and standards of conduct;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines; and
7. Responding promptly to detected offenses and developing corrective action.

Organizations should implement compliance activities in the area of time and effort reporting that are consistent with the basic compliance principles outlined above. For example:

- Organizations should review their time and effort reporting procedures to ensure they comply with the relevant standards, and that the chosen accounting and reporting systems are effective and consistently applied. As a first step, an organization should carefully review the applicable OMB Circular or regulation. Those documents enumerate specific standards applicable to universities (OMB Circular A-21), non-profit organizations (OMB Circular A-122), and hospitals (45 CFR Part 74, App. E). Compliance policies and procedures are critical elements to any organization's time and effort reporting activities. Organizations should consider retaining outside counsel to conduct an external review of their time and effort reporting activities and compliance program.
- Documentation must be adequate to support reimbursement claims. Common auditable problems include investigators' failure to sign effort reporting forms, and confirmation signatures given by personnel who do not have first-hand knowledge of the actual effort expended.
- Organizations should demonstrate their commitment to compliance. They should allocate adequate resources to their compliance program activities and designate a visible high-level individual who is accountable for compliance with time and effort reporting standards.
- Organizations should ensure that individuals at all levels comply with, and are held accountable for, the applicable standards and policies. An institutional education and training program is an essential component of ensuring investigators' compliance with relevant reporting requirements. Effective educational programs should provide information on the relevant time and effort reporting requirements, practical guidance for investigator reporting responsibilities, and examples of accurate accounting for professional and research activities. Specifically, institutions should present their standard reporting forms in the context of a formal training session and provide instruction, with examples, for their accurate use. Training should be offered at least annually, with attendance attested to by researchers and documented by the institution. Attendance should be required at a baseline training session, and provisions made to update trainings as needed.
- The institutional education program should provide resources containing, or summarizing, the governing federal standards so that individuals can easily access references that explain both the "how" and "why" of their time and effort reporting.
- Systems for reporting detected errors should be established, and should provide individuals direct access to an independent compliance officer.
- The institution's internal audit department should produce, and department heads and principal investigators should review, regular reports listing the employees charged to research grants to ensure that the current percentage of effort reported for each employee whose salary is charged to a grant remains accurate.
- Organizations must also evaluate the success of their compliance efforts through ongoing sampled monitoring of the accuracy of effort reports. Although compliance with all relevant standards is required, compliance reviewers should especially ensure that they have tracked and corrected any compliance problems in the "hot spot" areas identified in this article.
- When effort reporting errors or other problems are identified, they should be addressed immediately. Audit findings should be summarized and

a corrective action plan should be documented. Steps should be taken to improve future compliance, such as remedial training and penalties assessed against the individuals responsible. Compliance officers should also consider conducting more frequent and focused reviews of departments or programs that have been shown to have problems adhering to the relevant time and effort reporting standards in past reviews.

In September 2003, the OIG announced that it would issue Compliance Program Guidance for Recipients of NIH Research Grants, and the agency indicated in its 2005 Work Plan that it is in the process of drafting that compliance guidance. In the initial announcement, time and effort reporting was identified as one of three compliance risk areas for federal grant recipients. Signaling its attention to effective management of federal research funds, the OIG stated that it was considering adopting a new compliance element that would address the area of defining roles and responsibilities and assigning oversight responsibility (68 Fed. Reg. 52874).

Establishing a compliance program that successfully provides for high-level oversight and accountability is a particular challenge for universities, whose organizational structures are typically less cohesive than are those of the entities to which prior compliance guidance documents have been addressed, such as pharmaceutical companies and hospitals. It is nevertheless essential that educational institutions adopt mechanisms to implement such high-level accountability to ensure that they are dedicating the appropriate resources to compliance and reinforcing their commitment to an organizational culture that encourages and supports compliance with the law.

Compliance officers should familiarize themselves thoroughly with the draft Compliance Program Guidance for Recipients of NIH Research Grants when it is eventually issued. In the meantime, organizations that take steps to develop, improve and maintain an effective compliance program governing their time and effort reporting practices can substantially reduce their risk of exposure to federal enforcement activity in this area. ▪

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Footnote

[1] See Guidelines for Inclusion of Clinical Practice Compensation in Institutional Base Salary Charged to NIH Grants and Contracts, NOT-OD-05-061 (Aug. 4, 2005).

Exhibit

Government Settlement Agreements: 2003 – 2005

Northwestern University settled charges that it overstated the effort of its researchers in several different ways (United States ex rel. Schwiderski v. Northwestern University, N.D. Ill., No. 02C-5287, settlement approved 2/6/2003). Most notably, the government alleged that Northwestern impermissibly inflated reimbursement by including in Institutional Base Salary (IBS) researchers' income from clinical activities compensated by an affiliated faculty practice plan, while excluding those same clinical activities in calculating effort devoted to grants. Northwestern agreed to pay $5.5 million, in addition to repaying the amount of unallowable costs it allegedly had received.

Johns Hopkins University agreed to pay $2.6 million plus past unallowable costs to settle charges that it, too, had overstated the percentage of effort that personnel at its Bayview Medical Center campus had worked on grants by failing properly to take into account their total activities (United States ex rel. Grau v. Johns Hopkins University, D. Md., No. CCB-99-1448, settlement announced 2/26/2004). As in the case of Northwestern, the government alleged that Hopkins had not maintained adequate compliance mechanisms to reconcile proposed effort commitments with actual reported effort, and that calculations of personnel costs were based on documents that could not reliably be used to estimate the percentage of effort for the personnel.

In a qui tam suit, the ***University of Alabama*** (UAB) paid $3.4 million plus past unallowable costs to settle charges that it improperly reported the effort of personnel engaged in research activities (United States ex rel. Gober v. University of Alabama at Birmingham, N.D. Ala., No. 01-CV-00977-VEH, settlement agreement filed 4/14/2005). In this case, the settlement agreement charged that UAB had overstated effort by properly failing to account for teaching or administrative activities and had failed properly to disclose research activities that potentially overlapped with the federal award. The government also alleged that UAB billed Medicare for research services that should have been billed to grants. Notably, the settlement order required UAB to continue to implement its corporate compliance program, and to continue to provide, at a minimum, the current level of resources to the compliance program for a period of three years.

The ***Mayo Foundation*** entered into a settlement whereby it agreed to pay $6.5 million plus past unallowable costs in the face of yet another whistleblower lawsuit (United States ex rel. Long v. Mayo Foundation, D. Minn., No. CV02-522-ADM/SRN, settlement announced 5/26/2005). The focus of the government's scrutiny in this case was on the reasonableness of direct costs charged to federal grants. Specifically, the Foundation allegedly reallocated direct costs, including salaries, from overspent grants to underspent grants to avoid refunding unused grant funds to the federal government. The adequacy and appropriateness of Mayo's accounting practices were a particular focus of the government.

Cornell University's Weill Medical College agreed to settle a qui tam action by paying nearly $4.4 million plus past unallowable costs (United States v. Weill Medical College of Cornell University, S.D.N.Y., No. 03-6761, settlement approved 6/21/2005). The government alleged that the medical school knowingly allowed certain researchers and certain research divisions effectively to dominate federal grant funds that had specifically conditioned that no one researcher or division use more than 33 percent of the overall grant. The complaint alleged that the Medical College's scientific advisory committee had abdicated oversight responsibility for this funding, as well as that the method for accounting for outpatient visits charged to the grant had been inadequate.