

Health Care Compliance LETTER

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IRS highlights tax-exempt hospitals' community benefit compliance

by Hilary Goehausen, Contributing Editor

The Internal Revenue Service (IRS) called upon practitioners to help their hospital clients meet the demands for more detailed exempt organization information required in IRS Form 990, justify their compensation, and determine whether IRS good governance standards resonate within their organization, during an October 8, 2007, program on tax issues for health care organizations held by the American Health Lawyers Association (AHLA). With tax-writing committees continuing to wonder how tax-exempt hospitals justify their exemptions, "tax exempt hospitals have been under tremendous pressure for the last several years," David Fish, Office of Associate Chief Counsel, IRS said. During the AHLA event, Fish and Steven Clark, another IRS representative, discussed compliance issues associated with community benefit rules facing tax-exempt organizations, as well as new developments affecting the exempt organization community.

Recent developments. Fish drew practitioners' attention to the new developments released by the IRS. Highlights include:

- Guidance sheet issued on 1023 applications;
- Guidance sheet to be issued in the near future on conservation easement issues;
- Guidance sheet on Code Sec. 509(a)(3) supporting organizations; and
- IRS Notice 2007-52, which will become an annual revenue procedure.

Hospital compliance project. Clark explained that the IRS is using its Hospital Compliance Project Report to look more specifically at the demographic data of the communities that hospitals serve because the community in which a hospital is located affects how the hospital should meet the community benefit standard. "For instance, we may look at whether a hospital is in a rural area, an urban area, and how that affects the community benefit they provide," Clark explained.

Electronic health records. "Electronic health records have really exploded in the last several years," Clark noted. He explained that earlier this year, the IRS was approached by a number of associations requesting guidance on whether hospitals could subsidize their medical staff's acquisition of electronic health record (EHR) systems. Clark reiterated that if a hospital meets the conditions set forth in the IRS' directive as well as the HHS conditions for the EHR safe harbor, any subsidy that hospitals provide to their medical staff physicians will not constitute prohibited or impermissible private benefit.

RHIO applications. The IRS has begun receiving applications for tax-exempt status from regional health information organizations (RHIO). According to Clark, the IRS is grappling with the issue of whether RHIOs are organized for tax-exempt

purposes, whether they should be tax-exempt, or whether they provide public benefit or private inurement, for example, to insurance companies. ■

AHLA Program on Tax Issues for Health Care Organizations, Oct. 8, 2007.

New Form 990 may change, but completion burdens remain, IRS reveals

by Hilary Goehausen,
Contributing Editor

The Internal Revenue Service (IRS) intends to make changes to its new Form 990 based on the number of comments it has received from the public, according to Ronald Schultz, Senior Technical Advisor, IRS Tax Exempt and Government Entities Division. Schultz spoke on October 8, 2007, during the American Health Lawyers Association (AHLA) program on tax issues for health care organizations. The IRS has received more than 650 comment letters, one-third of which concern hospitals, Schultz said. Despite the number of comments received, the IRS has no plans to change the timetable it has set to release the new Form 990 for the 2008 tax year. During the AHLA program, Schultz highlighted a number of the changes that practitioners will see, as well as features that will remain the same.

Form 990 comments. The IRS received comments on overall record-keeping requirements, whether certain information should be made public, the content of the core form and schedules, and whether there will be a transitional period for the new Form 990. According to Schultz, the IRS remains committed to the overall structure and form of the new Form 990.

Increased burdens. Mary Rauschenberg, Director of Deloitte Tax LLP's Chicago healthcare and not-for-profit tax practices, revealed that many tax-exempt organizations may have to fill out 14 of the 15 schedules, or even all of them. According to Rauschenberg, only the small "mom and pop" type organizations will see no increased burden, while the large organizations will have their hands full complying with the new Form 990. For

example, "for all but the smallest of the small" there will be an increased burden completing the core form itself. This, in effect, will cause an increased burden in gathering the information for the return, Rauschenberg added.

It also will be the rare organization that does not need to fill out two compensation schedules, Schedule J and Part II of the new Form 990, Rauschenberg said. Schedule J asks for additional detail on taxable and nontaxable compensation and must be filed, for example, if an executive has more than \$150,000 in reportable compensation or \$250,000 in total compensation, or if any person listed on the core form has compensation from a source other than the organization or a related organization. Tax-exempt organizations other than 501(c)(3)s may find this burdensome, predicted Rauschenberg. It is "highly likely," however, that the controversial nontaxable expense reimbursement part of the new form will be eliminated, she indicated.

Schedule D. Schedule D, which requests supplemental financial information, appears to pose a significant burden, said Schultz. According to Schultz, the IRS is considering eliminating the first six parts of the schedule, keeping the parts but creating subcategories, or drafting narrative questions. "The only thing that is certain" is that the IRS, in some way, will change the six parts to Schedule D, Schultz explained.

Schedule H. Schedule H requests information about tax-exempt hospitals' charity policies and efforts to make those policies known to the public. It also requires filers to categorize charity cases and community benefit expenses separately. According to Schultz, the IRS is contemplating whether to permit aggregated reporting of all hospitals under one employer identification number, or require hospital-by-hospital community benefit reporting.

Governance reporting. Part III of the redesigned Form 990 is fallout from Sarbanes-Oxley and Enron, Schultz said. The IRS' concern about governance issues and how nonprofit hospitals are structuring their boards culminated in the new Part III of the form, requesting

information on the governance practices of nonprofits.

More changes. Schultz revealed that transitional relief likely will be provided for targeted parts of Form 990. The IRS is eliminating from the summary page the matrix on fundraising as well as the column requesting information on a tax-exempt organization's percentage of revenue. No changes were made to Schedule B. ■

AHLA Program on Tax Issues for Health Care Organizations, Oct. 8, 2007.



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Matthew Mann, J.D.
Valerie Witmer, J.D.

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SEC—Peter Feltman

Health Law—Catherine Hubbard, M.A.
Tax—Jeff Carlson, Steve Cooper

Designer
Heather Buchanan

Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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CMS rejects physician recruitment arrangement

by Valerie L. Witmer, J.D.,
Contributing Editor

In an advisory opinion issued on October 3, 2007, CMS determined that the deletion of the excess receipts provision related to an income guarantee loan in a physician recruitment arrangement would pose a risk of abuse to the federal health care programs.

A physician recruitment arrangement, if amended to delete the excess receipts provision of the income guarantee, would not meet the requirements of the recruitment exception to the physician referral prohibition. A hospital agreed to provide financial assistance, including an income guarantee loan, to a physician if the physician would relocate to the geographic area served by the hospital. The income guarantee loan provision included an excess receipts provision, which specified that, if the physician's receipts exceeded the sum of the guaranteed revenue and physician expenses in any monthly period, the physician would have to return the excess amount to the hospital, up to the amount of the then-outstanding principal and accrued interest under the income guarantee loan.

The arrangement was amended to include the physician-owned medical group practice into which the physician was recruited. Under 42 C.F.R. §411.357(e)(4)(iii), the costs allocated by the physician practice to the recruited physician cannot exceed the actual additional incremental costs attributable to the recruited physician. Although the recruitment exception does not require the use of an excess receipts provision, the parties cannot now delete it from the arrangement. Because the physician has already relocated his medical practice, any additional compensation would not be for the purpose of inducing relocation and may directly or indirectly reflect the volume or value of the recruited physician's actual or potential referrals. ■

CMS Advisory Opinion, No. AO-2007-01, Oct. 3, 2007, *Health Care Compliance Reporter* ¶350,061.

OIG approves on-call coverage arrangement

by Valerie L. Witmer, J.D.,
Contributing Editor

The Office of Inspector General (OIG) approved a medical center's on-call coverage and uncompensated inpatient care arrangement in an advisory opinion issued on September 20, 2007.

A medical center's physician on-call coverage and uncompensated inpatient care arrangement could potentially generate prohibited remuneration under the anti-kickback statute, but administrative sanctions would not be imposed by the OIG in connection with the arrangement. Physicians on the medical center's staff in certain medical specialties provide emergency department (ED) on-call coverage, respond to patient emergencies in the ED, and provide inpatient care for uninsured patients. Physicians participating in this arrangement are paid a *per diem* rate for each day spent on call in the ED, except for one and one-half uncompensated days that each physician must contribute to the rotation schedule monthly.

Although on-call coverage compensation could be misused to entice physi-

cians to join or remain on the medical center's staff or to generate additional business for the medical center, the arrangement presents a low risk of abuse because: (1) the medical center has certified that the payments are fair market value for services needed and provided, without regard to the volume or value of business generated between the medical center and the physicians; (2) the medical center has a legitimate, unmet need for on-call coverage and uncompensated physician services; (3) the arrangement is offered uniformly to all physicians in the relevant specialties; (4) monthly call coverage obligations in each specialty are divided as equally as possible; (5) physicians must provide inpatient follow-up care to any patient seen in the ED while on call, if the patient is admitted to the medical center, regardless of the patient's ability to pay; and (6) the physicians are required to document their services in medical records, thus promoting transparency and accountability. As structured, the arrangement contains safeguards sufficient to minimize the risk that remuneration is intended to generate referrals of federal health care program business. ■

OIG Advisory Opinion, No. 07-10, Sept. 20, 2007, *Health Care Compliance Reporter* ¶500,167.

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Evaluating and minimizing research misconduct risks

by Michael E. Clark, Esq., Contributing Editor

“The chief difference [between health care fraud and research fraud] lies in the fact that research fraud is often not motivated by pecuniary gain.... There are at least two other motives for research fraud. The first is the social pressure to make important discoveries.... The second motive is the pursuit of progress or knowledge to elevate an investigator in the eyes of his peers.”¹

Commentators indicate that some of the great scientists we learned about in school may have done some questionable things that today could be the subject of investigations and sanctions if their work were federally funded: “Ptolemy, Galileo, Newton, and Mendel are among the scientific greats whose achievements have been scrutinized in modern times because of suspicions that some of those achievements were obtained in less than honest ways.”² Yet, even as the laws and regulations related to publicly-funded scientific research have increased to address such problems, these measures have not been as effective as anticipated by lawmakers and regulators—who, perhaps, failed to understand that scientists do not engage in fraudulent conduct primarily for monetary reasons.³

In the 1980’s, Congress responded to reports of research fraud discovered at large public institutions (which had received federal grants) by enacting the Health Research Extension Act.⁴ Under the Act, institutions receiving research grants must implement programs to investigate, timely report, and sanction individuals who have committed research fraud.⁵ Notably, two decades before the Act, President Eisenhower, in his 1961 Farewell Address, warned of the dangers involved with empowering the scientific, technological elite by providing large federal grants to research institutions.⁶ Despite these sage warnings, the federal grants provided to researchers have not decreased, but, instead, have increased almost geometrically. For example, in fiscal year 1998, federal funding for scientific research grew to \$74 billion, which included about 350 government-run research labs that spent \$23 billion, while the remaining \$51 billion went to universities and hospitals to support an estimated 200,000 extramural researchers funded by the Public Health Service (PHS) through the National Institutes of Health (NIH).⁷

Preventing and punishing research fraud is an important government priority. Not only are federal monies at stake, but the underlying conduct may endanger the public health.⁸ This article explores the problems associated with research fraud and the need for heightened compliance by

hospitals, medical colleges, and others who receive federal grants to avoid incurring the various costs and problems associated with administrative, civil, or criminal litigation if research fraud is discovered.

Oversight responsibilities of the Office of Research Integrity and the National Science Foundation

Although the federal focus about addressing the problem of research misconduct did not develop until the late 1980’s,⁹ two federal agencies are now primarily involved with preventing research misconduct and overseeing its discovery and punishment by institutions receiving federal funds: (1) the Office of Research Integrity (ORI); and (2) the National Science Foundation (NSF), through its Office of Inspector General.¹⁰ Note, however, that the Food and Drug Administration has long addressed related issues as part of its oversight role in the drug and medical device development and approval process.¹¹

In 1993, Congress created the ORI and placed the new agency within HHS’ Office of the Assistant Secretary for Health (OASH).¹² (Not long thereafter, the responsibility for ORI was moved to HHS’ Office of Public Health and Science.¹³) Congress tasked the ORI with addressing problems that arise from what is referred to as misconduct in science (or scientific misconduct)—a term that was later renamed research misconduct. Although the applicable definition of what constitutes actionable research misconduct has evolved over the years,¹⁴ the current definition basically focuses on falsification, fabrication, and plagiarism related to research funded through federal monies and excludes honest errors.¹⁵ The ORI and NSF rely on grantee universities to conduct the initial investigations of research misconduct allegations and timely report their findings for review. Grantee institutions must file annual “mutual assurances” that they agree to abide by the applicable rules and regulations related to research misconduct allegations. According to the OIG:

Congress ... perceived the increased volume of reported cases of misconduct as a threat to ... biomedical research.... [T]o address the issue, Congress passed a section within the Health Research Extension Act of 1985.... [T]hose applying for NIH funds [must] ... submit with their application an assurance that they have procedures in place for dealing with scientific misconduct. They also must have an administrative process to review reports of misconduct and to report to the Secretary of [HHS].... investigations which produce substantial evidence of unscientific practices.¹⁶

Because of considerable controversies about how ORI's predecessor agencies handled research misconduct allegations,¹⁷ ORI's role has evolved from direct intervention in investigating and adjudicating cases of alleged misconduct to an educational and oversight role with institutions that are required to conduct the initial investigations and timely report their findings.¹⁸ The Director of ORI succinctly explains the applicable standards for making an actionable finding of research misconduct as follows:

[T]o make a finding of research misconduct, the institution or ORI must find that there was a "significant departure from accepted practices of the relevant research community," that the misconduct was "committed intentionally, knowingly, or recklessly," and that "[t]he allegation [was] proven by a preponderance of the evidence." [42 C.F.R. §93.104] The institution or ORI has the burden of proof for finding research misconduct. [42 C.F.R. §93.106(b) (1)] While honest error or honest difference of opinion can negate a finding of research misconduct, the "respondent has the burden of going forward with and proving, by a preponderance of the evidence," that honest error or honest difference of opinion occurred. [42 C.F.R. §93.106(b)(2)-(3)].¹⁹

Other types of unsavory conduct by researchers exist that may not reach the threshold for actionable research misconduct unless it can be demonstrated that the actions were intentional, knowing, or reckless—such as bias in interpreting and reporting research data, dropping data points without a legitimate scientific justification, inadequate recordkeeping, failure to report data that contradicts the researcher's project, and republishing the same data to create the illusion the data is more significant than deserved.²⁰

It is worth noting that, in addition to the applicable regulatory standards, institutions are permitted to adopt additional policies to address issues of research misconduct and integrity.²¹ As ORI explains:

Under §93.319, institutions may have internal standards of conduct different from the HHS standards and may impose administrative actions for violations of those standards. If an institution has such internal standards and administrative actions, ORI recommends that they be included in its policies and procedures, or clearly cross-referenced so that researchers are given advance notice on the institutional response to research misconduct or other integrity violations.²²

In other words, the federal standards constitute the minimum baseline requirements.

Compliance considerations

A number of serious consequences will likely follow a determination of research misconduct, not the least being the various sanctions that can be imposed, such as: (1) requiring the retraction of published articles or the inclusion of disclaimers; (2) repayment of grant monies; (3) suspension, termination, and censure of grant recipients; and (4) debarment or disqualification from being able to participate in research projects funded through federal monies.²³ Not only must research institutions worry about complying with the federal government's rules and regulations applicable to funds for research grants under various theories of liability, the institutions—and individuals who investigate allegations of research misconduct on their behalf—may be sued by parties who have been investigated and reported for having committed research misconduct.

Cases have been filed by such private plaintiffs alleging defamation, slander, and libel; civil rights violations under 18 U.S.C. §1983; wrongful discharge or termination; breach of contract; and intentional or negligent infliction of emotional distress.²⁴ Other plaintiffs have filed whistleblower actions under the federal civil False Claims Act, seeking to recover treble damages.²⁵ Moreover, the Department of Justice has pursued some individuals civilly²⁶ and criminally for egregious research misconduct.²⁷

Unfortunately, when entities investigate and report their findings about research misconduct, they have no recognized immunity—such as that available for peer review activities by health care entities under the Health Care Quality Improvement Act (HCQIA) for qualifying peer review activities.²⁸ Moreover, although research institutions that receive federal grants are required to conduct investigations into allegations of research misconduct, courts that have considered the issue of qualified immunity have rejected it, reasoning that the conduct constitutes private action, not government action.

The absence of recognized immunity protection makes it critical for research institutions to consider indemnifying and advancing legal fees to those professionals and employees who must investigate and report about alleged research misconduct, so that they do not have to worry about legal exposure from civil suits. Delaware provides the best known model.²⁹ Companies incorporated under Delaware law may provide mandatory or discretionary indemnification of legal fees and costs to certain officers, directors, and board members. Delaware encourages companies to advance such fees and permits aggrieved parties who have not been advanced such fees the right to recover “fees on fees” if they must sue to recover their costs if they prevail in their defense.³⁰

Conclusion/best practices

Institutions that conduct research activities funded in part through federal grants must develop mechanisms to educate Investigational Review Boards, researchers, and their staff about research misconduct. The ORI provides excellent educational materials at its website (<http://ori.dhhs.gov>). Attorneys who represent institutions that receive federal grant funds should carefully review employment and contractor agreements with individuals involved in scientific research to ensure that they are bound to fully cooperate with the institution when it has to investigate allegations of research misconduct. Employees and others should know, ahead of time, that any refusal to timely respond or cooperate with such an investigation constitutes grounds for sanctions, which may include termination. The institution should follow the policies and procedures developed for the research community as a model by ORI, including the various due process and fair hearing procedures. Finally, as a practical consideration, because institutions that receive federal grants have a built-in conflict of interest when called upon to investigate research misconduct allegations (since a finding of misconduct will reflect badly, may require it to return grant monies, and could lead to civil liability) counsel must ensure that research misconduct investigations are thoroughly conducted, timely completed, and substantively correct.

Michael E. Clark, a member of the CCH Health Care Compliance Letter's Editorial Advisory Board, serves on the Governing Council and is Chair of the Publications Committee for the American Bar Association (ABA) Health Law Section. He also serves on the ABA-wide Standing Committee on Publishing Oversight, is Chair of the White Collar Crimes Committee of the ABA Business Law Section and a member of the Editorial Board of its quarterly publication, "The Business Lawyer." In addition, Mr. Clark sits on the Editorial Board for the "Business Crimes Bulletin." He has substantial litigation experience and represents professionals and businesses in administrative, civil, and criminal proceedings throughout the nation. Mr. Clark is the developer and editor-in-chief of a treatise being jointly published by BNA & the ABA Health Law Section entitled "PHARMACEUTICAL LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING." ■

- ¹ Daniel Goldberg, *Research Fraud: A Sui Generis Problem Demands a Sui Generis Solution (Plus a Little Due Process)*, 20 T.M. COOLEY L. REV. 47, 50 (2003) (internal notes omitted).
- ² Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357, 358-59 (1992) (internal notes omitted). See also Glenn Harlan Reynolds, *Thank God for the Lawyers: Some Thoughts on the (Mis)Regulation of Scientific Misconduct*, 66 TENN. L. REV. 801, 803 (1999), and Michael E. Clark, *Research Misconduct Difficult to Prove*, 3 HEALTH CARE FRAUD & ABUSE NEWSL. 1 (Nov. 2000) (same).
- ³ See, e.g., Goldberg, *supra* note 1, at 50.
- ⁴ In 1993, Congress established the Office of Research Integrity (ORI) pursuant to the Health Research Act of 1985 (PubLNo 99-158) §493, 99 Stat. 820, 874-75 (1985), codified as amended at 42 U.S.C. §289(b) a.
- ⁵ See, e.g., Jesse A. Goldner, *The Unending Saga of Legal Controls over Scientific Misconduct: A Clash of Cultures Needing Resolution*, 24 AM. J.L. & MED. 293, 295 (1998); Sandy Kline, *Scientific Misconduct: A Form of White Coat Crime*, 2 J. PHARMACY & LAW 15, 27 (1993); Karen A. Goldman & Montgomery K. Fisher, *The Constitutionality of the Other Serious Deviation from Accepted Practices Clause*, 37 JURIMETRICS J. 149-150 (1997).
- ⁶ See Clark, *supra* note 2 (citing from part of the Farewell Address).
- ⁷ Nisan A. Steinberg, *Regulation of Scientific Misconduct in Federally Funded Research*, S. CAL. INTERDISCIPLINARY L.J. 41, 44-5 (2000).
- ⁸ See *id.* at 45 (explaining that medical products developed using fraudulent or unreliable data may put the public at risk). See also Robert A. Andersen, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121, 123 (1998) (“[M]isconduct in biotechnological research could result in releases of pathogenic organisms into the environment. Deliberate mishandling or improper disposal of toxic chemicals in a laboratory poses similar health risks. Medical research often presents the potential for abuse of human and animal research subjects.”) (internal notes omitted).
- ⁹ See, e.g., Office of Inspector General [hereinafter OIG], Report No. OAI-88-07-00420, March 1989, at 2.
- ¹⁰ See, e.g., Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON IND. L. REV. 305, 321-22 (1995) (discussing federal agencies that investigate and address research misconduct problems).
- ¹¹ See Steinberg, *supra* note 7, at 55.
- ¹² See generally Lynne Bernabei & Alan R. Kabat, *The Status of Private Practice Physicians under Employment Discrimination and Labor Laws*, ALA-ABA Course No. SG013 (2001); Goldner, *supra* note 5, at 296-97.
- ¹³ Goldner, *supra* note 5, at 297 (internal notes omitted).
- ¹⁴ See Debra M. Parrish, *Research Misconduct and Plagiarism*, 33 J.C. & U.L. 65, 71-2 (2006). See also Chris B. Pascal, Director, Office of Research Integrity, *The Federal Definition and Policies on Research Misconduct- Revised PHS Misconduct Regulations* (noting that ORI has implemented the new government definition of “research misconduct” adopted by OSTP, which deletes the controversial “other serious deviations” clause from the prior definition, but adds plagiarism during the peer review process as misconduct).
- ¹⁵ The applicable research misconduct regulations vary slightly between NSF (45 C.F.R. Part 689) and PHS (42 C.F.R. §693.103).
- ¹⁶ See OIG, *supra* note 9, at 1.

On The Front Lines (cont.)

- ¹⁷ See, e.g., Roy G. Speece, Jr. & John J. Marchalonis, *Fourth Amendment Restrictions on Scientific Misconduct Proceedings at Public Universities*, 11 HEALTH MATRIX 571, 607-08 (2001) (discussing the former Office of Scientific Integrity); Debra M. Parrish, *The Federal Government and Scientific Misconduct Proceedings, Past, Present, and Future as Seen Through the Thereza Imanishi-Kari Case*, 24 J.C. & U.L. 581, 586-87, 592-93 (1998) (discussing problems with former appeals to the Department Appeals Board); Reynolds, *supra*, note 2, at 807-15 (describing some sensational cases investigated and pursued by ORI and its predecessors).
- ¹⁸ See generally Barbara K. Redman & Arthur L. Caplan, *Off with their Heads: The Need to Criminalize Some Forms of Scientific Misconduct*, 33 J.L. MED. & ETHICS 345, 345-46 (2005); 45 C.F.R. §689.4(a); 42 C.F.R. §93.100(b). See also U.S. Government Accountability Office, Report No. GAO/HEHS-95-134, Aug. 3, 1995, at 4.
- ¹⁹ Chris B. Pascal, *The Office of Research Integrity: Experience and Authorities*, 35 HOFSTRA L. REV. 795, 797 (2006) (internal citations omitted).
- ²⁰ See *id.* at 797; Burk, *supra* note 10, at 311-12 (discussing data “trimming” to make the researcher’s observations fit a hypothesis and selective data reporting so that only the data reported fits the conclusions); Kuzma, *supra* note 2, at 367-69 (same).
- ²¹ See Chris B. Pascal, *Research Integrity: Institutional Standards, Misconduct, Protection of Human Subjects, and More*, St. Vincent Hospital Research Symposium, Indianapolis, IN (2005), at 10.
- ²² See “Requirements for Institutional Policies and Procedures on Research Misconduct under the New PHS Policies on Research Misconduct - 42 CFR Part 93,” available at <http://ori.hhs.gov/policies/Requirements-Reg-6-05.shtml>.
- ²³ See Goldner, *supra* note 5, at 301.
- ²⁴ See, e.g., *Angelides v. Baylor Coll. of Med.*, 117 F.3d 833 (5th Cir. 1997) (suit by terminated researcher settled after court held that collateral order doctrine precluded review of district court’s immunity and exhaustion decisions); *Bagasra v. Thomas Jefferson Univ.*, 1999 WL 517404 (E.D. Pa. July 20, 1999) (granting and denying in part institution’s motion to dismiss terminated researcher’s suit alleging wrongful discharge in retaliation for accusing colleagues of research misconduct, civil False Claims Act violations, and state tort claims); *Radolf v. Univ. of Conn.*, 364 F. Supp. 2d 204 (D. Conn. 2005) (dismissing suit filed by researcher who was put on academic probation for three years, despite having agreed to voluntary exclusion after admitting to scientific misconduct involving NIH-funded research).
- ²⁵ See, e.g., *Gross ex rel. United States v. Aids Research Alliance-Chicago*, 2004 WL 905952 (N.D. Ill. Apr. 16, 2004) (dismissing *qui tam* action filed by former patient in a study sponsored by FDA and NIH to investigate the effectiveness of a combination of drugs on HIV patients); *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402 (3d Cir. 1999) (reversing in part summary judgment against a medical school professor who filed a *qui tam* suit after his complaints about a colleague’s research misconduct were allegedly swept aside by the university); *United States ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1462 (4th Cir. 1997) (reversing doctoral student’s *qui tam* award because the alleged research misconduct was far too attenuated to support the verdict). Under the Eleventh Amendment of the United States Constitution, the applicability for private recovery is precluded if the institution is state-affiliated. See *Vt. Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000); *United States ex rel. Foulds v. Tex. Tech Univ.*, 171 F.3d 279 (5th Cir. 1999). Moreover, some federal appeals courts, notably the Fifth Circuit, require that any alleged false claims must relate to demands for payment from the federal government to be materially false and actionable, which may preclude relators from obtaining recoveries under the so-called “tainted claims” or “impliedly false certification” theories. See *United States v. Southland Mgmt. Corp.*, 288 F.3d 665 (5th Cir. 2002). See also, Michael E. Clark, *Whether the False Claims Act is a Proper Legal Tool for the Government to use for Improving the Quality of Care in Long Term Care Facilities?*, 15 No. 1 HEALTH LAW. 12, 13-5 (2002).
- ²⁶ See, e.g., DOJ Press Release, “U.S. Sues Canadian Hospital for \$500,000 for Breast Cancer Research Fraud,” May 30, 1995 (indicating that the government was seeking reimbursement from St. Luc Hospital in Montreal of costs incurred in investigating and eliminating false data submitted by a cancer surgeon in an international breast cancer study funded by NIH).
- ²⁷ See Kuzma, *supra* note 2, at 357 (discussing the case a former university research psychologist who pled guilty to falsifying results from research funded in part through grants from the National Institute of Mental Health to investigate the effects of treating hyperactive retarded children with Ritalin and Dexedrine).
- ²⁸ 42 U.S.C. §§ 11101, et seq. To see the inconsistent treatment by federal courts as to claims of qualified immunity for individuals and entities who investigate research misconduct allegations, as opposed to federal agents, compare *Angelides*, 117 F.3d 833, with *Popovic v. United States*, 997 F. Supp. 672 (D. Md. 1998).
- ²⁹ See 8 DEL. C. § 145.
- ³⁰ See, e.g., *Fasciana v. Elec. Data Sys. Corp.*, 829 A.2d 178 (Del. Ch. 2003); *Perconti v. Thornton Oil Corp.*, 2002 WL 982419 (Del. Ch. 2002); *Reddy v. Elec. Data Sys. Corp.*, 2002 WL 1358761 (Del. Ch. Jun 18, 2002); *Stifel Fin. Corp. v. Cochran*, 809 A.2d 555 (Del. 2002); *VonFeldt v. Stifel Fin. Corp.*, 714 A.2d 79 (Del. 1998); *Waltuch v. Conticommodity Servs., Inc.*, 88 F.3d 87 (2d Cir. 1996); *Witco Corp. v. Beehuis*, 38 F.3d 682 (3rd Cir. 1994).

OIG approves cancer treatment subsidies

by Valerie L. Witmer, J.D.,
Contributing Editor

A charitable organization's proposal to establish a foundation to provide financially needy cancer patients with grants to defray their out-of-pocket treatment costs would not constitute grounds for the imposition of civil monetary penalties and administrative sanctions under the anti-kickback statute, according to an advisory opinion issued by the Office of Inspector General on September 28, 2007.

It is unlikely that donor contributions would improperly influence referrals by the organization because the foundation would: (1) have absolute, independent, autonomous control over the use of donor contributions; (2) award assistance in an independent manner that severs any link between donors and beneficiaries; (3) award assistance without regard to any donor's interests or the beneficiary's choice of product, provider, practitioner, supplier, or insurance plan; (4) provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner; and (5) not provide donors with data that would enable them to correlate the amount or frequency of their donations with the amount or frequency of the use of their products or services.

Moreover, the arrangement would not be likely to improperly influence beneficiaries' selection of a provider, practitioner, supplier, or product because: (1) the foundation would assist all eligible patients on a first-come, first-served basis, to the extent funding is available; (2) the foundation's determination of a beneficiary's qualification for assistance will be based solely on financial need; (3) the subsidies will expand beneficiaries' freedom of choice; and (4) the foundation's interest as a charitable, tax-exempt entity ensures that it will monitor utilization to keep subsidies at a minimum. ■

OIG Advisory Opinion, No. 07-11, Sept. 28, 2007, *Health Care Compliance Reporter* ¶500,168.

In the News

Pharmacy bill won't foster quality, efficiency, FTC says

The Federal Trade Commission (FTC) is opposed to the "Community Pharmacy Fairness Act of 2007" (H.R. 971), a bill that would create an exemption in the antitrust laws to allow pharmacies to engage in collective bargaining to secure higher fees and more favorable contract terms from health plans. In testimony before the House of Representatives' Antitrust Task Force, David P. Wales, Jr., Deputy Director of the FTC Bureau of Competition, said that the commission believes the bill would dull competitive pressures that drive pharmacies to improve quality and efficiency. Rather than a sweeping antitrust exemption, a narrowly tailored solution to the difficulties facing small pharmacies would be more appropriate, Wales said. ■

FTC Press Release, Oct. 18, 2007.

HHS awards HIE contracts to test EHR security

Contracts totaling \$22.5 million have been awarded to nine health information exchanges (HIEs) by HHS Secretary Mike Leavitt to begin trial implementations of the Nationwide Health Information Network (NHIN). HIEs are networks that securely connect electronic health records (EHRs) for providers and patients and form the foundation of the NHIN—part of President Bush's goal of providing patients access to secure EHRs by 2014. The contracts were awarded to state and regional HIEs that will participate in the NHIN Cooperative, a collaborative endeavor that will test and demonstrate the exchange of secure health information among providers, patients, and other stakeholders. For more details on these contracts, visit <http://www.hhs.gov/healthit>. ■

HHS News Release, Oct. 5, 2007.

Medicare to recoup billions from Part D plan sponsors

CMS has announced that it will collect \$4 billion from Part D drug plan sponsors due to lower-than-expected drug costs in 2006, the first year of the Medicare drug program. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (PubLNo. 108-173), CMS is required to pay the plan sponsors prospectively based on their bids. After the end of the contracting year, when all the claims data is available, the prospective payments are compared to actual incurred costs and other related data, and appropriate adjustments are made to the plan payments. Actual drug costs for almost all Part D plans were below expected levels in their 2006 bids. The lower than expected spending came in part because: (1) 2006 marked the first time that plans were bidding on the new Part D program; and (2) there were higher levels of generic drug utilization in Part D than anticipated. As plans have further experience with the Part D program, their bid submissions in future years will more accurately anticipate their actual costs to provide prescription drug coverage. The 2007 bid submissions were significantly lower than those submitted in 2006 and were a reflection of the actual 2006 Part D drug program experience. Accordingly, CMS anticipates that amounts collected from or paid to plans in future years as a result of final reconciliation and risk sharing will be significantly lower than the reconciliation for the 2006 plan year. ■

CMS News Release, Oct. 5, 2007.