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# MEDICs identify Part D fraud and abuse, OIG reviews

One of the key aspects of CMS' strategy to combat Medicare Part D fraud and abuse is the use of innovative techniques for data analysis by Medicare Drug Integrity Contractors (MEDICs). Beginning in 2007, CMS awarded contracts to three regional MEDICs to address potential Part D fraud and abuse. For this report, the Office of Inspector General (OIG) reviewed MEDIC data covering FY 2008, the second year of MEDICs' operations, to determine: (1) the extent to which MEDIC identified and investigated potential Part D fraud and abuse incidents, (2) whether these incidents were identified through external sources or proactive methods, and (3) any issues or barriers MEDICs encountered in identifying or investigating potential fraud and abuse incidents. The OIG made the following findings:

**Incidents.** MEDICs identified 4,194 incidents of potential fraud and abuse. Eighty-seven percent (3,641) of potential fraud and abuse incidents were identified through external sources, primarily complaints. The remaining 13 percent (553) were identified through proactive methods, such as data analysis.

**Investigations.** MEDICs conducted 1,320 investigations. Ninety-six percent of the investigations involved incidents of potential fraud and abuse identified through external sources. From these investigations, MEDICs made 65 referrals and 34 immediate advisements to the OIG, 257 referrals to state insurance commissioners, and 39 referrals to CMS for administrative action.

**Data access problems.** MEDICs need both Part D prescription drug event (PDE) data and data regarding Medicare Part B to effectively identify and investigate potential Part D fraud and abuse. MEDICs, however, did not receive access to PDE data until August 2007, nearly a year after their contracts began. Two MEDICs were not given access to Part B data until the fall of 2008, two years after their contracts began. The third MEDIC did not receive access to Part B data before its contract ended.

**Data use problems.** After receiving access to PDE data, MEDICs reported that important variables were not part of the data, making effective data analysis difficult. The PDE data also had prescriber identifiers stored in incorrect fields, which affected their data analysis.

**Lack of authority.** MEDICs did not have the authority to obtain prescriptions and medical records directly from pharmacies, pharmacy benefit managers, and physicians. MEDICs had authority to request information only from the plan sponsors. This restriction hindered their ability to investigate.

**Non-referral by plan sponsors.** MEDICs may not have been aware of some potential incidents of fraud and abuse because plan sponsors are encouraged to refer incidents, but not required to do so. One MEDIC received relatively few re-

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ferrals compared to the number of plan sponsors in its jurisdiction. The other two MEDICs indicated some plans had never referred any such incidents.

**Lack of audit authority.** While MEDICs are responsible for conducting audits of plan sponsors' compliance plans, none of these audits were conducted in FY 2008 because CMS did not give its approval. Between October and December 2008, two years after MEDICs' regional contracts began, the two remaining MEDICs did receive approval from CMS to begin 10 audits of plan sponsors' compliance plans.

**OIG recommendations.** The OIG recommends that CMS: (1) ensure MEDICs have access to accurate and comprehensive data to assist them in identifying and investigating potential fraud and abuse and conducting proactive data analysis; (2) authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from pharmacies, pharmacy benefit managers, and physicians; (3) require plan sponsors to report all potential fraud and abuse incidents that are referred to law enforcement agencies to MEDICs as well; and (4) ensure MEDICs have approval to conduct compliance plan audits that they are responsible for under their task orders and Statement of Work.

**CMS response.** CMS concurred with the first OIG recommendation regarding access to data, but it did not provide a time frame for implementation. CMS did not indicate whether it concurred with the second recommendation, stating it recognized the value of the recommendation, but that its statutory authority to collect information directly from downstream entities was limited. CMS concurred with the third recommendation, but did not believe that it currently had the regulatory authority to require that plan sponsors report these incidents. CMS concurred with the fourth recommendation, but did not provide details on the number of compliance plan audits it would approve. ■

*OIG Report, OEI-03-08-00420, Oct. 2009, Health Care Compliance Reporter, ¶530,736*

# Quality of Care

## 2010 physician fee schedule changes to MIPPA quality incentives

The 2010 Medicare physician fee schedule (PFS) implements a number of provisions in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PubLNo 110-275), including provisions related to the Physician Quality Reporting Initiative (PQRI) and the E-Prescribing Incentive Program.

**PQRI.** The PQRI is a voluntary reporting program that provides an incentive payment to eligible professionals who satisfactorily report data on quality measures for covered professional services during a specified reporting period. The term "eligible professional" means any of the following: (1) physician, (2) practitioner, (3) physical or occupational therapist or a qualified speech-language pathologist, or (4) qualified audiologist. Beginning in 2010, participants may earn an incentive payment of two percent of the eligible professionals' estimated total allowed charges for professional services covered under Part B. The PFS moreover adds 30 individual PQRI measures and six measures groups, and an electronic health record-based reporting mechanism to promote the use of electronic health records. CMS will post on its website the names of eligible professionals and group practices that satisfactorily report quality measures following the distribution of the 2010 incentive payments.

**E-Prescribing Incentive Program.** The E-Prescribing Incentive Program provides for incentive payments to eligible professionals who are successful electronic prescribers (e-prescribers). Beginning in 2010, the program will impose penalties on eligible professionals who are not successful e-prescribers. CMS will broaden eligibility for the e-prescribing incentive by including professional services furnished in skilled nursing facilities, domiciliary care, or the home care setting as part of the list of services for which the electronic prescribing measure is reportable, and enable group practices to qualify for a 2010 e-prescribing incentive payment based on a determination at the group practice level, rather than at the individual level. CMS will post on its website the names of

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individual eligible professionals and group practices that are successful e-prescribers for the 2010 E-Prescribing Incentive Program following the distribution of the 2010 incentive payments. ■

*CCH Chicago Bureau, Oct. 30, 2009.*

## OIG: Ryan White program grantees compliant

Almost all grantees of the Ryan White program complied with the core medical services pursuant to the Ryan White CARE Act, according to the Office of Inspector General (OIG).

**Ryan White program.** The Ryan White CARE Act established the program to provide funding to grantees to develop and operate health care and support services for people with HIV and AIDS. The program is administered by the Health Resources and Services Administration (HRSA) and is the largest federally funded program dedicated to providing services to people with HIV/AIDS.

The Ryan White HIV/AIDS Treatment Modernization Act of 2006 changed how Ryan White funds may be used. One key change established a requirement that certain grantees spend at least 75 percent of awarded grant funds on core medical services unless they receive waivers of this requirement.

The core medical services requirement applies to funds provided under Parts A, B and C of the Ryan White CARE Act. Part A grants are awarded to metropolitan areas for HIV-related services. Part B base grants, along with supplemental funds, are awarded to states and territories to improve the quality, availability, and organization of health care and support services. Part C Early Intervention Services grants are made to public and private nonprofit organizations to fund comprehensive primary health care in an outpatient setting for people living with HIV.

**Core medical services requirement.** The core medical services requirement established in 2006 states that Parts A, B and C grantees must spend at least 75 percent of their funds on core medical services. The core medical services include: outpatient and ambulatory health services; pharmaceutical assistance, including medications provided through the AIDS Drug Assistance Program; and oral health care, among others.

**Compliance with core medical services requirement.** The majority of grantees complied with the core medical services requirement in 2007 and 2008. Parts A, B and C grantees collectively spent an average of 93 percent of their grant funds on core medical services in 2007. The average spending of Part A grantees on core medical services in 2007 and their allocated expenditures in 2008 were 82 percent. Part B and Part C grantees' average spending on core medical services in 2007 were 94 and 95 percent, respectively; in 2008, their allocated expenditures for core medical services were both 94 percent.

The grantees' 2006 expenditures showed that they were already spending a high proportion of grant funds on core medical services prior to the implementation of the requirement. From 2006 to 2007, Part A grantees' average spending on core medical services changed from 74 percent to 82 percent, Part B grantees' average spending changed from 95 percent to 94 percent, and Part C grantees' average spending remained at 95 percent. A number of grantees offered a number of suggestions regarding the requirement, including: expanding the definitions of the core medical service categories to include case management, inpatient substance abuse treatment, and transportation; and seeking provider and consumer input during the next reauthorization.

**Effect on administrative practices.** Parts A, B and C grantees indicated that implementing the requirement was easy. However, they indicated that the requirement created additional burdens on administrative practices: 14 percent of all grantees reported that the core medical services requirement increased their administrative burden.

**HRSA guidance.** Eighty-one percent of grantees received guidance from HRSA on the requirement, and 95 percent of grantees that received guidance indicated that they found the guidance helpful. However, 71 percent of grantees reported experiencing project officer turnover and limited experience of project officers that resulted in inconsistent grantee oversight. Further, the OIG found that issues with project officer oversight continue to cause vulnerabilities within the Ryan White program. ■

*OIG Report, No. OEI-07-08-00240, Oct. 2009*

# RACs and HEAT and TARP – Oh, My! – Part 2

**by Michael E. Clark, JD**

*Health care professionals face escalating dangers that increase the likelihood of serious consequences. In Part 1, the author discussed 2 of 5 recent developments that have created this environment. In Part 2, Mr. Clark discusses the remaining three developments: federal contractors' compliance obligations under the Federal Acquisition Regulations (FAR); the conditions on the stimulus funds under the TARP; and amendments to the federal civil False Claims Act.*

## Heightened Obligations for Federal Contractors Imposed By FAR[21]

Since December 2008, healthcare providers funded in whole or through federal contract grants must be mindful of new self-reporting obligations imposed under the FARs, or risk possible suspension or debarment.[22] In particular, three mandatory disclosure requirements pursuant to the FARs must be considered, as discussed in more detail below:[23]

1. ***Disclosure required by FAR 3.1003(a)(2), (3) to avoid suspension or debarment.***
   FAR 3.1003 sets out the following requirements, in pertinent part:
   (a)(2) *Whether or not the clause at 52.203-13 is applicable*, a contractor may be suspended and/or debarred for knowing failure ... to timely disclose to the Government, in connection with the award, performance, or closeout of a Government contract performed by the contractor or a subcontract awarded thereunder, *credible evidence* of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act. Knowing failure to timely disclose credible evidence of any of the above ... remains a cause for suspension and/or debarment until 3 years after final payment on a contract ....
   (3) The Payment clauses at FAR 52.212-4(i)(5), 52.232-25(d), 52.232-26(c), and 52.232-27(l) require that, if the contractor becomes aware that the Government has overpaid on a contract financing or invoice payment, the contractor shall remit the overpayment amount to the Government. A contractor may be suspended and/or debarred for knowing failure ... to *timely disclose* credible evidence of a significant overpayment ....
2. ***Disclosure required by FAR 52.203-13(b)(3), the Contract Clause.***
   FAR 52.203-13 provides, in relevant part, that:
   (b) Code of business ethics and conduct.
   * * *
   (3)(i) The Contractor *shall timely disclose*, in writing, to the agency ...[OIG], with a copy to the Contracting Officer, *whenever*, in connection with the award, performance, or closeout of this contract or any subcontract thereunder, the *Contractor has credible evidence* that a principal, employee, agent, or subcontractor of the Contractor has committed—
   (A) A violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code; or
   (B) A violation of the civil False Claims Act (31 U.S.C. 3729-3733).
   * * *
   (iii) If the violation relates to an order against a Government[-]wide acquisition contract, a multi-agency contract, a multiple-award schedule contract such as the Federal Supply Schedule, or any other procurement instrument intended for use by multiple agencies, the Contractor shall notify the OIG of the ordering agency and the IG of the agency responsible for the basic contract.

   Notably, the disclosure requirement applies to all government contractors *except* for *small businesses* or contracts that are *limited to commercial purposes*.[24]
3. ***Disclosure required by FAR 52.203-13(c)(2)(ii)(F) for an internal control system.***
   FAR 52.203-13(c)(2)(ii)(F) also excludes small business concerns or contracts for the awards of commercial items. It provides, in relevant part, that:
   (c) Business ethics awareness and compliance program and internal control system. ... The Contractor shall establish the following within 90 days after contract award, unless the Contracting Officer establishes a longer time period:
   * * *
   (2) An internal control system.
   * * *
   (ii) At a minimum, the Contractor's internal control system shall provide for the following:
   * * *
   (F) *Timely disclosure*, in writing, to the agency OIG, with a copy to the Contracting Officer, *whenever*, in connection with the award, performance, or closeout of any Government contract performed by the Contractor or a subcontract thereunder, *the Contractor has credible evidence*

> that a principal, employee, agent, or subcontractor of the Contractor has committed a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 U.S.C. or a violation of the civil False Claims Act (31 U.S.C. 3729-3733).
>
> * * *

As should be evident, these FAR provisions pose significant downstream liability issues for contractors, whose risks are tied to the conduct of their subcontractors and third parties. Therefore, it is critical for entities receiving government contract awards to establish systems and controls designed to discover "credible evidence" about the type of misconduct forbidden by the FARs so that credible evidence can be gathered and "timely reports" made to responsible government officials.

So what constitutes *credible evidence* and what is a *timely report* under these FAR provisions? As explained below, the term *credible evidence* is a modification of an earlier proposed standard. It seems to mean that a contractor will be accorded a reasonable time to assess the evidence before it must be disclosed (or not):

> [T]he term "credible evidence" is a change from the originally proposed "reasonable grounds to believe," and the commentary discloses that this change "indicates a higher standard, *implying that the contractor will have the opportunity to take some time for preliminary examination of the evidence to determine its credibility before deciding to disclose to the government*." Adding that "[u]ntil the contractor has determined the evidence to be credible, there can be no 'knowing failure to disclose' [and that t]his does not impose upon the contractor an obligation to carry out a complex investigation, but only to take reasonable steps that the contractor considers sufficient to determine that the evidence is credible."[25]

Presumably, a contractor should conduct an internal investigation (or "preliminary evaluation") into misconduct allegations to assess whether there is enough evidence to support the claims and if the evidence is credible or not.[26] Unfortunately, however, a contractor's determination of insufficient credible evidence to mandate self-disclosure easily could be open to governmental second-guessing; this could lead contractors to play it safe by over-reporting marginal evidence of misconduct.[27] Whether this will be the case is still too early to tell.

## Strict Terms and Conditions Tied to TARP Funds

As our nation has been struggling to recover from several major economic problems stemming from the subprime debacle and the subsequent broader, threatened collapse of major financial institutions and large employers, our leaders have moved quickly to provide unprecedented amounts of stimulus funds to prevent a systemic collapse and restore consumer confidence. Not surprisingly, there are significant obligations associated with the receipt of these funds,[28] measures which are intended to prevent fraud or otherwise punish bad actors.

Among the critical pieces of legislation quickly ushered through Congress as part of the reform measures was The Emergency Economic Stabilization Act of 2008.[29] It broadly authorized, *inter alia*, The Troubled Asset Relief Program ("TARP")[30] and created the position of the Special Inspector General for TARP ("SIG TARP").[31]

In light of the unprecedented magnitude and speed of the federal government's cash infusion (up to $700 billion to buy troubled assets[32]) into the economy through TARP, it would be surprising if a significant amount of fraud and abuse tied to the disbursement and use of these funds is not uncovered before long.[33] This is where the SIG TARP's role is important.

The Emergency Economic Stabilization Act of 2008 created a "Financial Stability Oversight Board" comprised of the Chairman of the Board of Governors of the Federal Reserve System, the Secretary the Treasury, the Director of the Federal Housing Finance Agency, the Chairman of the Securities Exchange Commission, and the Secretary of Housing and Urban Development. It charged this Board with, among other things, "reporting any suspected fraud, misrepresentation, or malfeasance to the Special Inspector General for the Troubled Assets Relief Program or the Attorney General of the United States ...."[34] The SIG TARP has also been well funded, having been allocated $50,000,000 by Congress in the Act to perform its duties.[35] It is charged with "conduct[ing], supervis[ing], and coordinat[ing] audits and investigations of the purchase, management, and sale of [TARP] assets ...."[36] In testimony provided to Congress, the Special Inspector General, Neil M. Barofsky (who was sworn into office on December 15, 2008), reported that his agency currently is actively investigating fraud in the use of TARP funds:

> SIGTARP's Investigations Division has developed rapidly and is quickly becoming a sophisticated white-collar law enforcement agency. As of June 30, 2009, SIGTARP had 35 ongoing criminal and civil investigations. These investigations include complex issues concerning suspecting accounting fraud, securities fraud, insider trading, mortgage servicer misconduct, mortgage fraud, public corruption, false statements, and tax investigations.[37]

At bottom, The Emergency Economic Stabilization Act of 2008 represents yet another step in the federal government's modern approach to crisis management[38]—that is, to increasingly manage corporate governance as exemplified by the Sarbanes-Oxley Act's[39] broad reform measures (which also followed on the heels of economic problems and scandals[40]) notwithstanding principles of federalism which should limit the federal government's intrusion into an area considered to be the province of the states' powers.

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## Substantial Amendments to the Federal Civil False Claims Act

The Fraud Enforcement and Recovery Act of 2009 ("FERA"), which was signed into law on May 29, 2009, likely represents the most dangerous of the recent developments facing the healthcare community. As noted FCA expert John T. Boese recently told an audience at the DRI's Annual Meeting in Chicago, Illinois, FERA represents a major power grab by the U.S. Department of Justice. He may not be off the mark.

Since the 1990s, reported *qui tam* actions have increased in number and size, almost exponentially. The lure to the federal government of being able to use the FCA as a means of finding and recovering federal monies lost to fraud and abuse is certainly strong. In addition, because of the impact of tort reform, increasing numbers of well-heeled plaintiffs' attorneys have moved away from securities fraud class actions and other once-highly remunerative causes of action in favor of the FCA because of its potentially enormous bounty reward. Clearly, in light of the number of claims routinely submitted by health care professionals and providers seeking reimbursement, as well as the amount of money tied to pharmaceuticals, this industry has seen its fair share of these suits.

As Congress intended, FERA's provisions now effectively nullify some of the successes that defense counsel had achieved with courts in how they construe some of the FCA's important, but undefined provisions. As commentators have ably observed,[41] FERA's key changes to the FCA include:

- reversing last year's unanimous Supreme Court decision in *Allison Engine* by eliminating the FCA's "specific intent" requirement—thereby making the FCA what the *Allison Engine* Court said it was not (before the amendments): an "all-purpose antifraud statute;"[42]
- expanding the definition of what constitutes a "claim" made to the government and facts that are "material" to the government's payment of a claim;[43]
- extending liability for the intentional retention of an "overpayment" from the government;[44]
- extending the statute of limitations to permit the government's complaint to "relate back" to filing of relator's original complaint, which can be years earlier;[45]
- making it easier to serve Civil Investigative Demands and gather information;[46] and
- expanding the class of persons entitled to "whistleblower" protection from retaliation.[47]

FERA's amendments to the FCA should significantly aid *qui tam* relators not only in making it easier to file whistleblower suits, but also, perhaps more importantly, in being able to keep them from being dismissed once filed.[48] By eliminating the presentment requirement and expanding the meaning of what constitutes an actionable "claim," FERA "will extend potentially liability to all fraud committed against [government] contractors and grantees."[49] In addition, by placing a new and less onerous definition of the term "materiality" within the FCA, Congress similarly eased the burdens for plaintiffs' counsel: "'Material' is now statutorily defined as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'"[50]

## Forewarned is Forearmed

This article has illustrated the new, ongoing, and potentially devastating consequences to professionals and providers operating in this very heavily regulated industry that fail to modify their affairs as and when necessary in light of changing government regulations. Proactive adjustment of corporate governance mechanisms and compliance plans is critical. It is far more cost effective to be proactive than reactive. It is also expected. In today's world, regulators and the public are not willing to tolerate mistakes, honest or not. ■

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21 FAR 3.1004(a) ("Contract Clauses") requires that the provisions of FAR Clause 52.203-13 be placed into solicitations and contracts greater than $5 million which have a performance period that is longer than 120 days.

22 The Final Rule was published in 73 FR 67064 (Nov. 12, 2008) ("Final Rule: Federal Acquisition Regulation; FAR Case 2007–006, Contractor Business Ethics Compliance Program and Disclosure Requirements") and took effect on December 12, 2008. In pertinent part, it explains: "The rule provides for the suspension or debarment of a contractor for knowing failure by a principal to timely disclose, in writing, to the agency Office of the Inspector General, with a copy to the contracting officer, certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. The final rule implements 'The Close the Contractor Fraud Loophole Act,' Public Law 110–252, Title VI, Chapter 1. The statute defines a covered contract to mean 'any contract in an amount greater than $5,000,000 and more than 120 days in duration.'"

The Close the Contractor Fraud Loophole Act provides in relevant part that "[t]he [FAR] … shall be amended within 180 days after the date of the enactment of this Act … to include provisions that require timely notification by Federal contractors of violations of Federal criminal law or overpayments in connection with the award or performance of covered contracts or subcontracts, including those performed outside the United States and those for commercial items." Eric W. Leonard and Jon W. Burd, *New FAR Rules Requiring Mandatory Disclosures*, Riley Fein (Dec. 11, 2008) (Powerpoint slides), *available at* http://www.pli.edu/emktg/compliance_coun/FARRules_ManDisc6.pdf.

23 Emphasis supplied. *See* Carol A. Poindexter, *Aftermath of the Financial Meltdown: Analyzing Future Litigation & Compliance Issues*, materials submitted for the ABA Business Law Section's Mid-Year Meeting, Vancouver, B.C. (April 17, 2009).

24 Emphasis supplied. *See* FAR 52.203-13(c), which provides in relevant that "… paragraph (c) does not apply if the Contractor has represented itself as a small business concern pursuant to the award of this contract or if this contract is for the acquisition of a commercial item as defined at FAR 2.101." A "commercial item" as defined in FAR 2.101 can mean one of several things, but generally is something used by the general public or non-governmental entities for purposes other than governmental ones. Nonetheless, as commentators have cautioned, FAR 9.406-2 and 9.407-2 were revised to include additional grounds for suspension and debarment, and these provisions require timely disclosure of credible evidence concerning the commission of federal criminal law violations involving fraud, etc., or FCA violations. Significantly, these revised FAR provisions apply to *all* contractors, and don't exempt contracts involving commercial items or small businesses. *See* Leonard and Burd, *New FAR Rules Requiring Mandatory Disclosures*, Riley Fein (Dec. 11, 2008).

25 Rick Kulevich, *Recent Amendments to the Federal Acquisition Rule: The Final Changes*, Corporate Compliance.org (Dec. 28, 2008), *available at* http://corporatecompliance.org/Content/NavigationMenu/Resources/IssuesAnswers/AmendmentsFederalAcquisitionRule.pdf (emphasis supplied). *See also*

73 FR at 67065, explaining in relevant part that "[t]he first proposed rule, published in the Federal Register on November 14, 2007, proposed … [¶ 2. Changes to the requirement for a code of business ethics and conduct (52.203–XX). … Require timely disclosure to the agency Office of the Inspector General (OIG), with a copy to the contracting officer, whenever the contractor has reasonable grounds to suspect a violation of criminal law in connection with the award or performance of the contract or any subcontract thereunder.")

[26] *See* Allison V. Feierabend and Jennifer A. Short, *New Regulations Require Government Contractors to Investigate and Self-Report Criminal Violations*, ABA Section of Criminal Justice White Collar Crimes Committee (March 13, 2009) ("[T]he FAR Councils that authored the rule have explained that the term 'credible evidence' implies that a contractor will undertake a 'preliminary examination of the evidence to determine its credibility before deciding to disclose to the Government.'") (Internal note omitted, citing 73 FR 67073), *available at* http://www.abanet.org/crimjust/wcc/march09feierabend.doc.

[27] *See, e.g.*, Leonard and Burd, *New FAR Rules Requiring Mandatory Disclosures*, Riley Fein (Dec. 11, 2008), at 15 ("Informal comments by Government representatives suggest that contractors should over-report when confronted with a potential violation that is 'on the edge.'"). *See also* John T. Boese, *FAR Amendment Requires Federal Contractors to Make Mandatory Disclosure if "Credible Evidence" of False Claims Act Violations Exists, But Lacks Clear Standards for Action*, The Judicial View, *available at* http://www.judicialview.com/Law-Articles/Contracts/Civil-False-Claims-Act/FAR-Amendment-Requires-Federal-Contractors-to-Make-Mandatory-Disclosure-if-Credible-Evidence-of-False-Claims-Act-Violations-Exists-But-Lacks-Clear-Standards-for-Action/13/5232=1 ("The following morsel of guidance on the 'credible evidence' standard is provided in the final rule: [¶] [T]he mere filing of a qui tam action ... is not sufficient to establish a violation under the statute, nor does it represent, standing alone, credible evidence of a violation. [¶] This recognizes that qui tam complaints are not 'credible evidence' of FCA violations, and that the duty to disclose cannot be premised on the filing of such complaints alone. Something more is required to trigger the mandatory duty to disclose. On the other hand, many contractors may decide to disclose qui tam cases without making a 'credible evidence' determination … to avoid the argument by the qui tam relator that the disclosure under the FAR was itself an admission of liability….").

[28] A good overview about some of the new reporting obligations imposed on recipients of TARP funds is provided by James Hamilton, *New Rules for TARP Firms Give Prominent Role to Compensation Committees and Require 10-K Certifications*, CCH Financial News Center (June 15, 2009) (noting that, "[a]mong other things, the principal executive and financial officers must certify that the compensation committee has met at least every six months during the prior fiscal year with the senior risk officers of the TARP company to discuss and evaluate senior executive officer compensation plans and employee compensation plans and the risks these plans pose to the TARP firm. They must also certify that the compensation committee has identified and limited the features in the senior officer compensation plans that could lead such officers to take unnecessary or excessive risks that could threaten the value of the TARP company; and, similarly, that they have identified any features in the employee compensation plans that pose risks to the company, and have limited those features to ensure that the TARP firm is not unnecessarily exposed to risks."), *available at* http://www.financialcrisisupdate.com.

[29] PubLNo 110-343, 122 Stat. 3765 (enacted Oct. 3, 2008).

[30] *See id.* at Title I ("Troubled Assets Relief Program").

[31] *See id.* § 121 ("Special Inspector General for the Troubled Asset Relief Program."). For a good overview about this new government office, see Vanessa K. Burrows, *The Special Inspector General for the Troubled Asset Relief Program (SIG TARP)*, Congressional Resource Services, Report RS22981 (Nov. 5, 2008).

[32] *See id.* at §§ 101, 115.

[33] *See* Poindexter, *Aftermath of the Financial Meltdown: Analyzing Future Litigation & Compliance Issues*.

[34] *See* The Emergency Economic Stabilization Act of 2008 § 104(a)(3), (b).

[35] *See id.* § 121(g).

[36] *See id.* § 121.

[37] Statement of Neil Barofsky, Special Inspector General for the Troubled Asset Relief Program, Before the Senate Committee on Banking, Housing, and Urban Affairs (September 24, 2009), at 4, *available at* http://images.thetruthaboutcars.com/2009/09/index-1.pdf.

[38] Robert J. Rhee, *Nationalization of Corporate Governance and Purpose During Crisis* (Working Paper, Sept. 5, 2009), *available at* http://ssrn.com/abstract=1447050 (observing, *inter alia*, that "where the government has strong supervisory authority, … the episode has shown that the government can … use substantive regulation of an industry as a device of corporate governance to serve a broader public purpose … and such potential has significant implication on the politics of corporate law.").

[39] PubLNo 107-204, 116 Stat. 745 (2002) (The actual title of the legislation is The Public Accounting Reform and Investor Protection Act, but is commonly known as the "Sarbanes–Oxley Act of 2002" or "Sarbanes-Oxley").

[40] *See generally*, Michael E. Clark, *Hamstrung or Properly Calibrated?* INTERNATIONAL JOURNAL OF DISCLOSURE AND GOVERNANCE, Vol. 1, No. 3 (October 2004) (describing Sarbanes-Oxley's broad hodgepodge of features, such as the various new corporate governance requirements, including quicker, more "real time" disclosures, the safeguarding of key financial information by publicly traded corporations, the filing of mandatory certifications about the integrity of information reported by key corporate executives, the new auditing oversight standards, and the new white collar crime offences that were enacted).

[41] *See* Alston & Bird, *Government Investigations, Health Care and Government Contracts Advisory* (June 1, 2009).

[42] *Id.* (referring to *Allison Engine Co. v. United States ex rel. Sanders*, 128 S.Ct. 2123 (2008), a unanimous decision holding that for claims presented to government intermediaries to be actionable, the presenter must have intended that its false statements be relied upon by the government to pay the false claims). *See* Peter B. Hutt II and Robert S. Salcido, *False Alarms*, Los Angeles Daily Journal (June 10, 2009), at p. 7.

[43] Alston & Bird, *Government Investigations, Health Care and Government Contracts Advisory* (June 1, 2009). *See also* John J. Carney and Robert M. Wolin, *Target Health Care Fraud (With the Industry in Government Crosshairs, Proactive Internal Measures can Make a Difference)*, NEW YORK LAW JOURNAL (July 13, 2009) ("FERA expands liability to any entity subcontracted by a company fraudulently claiming money, 'any portion of which' the federal government provided. That is, while the subcontractor is not paid by and owes no obligation directly to the federal government, it can still be liable under the FCA if it has contracted under a company that receives some federal dollars. In practice, this also means that there can be federal violations for those third parties who indirectly receive income from state health funds as a portion of these derived from federal funds.").

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *See, e.g.*, Scot T. Hasselman, Andrew C. Bernasconi, and Nathan Fennessy, *The President Signs a Significant Amendment to the Federal False Claims Act*, FINANCIAL FRAUD LAW REPORT (Sept. 2009).

[49] *Id.*

[50] 21 NO. 6 HEALTH LAW 14, 18 (2009).

## Employment

### New requirements for patient care technicians

The new conditions for coverage (CfCs) for end-stage renal disease (ESRD) facilities include certification requirements for dialysis patient care technicians (PCTs). PCTs are defined as "any unlicensed staff member who has responsibility for direct patient care, including setting up the dialysis machine for patient use and testing reprocessed dialyzers that have been placed on the machine for presence or absence of germicide." The certification requirements do not apply to those with no direct patient care contact. According to the new CfCs, any PCTs who were hired on or before October 14, 2008, must be certified by a state or national PCT certification program by April 15, 2010. PCTs hired after October 14, 2008, must be certified within 18 months of their hire date. The new certification requirements are already in effect. State agencies have thirty days to disseminate this information.

**Certification programs.** The certification must be obtained from a CMS-approved program. To be CMS-approved, the program must include: (1) a qualified standardized test, (2) an independently proctored and protected testing environment, and (3) ongoing recertification. Sponsoring organizations must apply for approval with CMS. To assist in the research of certification program requirements, CMS released two appendices along with this Memorandum. Appendix A lists states that have state-provided PCT programs or require national program certification, and Appendix B describes the national certification programs.

**Other PCT requirements.** In addition to the certification program requirements, PCTs must meet further federal and state requirements for education, training and competency. For example, federal requirements mandate that a PCT must have a high school diploma or equivalency (GED), with some exception, and complete a job-specific training program related to the CfCs. ■

*CMS Memorandum to State Survey Agency Directors, No. S&C-10-03-ESRD, Oct. 30, 2009, Health Care Compliance Reporter, ¶350,186*

# In the News

### Initiative launched to reduce harm from medication use

The Safe Use Initiative, a program aimed at reducing the likelihood of preventable harm from medication use, was recently launched by the Food and Drug Administration (FDA) to partner with healthcare professionals and other relevant healthcare entities to improve patient health. The initiative will identify, using a transparent and collaborative process, specific candidate cases such as drugs, drug classes, and therapeutic situations that are associated with significant amounts of preventable harm. The cases will be analyzed for potential FDA-coordinated actions to provide and develop activities and evaluation metrics. The initiative was created because of the risk of harm involved whenever medications were not used optimally. The FDA will open a public docket to receive suggestions and comments related to its initiative, risk management issues, and proposed candidate cases, among other things.

*CCH Chicago Bureau, Nov. 4, 2009*

### HHS Secretary calls for enrollment of uninsured children

In a speech at a three-day conference sponsored by CMS, HHS Secretary Kathleen Sebelius recently called on states and communities to increase efforts to find and enroll the 5 million children who are currently eligible for Medicaid or the Children's Health Insurance Program (CHIP) yet are still not covered. "As a society and as parents, we have no greater responsibility than to provide quality health care for our children," Secretary Sebelius said. State Medicaid and CHIP officials, local government, community-based organizations, safety net providers and others who are working to promote enrollment in children's health programs will exchange proven strategies for finding and enrolling children in health programs as well as removing program barriers that sometimes prevent children from staying in these programs despite continued eligibility. More information about free or low-cost children's health insurance is available at http://www.insurekidsnow.gov/ or by calling 1-877-KIDS-NOW.

*CCH Chicago Bureau, Nov. 4, 2009*

### Interim final rule implements HITECH provisions

The enforcement regulations for the Health Insurance Portability and Accountability Act (PubLNo 104-191) (HIPAA) are being amended as they relate to the imposition of civil money penalties (CMPs) that incorporate the Health Information Technology for Economic and Clinical Health Act's (HITECH) categories of violations, tiered ranges of CMPs, and revised limitations on the Secretary's authority to impose CMPs for established violations of HIPAA's administrative simplification rules. This *Interim final rule* distinguishes between violations that occurred before February 18, 2009, and violations after that date with respect to the potential CMP amount and the affirmative defenses available to covered entities. Changes include, among other things, a revision of the range of potential CMP amounts a covered entity will be subject to based on the HITECH Act's amendments at 42 C.F.R. § 160.404(b), and amendment of 42 C.F.R. § 160.410 in relation to affirmative defenses. HHS is seeking public comment on all aspects of this *Interim final rule*. This *Interim final rule* will become effective November 30, 2009.

*Final rule, 74 FR 56123, Oct. 30, 2009, Health Care Compliance Reporter, ¶700,236.*